

GENTA INC DE/  
Form S-1  
August 29, 2008

**Table of Contents**

**As filed with the Securities and Exchange Commission on August 29, 2008**  
**Registration No. 333-**

**UNITED STATES SECURITIES AND EXCHANGE COMMISSION**  
**Washington, D.C. 20549**  
**Form S-1**  
**REGISTRATION STATEMENT**  
**UNDER**  
**THE SECURITIES ACT OF 1933**  
**GENTA INCORPORATED**

*(Exact name of registrant as specified in its charter)*

**Delaware**

*(State or other jurisdiction of  
incorporation or organization)*

**2836**

*(Primary Standard Industrial  
Classification Code Number)*

**33-0326866**

*(I.R.S. Employer  
Identification Number)*

**200 Connell Drive**  
**Berkeley Heights, New Jersey 07922**  
**(908) 286-9800**

*(Address, including zip code, and telephone number, including area code, of registrant's principal executive offices)*

**Raymond P. Warrell, Jr., M.D.**  
**Chairman and Chief Executive Officer**  
**Genta Incorporated**  
**200 Connell Drive**  
**Berkeley, New Jersey 07922**

*(Name, address, including zip code, and telephone number, including area code, of agent for service)*

*Copies to:*

**Emilio Ragosa, Esq.**  
**Morgan, Lewis & Bockius LLP**  
**502 Carnegie Center**  
**Princeton, New Jersey 08540**  
**tel: (609) 919-6600**  
**fax: (609) 919-6701**

**Approximate date of commencement of proposed sale to the public:** As soon as practicable after the effective date of this Registration Statement.

If any of the securities being registered on this Form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933, check the following box.

If this Form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, please check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering.

If this form is a post-effective amendment filed pursuant to Rule 462(c) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering.

If this form is a post-effective amendment filed pursuant to Rule 462(d) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering.

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     Smaller reporting company   
 (Do not check if a smaller reporting company)

### CALCULATION OF REGISTRATION FEE

Title of Each Class of Securities to be Registered	Proposed Maximum Aggregate Offering Price	Amount of Registration Fee
Common Stock par value \$0.001 per share	\$23,000,000(1)(2)	\$905

(1) Estimated solely for the purpose of calculating the amount of the registration in accordance with Rule 457(o) under the Securities Act of 1933, as amended.

(2) Includes [       ] shares of common stock subject to the underwriters' over-allotment option.

**The Registrant hereby amends this Registration Statement on such date or dates as may be necessary to delay its effective date until the Registrant shall file a further amendment which specifically states that this Registration Statement shall thereafter become effective in accordance with Section 8(a) of the Securities Act of 1933 or until the Registration Statement shall become effective on such date as the Commission, acting**

**pursuant to said Section 8(a), may determine.**

---

**Table of Contents**

The information in this preliminary prospectus is not complete and may be changed. We may not sell these securities until the Registration Statement filed with the SEC is effective. This preliminary prospectus is not an offer to sell these securities and we are not soliciting an offer to buy these securities in any state where the offer or sale is not permitted.

**SUBJECT TO COMPLETION, DATED AUGUST 29, 2008**

**PROSPECTUS**

**GENTA INCORPORATED**

[ ] shares of Common Stock

We are offering [ ] shares of our common stock. Please refer to Underwriters beginning on page 83. All costs associated with this registration will be borne by us.

On August 22, 2008, the closing price of our common stock was \$0.40 per share. Our common stock is quoted on the OTC Bulletin Board under the symbol GNTA.OB .

[ ] is an underwriter within the meaning of the Securities Act of 1933, as amended (the Securities Act ), in connection with the sale of our common stock.

Brokers or dealers effecting transactions in these shares should confirm that the shares are registered under the applicable state law or that an exemption from registration is available.

These securities are speculative and involve a high degree of risk.

**Please refer to Risk Factors beginning on page 7.**

	Price to Public	Underwriting Discounts and Commissions	Proceeds to Genta, Before Expenses
Per Share	\$ [ ]	\$ [ ]	\$ [ ]
Total	\$ [ ]	\$ [ ]	\$ [ ]

This is a firm commitment underwriting. We have granted the underwriters the right for a period of 30 days to purchase up to an additional [ ] shares to cover over-allotments.

With the exception of [ ], which is an underwriter within the meaning of the Securities Act, no other underwriter or person has been engaged to facilitate the sale of shares of common stock in this offering. None of the proceeds from the sale of stock will be placed in escrow, trust or any similar account.

The SEC and state securities regulators have not approved or disapproved of these securities, or determined if this prospectus is truthful or complete. Any representation to the contrary is a criminal offense.

[ ] expects to deliver the shares to purchasers on [ ], 2008.

[UNDERWRITERS]

The date of this prospectus is [ ], 2008.

---

## TABLE OF CONTENTS

	<b>Page</b>
<u>PROSPECTUS SUMMARY</u>	1
<u>RISK FACTORS</u>	7
<u>FORWARD-LOOKING STATEMENTS</u>	20
<u>USE OF PROCEEDS</u>	21
<u>DIVIDEND POLICY</u>	21
<u>CAPITALIZATION</u>	22
<u>DILUTION</u>	23
<u>DESCRIPTION OF BUSINESS</u>	24
<u>LEGAL PROCEEDINGS</u>	36
<u>PRICE RANGE OF COMMON STOCK</u>	37
<u>SELECTED FINANCIAL INFORMATION</u>	38
<u>SUPPLEMENTARY FINANCIAL INFORMATION</u>	39
<u>MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS</u>	40
<u>CHANGE IN INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM</u>	55
<u>QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK</u>	55
<u>MANAGEMENT</u>	56
<u>PRINCIPAL STOCKHOLDERS</u>	72
<u>CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS</u>	73
<u>DESCRIPTION OF SECURITIES</u>	74
<u>UNDERWRITERS</u>	77
<u>LEGAL MATTERS</u>	79
<u>EXPERTS</u>	79
<u>HOW TO GET MORE INFORMATION</u>	79
<u>INDEX TO FINANCIAL STATEMENTS</u>	F-1
<u>PART II</u>	II-1
<u>EX-5.1: OPINION OF MORGAN LEWIS &amp; BOCKIUS LLP</u>	
<u>EX-21: SUBSIDIARIES OF THE REGISTRANT</u>	
<u>EX-23.1: CONSENT OF DELOITTE &amp; TOUCHE LLP</u>	

You should rely only on the information contained in this prospectus. We have not authorized anyone to provide you with information different from the information contained in this prospectus. We are offering to sell shares of common stock, and seeking offers to buy shares of common stock, only in jurisdictions where offers and sales are permitted. The information contained in this prospectus is accurate only as of the date of this prospectus, regardless of when this prospectus is delivered or when any sale of our common stock occurs.

For investors outside the United States: Neither we nor any of the underwriters have done anything that would permit this offering or possession or distribution of this prospectus in any jurisdiction where action for that purpose is required, other than in the United States. You are required to inform yourselves about and to observe any restrictions

relating to this offering and the distribution of this prospectus.

---



**Table of Contents**

**PROSPECTUS SUMMARY**

*This summary does not contain all of the information you should consider before buying shares of our common stock. You should read the entire prospectus carefully, especially the Risk Factors section and our consolidated financial statements and the related notes appearing at the end of this prospectus, before deciding to invest in shares of our common stock.*

**Introduction**

Unless otherwise stated, all references to us, our, we, Genta, the Company and similar designations refer to Genta Incorporated and its subsidiaries.

This offering relates to the sale of [ ] shares of our common stock.

**Overview**

We are a biopharmaceutical company engaged in pharmaceutical, or drug, research and development, our 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<sup>®</sup>, an oblimersen sodium injection. Genasense<sup>®</sup> is designed to block the production of a protein known as Bcl-2. Current science suggests that Bcl-2 is a fundamental, although not the sole, cause of the inherent resistance of cancer cells to anticancer treatments, such as chemotherapy, radiation, and monoclonal antibodies. While Genasense<sup>®</sup> 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<sup>®</sup> 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<sup>®</sup> in seven different diseases: melanoma; chronic lymphocytic leukemia, commonly known as CLL; multiple myeloma; acute myeloid leukemia, commonly known as 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, or NCI, we are currently conducting additional clinical trials. We are especially interested in the development, regulatory approval, and commercialization of Genasense<sup>®</sup> in at least three diseases: melanoma; CLL; and non-Hodgkin's lymphoma, commonly known as NHL.

Genasense<sup>®</sup> has been submitted for regulatory approval in the U.S. on two occasions and to the European Union, or EU, once. These applications proposed the use of Genasense<sup>®</sup> plus chemotherapy for patients with advanced melanoma in the U.S. and EU, and relapsed or refractory chronic lymphocytic leukemia in the U.S. only. None of these applications were successful. Nonetheless, we believe that Genasense<sup>®</sup> can ultimately be approved and commercialized for both of these indications, as well as for other diseases, and we have undertaken a number of initiatives in this regard that are described below.

The New Drug Application, or NDA, for Genasense<sup>®</sup> in melanoma was withdrawn in 2004 after an advisory committee to the Food and Drug Administration, or FDA, failed to recommend approval. A negative decision was

also received for a similar application in melanoma from the European Medicines Agency, or EMEA, in 2007. In 2006, data from the pivotal Phase 3 trial that comprised the primary basis for these applications were published in a peer-reviewed journal. These results showed that Genasense® treatment compared with chemotherapy alone in patients with advanced melanoma was associated with a statistically significant increase in overall response, complete response, durable response, and progression-free survival, or PFS. However, the primary endpoint of overall survival approached but did not quite reach statistical significance (P=0.077). Subsequently, our analysis of this trial showed that there was a significant treatment interaction effect related to levels of a blood enzyme known as LDH. 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). Moreover, this benefit was

## **Table of Contents**

particularly noteworthy for patients whose baseline LDH did not exceed 80% of the upper limit of normal for this lab value.

Based on this data, in August 2007 we initiated a new 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 or dacarbazine alone. The study uses LDH as a biomarker to identify patients who are most likely to respond to Genasense®, based on data obtained from our preceding trial in melanoma. The co-primary endpoints of AGENDA are progression-free survival and overall survival.

The trial is designed to expand evidence for the safety and efficacy of Genasense® combined with dacarbazine, commonly known as DTIC, chemotherapy for patients who have not previously been treated with chemotherapy. The study prospectively targets patients who have low-normal levels of LDH. We expect to enroll approximately 300 subjects at approximately 90 sites worldwide in this trial. Genasense® in melanoma has been designated an Orphan Drug in Australia and the United States, and the drug has Fast Track designation in the United States. Target accrual of 300 patients is expected to complete in the fourth quarter of 2008. Initial data on the interim assessment of progression-free survival is expected in the first half of 2009. If the initial assessment of progression-free survival is positive, we expect to discuss these results with the FDA and EMEA and to secure agreement from these agencies that we may commence submission of new regulatory applications for the approval of Genasense® plus chemotherapy in patients with advanced melanoma. Approval by FDA and EMEA will allow Genasense® to be commercialized by us in the U.S. and in the EU.

Given our belief in the activity of Genasense® in melanoma, we have initiated and expect to initiate additional clinical studies in this disease. One such study is the Phase 2 trials of Genasense® plus a different chemotherapy regimen consisting of Abraxane®, commonly known as paclitaxel albumen, plus Temodar®, commonly known as temozolomide. We also expect to examine different dosing regimens that will improve the dosing convenience and commercial acceptance of Genasense®, including its administration by brief 1 to 2 hour intravenous, or IV, infusion.

As noted, our initial NDA for the use of Genasense® plus chemotherapy in patients with relapsed or refractory in CLL was also unsuccessful. In CLL, we conducted a randomized Phase 3 trial in 241 patients with relapsed or refractory disease who were treated with fludarabine and cyclophosphamide, commonly known as 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, or CR, defined as a complete or nodular partial response. Patients who achieved this level of response also experienced disappearance of predefined disease symptoms. 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®. 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 Flu/Cy for the treatment of patients with relapsed or refractory CLL who had previously received fludarabine. In December 2006 we received a non-approvable notice on that application from FDA. However, we believed that our application had met the regulatory requirements for approval, and in April 2007, we filed an appeal of that notice using FDA's Formal Dispute Resolution process. In March, 2008, we received a formal notice from FDA that indicated additional confirmatory evidence would be required to support approval of

Genasense® in CLL. In that communication, FDA recommended two alternatives for exploring that confirmatory evidence. One option was to conduct an additional clinical trial. The other option was to collect additional information regarding the clinical course and progression of disease in patients from the completed trial. We have elected to pursue both of these options.

## **Table of Contents**

For the first option, we submitted a new protocol in the second quarter of 2008 that sought Special Protocol Assessment, or SPA, from the FDA and Scientific Advice from the EMEA. This protocol is similar in design to the completed trial and uses the same chemotherapy and randomization scheme. The major difference is that the trial focuses on the patient population who derived maximal benefit in the completed trial. This group is characterized by patients who had received less extensive chemotherapy prior to entering the trial and who were defined as being non-refractory to fludarabine. We have deferred initiation of this trial until we receive a response to the second option, described below.

For the second option, we sought information regarding long-term survival on patients who had been accrued to our already completed Phase 3 trial. At the ASCO meeting in June 2008, we announced the results of long-term follow-up from the completed Phase 3 trial that had comprised the original NDA for Genasense® in CLL. With 5 years of follow-up, we showed that patients who achieved either a CR or a partial response, or PR, had also achieved a statistically significant increase in survival.

Previous analyses had shown a significant survival benefit in patients who attained CR. Extended follow-up showed that all major responses, CP and PR, achieved with Genasense were associated with significantly increased survival compared with all major responses achieved with chemotherapy alone (median = 56 months vs. 38 months, respectively). After 5 years of follow-up, 22 of 49, or 45%, responders in the Genasense group were alive compared with 13 of 54, or 24%, responders in the chemotherapy-only group (hazard ratio = 0.6; P = 0.038). Moreover, with 5 years of follow-up, 12 of 20 patients, or 60%, in the Genasense group who achieved CR were alive. Five of these patients remained in continuous CR without relapse, and 2 additional patients had relapsed but had not required additional therapy. By contrast, only 3 of 8 CR patients in the chemotherapy-only group were alive, all 3 had relapsed, and all 3 had required additional anti-leukemic treatment.

We believe that the significant survival benefit associated with major responses to Genasense® may provide the confirmatory evidence of clinical benefit that was requested by the FDA. We submitted this new data to FDA in the second quarter of 2008, and the submission was accepted as a complete response to the non-approvable decision letter on July 11, 2008. In that notice of acceptance, the FDA assigned a user fee goal date of December 3, 2008, meaning that the FDA will respond to the new submission regarding approvability of the CLL NDA on or before that date. We have elected not to initiate the aforementioned confirmatory trial until the FDA has rendered its decision on the pending NDA.

As with melanoma, we believe the clinical activity in CLL should be explored with additional clinical research. We plan to explore combinations of Genasense with other drugs that are used for the treatment of CLL, and to examine more convenient dosing regimens.

Lastly, several trials have shown definite evidence of clinical activity for Genasense® in patients with NHL. We would like to conduct additional clinical studies in patients with NHL to test whether Genasense can be approved in this indication.

Previously, we reported that randomized trials of Genasense® in patients with myeloma, AML, hormone-refractory prostate cancer, commonly known as HRPC, small cell lung cancer and non small cell lung cancer were not sufficiently positive to warrant further investigation on the dose-schedules that were examined or with the chemotherapy that was employed in these trials. Data from these trials have been presented at various scientific meetings. However, we believe that alternate dosing schedules, in particular the use of brief high-dose infusions, offer the opportunity to re-examine the drug's activity in some of these indications, in particular multiple myeloma.

On March 7, 2008, we obtained an exclusive worldwide license for tesetaxel, a novel taxane compound that is taken by mouth. Tesetaxel has completed Phase 2 trials in a number of cancer types, and the drug has shown definite

evidence of antitumor activity in gastric cancer and breast cancer. Tese-taxel also appears to be associated with a lower incidence of peripheral nerve damage, a common side effect of taxanes that limits the maximum amount of these drugs that can be given to patients. At the time we obtained the license, tesse-taxel was on clinical hold by FDA due to the occurrence of several fatalities in the setting of severe neutropenia. In the second quarter of 2008, we filed a response to the FDA requesting a lift of the clinical hold that was granted on June 23, 2008. Before clinical testing can resume, we plan to submit to FDA an amendment to the existing Drug Master File for a change in the manufacturing process that addresses minor changes in the formulation of the drug capsules. With the input of

## **Table of Contents**

clinical investigators, we are currently determining the sites that will participate in the initial clinical trial that has been allowed by FDA.

The tesetaxel program seeks to secure a first-to-market advantage for tesetaxel relative to other oral taxanes. We believe success in this competitive endeavor will maximize return to stockholders. Accordingly, we have identified three oncology indications in which we believe tesetaxel may have sufficient efficacy and safety to warrant regulatory approval. We believe it may be possible to secure regulatory approval in these indications on the basis of endpoints that can be identified in clinical trials that are relatively limited in scope.

In addition to these three smaller indications, we are interested in examining the activity of tesetaxel in patients with HRPC. Docetaxel, also known as Taxotere<sup>®</sup>, is the only taxane approved for first-line use in patients with HRPC. Although docetaxel has been shown to extend survival in men with HRPC, its use is associated with a high incidence of moderate-to severe toxicity. If tesetaxel is shown to be active in HRPC, we believe its safety profile may be substantially superior to docetaxel and may supplant that drug for first-line use in this indication. However, the development of drugs in this indication is very costly. We expect that proceeds from the convertible note financing will enable only the earliest clinical evaluation in HRPC, and that additional funds will be required to support the extended clinical testing that will be required to secure regulatory approval in HRPC.

Our third pipeline product is G4544, which is a novel oral formulation of a gallium-containing compound that we developed in collaboration with Emisphere Technologies, Inc. We completed a single-dose Phase 1 study of an initial formulation of this new drug, known as G4544(a), and the results were presented at a scientific meeting in the second quarter of 2008. We are planning another study using a modified formulation, known as G4544(b). The FDA has indicated that a limited, animal toxicology study in a single species will be required prior to initiation of multi-dose studies of G4544(b). Funding for the G4544 program was suspended in the first quarter of 2008 when our cash resources became extremely constrained. We plan to use proceeds from the convertible note financing to re-open the G4544 program.

We currently intend to pursue a 505(b)(2) strategy to establish bioequivalence to our marketed product, Ganite<sup>®</sup>, for the initial regulatory approval of G4544. However, we believe this drug may also be useful for treatment of other diseases associated with accelerated bone loss, such as bone metastases, Paget's disease and osteoporosis. In addition, new uses of gallium-containing compounds have been identified for treatment of certain infectious diseases, particularly severe infections involving the bacteria *Pseudomonas aeruginosa*, which are frequently lethal in patients with cancer and cystic fibrosis. While we have no current plans to begin clinical development in the area of infectious disease, we intend to support research conducted by certain academic institutions by providing clinical supplies of our gallium-containing drugs.

We maintain an active Business Development program. We are seeking to both license our current drugs for partnerships with other companies, which may help us reduce the costs of development and assist us with commercialization, and also to acquire additional drugs that address oncology indications in order to enhance the value of our pipeline to stockholders.

## **About Us**

Genta was incorporated in Delaware on February 4, 1988. Our principal executive offices are located at 200 Connell Drive, Berkeley Heights, New Jersey 07922. Our telephone number is (908) 286-9800. The address of our website is [www.Genta.com](http://www.Genta.com). Information on our website is not part of this prospectus. Our website address is included in this prospectus as an inactive technical reference only.





**Table of Contents****THE OFFERING**

Common Stock Offered	[       ] shares
Common Stock Outstanding After the Offering	[       ] shares
Over-allotment option offered by us	[       ] shares
Use of Proceeds	For advancing our product candidates through preclinical studies and clinical trials, the commercialization of our product candidates, if and when approved, and general corporate purposes, including working capital needs and potential product acquisitions or in-licensing opportunities. See Use of Proceeds .
Risk Factors	You should read the Risk Factors section of this prospectus for a discussion of factors to consider carefully before deciding to invest in shares of our common stock.
OTC Bulletin Board Symbol	GNTA.OB

The number of shares of our common stock that will be outstanding after this offering is based on 36,740,558 shares of common stock outstanding as of June 30, 2008. This amount excludes:

2,331,267 shares of common stock issuable upon exercise of stock options outstanding under our 1998 Stock Incentive Plan as of June 30, 2008 at a weighted average exercise price of \$24.21 per share, of which, options to purchase 1,371,266 shares were exercisable;

111,823 shares of common stock issuable upon exercise of stock options outstanding under our 1998 Non-Employee Directors Stock Incentive Plan as of June 30, 2008 at a weighted average exercise price of \$30.49 per share, of which, options to purchase 109,157 shares were exercisable;

4,174,000 shares of common stock issuable upon exercise of stock options outstanding under our 2007 Stock Incentive Plan as of June 30, 2008 at a weighted average exercise price of \$1.39 per share, of which, options to purchase 603,000 shares were exercisable, however the 2007 Stock Incentive Plan requires stockholder approval;

4,326,000 shares of common stock available for future grant under our 2007 Stock Incentive Plan as of June 30, 2008 and 170,205 shares of common stock available for future grant under our 1998 Non Employee Directors Stock Incentive Plan as of June 30, 2008;

40,000,000 shares of common stock issuable upon exercise of warrants outstanding as of June 30, 2008 at an exercise price of \$0.02 per share;

1,181,482 shares of common stock issuable upon the conversion of our Series A Convertible Preferred Stock as of June 30, 2008; and

4,000,000,000 shares of common stock issuable upon the conversion of our 15% Senior Secured Convertible Notes due 2010, of which 2,000,000,000 shares of common stock are potentially issuable as of June 30, 2008

from the first closing of our convertible notes.

Unless otherwise indicated, all information in this prospectus assumes no exercise by the underwriters of their over-allotment option, no conversion of convertible notes or preferred stock and no exercise of stock options or warrants after June 30, 2008.

**Table of Contents****SUMMARY OF SELECTED FINANCIAL INFORMATION**

The following table summarizes our selected financial information. You should read the selected financial information together with our consolidated financial statements and the related notes appearing at the end of this prospectus, and the Management's Discussion and Analysis of Financial Condition and Results of Operations section and other financial information included in this prospectus.

The as adjusted balance sheet data below gives effect to the sale of our common stock in this offering, at an assumed public offering price of \$[ ] per share, after deducting underwriting discounts and commissions and estimated offering expenses.

	<b>Six Months Ended</b>		<b>Year Ended December 31,</b>		
	<b>2008</b>	<b>2007</b>	<b>2007</b>	<b>2006</b>	<b>2005</b>
	<b>(Unaudited)</b>		<b>(In thousands except per share amounts)</b>		
	<b>(In thousands except per share amounts)</b>		<b>(In thousands except per share amounts)</b>		
<b>Consolidated Statements of Operations Data:</b>					
License fees & royalties	\$	\$	\$	\$	\$ 5,241
Development funding					20,988
Product sales net	248	199	580	708	356
Total revenues	248	199	580	708	26,585
Costs of goods sold	54	48	90	108	52
Operating expenses gross	20,083	14,468	26,116	59,764	37,006
sanofi-aventis reimbursement					(6,090)
Operating expenses net	20,083	14,468	26,116	59,764	30,916
Gain on forgiveness of debt					1,297
Amortization of deferred financing costs	(840)				
Fair value conversion feature liability	(720,000)				
Fair value warrant liability	(7,200)				
All other (income) expense-net	(92)	478	836	1,454	502
Loss before income taxes	(748,021)	(13,839)	(24,790)	(57,710)	(2,584)
Income tax benefit			1,470	929	381
Net loss	\$ (748,021)	\$ (13,839)	\$ (23,320)	\$ (56,781)	\$ (2,203)
Net loss per basic and diluted share*	\$ (21.21)	\$ (0.48)	\$ (0.79)	\$ (2.52)	\$ (0.13)
Shares used in computing net loss per basic and diluted share*	35,261	28,604	29,621	22,553	17,147

\* all figures prior to July 2007 have been retroactively adjusted for 1-for-6 reverse stock split in July 2007

**Six Months Ended June 30,**

	<b>2008 (as Adjusted)</b>	<b>2008 (Actual) (Unaudited) (In thousands)</b>
<b>Balance Sheet Data:</b>		
Cash, cash equivalents and marketable securities	\$ [ ]	\$ 16,278
Working capital (deficit)*	[ ]	(750,173)
Total assets	[ ]	44,029
Total stockholders' equity (deficit)	[ ]	(741,957)

---

\* Includes fair value of the conversion feature liability in the amount of \$740.0 and the warrant liability in the amount of \$14.8 million.

**Table of Contents**

**RISK FACTORS**

*You should carefully consider the following risks and all of the other information set forth in this prospectus before deciding to invest in shares of our common stock. The risks described below are not the only ones facing 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.*

**Risks Related to Our Business**

***If our stockholders do not approve our amended certificate of incorporation, we will be in a default under the terms of the June 2008 convertible note financing.***

At our annual meeting of stockholders to be held later in 2008, we have requested that our stockholders approve an amendment to our restated certificate of incorporation, as amended, to increase the total number of authorized shares of capital stock available for issuance from 255,000,000, consisting of 250,000,000 shares of common stock and 5,000,000 shares of preferred stock, to 6,005,000,000, consisting of 6,000,000,000 shares of common stock and 5,000,000 shares of preferred stock. The amendment would satisfy the conditions contained in the terms of the June 2008 convertible note financing. We have recommended that the stockholders vote in favor of such proposal.

If the stockholders do not approve the amendment to our restated certificate of incorporation and an event of default occurs under the terms of the notes, the holders of the notes may at any time at their option declare the entire unpaid principal balance of such note, together with all accrued interest thereon, due and payable, and such note shall be accelerated; provided, however, that upon the occurrence of an event of default, the holder may (a) demand the redemption of such note pursuant to Section 3.6(a) of such note (as described below), (b) demand that the principal amount of the note then outstanding and all accrued and unpaid interest thereon be converted into shares of common stock at the conversion price per share on the trading day immediately preceding the date the holder demands conversion, or (c) exercise or otherwise enforce any one or more of the holder's rights, powers, privileges, remedies and interests under the transactions documents or applicable law.

Section 3.6(a) of the notes provide for prepayment of the notes in connection with an event of default. The holder may require us to prepay all or a portion of a note in cash at a price equal to the sum of (i) the greater of (A) one hundred fifty percent (150%) of the aggregate principal amount of such note plus all accrued and unpaid interest and (B) the aggregate principal amount of such note plus all accrued but unpaid interest hereon, divided by the conversion price on (x) the date the prepayment price (as defined below) is demanded or otherwise due or (y) the date the prepayment price is paid in full, whichever is less, multiplied by the Daily VWAP (as defined in the note) on (x) the date the prepayment price is demanded or otherwise due, and (y) the date the prepayment price is paid in full, whichever is greater, and (ii) all other amounts, costs, expenses and liquidated damages due in respect of such note and the other transaction documents, referred to herein as the Prepayment Price.

If the stockholders do not approve the increase in authorized shares within 120 days of the initial closing date, we will be in default and the above provisions apply

We cannot guarantee that such amendment will be approved by our stockholders and will not result in a breach under the terms of the June 2008 convertible note financing. If such amendment is not approved by our stockholders, we will be in default under the terms of the June 2008 convertible note financing. Upon an event of default, the holders may require prepayment of principal, plus accrued interest under the notes, plus a premium as set forth in the notes. This event would likely have a harmful effect on the company, including the possibility of bankruptcy.

***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

**Table of Contents**

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<sup>®</sup> 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<sup>®</sup>. 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 December 2005, we completed submission of an NDA to the FDA that sought accelerated approval for the use of Genasense<sup>®</sup> in combination with Flu/Cy 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<sup>®</sup> 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, or 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 had decided that additional confirmatory evidence would be required to support approval of Genasense<sup>®</sup> 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. CDER recommended two alternatives for exploring the efficacy of Genasense<sup>®</sup> that could provide such confirmatory evidence. One option was to conduct an additional clinical trial. The other option was to collect additional information regarding the clinical course and progression of disease in patients from the completed trial. We currently plan to pursue both of these options. Information from the completed trial should be available by the third quarter of 2008. In the second quarter of 2008, we submitted a new protocol seeking Special Protocol Assessment, or SPA, from the FDA and Scientific Advice from the EMEA. This protocol is similar in design to the completed trial and uses the same chemotherapy and randomization scheme. The major difference is that the trial focuses on the patient population who derived maximal benefit in the completed trial. This group is characterized by patients who had received less extensive chemotherapy prior to entering the trial and who were defined as being non-refractory to fludarabine. The earliest date this new trial could begin patient accrual would be the fourth quarter of 2008. However, we do not currently have sufficient resources to finance this trial, and at present we do not expect to begin this trial absent funding from a partnership or

other sources.

In January 2006, we completed a MAA to the EMEA, which sought approval for use of Genasense<sup>®</sup> 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, or 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 by a Scientific Advisory Group had reaffirmed the negative opinion. We contemplate no further action on the MAA.



## **Table of Contents**

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 additional 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.

On June 5, 2008, we entered into definitive agreements with institutional and accredited investors to place senior secured convertible notes due 2010 totaling in aggregate up to \$40 million in gross proceeds before fees and expenses. The closing of the first \$20 million of the senior secured convertible notes took place on June 9, 2008.

The senior secured convertible notes bear interest at an annual rate of 15% payable at quarterly intervals in stock or cash at our option, and are convertible into shares of our common stock at a conversion rate of 100,000 shares of common stock for every \$1,000.00 of principal. Holders of the senior secured convertible notes have the right, but not the obligation, for the 12 months following the initial closing date to purchase in whole or in part up to an additional \$20 million of senior secured convertible notes. We have the right to force conversion of the senior secured convertible notes in whole or in part if the closing bid price of our common stock exceeds \$0.50 for a period of 20 consecutive trading days. Certain members of our senior management participated in this offering. The senior secured convertible notes are secured by a first lien on all of our assets. The senior secured convertible notes include certain events of default, including a requirement that we obtain stockholder approval within a specified period of time to amend our certificate of incorporation to authorize additional shares of our common stock.

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.

**Table of Contents**

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 first quarter of 2009. 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.

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 June 30, 2008, we have incurred a cumulative net deficit of \$1,186.3 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.

## **Table of Contents**

### ***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

## **Table of Contents**

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.

Our 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;

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.



**Table of Contents**

Between 2004 and 2007, we reported that randomized trials of Genasense® in patients with myeloma, AML, hormone-refractory prostate cancer, small cell lung cancer and non small cell lung cancer were not sufficiently positive to warrant further investigation on the dose-schedules that were examined or with the chemotherapy that was employed in these trials. Data from these trials have been presented at various scientific meetings.

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.

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.

## **Table of Contents**

***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.

**Table of Contents**

***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;

## **Table of Contents**

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 pending stockholder class action and stockholder 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 our stockholders who purchased its securities during several class periods. The complaints were consolidated into a single action and alleged that we and certain of our principal officers violated the federal securities laws by issuing materially false and misleading statements regarding Genasense® for the treatment of malignant melanoma that had the effect of artificially inflating the market price of our securities. The stockholder class action complaint sought monetary damages in an unspecified amount and recovery of plaintiffs' costs and attorneys' fees. We reached an agreement



## **Table of Contents**

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 stockholder 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. An order approving the settlement was issued on May 27, 2008 and the settlement became final on June 27, 2008.

The settlement and potential settlement did 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 the 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 filed a motion dated March 24, 2008 to reinstate the complaint, which was granted by the Court on April 11, 2008 at which time the Court adopted a discovery schedule that concludes in December 2008. 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 stockholders 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<sup>2</sup>/<sub>3</sub>% 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.

In September 2005, 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.

**Table of Contents**

***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 June 30, 2008, we had 36.7 million shares of common stock outstanding, 43.4 million additional shares reserved for the conversion of convertible preferred stock and the exercise of outstanding options and warrants. 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 Stockholders held on July 11, 2007, our stockholders 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.

Effective May 7, 2008, we moved the trading of our common stock from The NASDAQ Capital Markets to the OTC Bulletin Board maintained by FINRA, formerly known as the NASD. This action was taken pursuant to receipt of notification from the NASDAQ Listing Qualifications Panel that we had failed to demonstrate our ability to sustain compliance with the \$2.5 million minimum stockholders equity requirement for continued listing on The NASDAQ Capital Markets. On July 10, 2008, we received notification from The NASDAQ Capital Market that The NASDAQ Capital Market had determined to remove our common stock from listing on such exchange. The delisting was

effective at the opening of the trading session on July 21, 2008.

***If our convertible noteholders convert their notes into shares of our common stock, you may be diluted.***

On June 5, 2008, we entered into a securities purchase agreement with certain institutional and accredited investors, to place up to \$40 million of senior secured convertible notes, referred to herein as the notes, with such investors. On June 9, 2008, we placed \$20 million of such notes in the initial closing. The notes bear interest at an annual rate of 15% per annum payable at quarterly intervals in stock or cash at our option, and will be convertible into shares of our common stock at a conversion rate of 100,000 shares of common stock for every \$1,000 of principal; provided, however, at no time may the holder of a note convert such note if such conversion would cause

## **Table of Contents**

the holder to beneficially own more than 4.999% of the then outstanding shares of our common stock. Until June 9, 2009, the holders of the notes have the right, but not the obligation, to purchase in whole or in part up to an additional \$20 million of notes. We have the right to force conversion of the notes in whole or in part if the closing bid price of our common stock exceeds \$0.50 for a period of 20 consecutive trading days. Certain members of our senior management participated in the initial closing. Pursuant to the general security agreement, the notes are secured by a first lien on all of our assets, subject to certain exceptions set forth in such security agreement. The notes include certain events of default, including a requirement that we obtain stockholder approval within a specified period of time to amend our certificate of incorporation to authorize additional shares of common stock.

The conversion of some or all of our notes will dilute the ownership interests of existing stockholders. Any sales in the public market of the common stock issuable upon conversion of the notes could adversely affect prevailing market prices of our common stock. In addition, the existence of the notes may encourage short selling by market participants because the conversion of the notes could depress the price of our common stock.

If holders of our notes elect to convert their notes and sell material amounts of our common stock in the market, such sales could cause the price of our common stock to decline, and such downward pressure on the price of our common stock may encourage short selling of our common stock by holders of our convertible notes or others. To the extent that holders of our convertible notes elect to convert the notes into shares of our common stock and sell material amounts of those shares in the market, our stock price may decrease as a result of the additional amount of shares available on the market. The subsequent sales of these shares could encourage short sales by holders of convertible notes and others, placing further downward pressure on our stock price.

If there is significant downward pressure on the price of our common stock, it may encourage the holders of the notes or others to sell shares by means of short sales to the extent permitted under the U.S. securities laws. Short sales involve the sale by a holder of notes, usually with a future delivery date, of common stock the seller does not own. Covered short sales are sales made in an amount not greater than the number of shares subject to the short seller's right to acquire common stock, such as upon conversion of notes. A holder of notes may close out any covered short position by converting its notes or purchasing shares in the open market. In determining the source of shares to close out the covered short position, a holder of notes will likely consider, among other things, the price of common stock available for purchase in the open market as compared to the conversion price of the notes. The existence of a significant number of short sales generally causes the price of common stock to decline, in part because it indicates that a number of market participants are taking a position that will be profitable only if the price of the common stock declines.

## **Risks Related to this Offering**

### ***Our use of the offering proceeds may not yield a favorable return on your investment.***

We currently anticipate that the net proceeds from this offering will be used primarily for clinical development, research and development activities, commercialization expenses and for general corporate purposes. In addition, we may also use such proceeds to acquire equipment, potential licenses and acquisitions of complementary products, technologies or businesses. Pending the application of the net proceeds, we intend to invest the net proceeds in investment-grade, interest-bearing securities. Our management has broad discretion over how these proceeds are used and could spend the proceeds in ways with which you may not agree. Pending the use of the proceeds in this offering, we will invest them. However, the proceeds may not be invested in a manner that yields a favorable or any return.

***As a new investor, you will incur substantial dilution as a result of this offering and future equity issuances, and as a result, our stock price could decline.***

The offering price will be substantially higher than the net tangible book value per share of our outstanding common stock. As a result, based on our capitalization as of June 30, 2008, investors purchasing common stock in this offering will incur immediate dilution of \$[ ] per share, based on the assumed offering price of \$[ ] per share. We believe that following this offering, our current cash, cash equivalents and short-term investments, together with the anticipated proceeds from this offering, will be sufficient to fund our operations through the third quarter of 2009; however, our projected revenue may decrease or our expenses may increase and that would lead to our cash resources being consumed earlier than currently anticipated. In addition to this offering, subject to market conditions and other

## **Table of Contents**

factors, we likely will pursue raising additional funds in the future, as we continue to build our business. In future years, we will likely need to raise significant additional funding to finance our operations and to fund clinical trials, regulatory submissions and the development, manufacture and marketing of other products under development and new product opportunities. Accordingly, we may conduct substantial future offerings of equity or debt securities. The exercise of outstanding options and warrants and future equity issuances, including future public offerings or future private placements of equity securities and any additional shares issued in connection with acquisitions, will also result in dilution to investors. In addition, the market price of our common stock could fall as a result of resales of any of these shares of common stock due to an increased number of shares available for sale in the market.

## **FORWARD-LOOKING STATEMENTS**

This prospectus contains certain forward-looking statements regarding management's plans and objectives for future operations including plans and objectives relating to our planned marketing efforts and future economic performance. The forward-looking statements and associated risks set forth in this prospectus include or relate to, among other things, (a) our projected sales and profitability, (b) our growth strategies, (c) anticipated trends in our industry, (d) our ability to obtain and retain sufficient capital for future operations, and (e) our anticipated needs for working capital. These statements may be found under Management's Discussion and Analysis of Financial Condition and Results of Operations and Business, as well as in this prospectus generally. Actual events or results may differ materially from those discussed in forward-looking statements as a result of various factors, including, without limitation, the risks outlined under Risk Factors and matters described in this prospectus generally. In light of these risks and uncertainties, there can be no assurance that the forward-looking statements contained in this prospectus will in fact occur.

The forward-looking statements herein are based on current expectations that involve a number of risks and uncertainties. Such forward-looking statements are based on assumptions that there will be no material adverse competitive or technological change in conditions in our business, that demand for our products and services will significantly increase, that our President will remain employed as such, that our forecasts accurately anticipate market demand, and that there will be no material adverse change in our operations or business or in governmental regulations affecting us or our manufacturers and/or suppliers. The foregoing assumptions are based on judgments with respect to, among other things, future economic, competitive and market conditions, and future business decisions, all of which are difficult or impossible to predict accurately and many of which are beyond our control. Accordingly, although we believe that the assumptions underlying the forward-looking statements are reasonable, any such assumption could prove to be inaccurate and therefore there can be no assurance that the results contemplated in forward-looking statements will be realized. In addition, as disclosed elsewhere in the Risk Factors section of this prospectus, there are a number of other risks inherent in our business and operations which could cause our operating results to vary markedly and adversely from prior results or the results contemplated by the forward-looking statements. Growth in absolute and relative amounts of cost of goods sold and selling, general and administrative expenses or the occurrence of extraordinary events could cause actual results to vary materially from the results contemplated by the forward-looking statements. Management decisions, including budgeting, are subjective in many respects and periodic revisions must be made to reflect actual conditions and business developments, the impact of which may cause us to alter marketing, capital investment and other expenditures, which may also materially adversely affect our results of operations. In light of significant uncertainties inherent in the forward-looking information included in this prospectus, the inclusion of such information should not be regarded as a representation by us or any other person that our objectives or plans will be achieved.

Some of the information in this prospectus contains forward-looking statements that involve substantial risks and uncertainties. Any statement in this prospectus and in the documents incorporated by reference into this prospectus that is not a statement of an historical fact constitutes a forward-looking statement. Further, when we use the words may, expect, anticipate, plan, believe, seek, estimate, internal and similar words, we intend to identify expressions that may be forward-looking statements. We believe it is important to communicate certain of our

expectations to our investors. Forward-looking statements are not guarantees of future performance. They involve risks, uncertainties and assumptions that could cause our future results to differ materially from those expressed in any forward-looking statements. Many factors are beyond our ability to control or predict. You are accordingly cautioned not to place undue reliance on such forward-looking statements.



## **Table of Contents**

Important factors that may cause our actual results to differ from such forward-looking statements include, but are not limited to, the risk factors discussed below. Before you invest in our common stock, you should be aware that the occurrence of any of the events described under Risk Factors below or elsewhere in this prospectus could have a material adverse effect on our business, financial condition and results of operation. In such a case, the trading price of our common stock could decline and you could lose all or part of your investment.

### **USE OF PROCEEDS**

We estimate that the net proceeds to us from our sale of [ ] shares of our common stock in this offering will be approximately \$[ ] million, or approximately \$[ ] million if the underwriters exercise their over-allotment option to purchase an additional [ ] shares from us in full, assuming a public offering price of \$[ ] per share and after deducting estimated underwriting discounts and commissions and offering expenses payable by us. Each \$0.10 increase or decrease in the assumed public offering price would increase or decrease, respectively, the net proceeds to us by approximately \$[ ], assuming the number of shares offered by us, as set forth above, remains the same and after deducting underwriting discounts and commissions and estimated offering expenses.

Investors will be relying on the judgment of our management, who will have broad discretion regarding the application of the proceeds of this offering. The amounts and timing of our actual expenditures will depend upon numerous factors, including the amount of cash generated by our operations, our cash needs and the amount of competition we face. We may find it necessary or advisable to use portions of the proceeds from this offering for other purposes.

We intend to use our net proceeds of this offering approximately as follows:

60% to advance our product candidates through preclinical studies and clinical trials. A portion of these funds will pay for the long-term follow-up of patients entered into our Phase 3 trial of Genasense in melanoma, known as AGENDA. Additional funds will be directed into advancing further clinical development of our next two clinical-stage pipeline products, tesetaxel and G4544. The clinical development plans for these products are described elsewhere in this document;

30% of the proceeds will be reserved to cover initial expenses that may be required to commercialize our product candidates, especially Genasense, if and when that drug is approved. However, there is no expectation that these funds will be sufficient to fully fund all expenses that we expect to incur in this effort, and additional funds will be required for this purpose; and

10% of the proceeds will be spent for general corporate purposes, including working capital needs and potential acquisitions or licenses to intellectual as may be needed to defend or expand our product portfolio as described below.

Our potential use of net proceeds for acquisitions may include the acquisition or licensing of marketed anti-cancer products or rights to potential new products or product candidates. Although we periodically evaluate acquisition and in-licensing opportunities, we currently have no commitments or agreements with respect to any specific acquisition or license.

Pending the uses described above, we intend to invest the net proceeds of this offering in short- to medium-term investment grade, interest-bearing securities.

### **DIVIDEND POLICY**

We have never declared or paid any cash dividends on our common stock. We currently intend to retain our future earnings, if any, to finance the expansion of our business and do not expect to pay any cash dividends in the foreseeable future. Payment of future cash dividends, if any, will be at the discretion of our board of directors after taking into account various factors, including our financial condition, operating results, current and anticipated cash needs and plans for expansion and restrictions imposed by lenders, if any.

**Table of Contents****CAPITALIZATION**

The following table describes our capitalization as of June 30, 2008:

on an actual basis; and

on an as adjusted basis to give effect to our sale of [ ] shares of common stock in this offering at an assumed public offering price of \$[ ] per share, after deducting estimated underwriting discounts and commissions and offering expenses.

You should read this capitalization table together with our consolidated financial statements and the related notes appearing at the end of this prospectus and the Management's Discussion and Analysis of Financial Condition and Results of Operations section and other financial information included in this prospectus.

	<b>As of June 30, 2008</b>	
	<b>Actual</b>	<b>As Adjusted</b>
	<b>(Unaudited)</b>	
	<b>(In thousands)</b>	
Common stock, \$.001 par value; 250,000 shares authorized, 36,741 shares issued and outstanding at June 30, 2008 and [ ] shares issued and outstanding at June 30, 2008 (as adjusted)	\$ 37	\$ [ ]
Preferred stock, 5,000 authorized:		
Series A convertible preferred stock, \$.001 par value; 8 shares issued and outstanding, liquidation value of \$385 at June 30, 2008 and [ ] shares issued and outstanding, liquidation value of \$[ ] at June 30, 2008 (as adjusted)		
Series G participating cumulative preferred stock, \$.001 par value; 0 shares issued and outstanding at June 30, 2008 and [ ] shares issued and outstanding at June 30, 2008 (as adjusted)		[ ]
Additional paid-in capital	444,315	[ ]
Accumulated deficit	(1,186,309)	[ ]
Total stockholders' (deficit)/ equity	(741,957)	[ ]
Total capitalization	\$ (741,957)	\$ [ ]

The number of shares of our common stock that will be outstanding after this offering is based on 36,740,558 shares of common stock outstanding as of June 30, 2008. This amount excludes:

2,331,267 shares of common stock issuable upon exercise of stock options outstanding under our 1998 Stock Incentive Plan as of June 30, 2008 at a weighted average exercise price of \$24.21 per share, of which, options to purchase 1,371,266 shares were exercisable;

111,823 shares of common stock issuable upon exercise of stock options outstanding under our 1998 Non-Employee Directors Stock Incentive Plan as of June 30, 2008 at a weighted average exercise price of \$30.49 per share, of which, options to purchase 109,157 shares were exercisable;

4,174,000 shares of common stock issuable upon exercise of stock options outstanding under our 2007 Stock Incentive Plan as of June 30, 2008 at a weighted average exercise price of \$1.39 per share, of which, options to purchase 603,000 shares were exercisable, however the 2007 Stock Incentive Plan requires stockholder approval;

4,326,000 shares of common stock available for future grant under our 2007 Stock Incentive Plan as of June 30, 2008 and 170,205 shares of common stock available for future grant under our 1998 Non Employee Directors Stock Incentive Plan as of June 30, 2008;

40,000,000 shares of common stock issuable upon exercise of warrants outstanding as of June 30, 2008 at an exercise price of \$0.02 per share;

**Table of Contents**

1,181,482 shares of common stock issuable upon the conversion of our Series A Convertible Preferred Stock as of June 30, 2008; and

4,000,000,000 shares of common stock issuable upon the conversion of our 15% Senior Secured Convertible Notes due 2010, of which 2,000,000,000 shares of common stock are potentially issuable as of June 30, 2008 from the first closing of our convertible notes.

Unless otherwise indicated, all information in this prospectus assumes no exercise by the underwriters of their over-allotment option, no conversion of convertible notes or preferred stock and no exercise of stock options after June 30, 2008.

**DILUTION**

Our net tangible book value as of June 30, 2008 was approximately \$(742.0) million, or \$(20.19) per share of common stock. Net tangible book value per share is determined by dividing our total tangible assets less total liabilities by the actual number of outstanding shares of our common stock. After giving effect to our issuance of [ ] shares of common stock at the assumed public offering price of \$[ ] per share, and after deducting estimated underwriting discounts and commissions and offering expenses payable by us, our net tangible book value as of June 30, 2008 would have been \$[ ] million or \$[ ] per share of common stock. This represents an immediate increase in pro forma net tangible book value of \$[ ] per share to our existing stockholders and an immediate dilution of \$[ ] per share to new investors in this offering. The following table illustrates this per share dilution:

Assumed public offering price per share		\$ [ ]
Net tangible book value per share as of June 30, 2008	\$ (20.19)	
Increase per share attributable to new investors	[ ]	
Pro forma net tangible book value per share after this offering		[ ]
Dilution per share to new investors		\$ [ ]

Dilution per share to new investors is determined by subtracting pro forma net tangible book value per share after this offering from the assumed public offering price per share paid by a new investor. If any shares are issued in connection with outstanding options or the underwriters' over-allotment option, you will experience further dilution. A \$0.10 increase or decrease in the assumed public offering price would increase or decrease, respectively, the pro forma as adjusted net tangible book value as of June 30, 2008 by \$[ ] million, or \$[ ] per share of common stock, and the dilution per share to new investors by \$[ ] per share, assuming the number of shares offered by us, as set forth above, remains the same and after deducting underwriting discounts and commissions and estimated offering expenses.

**Table of Contents**

**DESCRIPTION OF BUSINESS**

**Overview**

We are a biopharmaceutical company engaged in pharmaceutical, or 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<sup>®</sup>, or oblimersen sodium injection. Genasense<sup>®</sup> 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<sup>®</sup> 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<sup>®</sup> 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<sup>®</sup> in seven different diseases: melanoma; chronic lymphocytic leukemia, commonly known as CLL; multiple myeloma; acute myeloid leukemia, commonly known as 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, or NCI, we are currently conducting additional clinical trials. We are especially focused on the development, regulatory approval, and commercialization of Genasense<sup>®</sup> in at least three diseases: melanoma; CLL; and non-Hodgkin's lymphoma, commonly known as NHL.

Genasense<sup>®</sup> has been submitted for regulatory approval in the U.S. on two occasions and to the European Union, or EU, once. These applications proposed the use of Genasense<sup>®</sup> plus chemotherapy for patients with advanced melanoma in the U.S. and EU, and relapsed or refractory chronic lymphocytic leukemia in the U.S. only. None of these applications were successful. Nonetheless, we believe that Genasense<sup>®</sup> can ultimately be approved and commercialized for both of these indications, as well as for other diseases, and we have undertaken a number of initiatives in this regard that are described below.

The New Drug Application, or NDA, for Genasense<sup>®</sup> in melanoma was withdrawn in 2004 after an advisory committee to the Food and Drug Administration failed to recommend approval. A negative decision was also received for a similar application in melanoma from the European Medicines Agency, or EMEA, in 2007. In 2006, data from the pivotal Phase 3 trial that comprised the primary basis for these applications were published in a peer-reviewed journal. These results showed, that Genasense<sup>®</sup> treatment, compared with chemotherapy alone, in patients with advanced melanoma was associated with a statistically significant increase in overall response, complete response, durable response and progression-free survival, or PFS. However, the primary endpoint of overall survival, approached but did not reach statistical significance (P=0.077). Subsequently, our analysis of this trial showed that there was a significant treatment interaction effect related to levels of a blood enzyme known as LDH. 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<sup>®</sup> (P=0.018; n=508). Moreover, this benefit was particularly noteworthy for patients whose baseline LDH did not exceed 80% of the upper limit of normal for this lab value.

Based on these data, in August 2007, we initiated a new Phase 3 trial of Genasense<sup>®</sup> 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<sup>®</sup> plus dacarbazine, commonly known as DTIC, or DTIC alone. The study uses LDH as a biomarker to identify patients who are most likely to respond to Genasense<sup>®</sup> based on data obtained from our preceding trial in melanoma. The co-primary endpoints of AGENDA are progression-free survival and overall survival.

The trial is designed to expand evidence for the safety and efficacy of Genasense<sup>®</sup> combined with DTIC chemotherapy for patients who have not previously been treated with chemotherapy. The study prospectively

## **Table of Contents**

targets patients who have low-normal levels of LDH. We expect to enroll approximately 300 subjects at approximately 90 sites worldwide in this trial. Genasense® in melanoma has been designated an Orphan Drug in Australia and the United States, and the drug has Fast Track designation in the United States. Target accrual of 300 patients is expected to complete in the fourth quarter of 2008. Initial data on the interim assessment of progression-free survival is expected in the first half of 2009. If the initial assessment of progression-free survival is positive, we expect to discuss these results with the FDA and EMEA and to secure agreement from these agencies that Genta may commence submission of new regulatory applications for the approval of Genasense® plus chemotherapy in patients with advanced melanoma. Approval by FDA and EMEA will allow Genasense® to be commercialized by us in the U.S. and in the European Union.

Given our belief in the activity of Genasense® in melanoma, we have initiated and expect to initiate additional clinical studies in this disease. One such study is the a Phase 2 trials of Genasense® plus a different chemotherapy regimen consisting of paclitaxel albumen, commonly known as Abraxane®, plus temozolomide, commonly known as Temodar®. We also expect to examine different dosing regimens that will improve the dosing convenience and commercial acceptance of Genasense®, including its administration by a brief 1 to 2 hour IV infusion.

As noted, our initial NDA for the use of Genasense® plus chemotherapy in patients with relapsed or refractory in CLL was also unsuccessful. In CLL, we conducted a randomized Phase 3 trial in 241 patients with relapsed or refractory disease who were treated with fludarabine and cyclophosphamide, commonly known as 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, 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 complete response, 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®. 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 Flu/Cy for the treatment of patients with relapsed or refractory CLL who had previously received fludarabine.

In December 2006 we received a non-approvable notice on that application from FDA. However, we believed that our application had met the regulatory requirements for approval, and in April 2007, we filed an appeal of that notice using FDA's Formal Dispute Resolution process. In March, 2008, we received a formal notice from FDA that indicated additional confirmatory evidence would be required to support approval of Genasense® in CLL. In that communication, FDA recommended two alternatives for exploring that confirmatory evidence. One option was to conduct an additional clinical trial. The other option was to collect additional information regarding the clinical course and progression of disease in patients from the completed trial. We have elected to pursue both of these options.

For the first option, we submitted a new protocol in the second quarter of 2008 that sought Special Protocol Assessment, or SPA, from the FDA and Scientific Advice from the EMEA. This protocol is similar in design to the completed trial and uses the same chemotherapy and randomization scheme. The major difference is that the trial focuses on the patient population who derived maximal benefit in the completed trial. This group is characterized by



patients who had received less extensive chemotherapy prior to entering the trial and who were defined as being non-refractory to fludarabine. We have deferred initiation of this trial until we receive a response to the second option, described below.

For the second option, we sought information regarding long-term survival on patients who had been accrued to our already completed Phase 3 trial. At the ASCO meeting in June 2008, we announced the results of long-term

## **Table of Contents**

follow-up from the completed Phase 3 trial that had comprised the original NDA for Genasense® in CLL. With 5 years of follow-up, we showed that patients who achieved either a complete response or a partial response had also achieved a statistically significant increase in survival.

Previous analyses had shown a significant survival benefit in patients who attained CR. Extended follow-up showed that all major responses, including complete responses and partial responses, achieved with Genasense were associated with significantly increased survival compared with all major responses achieved with chemotherapy alone (median = 56 months vs. 38 months, respectively). After 5 years of follow-up, 22 of 49, or 45%, responders in the Genasense group were alive compared with 13 of 54, or 24%, responders in the chemotherapy-only group (hazard ratio = 0.6; P = 0.038). Moreover, with 5 years of follow-up, 12 of 20, or 60%, patients in the Genasense group who achieved a complete response were alive, 5 of these patients remained in continuous complete response without relapse, and 2 additional patients had relapsed but had not required additional therapy. By contrast, only 3 of 8 complete response patients in the chemotherapy-only group were alive, all 3 had relapsed, and all 3 had required additional anti-leukemic treatment.

We believe that the significant survival benefit associated with major responses to Genasense® may provide the confirmatory evidence of clinical benefit that was requested by FDA. We submitted this new data to FDA in the second quarter of 2008, and the submission was accepted as a complete response to the non-approvable decision letter on July 11, 2008. In that notice of acceptance, FDA assigned a user fee goal date of December 3, 2008, meaning that FDA will respond to the new submission regarding approvability of the CLL NDA on or before that date. We have elected not to initiate the aforementioned confirmatory trial until FDA has rendered its decision on the pending NDA.

As with melanoma, we believe the clinical activity in CLL should be explored with additional clinical research. We plan to explore combinations of Genasense with other drugs that are used for the treatment of CLL, and to examine more convenient dosing regimens.

Lastly, several trials have shown definite evidence of clinical activity for Genasense® in patients with NHL. We would like to conduct additional clinical studies in patients with NHL to test whether Genasense can be approved in this indication.

Previously, we reported that randomized trials of Genasense® in patients with myeloma, AML, hormone-refractory prostate cancer, or HRPC, small cell lung cancer and non small cell lung cancer were not sufficiently positive to warrant further investigation on the dose-schedules that were examined or with the chemotherapy that was employed in these trials. Data from these trials have been presented at various scientific meetings. However, we believe that alternate dosing schedules, in particular the use of brief high-dose infusions, offer the opportunity to re-examine the drug's activity in some of these indications, in particular multiple myeloma.

On March 7, 2008, we obtained an exclusive worldwide license for tesetaxel, a novel taxane compound that is taken by mouth. Tesetaxel has completed Phase 2 trials in a number of cancer types and the drug has shown definite evidence of antitumor activity in gastric cancer and breast cancer. Tesetaxel also appears to be associated with a lower incidence of peripheral nerve damage, a common side effect of taxanes that limits the maximum amount of these drugs that can be given to patients. At the time we obtained the license, tesetaxel was on clinical hold by FDA due to the occurrence of several fatalities in the setting of severe neutropenia. In the second quarter of 2008, we filed a response to the FDA requesting a lift of the clinical hold that was granted on June 23, 2008. Before clinical testing can resume, we plan to submit to FDA an amendment to the existing Drug Master File for a change in the manufacturing process that addresses minor changes in the formulation of the drug capsules. With the input of clinical investigators, we are currently determining the sites that will participate in the initial clinical trial that has been allowed by FDA.

The tesetaxel program seeks to secure a first-to-market advantage for tesetaxel relative to other oral taxanes. We believe success in this competitive endeavor will maximize return to stockholders. Accordingly, we have identified three oncology indications in which we believe tesetaxel may have sufficient efficacy and safety to warrant regulatory approval. We believe it may be possible to secure regulatory approval in these indications on the basis of endpoints that can be identified in clinical trials that are relatively limited in scope.

## **Table of Contents**

In addition to these three smaller indications, we are interested in examining the activity of tasetaxel in patients with HRPC. Docetaxel, commonly known as Taxotere<sup>®</sup>, is the only taxane approved for first-line use in patients with HRPC. Although docetaxel has been shown to extend survival in men with HRPC, its use is associated with a high incidence of moderate-to severe toxicity. If tasetaxel is shown to be active in HRPC, we believe its safety profile may be substantially superior to docetaxel and may supplant that drug for first-line use in this indication. However, the development of drugs in this indication is very costly. We expect that proceeds from the convertible note financing will enable only the earliest clinical evaluation in HRPC, and that additional funds will be required to support the extended clinical testing that will be required to secure regulatory approval in HRPC.

Our third pipeline product is G4544, which is a novel oral formulation of a gallium-containing compound that we developed in collaboration with Emisphere Technologies, Inc. We completed a single-dose Phase 1 study of an initial formulation of this new drug known as G4544(a) and the results were presented at a scientific meeting in the second quarter of 2008. We are planning another study using a modified formulation, known as G4544(b). The FDA has indicated that a limited, animal toxicology study in a single species will be required prior to initiation of multi-dose studies of G4544(b). Funding for the G4544 program was suspended in the first quarter of 2008 when our cash resources became extremely constrained. We plan to use proceeds from the convertible note financing to re-open the G4544 program.

We currently intend to pursue a 505(b)(2) strategy to establish bioequivalence to our marketed product, Ganite<sup>®</sup>, for the initial regulatory approval of G4544. However, we believe this drug may also be useful for treatment of other diseases associated with accelerated bone loss, such as bone metastases, Paget's disease and osteoporosis. In addition, new uses of gallium-containing compounds have been identified for treatment of certain infectious diseases, particularly severe infections involving the bacteria *Pseudomonas aeruginosa*, which are frequently lethal in patients with cancer and cystic fibrosis. While we have no current plans to begin clinical development in the area of infectious disease, we intend to support research conducted by certain academic institutions by providing clinical supplies of our gallium-containing drugs.

We maintain an active Business Development program. We are seeking to both license our current drugs for partnerships with other companies, which may help us reduce the costs of development and assist us with commercialization, and also to acquire additional drugs that address oncology indications in order to enhance the value of our pipeline to stockholders.

## **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<sup>®</sup>, 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, commonly

**Table of Contents**

known as 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, or mRNA. The sequence of mRNA that encodes a protein is oriented in only one direction, which is known as the sense orientation.

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

We have devoted significant resources towards the development of antisense oligos that contain a 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, a protein may contribute to the malignant nature of cancer 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.

## **Table of Contents**

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, 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.

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, or 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, or 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

## **Table of Contents**

cancer who had not previously received chemotherapy. The trial included approximately 65 patients who were randomly assigned to receive Genasense<sup>®</sup> 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<sup>®</sup> did not increase survival at 12 months.

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

In August 2007, we announced that the first patients had been enrolled in a confirmatory Phase 3 trial of Genasense<sup>®</sup> 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<sup>®</sup> plus 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<sup>®</sup> combined with temozolomide, commonly known as Temodar<sup>®</sup>, plus albumen bound paclitaxel, commonly known as Abraxane<sup>®</sup>.

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<sup>®</sup> 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<sup>®</sup> administered by bolus subcutaneous, or 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<sup>®</sup> 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<sup>®</sup> 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<sup>®</sup> 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<sup>®</sup> 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<sup>®</sup>**

### ***Ganite<sup>®</sup> as a Treatment for Cancer-Related Hypercalcemia***

On October 6, 2003, we began marketing Ganite<sup>®</sup> for the treatment of cancer-related hypercalcemia. Ganite<sup>®</sup> is our first drug to receive marketing approval. The principal patent covering the use of Ganite<sup>®</sup> 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.

## **Table of Contents**

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., referred to herein as 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, or 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, we licensed patents and technology from the 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.

***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

## **Table of Contents**

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. Our 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<sup>®</sup> 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<sup>®</sup> expected to expire in 2020 and 2026, with approximately 50 corresponding foreign patent applications and granted patents.

Included among our 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<sup>®</sup> and methods employing them. Other related U.S. and corresponding foreign patent applications are still pending.

The principal patent covering the use of Ganite<sup>®</sup> 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 us 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

## **Table of Contents**

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.

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 us 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 us, and made our exclusive property. 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 us 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. For the six months ended June 30, 2008 and June 30, 2007, we recorded research and development expenses of \$10.9 million and \$7.5 million, respectively.

## **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<sup>®</sup>. We believe this agreement is sufficient for our production needs with respect to Genasense<sup>®</sup>.

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<sup>®</sup>; however, there are no minimum purchase requirements.

## **Table of Contents**

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 June 30, 2008, we had 23 employees, 6 of whom hold doctoral degrees. As of that date, there were 14 employees engaged in research, development and other technical activities and 9 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

## **Table of Contents**

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

## **Table of Contents**

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.

## **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 its principal officers on behalf of purported classes of our stockholders who purchased its securities during several class periods. The complaints were consolidated into a single action and alleged that we and certain of its principal officers violated the federal securities laws by issuing materially false and misleading statements regarding Genasense® for the treatment of malignant melanoma that had the effect of artificially inflating the market price of our securities. The stockholder 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 stockholder class. The cash portion of the proposed settlement will be covered by our insurance carriers. Effective June 25, 2007, we executed a written Stipulation and Agreement of Settlement with the plaintiffs, 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. An order approving the settlement was issued on May 27, 2008 and the settlement became final on June 27, 2008.

The settlement and potential settlement did not constitute an admission of guilt or liability.

In February 2007, a complaint was filed against us in the Superior Court of New Jersey by Howard H. Fingert, M.D., our former employee. The complaint alleges, among other things, breach of contract as to our stock option plan and as to a consulting agreement allegedly entered into between us and Dr. Fingert subsequent to termination of Dr. Fingert's employment, 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 the 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 filed a motion dated March 24, 2008 to reinstate the complaint, which was granted by the Court on April 11, 2008 at which time the Court adopted a discovery schedule that concludes in December 2008. We deny the allegations in the complaint and intend to vigorously defend this lawsuit.

In November 2007, a complaint was filed against us 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 a Company stockholder which have been incurred by Ridge. We filed our Answer

and Affirmative Defenses on February 27, 2008 to respond to the complaint. We deny the allegations in the complaint and intend to vigorously defend this lawsuit.

**Table of Contents****PRICE RANGE OF COMMON STOCK**

Our common stock was traded on the NASDAQ Global Market under the symbol GNTA until May 7, 2008. The following table sets forth the high and low prices per share of our common stock, as reported on the NASDAQ Global Market, for the periods indicated.

	<b>High*</b>	<b>Low*</b>
<b>2006</b>		
First Quarter	\$ 20.16	\$ 8.58
Second Quarter	\$ 12.84	\$ 7.98
Third Quarter	\$ 10.80	\$ 2.94
Fourth Quarter	\$ 5.28	\$ 2.64
<b>2007</b>		
First Quarter	\$ 3.36	\$ 1.86
Second Quarter	\$ 2.46	\$ 1.68
Third Quarter	\$ 1.80	\$ 0.80
Fourth Quarter	\$ 1.31	\$ 0.52
<b>2008</b>		
First Quarter	\$ 0.87	\$ 0.37
Second Quarter (through May 7, 2008)	\$ 0.45	\$ 0.15

---

\* all figures prior to July 2007 have been retroactively adjusted for 1-for-6 reverse stock split in July 2007.

Our common stock began trading on the OTC Bulletin Board under the symbol GNTA.OB on May 7, 2008. The following table sets forth the high and low prices per share of our common stock, as reported on the OTC Bulletin Board, for the periods indicated.

	<b>High</b>	<b>Low</b>
<b>2008</b>		
Second Quarter (from May 7, 2008)	\$ 0.41	\$ 0.10
Third Quarter (through August 22, 2008)	\$ 0.77	\$ 0.28

The closing price of our common stock on the OTC Bulletin Board on August 22, 2008 was \$0.40 per share. As of August 22, 2008, we had 553 holders of record of our common stock.



**Table of Contents****SELECTED FINANCIAL INFORMATION**

The following tables summarize our selected financial information. You should read the selected financial information together with our consolidated financial statements and the related notes appearing at the end of this prospectus, and the Management's Discussion and Analysis of Financial Condition and Results of Operations section and other financial information included in this prospectus.

	<b>Six Months Ended</b>		<b>Year Ended December 31,</b>				
	<b>2008</b>	<b>2007</b>	<b>2007</b>	<b>2006</b>	<b>2005</b>	<b>2004</b>	<b>2003</b>
	<b>June 30,</b>						
	<b>(Unaudited)</b>						
	<b>(In thousands except</b>		<b>(In thousands except per share amounts)</b>				
	<b>per share amounts)</b>						
<b>Consolidated Statements of Operations Data:</b>							
License fees & royalties	\$	\$	\$	\$	\$ 5,241	\$ 3,022	\$ 1,045
Development funding					20,988	12,105	4,194
Product sales - net	248	199	580	708	356	(512)	1,420
Total revenues	248	199	580	708	26,585	14,615	6,659
Costs of goods sold	54	48	90	108	52	170	404
Provision for excess inventory						1,350	
Total cost of goods sold	54	48	90	108	52	1,520	404
Operating expenses - gross	20,083	14,468	26,116	59,764	37,006	101,324	112,918
sanofi-aventis reimbursement					(6,090)	(43,292)	(55,891)
Operating expenses - net	20,083	14,468	26,116	59,764	30,916	58,032	57,027
Gain on forgiveness of debt					1,297	11,495	
Amortization of deferred financing costs	(840)						
Fair value - conversion feature liability	(720,000)						
Fair value - warrant liability	(7,200)						
All other (income) expense-net	(92)	478	836	1,454	502	(147)	669
Loss before income taxes	(748,021)	(13,839)	(24,790)	(57,710)	(2,584)	(33,589)	(50,103)
Income tax benefit			1,470	929	381	904	(6)
Net loss	\$ (748,021)	\$ (13,839)	\$ (23,320)	\$ (56,781)	\$ (2,203)	\$ (32,685)	\$ (50,109)
Net loss per basic and diluted share*	\$ (21.21)	\$ (0.48)	\$ (0.79)	\$ (2.52)	\$ (0.13)	\$ (2.46)	\$ (4.00)
Shares used in computing net loss per basic and diluted	35,261	28,604	29,621	22,553	17,147	13,300	12,516

share\*

\* all figures prior to July 2007 have been retroactively adjusted for 1-for-6 reverse stock split in July 2007

	<b>Six Months Ended</b>		<b>2007</b>	<b>Year Ended December 31,</b>			<b>2003</b>
	<b>2008</b>	<b>2007</b>		<b>2006</b>	<b>2005</b>	<b>2004</b>	
	<b>(Unaudited)</b>			<b>(In thousands)</b>			
	<b>(In thousands)</b>			<b>(In thousands)</b>			
<b>Balance Sheet Data:</b>							
Cash, cash equivalents and marketable securities	16,278	22,446	\$ 7,813	\$ 29,496	\$ 21,282	\$ 42,247	\$ 82,929
Working capital (deficit)	(750,173)	9,959	877	12,682	11,703	(4,269)	81,252
Total assets	44,029	43,847	29,293	51,778	27,386	50,532	114,675
Total stockholders equity (deficit)	(741,957)	11,857	2,931	14,642	15,697	1,752	12,254

\* Includes fair value of the conversion feature liability in the amount of \$740.0 million and the warrant liability in the amount of \$14.8 million.

**Table of Contents****SUPPLEMENTARY FINANCIAL INFORMATION**

The following table presents our condensed operating results for each of the ten (10) fiscal quarters through the period ended June 30, 2008. The information for each of these quarters is unaudited. In the opinion of management, all necessary adjustments, which consist only of normal and recurring accruals, have been included to fairly present the unaudited quarterly results. This data should be read together with our consolidated financial statements and the notes thereto, the Report of Independent Registered Public Accounting Firm and Management's Discussions and Analysis of Financial Condition and Results of Operations.

	<b>Three Months Ended</b>									
	<b>June 30</b>	<b>Mar 31</b>	<b>Dec 31</b>	<b>Sep 30</b>	<b>June 30</b>	<b>Mar 31</b>	<b>Dec 31</b>	<b>Sep 30</b>	<b>Jun 30</b>	<b>Mar 31</b>
	<b>2008</b>	<b>2008</b>	<b>2007</b>	<b>2007</b>	<b>2007</b>	<b>2007</b>	<b>2006</b>	<b>2006</b>	<b>2006</b>	<b>2006</b>
	<b>(Unaudited)</b>									
	<b>(In thousands except per share amounts)</b>									
Revenues	\$ 131	\$ 117	\$ 266	\$ 115	\$ 105	\$ 94	\$ 117	\$ 145	\$ 379	\$
Expenses	\$ (738,364)	\$ (9,657)	\$ (1,748)	\$ (7,732)	\$ (8,235)	\$ (5,605)	\$ (17,304)	\$ (14,940)	\$ (14,642)	\$
Income before income taxes										
Income tax expense										
Net income	\$ (20.10)	\$ (0.29)	\$ (0.06)	\$ (0.25)	\$ (0.27)	\$ (0.21)	\$ (0.68)	\$ (0.66)	\$ (0.66)	\$
Weighted average shares outstanding	36,741	33,781	30,621	30,621	30,621	26,565	25,620	22,598	22,278	1

\* all figures prior to July 2007 have been retroactively adjusted for 1-for-6 reverse stock split in July 2007

**Table of Contents**

**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. Our drug portfolio consists of products derived in two Programs: DNA/RNA Medicines, which includes our lead oncology drug, Genasense®; and Small Molecules, which includes our marketed product, Ganite®, and the investigational compounds tesetaxel and G4544. We have had recurring annual operating losses since 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 the eventual establishment of a sales and marketing organization. From our inception to June 30, 2008, we have incurred a cumulative net deficit of \$(1,186.3) million. Our recurring losses from operations and our negative cash flow from operations 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®, is approved by one or more regulatory authorities 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 \$16.3 million of cash, cash equivalents and marketable securities on hand at June 30, 2008. Cash used in operating activities during the first six months of 2008 was \$14.4 million.

Irrespective of whether regulatory applications, such as a New Drug Application, or NDA, or Marketing Authorization Application, 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, debt 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 funds 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 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. On June 5, 2008, we entered into a securities purchase agreement with certain institutional and accredited investors to place up to \$40 million of our senior secured convertible notes with investors. On June 9, 2008, we placed \$20 million of such notes in the initial closing. Presently, with no further financing, we project that we will run out of funds in the first quarter of 2009. We currently do not have any additional financing in place. If we are unable to raise additional funds, 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, or sell certain assets. There can be no assurance that we can obtain financing, if at all, on terms acceptable to us.

Our financial results have been and will continue to be significantly affected by regulatory actions related to Genasense®.

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, commonly known as CLL; multiple myeloma; acute myeloid leukemia, commonly known as 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, or NCI, we are currently conducting additional clinical trials. We are especially interested in the development, regulatory approval, and commercialization of Genasense® in at least three diseases: melanoma; CLL; and non-Hodgkin's lymphoma, commonly known as NHL.

**Table of Contents**

Genasense® has been submitted for regulatory approval in the U.S. on two occasions and to the European Union, or EU, once. These applications proposed the use of Genasense® plus chemotherapy for patients with advanced melanoma in the U.S. and EU and relapsed or refractory chronic lymphocytic leukemia in the U.S. only. None of these applications were successful. Nonetheless, we believe that Genasense® can ultimately be approved and commercialized for both of these indications, as well as for other diseases, and we have undertaken a number of initiatives in this regard that are described below.

The New Drug Application for Genasense® in melanoma was withdrawn in 2004 after an advisory committee to the Food and Drug Administration, or FDA, failed to recommend approval. A negative decision was also received for a similar application in melanoma from the European Medicines Agency, or EMEA, in 2007. Data from the pivotal Phase 3 trial that comprised the primary basis for these applications were published in a peer-reviewed journal in 2006. These results showed that treatment with Genasense® plus dacarbazine compared with dacarbazine alone in patients with advanced melanoma was associated with a statistically significant increase in overall response, complete response, durable response, and progression-free survival, or PFS. However, the primary endpoint of overall survival approached but did not quite reach statistical significance ( $P=0.077$ ). Subsequently, our analysis of this trial showed that there was a significant treatment interaction effect related to levels of a blood enzyme known as LDH. 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® ( $P=0.018$ ;  $n=508$ ). Moreover, this benefit was particularly noteworthy for patients whose baseline LDH did not exceed 80% of the upper limit of normal for this lab value.

Based on these data, in August 2007 we initiated a new 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 or dacarbazine alone. The study uses LDH as a biomarker to identify patients who are most likely to respond to Genasense®, based on data obtained from our preceding trial in melanoma. The co-primary endpoints of AGENDA are progression-free survival and overall survival.

AGENDA is designed to expand evidence for the safety and efficacy of Genasense® combined with dacarbazine chemotherapy for patients who have not previously been treated with chemotherapy. The study prospectively targets patients who have low-normal levels of LDH. We expect to enroll approximately 300 subjects at approximately 90 sites worldwide in this trial. Genasense® in melanoma has been designated an Orphan Drug in Australia and the United States, and the drug has Fast Track designation in the United States. Target accrual of 300 patients is currently projected to complete in the fourth quarter of 2008. Initial data on the interim assessment of progression-free survival is expected in the first half of 2009. If the initial assessment of progression-free survival is positive, we expect to discuss these results with the FDA and EMEA and to secure agreement from these agencies that we may commence submission of new regulatory applications for the approval of Genasense® plus chemotherapy in patients with advanced melanoma. Approval by FDA and EMEA will allow Genasense® to be commercialized by us in the U.S. and in the EU.

Given our belief in the activity of Genasense® in melanoma, we have initiated and expect to initiate additional clinical studies in this disease. One such study is the Phase 2 trial of Genasense® plus a chemotherapy regimen consisting of Abraxane®, commonly known as paclitaxel albumen, plus Temodar®, commonly known as temozolomide. We also expect to examine different dosing regimens that will improve the dosing convenience and commercial acceptance of Genasense®, including its administration by brief 1-2 hour IV infusions.

Our initial NDA for the use of Genasense® plus chemotherapy in patients with relapsed or refractory CLL was also unsuccessful. We conducted a randomized Phase 3 trial in 241 patients with relapsed or refractory CLL who were treated with fludarabine and cyclophosphamide, commonly known as 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, defined as a complete or nodular partial response. Patients who achieved this level of response also experienced disappearance of predefined disease symptoms. A key secondary endpoint, duration of complete response, 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).

**Table of Contents**

Several secondary endpoints were not improved by the addition of Genasense®. 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 submitted a NDA to the FDA that sought accelerated approval for the use of Genasense® in combination with Flu/Cy for the treatment of patients with relapsed or refractory CLL who had previously received fludarabine. In December 2006, we received a non-approvable notice for that application from the FDA. However, since we believed that our application had met the regulatory requirements for approval, in April 2007 we filed an appeal of the non-approvable notice using FDA's Formal Dispute Resolution process. In March 2008, we received a formal notice from the FDA that indicated additional confirmatory evidence would be required to support approval of Genasense® in CLL. In that communication, the FDA recommended two alternatives for exploring that confirmatory evidence. One option was to conduct an additional clinical trial. The other option was to collect additional information regarding the clinical course and progression of disease in patients from the completed trial. We have elected to pursue both of these options.

For the first option, we submitted a new protocol in the second quarter of 2008 that sought Special Protocol Assessment, or SPA, from the FDA and Scientific Advice from the EMEA. This protocol is similar in design to the completed trial and uses the same chemotherapy and randomization scheme. The major difference is that the trial focuses on the patient population who derived maximal benefit in the completed trial. This group is characterized by patients who had received less extensive chemotherapy prior to entering the trial and who were defined as being non-refractory to fludarabine. We have deferred initiation of this trial until we receive a response to the second option, described below.

For the second option, we sought information regarding long-term survival on patients who had been accrued to our already completed Phase 3 trial. At a scientific meeting in June 2008, we announced the results of long-term follow-up from the completed Phase 3 trial that comprised the original NDA. With 5 years of follow-up, we showed that patients treated with Genasense® plus chemotherapy who achieved either a complete response or a partial response had also achieved a statistically significant increase in survival.

Previous analyses had shown a significant survival benefit accrued to patients in the Genasense® group who attained CR. Extended follow-up showed that all major responses (a complete response plus a partial response) achieved with Genasense® were associated with significantly increased survival compared with all major responses achieved with chemotherapy alone (median = 56 months vs. 38 months, respectively). After 5 years of follow-up, 22 of 49, or 45%, responders in the Genasense® group were alive compared with 13 of 54, or 24%, responders in the chemotherapy-only group (hazard ratio = 0.6; P = 0.038). Moreover, with 5 years of follow-up, 12 of 20 patients, or 60%, in the Genasense® group who achieved CR were alive, 5 of these patients remained in continuous CR without relapse, and 2 additional patients had relapsed but had not required additional therapy. By contrast, only 3 of 8 CR patients in the chemotherapy-only group were alive, all 3 had relapsed, and all 3 had required additional anti-leukemic treatment.

We believe that the significant survival benefit associated with major responses to Genasense® may provide the confirmatory evidence of clinical benefit that was requested by the FDA. We submitted these new data to FDA in the second quarter of 2008, and the submission was accepted as a complete response to the non-approvable decision letter on July 11, 2008. In that notice of acceptance, the FDA assigned a user fee goal date of December 3, 2008, meaning that the FDA will respond to the new submission regarding approvability of the CLL NDA on or before that date. We have elected not to initiate the aforementioned confirmatory trial until the FDA has rendered its decision on the pending NDA.



As with melanoma, we believe the clinical activity in CLL should be explored with additional clinical research. We plan to explore combinations of Genasense with other drugs that are used for the treatment of CLL, and to examine more convenient dosing regimens.

Lastly, several trials have shown definite evidence of clinical activity for Genasense® in patients with NHL. We would like to conduct additional clinical studies in patients with NHL to test whether Genasense® can be approved

**Table of Contents**

in this indication. Previously, we reported that randomized trials of Genasense® in patients with myeloma, AML, hormone-refractory prostate cancer, or HRPC, small cell lung cancer and non small cell lung cancer were not sufficiently positive to warrant further investigation on the dose-schedules that were examined or with the chemotherapy that was employed in these trials. Data from these trials have been presented at various scientific meetings. However, we believe that alternate dosing schedules, in particular the use of brief high-dose infusions, offer the opportunity to re-examine the drug's activity in some of these indications, in particular multiple myeloma.

On March 7, 2008, we obtained an exclusive worldwide license for tesetaxel, a novel taxane compound that is taken by mouth. Tesetaxel has completed Phase 2 trials in a number of cancer types, and the drug has shown definite evidence of antitumor activity in gastric cancer and breast cancer. Tesetaxel also appears to be associated with a lower incidence of peripheral nerve damage, a common side effect of taxanes that limits the maximum amount of these drugs that can be given to patients. At the time we obtained the license, tesetaxel was on clinical hold by FDA due to the occurrence of several fatalities in the setting of severe neutropenia. In the second quarter of 2008, we filed a response to the FDA requesting a lift of the clinical hold, which was granted on June 23, 2008. Before clinical testing can resume, we plan to submit to FDA an amendment to the existing Drug Master File for a change in the manufacturing process. We are currently determining the sites that will participate in the initial clinical trial that has been allowed by the FDA.

The tesetaxel program seeks to secure a first-to-market advantage for tesetaxel relative to other oral taxanes. We believe success in this competitive endeavor will maximize return to stockholders. Accordingly, we have identified three oncology indications in which we believe tesetaxel may have sufficient efficacy and safety to warrant regulatory approval. We believe it may be possible to secure regulatory approval in these indications on the basis of endpoints that can be achieved in clinical trials that may be relatively limited in scope.

In addition to these three smaller indications, we are interested in examining the activity of tesetaxel in patients with HRPC. Docetaxel, or Taxotere®, is the only taxane approved for first-line use in patients with HRPC. Although docetaxel has been shown to extend survival in men with HRPC, its use is associated with a high incidence of moderate-to-severe toxicity. If tesetaxel is shown to be active in HRPC, we believe its safety profile may be substantially superior to docetaxel and may supplant that drug for first-line use in this indication. However, the development of drugs in this indication is very costly. Additional funding will be required to support the extended clinical testing that will be required to secure regulatory approval in HRPC.

Our third pipeline product is G4544, which is a novel oral formulation of a gallium-containing compound that we developed in collaboration with Emisphere Technologies, Inc. We completed a single-dose Phase 1 study of an initial formulation of this new drug known as G4544(a) and the results were presented at a scientific meeting in the second quarter of 2008. We are planning another study using a modified formulation, known as G4544(b). The FDA has indicated that a limited, animal toxicology study in a single species will be required prior to initiation of multi-dose studies of G4544(b). Progress in the clinical development of G4544 program was delayed in 2008 due to financial constraints, but we currently expect to continue our program as planned.

We currently intend to pursue a 505(b)(2) strategy to establish bioequivalence to our marketed product, Ganite®, for the initial regulatory approval of G4544. However, we believe this drug may also be useful for treatment of other diseases associated with accelerated bone loss, such as bone metastases, Paget's disease and osteoporosis. In addition, new uses of gallium-containing compounds have been identified for treatment of certain infectious diseases, particularly severe infections involving the bacteria *Pseudomonas aeruginosa*, which are frequently lethal in patients with cancer and cystic fibrosis. While we have no current plans to begin clinical development in the area of infectious disease, we intend to support research conducted by certain academic institutions by providing clinical supplies of our gallium-containing drugs.

Lastly, we have announced our intention to seek a buyer for Ganite<sup>®</sup>, our sole marketed product. Our financial constraints have prevented us from investing in adequate commercial support for Ganite<sup>®</sup>, and the intellectual property that provided us with an exclusive position in the United States has now expired.

**Table of Contents****Results of Operations for the Three Months Ended June 30, 2008 and June 30, 2007**

	<b>2008</b>	<b>2007</b>
	(\$ thousands)	
Product sales net	\$ 131	\$ 105
Cost of goods sold	29	26
Gross margin	102	79
Operating expenses:		
Research and development	4,454	4,099
Selling, general and administrative	2,587	4,735
Settlement of office lease obligation	3,307	
Reduction in liability for settlement of litigation, net	(80)	(240)
Total operating expenses	10,268	8,594
Other (expense)/income:		
Amortization of deferred financing costs	(840)	0
Fair market value conversion feature liability	(720,000)	0
Fair market value warrant liability	(7,200)	0
All other (expense)/ income, net	(158)	280
Total other (expense)/income, net	(728,198)	280
Net loss	\$ (738,364)	\$ (8,235)

**Product sales-net**

Product sales-net of Ganite<sup>®</sup> were \$131 thousand for the three months ended June 30, 2008, compared with \$105 thousand for the three months ended June 30, 2007. Product sales-net in 2008 include \$5 thousand through the named-patient program managed for us by IDIS Limited (a privately owned company based in the United Kingdom), whereby IDIS distributes Ganite<sup>®</sup> and Genasense<sup>®</sup> on a named patient basis. Named patient distribution refers to the distribution or sale of a product to a specific healthcare professional for the treatment of an individual patient.

**Cost of goods sold**

There was a higher cost of goods sold in the three months ended June 30, 2008 than in the three months ended June 30, 2007 as a result of a larger number of units sold.

**Research and development expenses**

Research and development expenses were \$4.5 million for the three months ended June 30, 2008, compared with \$4.1 million for the three months ended June 30, 2007. This increase was primarily due to higher expenses from the AGENDA clinical trial, partially offset by lower payroll costs, resulting from lower headcount. In April 2008 and in May 2008, we reduced our workforce to conserve cash.

Research and development expenses incurred on the Genasense<sup>®</sup> project during the three months ended June 30, 2008 were approximately \$4.3 million, representing 96% of research and development expenses.

Due to the significant risks and uncertainties inherent in the clinical development and regulatory approval processes, the nature, timing and costs of the efforts necessary to complete projects in development are 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.

**Table of Contents****Selling, general and administrative expenses**

Selling, general and administrative expenses were \$2.6 million for the three months ended June 30, 2008, compared with \$4.7 million for the three months ended June 30, 2007. This decrease was primarily due to lower payroll costs, resulting from the two reductions in workforce, as well as lower administrative expenses.

**Settlement of office lease obligation**

In May 2008, we entered into an amendment of our Lease Agreement with The Connell Company, referred to herein as Connell, whereby the lease for one floor of our office space in Berkeley Heights, New Jersey was terminated. Connell received a termination payment of \$1.3 million, comprised of our security deposits and will receive a future payment from us of \$2.0 million upon the earlier of July 1, 2009 or our receipt of at least \$5.0 million in upfront cash from a business development deal. We accrued for the \$2.0 million and it is included in accounts payable and accrued expenses on our Consolidated Balance Sheets. This transaction resulted in an incremental \$3.3 million in expenses for the three months ended June 30, 2008.

**Provision for settlement of litigation, net**

In the fourth quarter of 2006, we recorded an expense of \$5.3 million that provides for the issuance of 2.0 million shares of our common stock, for a settlement in principle of class action litigation. The expense is net of insurance recovery of \$18.0 million. At June 30, 2007, the revised estimated value of the common shares portion of the litigation settlement was \$3.5 million, resulting in a reduction in the provision of \$0.2 million for the second quarter of 2007. At June 27, 2008, the date that the settlement became final, the revised value of the common stock portion of the litigation settlement was \$0.7 million, based on a closing price of our common stock of \$0.35 per share, resulting in a reduction in the provision of \$0.1 million for the second quarter of 2008.

**Amortization of deferred financing costs**

On June 9, 2008, we issued \$20 million of our senior secured convertible notes, issued our private placement agent a warrant to purchase 40,000,000 shares of our common stock at an exercise price of \$0.02 per share and incurred a financing fee of \$1.2 million. The deferred financing costs including the financing fee and the issuance of the warrant are being amortized over the two-year term of the convertible notes, resulting in amortization of \$0.8 million in the month of June 2008.

**Fair value conversion feature liability**

On the issuance date of the convertible notes there was an insufficient number of authorized shares of common stock in order to permit exercise of all of the notes. In accordance with EITF 00-19, Accounting for Derivative Financial Instruments Indexed to, and Potentially Settled in, a Company's Own Stock (EITF 00-19), when there are insufficient authorized shares, the conversion feature for the notes was determined to be an embedded derivative instrument. As a result, it has been classified as a liability measured at fair value on the balance sheet.

On June 9, 2008, we valued the conversion feature based upon a Black-Scholes valuation model that included a closing price of our common stock of \$0.20 per share and calculated a fair value of the conversion feature to be \$380.0 million and expensed \$360.0 million, the amount that exceeded the proceeds of the \$20.0 million from the initial closing. On June 30, 2008, based upon a Black-Scholes valuation model that included a closing price of our common stock of \$0.38 per share, we expensed an additional \$380.0 million to mark the conversion feature liability to market, resulting in a total expense in June of \$740.0 million.

***Fair value warrant liability***

The warrant was also treated as a liability and was recorded at a fair value of \$7.6 million based upon a Black-Scholes valuation model that included a closing price of our common stock of \$0.20 per share. On June 30, 2008, based on a Black-Scholes valuation model that included a closing price of our common stock of \$0.38 per share, we expensed \$7.2 million to mark the warrant liability to market.

**Table of Contents**

We will continue to mark the convertible note and the warrant to market until the date that stockholders approve an increase in the number of authorized shares. We are planning to have an Annual Meeting of Stockholders later this year and our Board of Directors has recommended that stockholders approve a charter amendment to increase the amount of our authorized shares. Once stockholders approve an increase in the amount of authorized shares, the mark-to-market liabilities for the conversion feature and the warrant will be transferred to Stockholders Equity.

**All other (expense)/ income, net**

Net other expense of \$0.2 million for the three months ended June 30, 2008 unfavorably compared to net other income of \$0.3 million for the three months ended June 30, 2007 due to lower investment income, resulting from lower investment balances and accrued interest on the recently issued convertible notes.

**Net loss**

We incurred a net loss of \$738.4 million, or (\$20.10) per share, for the three months ended June 30, 2008 and \$8.2 million, or (\$0.27) per share, for the three months ended June 30, 2007.

The larger net loss in 2008 is primarily due to the mark-to-market charge on the conversion feature liability of \$720.0 million, the mark-to-market charge on the warrant liability of \$7.2 million, the expenses resulting from the reduction in our office space of \$3.3 million, higher expenses resulting from the AGENDA clinical trial and the amortization of deferred financing costs of \$0.8 million, slightly offset by lower payroll costs, resulting from the two reductions in workforce, as well as lower administrative expenses.

**Results of Operations for the Six Months Ended June 30, 2008 and June 30, 2007**

	<b>2008</b>	<b>2007</b>
	<b>(\$ thousands)</b>	
Product sales net	\$ 248	\$ 199
Cost of goods sold	54	48
Gross margin	194	151
Operating expenses:		
Research and development	10,891	7,481
Selling, general and administrative	6,225	8,787
Settlement of office lease obligation	3,307	
Reduction in liability for settlement of litigation, net	(340)	(1,800)
Total operating expenses	20,083	14,468
Other (expense)/income:		
Amortization of deferred financing costs	(840)	0
Fair market value conversion feature liability	(720,000)	0
Fair market value warrant liability	(7,200)	0
All other (expense)/ income, net	(92)	478
Total other (expense)/income, net	(728,132)	478
Net loss	\$ (748,021)	\$ (13,839)



**Product sales-net**

Product sales-net of Ganite® were \$248 thousand for the six months ended June 30, 2008, compared with \$199 thousand for the six months ended June 30, 2007. Product sales-net in 2008 includes \$15 thousand through the named-patient program managed for us by IDIS.

**Table of Contents**

**Cost of goods sold**

There was a higher cost of goods sold in the six months ended June 30, 2008 than in the six months ended June 30, 2007 as a result of a larger number of units sold.

**Research and development expenses**

Research and development expenses were \$10.9 million for the six months ended June 30, 2008, compared with \$7.5 million for the six months ended June 30, 2007. This increase was primarily due to the recognition in March 2008 of \$2.5 million for license payments on tesetaxel and higher expenses from the AGENDA clinical trial, partially offset by lower payroll costs, resulting from lower headcount.

Research and development expenses incurred on the Genasense<sup>®</sup> project during the six months ended June 30, 2008 were approximately \$7.7 million, representing 70% of research and development expenses (including the \$2.5 million for license payments of tesetaxel). Excluding the expense of \$2.5 million that was recorded for license payments of tesetaxel, research and development expenses incurred on the Genasense<sup>®</sup> represented 92% of research and development expenses.

**Selling, general and administrative expenses**

Selling, general and administrative expenses were \$6.2 million for the six months ended June 30, 2008, compared with \$8.8 million for the six months ended June 30, 2007. The decrease is primarily due to our efforts at lowering administrative expenses and lower payroll costs, resulting from the two reductions in workforce.

**Provision for settlement of litigation, net**

From January 1, 2008 through June 27, 2008, the date that the settlement of class action litigation became final, the reduction in the price of our common stock resulted in a reduction in the provision of \$0.3 million. During the six months ended June 30, 2007, the provision for settlement of litigation declined \$1.8 million due to the reduction in the price of our common stock.

**All other (expense)/ income, net**

Net other expense of \$0.1 million for the six months ended June 30, 2008 unfavorably compared to net other income of \$0.5 million for the six months ended June 30, 2007 due to lower investment income, resulting from lower investment balances and accrued interest on the recently issued convertible notes.

**Net loss**

We incurred a net loss of \$748.0 million, or \$21.21 per share, for the six months ended June 30, 2008 and \$13.8 million, or \$0.48 per share, for the six months ended June 30, 2007.

The larger net loss in 2008 is primarily due to the mark-to-market charge on the conversion feature liability of \$720.0 million, the mark-to-market charge on the warrant liability of \$7.2 million, the expenses resulting from the reduction in our office space of \$3.3 million, the recognition in March 2008 for our license payments on tesetaxel of \$2.5 million, higher expenses resulting from the AGENDA clinical trial and the amortization of deferred financing costs of \$0.8 million, slightly offset by lower payroll costs, resulting from the two reductions in workforce, as well as lower administrative expenses.



**Table of Contents****Results of Operations for the Years Ended December 31, 2007, December 31, 2006 and December 31, 2005****Summary Operating Results  
for the Years Ended December 31,**

	<b>\$ Change</b>				
	<b>2007</b>	<b>2006</b>	<b>2005</b>	<b>07 vs. 06</b>	<b>06 vs. 05</b>
	(\$ thousands)				
<b>Revenues:</b>					
License fees and royalties	\$	\$	\$ 5,241	\$	\$ (5,241)
Development funding			20,988		(20,988)
Product sales net	580	708	356	(128)	352
<b>Total revenues</b>	<b>580</b>	<b>708</b>	<b>26,585</b>	<b>(128)</b>	<b>(25,877)</b>
Cost of goods sold	90	108	52	(18)	56
<b>Operating expenses:</b>					
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)
<b>Total operating expenses gross</b>	<b>26,116</b>	<b>59,764</b>	<b>37,006</b>	<b>(33,648)</b>	<b>22,758</b>
Less: sanofi-aventis reimbursement			(6,090)		6,090
<b>Total operating expenses net</b>	<b>26,116</b>	<b>59,764</b>	<b>30,916</b>	<b>(33,648)</b>	<b>28,848</b>
Gain on forgiveness of debt			1,297		(1,297)
Other income/(expense), net	836	1,454	502	(618)	952
<b>Loss before income taxes</b>	<b>(24,790)</b>	<b>(57,710)</b>	<b>(2,584)</b>	<b>32,920</b>	<b>(55,126)</b>
Income tax benefit	1,470	929	381	541	548
<b>Net loss</b>	<b>\$ (23,320)</b>	<b>\$ (56,781)</b>	<b>\$ (2,203)</b>	<b>\$ 33,461</b>	<b>\$ (54,578)</b>

**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, or 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.

**Table of Contents**

**Cost of goods sold**

Lower cost of goods sold in 2007 than in 2006 is the result of lower sales of Ganite<sup>®</sup>, as well as sales of Genasense<sup>®</sup> 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<sup>®</sup>.

**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<sup>®</sup> 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 for the Year Ended December 31, 2007, 2006 and 2005). Research and development expenses incurred on the Genasense<sup>®</sup> 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<sup>®</sup> 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<sup>®</sup> 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<sup>®</sup> 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.

**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<sup>®</sup>. 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.

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<sup>®</sup> 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 stockholders 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

**Table of Contents**

cash for the benefit of plaintiffs and the stockholder 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 Consolidated Financial Statements for the Year Ended December 31, 2007, 2006 and 2005). 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 Consolidated Financial Statements for the Year Ended December 31, 2007, 2006 and 2005).

**sanofi-aventis reimbursement**

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

**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

## **Table of Contents**

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**

We 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.

## **Liquidity and Capital Resources**

At June 30, 2008, we had cash, cash equivalents and marketable securities totaling \$16.3 million compared with \$7.8 million at December 31, 2007 reflecting in part, the net proceeds from the placement of \$20 million of notes on June 9, 2008.

The notes bear interest at an annual rate of 15% payable at quarterly intervals in stock or cash at our option, and the notes are convertible into shares of our common stock at a conversion rate of 100,000 shares of common stock for every \$1,000.00 of principal. Holders of the notes have the right, but not the obligation, for the 12 months following the initial closing date to purchase in whole or in part up to an additional \$20 million of the notes. We have the right to force conversion of the notes in whole or in part if the closing bid price of our common stock exceeds \$0.50 for a period of 20 consecutive trading days. Certain members of our senior management participated in this offering. The notes include certain events of default, including a requirement that we obtain stockholder approval within a specified period of time to amend our certificate of incorporation to authorize additional shares of common stock. In addition, the notes prohibit any additional financing without the approval of holders of more than two-thirds of the principal amount of the notes.

Upon the occurrence of an event of default, holders of the notes have the right to require us to prepay all or a portion of their notes as calculated as the greater of (a) 150% of the aggregate principal amount of the note plus accrued

interest or (b) the aggregate principal amount of the note plus accrued interest divided by the conversion price; multiplied by a weighted average price of our common stock. Pursuant to a general security agreement, entered into concurrent with the notes, the notes are secured by a first lien on all of our assets.

During the first six months of 2008, cash used in operating activities was \$14.4 million compared with \$16.8 million for the same period in 2007. Lower cash used in operating activities was primarily due to the timing of payments in the two respective periods.

**Table of Contents**

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, before estimated fees and expenses of approximately \$203 thousand.

Effective May 7, 2008, we moved the trading of our common stock from The NASDAQ Capital Markets to the Over-the-Counter Bulletin Board, or OTCBB, maintained by FINRA (formerly, the NASD). This action was taken pursuant to receipt of notification from the NASDAQ Listing Qualifications Panel that we had failed to demonstrate our ability to sustain compliance with the \$2.5 million minimum stockholders' equity requirement for continued listing on The NASDAQ Capital Markets. On July 10, 2008, we received notification from The NASDAQ Capital Market that The NASDAQ Capital Market had determined to remove our common stock from listing on such exchange. The delisting was effective at the opening of the trading session on July 21, 2008.

Irrespective of whether an NDA or MAA for Genasense® are approved, we will require additional cash in order to maximize this commercial opportunity and to 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, profits from named-patient sales, and other potential sources of financing. However, there can be no assurance that any such collaborative agreements or other sources of funding will be available to us on favorable terms, if at all.

We 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, we project that we will run out of funds in the first quarter of 2009. 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 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 June 30, 2008 are as follows (\$ thousands):

		Less Than		3 -	More Than
	Total	1 Year	1 - 3 Years	5 Years	5 Years
Convertible notes	\$ 26,000	\$ 3,000	\$ 23,000	\$ 0	\$ 0
Uncertain tax positions*	\$ 776	\$ 776	\$ 0	\$ 0	\$ 0
Operating lease obligations	\$ 1,161	\$ 706	\$ 455	\$ 0	\$ 0

Total	\$ 27,937	\$ 4,482	\$ 23,445	\$ 0	\$ 0
-------	-----------	----------	-----------	------	------

---

\* see Note 13 to our Consolidated Financial Statements for the Years Ended December 31, 2007 and 2006.

Virtually all of the operating lease obligations result from our lease of approximately 25 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<sup>®</sup> 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 us to purchase a percentage of our global Genasense<sup>®</sup> bulk drug requirements from Avecia during the term of the agreement. Due to the uncertainties regarding the timing of any Genasense<sup>®</sup> approval and sales/volume projections, specific obligation amounts cannot be estimated at this time. Due to past purchases of

## **Table of Contents**

Genasense® bulk drug substance, we have access to sufficient drug for our 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 with Daiichi Sankyo Company, Limited, a Japanese corporation based in Tokyo, Japan, whereby we obtained the exclusive license for tesetaxel. At the time, Tesetaxel had been placed on clinical hold by the FDA. In the second quarter of 2008, we filed a response to the FDA requesting a lift of the clinical hold, which was granted on June 23, 2008. Before clinical testing can resume, we plan to submit to FDA an amendment to the existing Drug Master File for a change in the manufacturing process.

Pursuant to such license 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 of 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 tesetaxel 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.

## **Recent Accounting Pronouncements**

In December 2007, the FASB issued SFAS 141(R), Business Combinations ( SFAS 141(R) ), which replaces SFAS 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 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, or 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 did not

have a material effect.

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.

**Table of Contents**

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 impact of this standard on the consolidated financial statements did not have a material effect.

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 impact of this standard on the consolidated financial statements did not have a material effect.

In September 2006, the FASB issued SFAS 157, *Fair Value Measurements* . 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 were required to adopt SFAS 157 beginning January 1, 2008. The impact of this standard on the consolidated financial statements did not have a material effect.

**Critical Accounting Policies**

Our significant accounting policies are more fully described in Note 3 to our Consolidated Financial Statements for the Year Ended December 31, 2007, 2006 and 2005 and Note 3 to our Consolidated Financial Statements for the Quarter Ended June 30, 2008 and 2007. 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:

*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. 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.

*Revenue recognition.* 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.



*Research and development costs.* All such costs are expensed as incurred, including raw material costs required to manufacture drugs for clinical trials.

*Estimate of fair value of convertible notes and warrant.* We use a Black-Scholes model to estimate the fair value of our convertible notes and warrant. Our Black-Scholes estimate is derived by our stock price and our estimates of stock price volatility and interest rates.

**Table of Contents**

**CHANGE IN INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM**

On July 16, 2008, following an extensive review and request-for-proposal process, our Audit Committee determined not to renew our engagement of Deloitte & Touche LLP as our independent registered public accounting firm and dismissed them as our auditors. On July 16, 2008, the Audit Committee recommended and approved the appointment of Amper Politziner & Mattia, P.C. as our auditors for the fiscal year ending December 31, 2008, commencing immediately on such date.

No accountant's report issued by Deloitte & Touche LLP on the financial statements for either of the past two (2) fiscal years contained an adverse opinion or a disclaimer of opinion, or was qualified or modified as to uncertainty, audit scope or accounting principles, except that Deloitte & Touche LLP's report on our consolidated financial statements as of and for the year ended December 31, 2007 contained an explanatory paragraph expressing substantial doubt as to our ability to continue as a going concern as a result of recurring losses and negative cash flows from operations.

During each of the fiscal years ended December 31, 2007 and December 31, 2006 and the subsequent interim period from January 1, 2008 through our notice to Deloitte & Touche LLP of its non-renewal on July 16, 2008: (i) there were no disagreements with Deloitte & Touche LLP on any matter of accounting principles or practices, financial statement disclosure, or auditing scope or procedure, which disagreement, if not resolved to the satisfaction of Deloitte & Touche LLP, would have caused it to make reference to the subject matter of the disagreement in connection with its reports; and (ii) there were no reportable events (as defined in Item 304(a)(1)(v) of Regulation S-K). In addition, Deloitte & Touche LLP's reports on our financial statements for the past two years did not contain an adverse opinion or a disclaimer of opinion, nor were such reports qualified or modified as to uncertainty, audit scope or accounting principles. Deloitte & Touche LLP's reports on our financial statements did include an explanatory paragraph relating to our ability to continue as a going concern and the our 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 an Interpretation of FASB Statement no. 109, effective January 1, 2007.

During our fiscal years ended December 31, 2006 and December 31, 2007 and the subsequent interim period from January 1, 2008 through the engagement of Amper Politziner & Mattia, P.C., we did not consult with Amper Politziner & Mattia, P.C. regarding the application of accounting principles to a specified transaction, either completed or proposed; the type of audit opinion that might be rendered on our consolidated financial statements, or any matter that was either the subject of disagreement, as that term is defined in Item 304(a)(1)(iv) of Regulation S-K; or a reportable event, as that term is defined in Item 304(a)(1)(v) of Regulation S-K.

**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. If our stock price were to increase, the Black Scholes model will calculate a higher estimate of the fair value of our convertible notes and warrant. If our stock price were to decrease, the Black Scholes model will calculate lower values. 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 for the Year Ended December 31, 2007, 2006 and 2005). 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 June 30, 2008. 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.

**Table of Contents****MANAGEMENT**

The Directors and executive officers of Genta, their age, positions in Genta, the dates of their initial election or appointment as Directors or executive officers, and the expiration of the terms are as follows:

<b>Name</b>	<b>Age</b>	<b>Position with the Company</b>
Raymond P. Warrell, Jr., M.D.	58	Chairman and Chief Executive Officer
Richard J. Moran, CPA	61	Sr. Vice President and Chief Financial Officer
Gary Siegel	50	Vice President, Finance
Loretta M. Itri, M.D., F.A.C.P.	58	President Pharmaceutical Development and Chief Medical Officer
W. Lloyd Sanders	47	Senior Vice President Commercial Operations
Martin J. Driscoll	49	Director
Christopher P. Parios	67	Director
Daniel D. Von Hoff, M.D.	60	Director
Douglass G. Watson	63	Director

All directors hold office until the annual meeting next following their election and/or until their successors are elected and qualified. Officers are elected annually by the Board of Directors (the Board) and serve at the discretion of the Board. Information with respect to the business expenses and affiliation of our directors and executive officers is set forth below:

*Raymond P. Warrell, Jr., M.D.*, 58, has been our Chief Executive Officer and a member of our Board since December 1999 and our Chairman since January 2001. From December 1999 to May 2003, he was also our President. From 1978 to 1999, Dr. Warrell was associated with the Memorial Sloan-Kettering Cancer Center in New York, where he held tenured positions as Member, Attending Physician, and Associate Physician-in-Chief, and with the Joan and Sanford Weill Medical College of Cornell University, where he was Professor of Medicine. Dr. Warrell also has more than 20 years of development and consulting experience in pharmaceuticals and biotechnology products. He was a co-founder and chairman of the scientific advisory board of PolaRx Biopharmaceuticals, Inc., which developed Trisenox<sup>®</sup>, a drug for the treatment of acute promyelocytic leukemia, which is now marketed by Cephalon, Inc. Dr. Warrell holds or has filed numerous patents and patent applications for biomedical therapeutic or diagnostic agents. He has published more than 100 peer-reviewed papers and more than 240 book chapters and abstracts, most of which are focused upon drug development in tumor-related diseases. Dr. Warrell is a member of the American Society of Clinical Investigation, the American Society of Hematology, the American Association for Cancer Research and the American Society of Clinical Oncology. Among many awards, he has received the U.S. Public Health Service Award for Exceptional Achievement in Orphan Drug Development from the FDA. He obtained a B.S. in Chemistry from Emory University, a M.D. from the Medical College of Georgia, and a M.B.A. from Columbia University Graduate School of Business. Dr. Warrell is married to Dr. Loretta M. Itri, President, Pharmaceutical Development and Chief Medical Officer of Genta.

*Richard J. Moran, CPA*, 61, became our Senior Vice President and Chief Financial Officer in September 2005 and retired in February 2008. Mr. Moran brought extensive and diversified finance experience from a long career with Johnson & Johnson (J&J) and several of its operating companies. He served as Chief Financial Officer, Vice President Finance, and member of the U.S.A. Board of Ortho Biotech from 1995 until 2002, and from 2000 to 2002 he assumed additional finance responsibility for the Ortho Biotech Worldwide Board. In that role, he was responsible for planning,

preparation, management, compliance and controls of the accounting and financial activities of this \$4.4 billion global business unit. From 2002 until his retirement in 2004, he served as Director at J&J's Corporate Headquarters, where he was charged with strategic development and implementation of Sarbanes-Oxley Section 404 compliance requirements at more than 350 worldwide locations with \$45 billion in annual sales. Mr. Moran previously served as Finance Group Controller for J&J's International Cilag, Ortho Pharmaceuticals, McNeil Pharmaceuticals (ICOM) Group from 1989 to 1994 during the launch of Eprex® in 50 countries and Procrit® in the U.S., and he served as a Board member for both Cilag Europe and the ICOM Group. From 1983 to 1988, Mr. Moran was a Director of J&J's Corporate Internal Audit Department. Mr. Moran is a member of the New Jersey Society of Certified Public Accountants, the American Institute of Certified Public Accountants, and has

**Table of Contents**

served as Chairman of the Board and Treasurer of the American Red Cross of Somerset County, NJ. Mr. Moran retired from Genta effective February 29, 2008.

*Gary Siegel, 50*, joined Genta in May 2003 as Director, Financial Services, was appointed Senior Director, Financial Services in April 2004 and was appointed Vice President, Finance in September 2007. During his tenure at Genta, Mr. Siegel has been accountable for the day-to-day accounting and financial operations of the Company including public and management reporting, treasury operations, planning, financial controls and compliance. Mr. Siegel became an executive officer of the Company and assumed the role of interim Principal Accounting Officer, interim Principal Financial Officer and interim Corporate Secretary, effective February 29, 2008, while the Company searches for Mr. Moran's successor. Prior to joining Genta, he worked for two years at Geller & Company, a private consulting firm, where he led the management reporting for a multi-billion dollar client. His twenty-two years of experience in the pharmaceutical industry include leadership roles at Warner-Lambert Company and Pfizer Inc., where he held positions of progressively increasing levels of responsibility including Director, Corporate Finance and Director, Financial Planning & Reporting.

*Loretta M. Itri, M.D., F.A.C.P., 58*, has been our President, Pharmaceutical Development and Chief Medical Officer since May 2003, prior to which she was Executive Vice President, Pharmaceutical Research and Development and Chief Medical Officer. Dr. Itri joined Genta in March 2001. Previously, Dr. Itri was Senior Vice President, Worldwide Clinical Affairs, and Chief Medical Officer at Ortho Biotech Inc., a Johnson & Johnson company. As the senior clinical leader at Ortho Biotech and previously at J&J's R.W. Johnson Pharmaceutical Research Institute (PRI), she led the clinical teams responsible for NDA approvals for Procrit® (epoetin alpha), that company's largest single product. She had similar leadership responsibilities for the approvals of Leustatin®, Renova®, Topamax®, Levaquin®, and Ultram®. Prior to joining J&J, Dr. Itri was associated with Hoffmann-La Roche, most recently as Assistant Vice President and Senior Director of Clinical Investigations, where she was responsible for all phases of clinical development programs in immunology, infectious diseases, antivirals, AIDS, hematology and oncology. Under her leadership in the areas of recombinant proteins, cytotoxic drugs and differentiation agents, the first successful Product License Application (PLA) for any interferon product (Roferon-A®; interferon alfa) was compiled. Dr. Itri is married to Dr. Warrell, our Chief Executive Officer and Chairman.

*W. Lloyd Sanders, 47*, assumed the position of Senior Vice President and Chief Operating Officer in March 2008. He had been our Senior Vice President, Commercial Operations since October 2006. Mr. Sanders joined Genta in January 2006 as Vice President, Sales and Marketing. He has twenty years of experience in the pharmaceutical industry. Prior to joining Genta, Mr. Sanders was associated with Sanofi-Synthelabo, and subsequently Sanofi-Aventis. From October 2004 through January 2006 he was Vice-President, Oncology Sales for the combined companies. In that role, he had key product sales responsibility for Eloxatin® (oxaliplatin), Taxotere® (docetaxel), Anzemet® (dolasetron mesylate), and ELITEK® (rasburicase). He led the successful restructuring, integration, deployment, strategic development, and tactical execution of the merged companies' sales forces. He was responsible for national account GPO contracting strategy and negotiations, and he shared responsibility for oncology sales training and sales operations. From October 2002 through October 2004, Mr. Sanders was Area Vice President, Oncology Sales. He led the 110-member team that achieved record sales for an oncology product launch with Eloxatin®. From 1987 until 2002, he held positions of progressively increasing levels of responsibility at Pharmacia, Inc. (now Pfizer), most recently as Oncology Sales Director, West/East. Mr. Sanders holds a Bachelor of Business Administration from Memphis State University.

*Martin J. Driscoll, 49*, has been a member of our Board since September 2005. Mr. Driscoll brings more than twenty-seven years of executive experience in pharmaceutical Marketing & Sales, Business Development and Commercial Operations to the Genta Board. In March 2008, Mr. Driscoll became Chief Executive Officer of Javelin Pharmaceuticals, Inc. (AMEX:JAV) of Cambridge, Massachusetts where he had also served as a director since 2006. Javelin is a specialty pharmaceutical company that applies innovative proprietary technologies to develop new drugs

and improved formulations of existing drugs that target current and underserved medical need in the pain management market. Mr. Driscoll joined Javelin from Pear Tree Pharmaceuticals, Inc., a development-stage company focused on women's prescription healthcare products. Mr. Driscoll was CEO of Pear Tree Pharmaceuticals from September 2007 until March 2008. From August 2005 until September 2007, Mr. Driscoll was President of MKD Consulting Inc., a pharmaceutical management and commercialization consulting firm, and a Partner at TGaS Consulting, a pharmaceutical commercial operations benchmarking firm. From July 2003 until August 2005,

**Table of Contents**

Mr. Driscoll was Senior Vice President of Marketing and Sales at Reliant Pharmaceuticals, a privately held company that markets a portfolio of branded pharmaceutical products, where he was a member of the Management Committee and an Executive Officer of the Company. From 1983 to 1990, Mr. Driscoll held positions of increasing responsibility at Schering Plough Corporation, including most recently as Vice President of Marketing and Sales for Schering's Primary Care Division. He previously served as Vice President, Marketing and Sales, for the Schering Diabetes Unit, and also for Key Pharmaceuticals, the largest Schering U.S. Business Unit. His experience includes management of franchises that encompass oncologic, cardiovascular, anti-infective, metabolic, CNS, pulmonary and dermatologic products. At both Reliant and Schering, Mr. Driscoll had extensive experience in the negotiation, implementation and management of collaborations with other companies. Prior to joining Reliant, from 2000 to 2002 Mr. Driscoll was Vice President, Commercial Operations and Business Development at ViroPharma Inc., where he built the first commercial Sales and Marketing operation, and was the ViroPharma Chair for the ViroPharma/Aventis Joint Steering Committee for their Phase 3 antiviral product collaboration.

*Christopher P. Parios*, 67, has been a member of our Board since September 2005. Mr. Parios has more than thirty-seven years of pharmaceutical industry experience, including product development, marketing and promotion, strategy and tactic development, and managing pharmaco-economic and reimbursement issues. He has worked with many of the major companies in the pharmaceutical industry including Hoffmann-LaRoche, Ortho-McNeil, Pfizer, Novartis, Schering Plough, Janssen, Ortho Biotech, and Bristol-Myers Squibb. For the period 1997 to May of 2008, Mr. Parios was Executive Director of The Dominion Group, an independent healthcare consulting firm that specializes in market research, strategic planning, and competitive intelligence monitoring. In this role, he was responsible for the full range of market research, consulting, and business planning activities to facilitate informed business decisions for clients regarding product development, acquisitions, product positioning, and promotion. Mr. Parios continues to consult with the Dominion Group on a part-time basis. Previously, Mr. Parios was President and Chief Operating Officer of the Ferguson Communication Group, as well as Vice Chairman of the parent company, CommonHealth USA, a leading full-service communications resource for the healthcare industry. Mr. Parios was a partner in Pracon, Inc., a health-care marketing consulting firm from 1982 to 1991, and helped engineer the sale of that firm to Reed-Elsevier in 1989. Over a twenty-year period, Mr. Parios held progressively senior positions at Hoffmann-LaRoche, Inc., most recently as Director of New Product Planning and Regulatory Affairs Management. This group established the project management system for drug development at Roche and coordinated developmental activities for such products as Versed®, Rocephin®, Roferon®, Accutane®, Rimadyl®, and Tegison®. Mr. Parios was also a member of the corporate team responsible for domestic and international product and technology licensing activities.

*Daniel D. Von Hoff, M.D., F.A.C.P.*, 60, has been a member of our Board since January 2000. Since November 2002, he has been Physician in Chief and Director of Translational Research at Translational Genomics Research Institute (TGen) in Phoenix, Arizona. He is also Chief Scientific Officer for US Oncology since January 2003 and he is also the Chief Scientific Officer, Scottsdale Clinical Research Institute since November 2005. Dr. Von Hoff's major interest is in the development of new anticancer agents, both in the clinic and in the laboratory. He and his colleagues were involved in the beginning of the development of many of the agents now used routinely, including: mitoxantrone, fludarabine, paclitaxel, docetaxel, gemcitabine, CPT-11, and others. At present, he and his colleagues are concentrating on the development of molecularly targeted therapies. Dr. Von Hoff's laboratory interests and contributions have been in the area of in vitro drug sensitivity testing to individualize treatment for the patient. He and his laboratory are now concentrating on discovery of new targets in pancreatic cancer. Dr. Von Hoff has published more than 531 papers, 129 book chapters, and more than 891 abstracts. Dr. Von Hoff was appointed to President Bush's National Cancer Advisory Board for June 2004 – March 2010. Dr. Von Hoff is the past President of the American Association for Cancer Research, a Fellow of the American College of Physicians, and a member and past board member of the American Society of Clinical Oncology. He is a founder of ILEX™ Oncology, Inc. (recently acquired by Genzyme). He is founder and the Editor Emeritus of Investigational New Drugs The Journal of New Anticancer Agents; and, Editor-in-Chief of Molecular Cancer Therapeutics.



*Douglas G. Watson*, 63, has been a member of our Board since April 2002 and was appointed Vice Chairman of our Board and Lead Director in March 2005. From 1999 through the present, Mr. Watson is the founder and has served as Chief Executive Officer of Pittencrieff Glen Associates, a leadership and management-consulting firm. Prior to taking early retirement in 1999, Mr. Watson spent 33 years with Geigy/Ciba-Geigy/Novartis, during which

## **Table of Contents**

time he held a variety of positions in the United Kingdom, Switzerland and the United States. From 1986 to 1996, he was President of Ciba U.S. Pharmaceuticals Division, and in 1996 he was appointed President & Chief Executive Officer of Ciba-Geigy Corporation. During this ten-year period, Mr. Watson was an active member of the Pharmaceutical Research & Manufacturers Association board in Washington, DC. Mr. Watson became President & Chief Executive Officer of Novartis Corporation in 1997 when the merger of Ciba-Geigy & Sandoz was approved by the Federal Trade Commission. Mr. Watson is currently Chairman of the Board of OraSure Technologies Inc., and Chairman of the Board of Javelin Pharmaceuticals Inc. He also serves on the boards of Dendreon Corporation and BioMimetic Therapeutics Inc.

## **Executive Compensation**

### ***Compensation Discussion and Analysis***

The Compensation Discussion and Analysis Section described herein includes reference to our 2007 Stock Incentive Plan, which is subject to stockholder approval. This plan is not yet approved.

### **Overview of Compensation Program**

The Compensation Committee, also referred to herein as the Committee, of the Board of Directors has responsibility for overseeing our compensation and benefit policies, evaluating senior executive performance, and determining compensation for our senior executives, including our executive officers. The Committee ensures that the total compensation paid to executive officers is fair, reasonable and competitive.

The individuals who serve as our Chairman of the Board & Chief Executive Officer (CEO) and the Chief Financial Officer (CFO) during 2007, as well as the other individuals included in the Summary Compensation Table below, are referred to as the executive officers .

### **Compensation Philosophy and Objectives**

Our compensation philosophy is based on our belief that our compensation programs should: be aligned with stockholder s interests and business objectives; reward performance; and be externally competitive and internally equitable. We seek to achieve three objectives, which serve as guidelines in making compensation decisions:

Providing a total compensation package which is competitive and therefore, enables us to attract and retain, high-caliber executive personnel;

Integrating compensation programs with our short-term and long-term strategic plan and business objectives; and

Encouraging achievement of business objectives and enhancement of stockholder value by providing executive management long-term incentive through equity ownership.

### **Role of Executive Officers in the Compensation Decisions**

The Committee makes all compensation decisions regarding the compensation of our executive officers. The CEO reviews the performance of our executive officers and except for the President, Pharmaceutical Development & Chief Medical Officer (President), who is the spouse of the CEO, the CEO makes recommendations to the Committee based on these reviews, including salary adjustments, variable cash awards and equity awards. The Committee can exercise its discretion in modifying any recommended adjustments or awards to executives. With respect to the President, the

Committee in its sole discretion determines the amount of any adjustments or awards.

*Establishing Executive Compensation*

Compensation levels for our executive officers are determined through comparisons with other companies in the biotechnology and pharmaceutical industries, including companies with which we compete for personnel. To determine external competitiveness practices relevant to the executive officers, we review data from two industry surveys of executive compensation: Radford Biotechnology Compensation Survey and Organization Resources Counselors (collectively, External Market Data). In addition, in 2007 the Committee retained Towers Perrin, a

**Table of Contents**

leading compensation consultant with expertise in biopharmaceutical industry compensation practices, to assist in its analysis of executive compensation. Towers Perrin provided a third-party perspective based on their extensive knowledge of the industry and they advised the Committee of developments in the design of compensation programs and provided benchmarks against which we compare our total compensation packages. Towers Perrin conducted a peer group analysis in order to weigh the competitiveness of the Company's overall compensation arrangements in relation to comparable biopharmaceutical companies. The peer companies were: Allos Therapeutics, Ariad Pharmaceuticals, Avalon Pharmaceuticals, Cell Genesys, Cell Therapeutics, Favril, Hana Biosciences, Introgen Therapeutics, NeoPharm, Pharmacyclics, Poniard Pharmaceuticals, Spectrum Pharmaceuticals, Telik and Vion Pharmaceuticals. These companies were selected for the peer group because, like Genta, they were oncology focused, public pharmaceutical companies with products in mid to late-stage development.

It is the Committee's objective to target total annual compensation of each executive officer at a level between the 50th and 75th percentiles for comparable positions. However, in determining the compensation for each executive officer, the Committee also considers a number of other factors including: an evaluation of the responsibilities required for each respective position, individual experience levels and individual performance and contributions toward achievement of our business objectives. There is no pre-established policy or target for the allocation between either cash and non-cash or short-term and long-term incentive compensation. Instead, the Committee determines the mix of compensation for each executive officer based on its review of the competitive data and its analysis of that individual's performance and contribution to our performance. In addition, in light of our stage of development, considerable emphasis is placed on equity-based compensation in an effort to preserve cash to finance our research and development efforts.

**Other Factors Considered in Establishing 2007 Compensation for Executive Officers**

Our potential products are in various stages of research and development and limited revenues have as yet been generated from product sales. As a result, the use of traditional performance standards, such as corporate profitability, is not believed to be appropriate in the evaluation of the performance of us or our individual executives. The compensation of our executive officers is based, in substantial part, on industry compensation practices, trends noted (in the External Market Data, peer group analysis and by Towers Perrin), as well as the extent to which business and the individual executive officers' objectives are achieved. Such objectives are established and modified as necessary to reflect changes in market conditions and other factors. Individual performance is measured by reviewing whether these objectives have been achieved.

Among the significant business objectives achieved during 2007 were initiation of the new Phase 3 AGENDA trial of Genasense® in patients with advanced melanoma; initiation of a first clinical trial with a new oral drug, G4544, to treat bone disease; execution of a supply and distribution agreement with IDIS Limited, whereby IDIS will distribute Ganite® and Genasense® on a named patient basis and completion of a common stock offering raising gross proceeds of approximately \$11 million.

The milestones described above enabled continued progress towards the commercialization and development of Genasense® and small molecule therapy, and were considered carefully in evaluating executive performance and making determinations regarding executive compensation. Notably, however, three significant factors warranted very substantial weight in evaluating our business performance and in making executive compensation decisions. These factors were: 1) our receipt from the European Medicines Agency's Committee for Medicinal Products for Human Use of a negative opinion regarding our Marketing Authorization Application for the use of Genasense® plus chemotherapy for treatment of patients with advanced melanoma; 2) our receipt from the FDA of notice that they had declined our initial appeal of the non-approvable notice from the FDA for the New Drug Application for the use of Genasense® plus chemotherapy in patients with chronic lymphocytic leukemia; and 3) our inability to raise additional operating capital before the close of the fiscal year.

The Committee reviewed peer analysis data, the compensation history of each executive officer including their annual salary, cash incentive bonus and stock option awards. During the Committee's year-end 2007 meeting, the CEO, Dr. Warrell, recommended that due to our failure to meet critical business and financial objectives as described above that there not be any annual salary increases and that there be no payment of any incentive bonuses for executives and all other employees. Following discussion, the Committee approved Dr. Warrell's

## **Table of Contents**

recommendation. The Committee had previously determined in September 2007 that there would be no year-end stock option grants for the executive officers and the general employee population. See the section below marked September 2007 Retention Stock Option Grants for a further explanation of the decision to not grant stock option awards based on 2007 performance.

Due to our depressed stock price, the equity-based long-term incentive compensation and total compensation level (annual salary, incentive bonus and equity based compensation) for each of the executive officers was below the median (50th percentile). In general, however, the Committee believes that executive compensation levels are otherwise reasonably competitive with companies in the biotechnology and pharmaceutical industries when taking into account: geographic location, relative company size, stage of development, individual responsibilities and experience, as well as individual and overall corporate performance.

### *Elements of Executive Compensation*

Our compensation package for executive officers generally consists of annual cash compensation, which includes both fixed (annual salary) and variable (cash incentive bonus program) elements; long-term compensation in the form of stock options and other perquisites. The main components are annual salary, cash incentive bonus and stock options, all of which are common elements of executive compensation pay in general and throughout the biotechnology and pharmaceutical industry.

### *Annual Salary*

We pay an annual salary to our employees and the executive officers as consideration for fulfillment of certain roles and responsibilities. Changes in annual salaries for executive officers, if any, are generally effective at the beginning of each year. As noted above, there were no annual salary increases for 2008.

### *Determining Annual Salary*

Increases to annual salary reflect a reward and recognition for successfully fulfilling the position's role and responsibilities, the incremental value of the experience, knowledge, expertise and skills the individual acquires and develops during employment with us and adjustments as appropriate based on external competitiveness and internal equity. Prevailing competitive market practices guide the percentage increases to annual salary. Although the External Market Data indicated that the trend for annual salary increases effective in 2008 was approximately 4%, as noted above, there were no salary increases made for the executive officers or any other employees due to our performance in 2007. Notably, there was a 15% reduction to Dr. Warrell's base salary from \$480,000 to \$408,000 effective January 1, 2008. This reduction was agreed to by the Committee and Dr. Warrell as part of the negotiation that occurred in 2007 related to Dr. Warrell's amended 2006 employment agreement. The rationale for this reduction was that we had yet to achieve critical business and financial objectives and this had to be reflected in the terms of Dr. Warrell's amended 2006 employment agreement. The 2008 annual salaries for Dr. Itri, Mr. Moran, Mr. Siegel and Mr. Sanders are \$467,500, \$320,000, \$210,000 and \$285,000, respectively. In order to conserve cash, on April 17, 2008, Drs. Warrell and Itri agreed to indefinitely defer the cash portions of their salaries, at least until we had raised additional capital. These agreements may be rescinded by Drs. Warrell and Itri at their discretion, and the cash amounts due them shall be accrued for by us. On February 29, 2008, Mr. Moran retired from Genta.

### *Cash Incentive Bonus Program*

Typically, we award cash incentive bonuses to employees, including the executive officers, as a reward and recognition for contributing to our achievement of specific annual business objectives. All employees are eligible for a form of cash incentive bonus, although payment of a cash incentive bonus is made at an individual level each year

contingent upon overall performance of the company. However, as described under the section **Other Factors Considered in Establishing 2007 Compensation for Executive Officers** , our business performance was insufficient in 2007 to warrant cash incentive bonuses to executive officers and all other employees; consequently no cash incentive bonuses were paid.

**Table of Contents**

*Determining the 2007 Cash Incentive Bonus Program Target*

The target for the cash incentive bonus program award for the CEO (forty percent of annual salary) and the President (thirty percent of annual salary) is based on the terms of their employment agreements as described below and the Committee determines the annual target for the other executive officers each year based on external competitiveness and internal equity. Based on the External Market Data, the target amounts for executive officers who were Senior Vice Presidents and Vice Presidents were established at thirty percent and twenty-five percent of annual salary, respectively. As noted above, there were no cash bonuses paid to any of the executive officers for 2007 performance.

*Equity-Based Compensation*

We grant equity-based compensation to employees, including executive officers, to attract, motivate, engage and retain highly qualified and highly sought-after employees. We grant stock options on a broad basis to encourage all employees to work with a long-term view. Stock options are inherently performance-based because they deliver value to the option holder only if the value of our stock increases. Thus, stock options are a potential reward for long-term value creation and serve as an incentive for employees who remain with us to contribute to the overall long-term success of the business.

*September 2007 Retention Stock Option Grants*

In July 2007 we completed a 1:6 reverse stock split in an attempt to increase the per share trading value of our common stock in order to maintain our listing on the NASDAQ Global Market. NASDAQ Global Market listing rules require that a company's stock have a \$1.00 minimum closing bid price. The reverse split resulted in an adjustment of all previous stock option awards issued to executives and all other employees, whereby the number of options held was reduced by a factor of six, and the exercise price of the option was multiplied by a factor of six. Subsequent to the 1:6 reverse stock split there was a significant decline in our stock price. As a result, of the reverse stock split and the declining stock price, management believed that the incentive value of the previous stock option awards was insufficient to retain our executive officers and other employees. Following careful analysis which included: 1) a review of market trends, including consultation with Aon Radford Consulting (a nationally recognized compensation consulting firm with specific expertise in dealing with the equity issues of biopharmaceutical companies); 2) consideration of the fact that the 1998 Plan would be expiring in 2008; and 3) the determination that the commitment and motivation of our workforce would be vital to ongoing efforts to commercialize Genasense® and achieve other corporate objectives, management recommended to the Committee that new stock option grants be issued to executive officers and all employees under a new 2007 Plan. The Committee then retained their own independent compensation consulting firm, Towers Perrin, to evaluate management's recommendation and advise the Committee. Following two discussions with Towers Perrin to review their findings and further discussions between the Committee and management, the Committee approved the 2007 Stock Incentive Plan, contingent upon stockholder approval in 2008, and approved stock option grants for four of the five executive officers and all other employees, all of which are subject to stockholder approval.

The stock option plan is subject to continued review by the Board of Directors and must be approved by the stockholders. The Board may, at its discretion, change the Plan prior to seeking stockholder approval. The stock option plan has not yet been submitted to stockholders for approval and thus has yet to take effect.

In conjunction with the amendment and restatement of his 2006 employment agreement, Dr. Warrell received a stock option grant of 2,400,000 shares at \$1.39 per share. Mr. Sanders and Mr. Siegel received stock option grants of 300,000 and 175,000 shares, respectively, at \$1.39 per share. Dr. Itri received a stock option grant of 500,000 shares at \$1.42 per share. Due to very specific and critical financial objectives, in lieu of a stock option grant, Mr. Moran received a grant of 60,000 restricted stock units from the 1998 Plan, whose vesting was contingent upon achievement



of certain financial transactions and satisfactory completion of certain financial and accounting services. Due to certain financial transactions not being achieved, 40,000 of the 60,000 restricted stock units granted to Mr. Moran failed to vest and were cancelled. The remaining 20,000 restricted stock units may still vest upon satisfactory completion of certain financial and accounting services through July 31, 2008, during which time Mr. Moran will be providing consulting services to us.

**Table of Contents***Acquisition Bonus Plan*

The 2007 Plan is subject to stockholder approval. Consequently, management recognized that until there was stockholder approval, the risk of a potential change in control fully mitigated the retention value of the stock option awards described above. Therefore, in order to assure retention of our executive officers and other employees prior to stockholder approval of the September 2007 stock option awards, concurrent with approving the 2007 Plan on September 17, 2007, the Committee also approved an Acquisition Bonus Plan, which was also approved by the Board of Directors. Under the program, participants are eligible to share in a portion of the proceeds realized from a change in control that occurs prior to the earlier of (i) December 31, 2008 or (ii) the approval by our stockholders of the 2007 Plan. On September 27, 2007, executive officers and employees were granted a number of units in the Acquisition Bonus Plan that corresponded to the number of shares granted to them under the September 2007 retention stock option grants, with the intent of providing an incentive value under the Acquisition Bonus Plan that was similar to the incentive value of the stock option grants, once the 2007 Plan was approved by stockholders. Dr. Warrell, Mr. Sanders and Mr. Siegel received 2,400,000, 300,000 and 175,000 units, respectively with a unit value of \$1.39, and Dr. Itri received 500,000 units with a unit value of \$1.42. To assure there were no duplication of benefits derived from the 2007 Plan and the Acquisition Bonus Plan, all shares issued under the 2007 Plan terminate and cease to be outstanding in the event the participant becomes entitled to receive a payment under the Acquisition Bonus Plan. As noted above, Mr. Moran did not receive a stock option award, and instead received restricted stock units under the 1998 Plan; therefore, he was not a recipient of an award under the Acquisition Bonus Plan.

*Determining the September 2007 Retention Stock Option Grants*

In making the decision to make 2007 retention stock option grants to executive officers, the Committee took into consideration External Market Data, sought advice from their independent consultant, Towers Perrin, and considered the relative importance of retaining the existing executive officers. Among the factors considered in determining the number of shares issued to each executive was the Tower s Perrin peer group analysis finding that both the long-term incentive value and total compensation value of each executive s total compensation was significantly below the median (or 50th percentile). The Committee also considered that the award value of the initial grants made to the executive officers at the time they were hired and all subsequent grants made based on annual performance no longer had any incentive value because those awards had post-reverse split strike prices significantly above the current market value of our common stock. The size of the stock option awards made to executive officers in September 2007 were based on the Committee s determination that the award should be at least equivalent to the size of an award that would be necessary to recruit a comparable individual to replace the executive officer. Coincident with making the retention grants, the Committee considered whether or not there should be year-end 2007 performance based equity grants, which would ordinarily be granted in January 2008. However, based on the fact that the September 2007 retention stock option grants were larger than typical year-end grants and the proximity in time of the September 2007 retention stock option grants to any potential January 2008 awards (only four months), the Committee determined that, irrespective of individual or corporate performance, there would be no 2007 year-end equity-based compensation for executive officers and all other employees and advised them of that fact in September 2007.

*Determining The Timing And Exercise Price Of Equity-Based Compensation*

We have a longstanding practice, since January 2002, of having the exercise price of a stock option grant coincide with the closing price of our stock on the date of the grant. This practice is intended to avoid a situation in which a stock option grant is issued at an exercise price below the fair market value of our stock on the date of the grant. In years in which we issue performance-based grants, our practice has been to make grants to employees and our executive officers during the month of January; however, as stated above, no grants were made in January 2008.

Regarding the September 2007 executive officer retention grants, in order to assure that there would be no perception that one of our executive's stock option grants was delayed to achieve a more favorable exercise price, the Committee prospectively determined that for any grants made to executives, the exercise price of the executive's stock option grant would be at the higher of the closing price of our stock on the date of the grant or the exercise price of the retention stock option grants issued to all other employees.

## **Table of Contents**

During August and September 2007, the Committee met on multiple occasions to discuss the proposed September 2007 equity retention program. In order to focus their discussions, they determined that decisions about awards for Dr. Warrell, Dr. Itri and Mr. Moran would be made separately from the decisions made regarding the remaining executive officers and all other employees. The September 2007 retention stock option grants were issued on the same dates that the Committee approved the grants. The grants were approved for Mr. Sanders and Mr. Siegel on September 17, 2007; consequently their grants were dated September 17, 2007 and the exercise price of \$1.39 per share corresponded with the closing price of our stock on September 17, 2007. Dr. Warrell's grant was approved on September 20, 2007; consequently his grant was dated September 20, 2007. However, since on September 20, 2007, the closing price of our stock was \$1.35 per share, in accordance with the Committee's terms for the grant (as noted above), the exercise price of Dr. Warrell's grant was set at \$1.39 per share, which corresponded with the higher exercise price that other executives and all other employees received for their September 17, 2007 grants. Dr. Itri's grant was approved on September 21, 2007; consequently her grant was dated September 21, 2007. On September 21, 2007, the closing price of our stock was \$1.42 per share, so the exercise price of Dr. Itri's grant was set at \$1.42 per share. The Committee made a determination regarding an equity award for Mr. Moran on September 21, 2007; in lieu of a stock option award, he received restricted stock units from the 1998 Stock Incentive Plan on September 21, 2007.

### **Option Grant Date Coordination With The Release Of Material Non-Public Information**

We established the date of the Committee meetings and grant dates in accordance with our policy, and do not determine these dates based on knowledge of material non-public information or in response to our stock price.

### **Retirement Benefits**

All employees are eligible to participate in the Genta Incorporated Savings & Retirement Plan (Savings Plan). This is a tax-qualified retirement savings plan, which allows contributions by the employee of the lesser of 50% of their annual salary or the limit prescribed by the Internal Revenue Service to the Savings Plan on a before-tax basis. We will match 100% of the first 4% of pay that is contributed to the Savings Plan and 50% of the next 2% of pay contributed. All contributions to the Savings Plan as well as any matching contributions are fully vested upon contribution. We provide retirement benefits because retirement benefits are an integral part of employee benefit programs within the biotechnology and pharmaceutical industry.

### **Perquisites**

Excluding our CEO and President, both of whom have employment agreements that describe any perquisites that are part of their compensation and are described below, none of our executive officers have perquisites in excess of \$10,000 in annual value.

### **Severance Benefits**

We have adopted a severance pay program for nearly all of our employees, including executive officers, except for Drs. Itri and Warrell, who are eligible for severance benefits under the terms of their employment agreements as described below. The severance pay program is intended to preserve employee morale and productivity and encourage retention in the face of the disruptive impact of an actual or rumored workforce reduction or a change in control of our company. In addition, for executives, the program is intended to align executive and stockholder interests by enabling executives to consider corporate transactions that are in the best interests of the stockholders and other of our constituents without undue concern over whether the transactions may jeopardize the executive's own employment.

These arrangements, like other elements of executive compensation, are structured with regard to practices at comparable companies for similarly-situated officers and in a manner we believe is likely to attract and retain high

quality executive talent.

**Table of Contents**

Although there are some differences in the benefit levels depending on the employee's job level, the basic elements are comparable for all employees, except for Drs. Itri and Warrell as noted above, and for Messrs. Sanders and Siegel, as noted below:

*Double trigger.* Unlike single trigger plans that pay out immediately upon a change in control, Genta's severance pay program requires a double trigger—a change in control followed by an involuntary loss of employment within one year thereafter. This is consistent with the purpose of the program, which is to provide employees with financial protection upon loss of employment.

*Covered terminations.* Employees may be eligible for payments, if there is either a workforce reduction or if within one year of a change in control, their employment is terminated without cause by the Company.

*Severance payment.* Subject to signing a release, eligible terminated employees may receive severance.

*Benefit continuation.* Subject to signing a release, basic health and dental insurance may be continued following termination of employment.

*Accelerated vesting of equity awards.* Upon a change in control, any unvested equity awards become vested.

**Potential Payments Upon a Reduction in Force or Change in Control**

Drs. Itri's and Warrell's eligibility for severance payments are described below, and the remaining executive officers are also eligible for certain payments in the event of their termination. In the event of their termination as a result of a reduction in force or change in control, Mr. Sanders and Mr. Siegel are eligible for up to twenty-four weeks of severance paid on a bi-weekly basis equal to \$131,538 and \$96,923, respectively. Mr. Sanders and Mr. Siegel are also eligible to continue their health/dental benefits at our expense for up to four months, with an estimated value of \$7,116 each.

**Deductibility of Executive Compensation**

As part of its role, the Committee reviews and considers the deductibility of executive compensation under Section 162(m) of the Internal Revenue Code, which provides that we may not deduct compensation of more than \$1,000,000 paid to an individual. For 2007, the total amount of compensation paid by us should be deductible and not affected by the Section 162(m) limitation.

**2008 Objectives and Executive Compensation Guidelines**

*Our business objectives for 2008 include:* completing enrollment of the phase 3 AGENDA trial of Genasense® in patients with advanced melanoma; obtaining a lifting of the clinical hold on our newly licensed oral taxane, tesetaxel, a late Phase 2 oncology product; and ongoing financing and business development activities that will further the development and commercialization of our products. At present, the 2008 compensation guidelines are comparable to the 2007 guidelines with respect to the following: components of compensation; anticipated salary adjustments; cash incentive bonus targets and equity-based compensation. The Committee will make adjustments if necessary based on their assessment of a variety of factors including: industry trends; competitive market data; business objectives and corporate performance.

**Table of Contents****Summary Compensation Table**

The following table sets forth certain information regarding compensation earned by or paid to our Chief Executive Officer, Chief Financial Officer and other executive officers (collectively, the named executive officers ) during the years ended December 31, 2007 and 2006, respectively.

Name and Principal Position	Year	Salary (\$)	Bonus (\$)	Stock Awards (\$)	Option Awards (\$)(1)	Non-Equity	Nonqualified	All Other Compensation (\$)(4)	Total (\$)
						Incentive Plan Compensation (\$)(2)	Deferred Compensation Earnings (\$)(3)		
Raymond P. Warrell, Jr., M.D. Chairman and Chief Executive Officer	2007	480,000			1,139,940			41,096(3)	1,661,036
	2006	460,000			2,743,824	50,000		40,462(3)	3,294,286
Richard J. Moran Senior Vice President, Chief Financial Officer and Corporate Secretary	2007	320,000		10,463	29,100			17,261(4)	376,824
	2006	304,500			35,900	100,000		11,000(4)	451,400
Gary Siegel Vice President, Finance	2007	196,846			32,007			11,250(5)	240,103
	2006	183,750			46,778	66,500		11,000(5)	308,028
Loretta M. Itri, M.D. President, Pharmaceutical Development and Chief Medical Officer	2007	467,500			459,201			21,836(6)	948,537
	2006	445,200			979,852			19,848(6)	1,444,980
W. Lloyd Sanders Senior Vice President and Chief Operating Officer	2007	285,000			39,100			40,405(7)	364,505
	2006	245,000			36,250	78,000		33,579(7)	392,829

(1) The amounts reflect the dollar amount recognized for financial statement reporting purposes for the years ended December 31, 2007 and December 31, 2006, respectively, in accordance with FAS 123(R). These figures include amounts from awards granted in 2003, 2004, 2005, 2006 and 2007. Assumptions used in the calculations of these amounts for the years ended December 31, 2005, 2006 and 2007, respectively, are in Note 16 of the Company's Annual Report on Form 10-K for the year ended December 31, 2007, as amended. There can be no assurance that the FAS 123(R) amounts will be realized.

(2) As described above, no payments were made for 2007 performance under our cash incentive bonus program.

(3) All other compensation for 2007 includes \$6,000 for auto allowance, \$13,419 for long-term disability, (including \$4,641 for income tax gross-up), \$10,427 for life insurance, (including \$3,592 for income tax gross-up) and \$11,250 Company match to the 401(k) Plan. All other compensation for 2006 includes \$6,000 for auto allowance, \$13,003 for long-term disability, (including 4,506 for income tax gross-up), \$10,459 for life insurance (including \$3,592 for income tax gross-up) and \$11,000 Company match to the 401(k) Plan.

(4) All other compensation for 2007 includes \$6,011 for life insurance, (including \$2,011 for income tax gross-up) and \$11,250 Company match to the 401(k) Plan. All other compensation for 2006 includes \$11,000 Company

match to 401(k) Plan.

- (5) All other compensation for 2007 includes \$11,250 Company match to the 401(k) Plan. All other compensation for 2006 includes \$11,000 Company match to the 401(k) Plan.
- (6) All other compensation for 2007 includes \$6,770 for long-term disability (including \$2,161 for income tax gross-up), \$3,816 for life insurance (including \$1,315 for income tax gross-up) and \$11,250 Company match to the 401(k) Plan. All other compensation for 2006 includes \$7,028 for long-term disability, (including \$2,421 for income tax gross-up), \$1,820 for life insurance, (including \$627 for income tax gross-up) and \$11,000 Company match to the 401(k) Plan.
- (7) All other compensation for 2007 includes \$4,497 for long-term disability (including \$1,235 for income tax gross-up), \$24,658 relocation reimbursement (including \$6,106 for income tax gross-up) and \$11,250 Company match to the 401(k) Plan. All other compensation for 2006 includes \$4,370 for long-term disability, (including \$1,108 for income tax gross-up), \$19,459 relocation reimbursement (including \$4,914 for income tax gross-up) and \$9,750 Company match to the 401(k) Plan.



**Table of Contents****Grants of Plan-Based Awards**

The table below supplements the Summary Compensation Table with details regarding 2007 plan-based awards, all of which have been granted as of their respective grant date below. There are no future payments pending based on 2007 performance or compensation plans.

Name	Grant Date	Estimated Future Payouts Under Non-Equity Incentive Plan Awards(1)			Estimated Future Payouts Under Equity Incentive Plan Awards(2)			All Other Stock Awards: Number of Shares of Stock or Units	All Other Option Awards: Number of Securities Underlying Options	Exercise Price of Option Awards	Grant Date Fair Value of Stock and Option Awards
		Threshold	Target	Maximum	Threshold	Target	Maximum	(#)(3)	(#)(4)	(\$/sh)	(\$)
	Date	(\$)	(\$)	(\$)	(# Shares)	(*# Shares)	(# Shares)				
Warrell	9/20/07	0	192,000	288,000	0	150,000	225,000	0	2,400,000	1.39	
Moran	9/21/07	0	96,000	128,000	0	30,000	40,000	60,000	0		85,200
Siegel	9/17/07	0	52,500	73,500	0	20,000	30,000	0	175,000	1.39	
Itri	9/21/07	0	140,250	233,750	0	30,000	50,000	0	500,000	1.42	
Sanders	9/17/07	0	85,500	114,000	0	30,000	40,000	0	300,000	1.39	

- (1) These columns show the range of payouts targeted for 2007 performance under the Genta Cash Incentive Bonus Program, which would ordinarily be paid in January 2008; however, there were no payments for 2007 performance.
- (2) These columns show the range of stock option awards targeted for 2007 performance under the 1998 Plan. For 2007, there were no awards for 2007 performance.
- (3) This column shows the number of restricted stock units awarded in 2007 under the 1998 Plan as part of the retention program. See the section labeled "September 2007 Retention Stock Option Grants" for an explanation of this award.
- (4) This column shows the number of stock options awarded in September 2007 as part of the retention program under the 2007 Plan, which is contingent upon stockholder approval. See the section labeled "September 2007 Retention Stock Option Grants" for an explanation of this award.
- (5) We have not recognized compensation expense for grants of stock options awarded in September 2007 as part of the retention program. This is because the grants of these options under the 2007 Plan is contingent upon stockholder approval. As such, a grant date as defined in FAS 123(R) has not occurred.

Table of Contents**Outstanding Equity Awards as of December 31, 2007**

Name	Option Awards				Stock Awards				
	Number of Securities Underlying Unexercised Options (#) Exercisable	Number of Securities Underlying Unexercised Options (#) Unexercisable	Equity Incentive Plan Awards: Number of Securities Underlying	Option Exercise Price (\$)	Option Expiration Date	Number of Shares or Units of Stock That Have not Vested (#)	Market Value of Shares or Units of Stock That Have not Vested (\$)	Equity Incentive Plan Awards: Number of Shares or Units of Stock That Have not Vested (#)	Market Payout Value of Unearned Shares, Rights That Have not Vested (#)
Dr. Warrell	529,251			16.01	10/27/09				
	132,313			16.01	02/14/10				
	50,000			47.81	01/01/11				
	50,000			82.20	01/25/12				
	50,000			47.17	01/28/13				
		166,667		59.28	05/16/13				
	12,500			61.92	01/04/14				
	18,750	6,250		9.72	01/28/15				
	132,313			16.01	10/28/15				
	18,750	18,750		12.30	01/23/16				
	55,560	111,106		12.96	03/31/16				
	4,167	12,500		2.74	01/12/07				
	441,000	1,959,000		1.39	09/20/17				
Mr. Moran	20,000			7.26	09/15/15				
	833	834		12.30	01/23/16				
	5,001	1,666		2.74	01/12/17				
						20,000	8,000		
Mr. Siegel	2,333			60.30	05/22/13				
	1,167			61.92	01/04/14				
	1,667			15.00	06/30/14				
	1,250	417		9.72	01/07/15				
	1,250	1,250		5.64	04/04/15				

Edgar Filing: GENTA INC DE/ - Form S-1

	833	834	5.40	04/15/15
	833	834	11.10	09/19/15
	833	834	12.30	01/23/16
	208	625	4.62	12/01/16
	500	1,500	2.74	01/12/17
		175,000	1.39	09/17/17
Dr. Itri	50,000		34.38	03/28/11
	6,667		82.20	01/25/12
	5,000		47.17	01/28/13
		50,000	71.70	08/05/13
	8,333		61.92	01/05/14
	3,750	1,250	9.72	01/07/15
	4,167	4,167	12.30	01/23/16
	14,351	68,982	9.54	07/27/16
	2,084	6,250	2.74	01/12/17
		500,000	1.42	09/21/17
Mr. Sanders	8,333	8,334	10.86	01/16/16
	1,250	3,750	2.74	01/12/17
		300,000	1.39	09/17/17

---

\* Stock options awarded in September 2007 as part of the retention program under the 2007 Plan, which is contingent upon stockholder approval. See the section labeled [September 2007 Retention Stock Option Grants](#) for an explanation of this award.

### Option Exercises and Stock Vesting in Last Year

There were no exercises of options or vesting of stock by the named executive officers in the year ended December 31, 2007.

**Table of Contents****Employment Agreements*****Employment Agreement with Raymond P. Warrell, Jr., M.D.***

Pursuant to an employment agreement dated as of January 1, 2006 between Genta and Dr. Warrell that was subsequently amended and restated and signed effective November 30, 2007, hereinafter referred to as the amended 2006 employment agreement, Dr. Warrell continues to serve as our Chairman and Chief Executive Officer. The amended 2006 employment agreement has an initial term of three years ending on December 31, 2010 and provides for automatic extensions for additional one-year periods. Under the amended 2006 employment agreement, Dr. Warrell's \$480,000 annual base salary was reduced by 15% effective January 1, 2008; and he now receives a base salary of \$408,000 per annum with annual percentage increases equal to at least the Consumer Price Index for the calendar year preceding the year of the increase. At the end of each calendar year, Dr. Warrell is eligible for a cash incentive bonus ranging from 0% to 60% of his annual base salary, subject to the achievement of agreed-upon goals and objectives.

Dr. Warrell received an initial option grant of 2,400,000 stock options under the 2007 Plan, subject to stockholder approval, that has not yet been received, on September 20, 2007 with an exercise price of \$1.39, of which (a) 1,440,000 shares vest over a 40 month vesting schedule (360,000 shares on the date of grant, 1,053,000 shares in 40 equal monthly increments of 27,000 each commencing on October 1, 2007 and the final 27,000 shares on December 31, 2010) and (b) the remaining 960,000 shares vest upon our achievement of specified milestones relating to the Genasense® product or its substantial equivalent. These milestones include the following: (1) 480,000 shares will become exercisable on the date the Genasense® product receives approval for any first indication in the United States from the FDA or any first indication in Europe from the EMEA, (2) 480,000 shares will become exercisable on the date that the total fair market value of all common stock of the Company then outstanding first exceeds \$350,000,000. Dr. Warrell is also entitled to receive annual stock options for the purchase of up to 225,000 shares of Common Stock, depending upon the achievement of agreed-upon goals and objectives. Such options will become fully exercisable upon a Trigger Event (i.e. the sale of Genasense® or our change in control). If a Trigger Event occurs during the term of the amended 2006 employment agreement or within 12 months thereafter, Dr. Warrell will be entitled to receive the stock option grants that he would have been entitled to receive in respect of the calendar year in which the Trigger Event occurs (assuming attainment of target levels of performance on all goals and objectives for the year), and such option will be fully vested and exercisable upon grant.

We may also, from time to time, grant Dr. Warrell additional cash, stock options, equity and/or other long-term incentive awards in the sole discretion of our Board. Dr. Warrell continues to be entitled to any and all medical insurance, dental insurance, life insurance, disability insurance and other benefit plans, which are generally available to our senior executives. He is also entitled to receive supplemental life insurance and supplemental disability insurance, as well as premium payments for medical malpractice insurance up to a maximum of \$25,000 annually. The aggregate amount of the benefits Dr. Warrell may receive are subject to parachute payment limitations under Section 280G of the Internal Revenue Code.

In the event Dr. Warrell's employment is terminated, he will be eligible for certain benefits whose value has been estimated herein, but only to the extent that the benefit is not otherwise provided to employees on a non-discriminatory basis. In the event Dr. Warrell's employment is terminated, he will be entitled to receive his accrued but unpaid base salary through his termination date, his accrued but unpaid expenses, a lump sum payment of his accrued vacation days (unless he is terminated by us for cause or he terminates his employment without good reason (both defined in the amended 2006 agreement)), his accrued but unpaid cash incentive bonus, a lump sum payment of his pro-rated cash incentive bonus for the year of his termination, valued up to \$163,200, (unless he is terminated by us for cause or he terminates his employment without good reason), and any other benefits due him in accordance with applicable plans, programs or agreements. In addition to the benefits listed in the preceding sentence,

in the event we terminate Dr. Warrell's employment without cause or Dr. Warrell terminates his employment for good reason and he executes a release, Dr. Warrell will be entitled to receive the base salary he would have received during the twelve-month period following the date of termination, valued at \$408,000, for a total potential payment of \$571,200. If we terminate Dr. Warrell's employment in anticipation of our change in control or, if either party terminates his employment upon a change in control or within thirteen months following a change in control, Dr. Warrell will instead receive a lump sum payment equal to two times his annual base salary, valued at \$816,000 and two times his target bonus for the calendar year of termination, valued at \$326,400, for a total potential payment

**Table of Contents**

of \$1,142,000. Dr. Warrell will also receive immediate vesting of all stock options that vest solely as a result of his continued employment. Finally, if either party gives notice that they do not wish to extend the amended 2006 employment agreement, Dr. Warrell will be entitled to receive his accrued, but unpaid, base salary through his termination date; his accrued, but unpaid, expenses; a lump sum payment of his accrued vacation days; his accrued but unpaid cash incentive bonus; a lump sum payment of his pro-rated cash incentive bonus for the year of his termination, valued up to \$163,200; and any other benefits due him in accordance with applicable plans, programs or agreements. If Dr. Warrell gives notice that he does not wish to extend his amended 2006 employment agreement, he will also receive immediate vesting of all stock options that would have vested during the 90 days following his termination date, if such stock options vest solely as a result of his continued employment. If we give notice that we do not wish to extend Dr. Warrell's amended 2006 employment agreement, he will receive immediate vesting of all stock options that vest solely as a result of his continued employment.

***Employment Agreement with Loretta M. Itri, M.D.***

Pursuant to an employment agreement dated as of March 28, 2006 between Genta and Dr. Itri and signed on July 27, 2006, Dr. Itri continues to serve as our President, Pharmaceutical Development and Chief Medical Officer. The employment agreement had an initial term of three years, beginning March 28, 2006 and continuing through March 27, 2009 and provides for automatic extensions for additional one-year periods. The agreement provides for a base annual salary of \$445,200, which may be reviewed annually for discretionary increases in a manner similar to our other senior executives and an annual cash incentive bonus ranging from 0% to 50% of her annual base salary to be paid if mutually agreed-upon goals and objectives are achieved for the year. Dr. Itri was also granted an incentive stock option to purchase 83,333 shares of our Common Stock at an exercise price of \$9.54 per share, of which 33,333 shares become exercisable upon the first FDA approval of Genasense®, 33,333 shares become exercisable upon approval by the EMEA in Europe of Genasense® in any first indication and 16,666 shares become exercisable over a period of approximately 32 months from the grant date by means of (i) an initial amount of 1,850 shares to be exercisable and vest on the Date of Grant, (ii) an additional amount of 14,344 shares in 31 equal monthly increments of 467 shares each, commencing on August 1, 2006 and continuing on the first day of each of the next successive 30 calendar months, and (iii) a final amount of 467 shares on March 1, 2009. The preceding reference to the number of shares granted takes into account the 1:6 reverse stock split in July 2007. We may also, from time to time, grant Dr. Itri additional stock options consistent with the stock option guidelines applicable to our other senior executives. Dr. Itri is entitled to any and all medical insurance, dental insurance, life insurance, disability insurance and other benefit plans, which are generally available to our senior executives. She is also entitled to receive supplemental life insurance and supplemental disability insurance. The aggregate amount of the benefits Dr. Itri may receive are subject to parachute payment limitations under Section 280G of the Internal Revenue Code.

In the event Dr. Itri's employment is terminated, she will be eligible for certain benefits whose value has been estimated herein, but only to the extent that the benefit is not otherwise provided to employees on a non-discriminatory basis. In the event Dr. Itri's employment is terminated, she will be entitled to receive her accrued, but unpaid, base salary through her termination date; her accrued, but unpaid, expenses; her accrued vacation days; any earned but unpaid cash incentive bonus; and any other benefits due her in accordance with applicable plans, programs or agreements. In addition to the benefits listed in the preceding sentence, in the event we terminate Dr. Itri's employment without good reason (as defined in the employment agreement), due to a change of control, or Dr. Itri terminates her employment for good reason (as defined in the employment agreement), and she executes a release, Dr. Itri will be entitled to receive a lump sum payment equal to her current annualized base salary, valued at \$467,500 plus a pro-rated cash incentive bonus for the calendar year of termination, valued up to \$140,250, for a total potential payment of \$607,750, and each of her outstanding stock options will immediately vest to the extent vesting depends solely on her continued employment. Finally, if either party gives notice that the employment agreement will not be extended, Dr. Itri will be entitled to receive her accrued, but unpaid, base salary through her termination date; her accrued, but unpaid, expenses; her accrued vacation days; any earned, but unpaid, cash incentive bonus; a pro-rated

cash incentive bonus for the year of her termination, valued up to \$140,250, for a total potential payment of \$607,750; and any other benefits due her in accordance with applicable plans, programs, or agreements. If we give notice that we do not wish to extend Dr. Itri's employment agreement, she will also receive immediate vesting of all stock options that would have vested during the 90 days following her termination date, if such stock options would have vested solely as a result of her continued employment.

**Table of Contents****Compensation of Directors**

Our non-employee directors receive \$15,000 per year for their services. In addition, under our Non-Employee Directors 1998 Stock Option Plan, non-employee directors currently receive a grant of 4,000 stock options upon their initial election to the Board and thereafter receive an annual grant of 3,333 stock options coinciding with their annual election to the Board. Non-employee directors receive an additional \$1,500 for each Board meeting attended in person or \$750 for each Board meeting attended telephonically. Non-employee directors attending committee meetings receive \$1,000 for each in-person meeting or \$750 for each meeting attended telephonically. Non-employee directors receive \$2,500 per day for Board or committee activities outside of normal activities. The Lead Director and each non-employee Chairperson of a Committee of the Board receive annual cash compensation of \$5,000 and a grant of 833 stock options coinciding with their annual election to the Board.

The following table sets forth certain information regarding compensation earned by the following non-employee directors of the Company during the year ended December 31, 2007:

Name	Fees Earned (\$)(1)	Stock Awards (\$)	Option Awards (\$)(2)	Change in Pension Value and Non-Equity Nonqualified Incentive			Total (\$)
				Plan Compensation (\$)	Deferred Compensation (\$)	All Other Compensation (\$)	
Martin J. Driscoll	\$ 45,500		\$ 15,879				\$ 61,379
Betsy McCaughey, PhD.(3)	\$ 18,750		\$ 4,933				\$ 23,683
Christopher P. Parios	\$ 42,000		\$ 13,413				\$ 53,413
Daniel D. Von Hoff, M.D.	\$ 26,500		\$ 4,933				\$ 31,433
Douglas G. Watson	\$ 47,000		\$ 7,399				\$ 54,399

(1) Reflects the dollar amount earned during 2007.

(2) Reflects the dollar amount recognized for financial statement purposes for the year ended December 31, 2007, in accordance with FAS 123(R) and thus, includes amounts from awards granted prior to 2007. There can be no assurance that the FAS 123(R) amounts will be realized. As of December 31, 2007, each Director has the following number of options outstanding: Martin J. Driscoll: 13,165; Betsy McCaughey: 26,220; Christopher P. Parios: 10,666; Daniel D. Von Hoff: 34,442; Douglas G. Watson: 27,330.

(3) Dr. McCaughey resigned from the Board, effective October 24, 2007.

**Committees of the Board of Directors and Director Independence**

The Board currently consists of five directors. They are Raymond P. Warrell, Jr., M.D., Martin J. Driscoll, Christopher P. Parios, Daniel D. Von Hoff, M.D., and Douglas G. Watson. The Board has determined that, except for



Dr. Warrell, all of the members of the Board are independent directors . Dr. Warrell is not considered independent, as he is an executive officer of the Company.

***Compensation Committee***

The Compensation Committee currently consists of Martin J. Driscoll, Christopher P. Parios and Douglas G. Watson. Mr. Watson serves as Chairman of this Committee. Each member of the Compensation Committee is independent.

***Nominating and Corporate Governance Committee***

The Nominating and Corporate Governance Committee currently consists of Martin J. Driscoll and Daniel D. Von Hoff, M.D. Mr. Driscoll serves as Chairman of this Committee. Each member of the Nominating and Corporate Governance Committee is independent.

**Table of Contents****Audit Committee**

The Audit Committee was established in accordance with Section 3(a)(58)(A) of the Securities Exchange Act of 1934, as amended. The Audit Committee currently consists of Martin J. Driscoll, Christopher P. Parios and Douglas G. Watson. Mr. Driscoll serves as Chairman of this Committee. Each member of the Audit Committee is independent.

**Compensation Committee Interlocks and Insider Participation**

None of the members of our Compensation Committee, Mr. Watson, Mr. Driscoll and Mr. Parios, had any interlock relationship to report during our year ended December 31, 2007.

**PRINCIPAL STOCKHOLDERS**

The following table sets forth, as of August 22, 2008, certain information with respect to the beneficial ownership of our Common Stock (the only voting class outstanding), (i) by each director, (ii) by each of the named executive officers and (iii) by all officers and directors as a group.

Name and Address(1)	Amount and Nature of Beneficial Ownership			
	Shares Beneficially Owned Prior to Offering(2)		Shares Beneficially Owned Immediately Following Offering	
	Number	Percentage	Number	Percentage
Raymond P. Warrell, Jr., M.D.	1,928,294(3)	4.999%	[ ](12)	4.999%
Loretta M. Itri, M.D.	1,932,518(4)	4.999%	[ ](13)	4.999%
Richard J. Moran	21,749(5)	*	21,749(5)	*
Gary Siegel	11,916(6)	*	11,916(6)	*
W. Lloyd Sanders	14,583(7)	*	14,583(7)	*
Martin J. Driscoll	14,332(8)	*	14,332(8)	*
Betsy McCaughey, PhD(9)	26,220(6)	*	26,220(6)	*
Christopher P. Parios	9,333(6)	*	9,333(6)	*
Daniel D. Von Hoff, M.D.	34,442(6)	*	34,442(6)	*
Douglas G. Watson	37,330(10)	*	37,330(10)	*
All Directors and Executive Officers as a group	4,030,717(11)	11.0%	[ ](14)	11.0%

\* Less than one percent (1%).

- (1) The address of each named holder is in care of Genta Incorporated, 200 Connell Drive, Berkeley Heights, NJ 07922.
- (2) Beneficial ownership is determined in accordance with the rules of the SEC and generally includes voting or investment power with respect to securities. Shares of Common Stock subject to options exercisable within 60 days of August 22, 2008 or issuable on conversion of Senior Secured Convertible Promissory Notes due June 9, 2010 are deemed outstanding for computing the percentage of the person holding such securities but are not deemed outstanding for computing the percentage of any other person. Except as indicated by footnote, and

subject to community property laws where applicable, the person named in the table has sole voting and investment power with respect to all shares of Common Stock shown as beneficially owned by them.

- (3) Consists of 91,615 shares of Common Stock and 1,065,179 shares of Common Stock issuable upon exercise of currently exercisable stock options. Also includes 771,500 shares of Common Stock issuable upon the conversion of Senior Secured Convertible Promissory Notes due June 9, 2010. Excludes 100,000 shares of Common Stock beneficially owned by Dr. Warrell's wife, Dr. Itri. Dr. Warrell disclaims beneficial ownership of such shares.
- (4) Consists of 16,666 shares of Common Stock and 94,352 shares of Common Stock issuable upon exercise of currently exercisable stock options. Also includes 1,821,500 shares of Common Stock issuable upon the conversion of Senior Secured Convertible Promissory Notes due June 9, 2010. Excludes 91,615 shares of

**Table of Contents**

- Common Stock, beneficially owned by Dr. Itri's husband, Dr. Warrell. Dr. Itri disclaims beneficial ownership of such shares.
- (5) Consists of 21,666 shares of Common Stock and 83 shares of Common Stock owned by Mr. Moran's wife Mr. Moran retired from the Company on February 28, 2008.
  - (6) Consists of shares of Common Stock issuable upon the exercise of currently exercisable stock options.
  - (7) Consists of 5,000 shares of Common Stock and 9,583 shares of Common Stock issuable upon exercise of currently exercisable stock options.
  - (8) Consists of 2,500 shares of Common Stock and 11,832 shares of Common Stock issuable upon the exercise of currently exercisable stock options.
  - (9) Dr. McCaughey resigned from the Board, effective October 24, 2007.
  - (10) Consists of 10,000 shares of shares of Common Stock and 27,330 shares of Common Stock issuable upon the exercise of currently exercisable stock options.
  - (11) Consists of 127,530 shares of Common Stock and 1,310,187 shares of Common Stock issuable upon the exercise of currently exercisable stock options. Also includes 2,593,000 shares of Common Stock issuable upon the conversion of Senior Secured Convertible Promissory Notes due June 9, 2010.
  - (12) Consists of 91,615 shares of Common Stock and 1,065,179 shares of Common Stock issuable upon exercise of currently exercisable stock options. Also includes [ ] shares of Common Stock issuable upon the conversion of Senior Secured Convertible Promissory Notes due June 9, 2010. Excludes 100,000 shares of Common Stock beneficially owned by Dr. Warrell's wife, Dr. Itri. Dr. Warrell disclaims beneficial ownership of such shares.
  - (13) Consists of 16,666 shares of Common Stock and 94,352 shares of Common Stock issuable upon exercise of currently exercisable stock options. Also includes [ ] shares of Common Stock issuable upon the conversion of Senior Secured Convertible Promissory Notes due June 9, 2010. Excludes 91,615 shares of Common Stock, beneficially owned by Dr. Itri's husband, Dr. Warrell. Dr. Itri disclaims beneficial ownership of such shares.
  - (14) Consists of 127,530 shares of Common Stock and 1,310,187 shares of Common Stock issuable upon the exercise of currently exercisable stock options. Also includes [ ] shares of Common Stock issuable upon the conversion of Senior Secured Convertible Promissory Notes due June 9, 2010.

Although each of the investors in the June 2008 convertible note transaction may elect to convert their notes into shares of our common stock, no holder is deemed to be a beneficial holder of 5.00% or greater of our common stock due to the existence of a provision in the convertible notes restricting each noteholder from beneficially owning greater than 4.999% of our common stock.

**CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS**

Dr. Daniel Von Hoff, one of Genta's directors, holds the position of Senior Investigator and Director of Translational Research at the Translational Genomics Research Institute (TGen), which provides preclinical testing services under direction of and by contract to Genta. During 2007, TGen performed services for which it was compensated by Genta

in the amount of approximately \$223,430. We believe that the payment of these services was on terms no less favorable than would have otherwise been provided by an unrelated party. In the Board's opinion, Dr. Von Hoff's relationship with TGen will not interfere with Dr. Von Hoff's exercise of independent judgment in carrying out his responsibilities as a Director of Genta.

We have set forth certain policies and procedures with respect to the review and approval of related-party transactions. Specifically, pursuant to our Audit Committee Charter, the Audit Committee is required to review and approve any related-party transactions. In connection with such review and approval, the Audit Committee may retain special legal, accounting or other advisors and may request any of our officers or employees or our outside counsel or independent auditors to meet with any members of, or advisors to, the Audit Committee as well as perform any other activities consistent with the Audit Committee Charter, our by-laws, and governing law, as the Audit Committee or the Board deems necessary or appropriate.

## **Table of Contents**

On June 5, 2008, we entered into a securities purchase agreement with certain institutional and accredited investors to place up to \$40 million of senior secured convertible notes with such investors. On June 9, 2008, we placed \$20 million of such notes in an initial closing. Each of Dr. Raymond Warrell, our Chief Executive Officer and Chairman, and Dr. Loretta Itri, our President, Pharmaceutical Development and Chief Medical Officer, participated in the initial closing by purchasing \$1,950,000 and \$300,000, respectively, of such notes. The remaining Board members independently discussed Dr. Warrell and Dr. Itri's participation in the transaction and resolved that such participation will not interfere with Dr. Warrell or Dr. Itri's exercise of independent judgment in carrying out their responsibilities in their respective positions. In connection with the June 2008 convertible note financing and in accordance with the Audit Committee Charter, the Audit Committee reviewed and approved the June 2008 convertible note financing with Dr. Warrell and Dr. Itri.

## **DESCRIPTION OF SECURITIES**

### **General**

Our authorized capital stock consists of 250,000,000 shares of common stock and 5,000,000 shares of preferred stock.

The following descriptions are summaries of the material terms of our restated certificate of incorporation and bylaws. Reference is made to the more detailed provisions of, and the descriptions are qualified in their entirety by reference to, the restated certificate of incorporation and bylaws and applicable law. Our restated certificate of incorporation, as amended and our amended and restated bylaws are incorporated by reference and copies are available upon request. See [How to Get More Information](#) in this prospectus.

### **Common Stock**

Except as required by law or by the restated certificate of incorporation, holders of common stock are entitled to one vote for each share held of record on all matters submitted to a vote of the stockholders. Subject to preferences that may be applicable to any then outstanding preferred stock, holders of common stock are entitled to receive ratably such dividends as may be declared by the Board of Directors out of funds legally available therefor. In the event of a liquidation, dissolution or winding up of Genta, holders of the common stock and the preferred stock are entitled to share ratably on an as-converted basis in all assets remaining after payment of liabilities and the liquidation preference of any then outstanding preferred stock. Holders of common stock have no right to convert their common stock into any other securities. There are no redemption or sinking fund provisions applicable to the common stock. All outstanding shares of common stock are fully paid and non-assessable.

In September 2005, the Board of Directors adopted a Stockholder Rights Plan and declared a dividend of one preferred stock purchase right, or Right, for each outstanding share of our common stock, payable to holders of record as of the close of business on September 27, 2005. In addition, Rights shall be issued in respect of all shares of common stock issued after such date, including the shares issued hereunder, pursuant to the Plan. 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 our 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 our 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. The terms and conditions of the Rights are set forth in a Rights Agreement dated September 20, 2005 between the Company and Mellon Investor Services, LLC, as Rights Agent.

### **Preferred Stock**

The Board of Directors has the authority, without further action by the stockholders, to issue up to 5,000,000 shares of preferred stock in one or more series and to fix the rights, preferences, privileges and restrictions thereof, including dividend rights, conversion rights, voting rights, terms of redemption, liquidation preferences and the number of shares constituting any series or the designation of such series. The issuance of

## **Table of Contents**

preferred stock could adversely affect the voting power of holders of common stock and could have the effect of delaying, deferring or preventing a change in control of Genta without further action by the stockholders and may adversely affect the voting and other rights of the holders of our common stock.

### ***Series A Convertible Preferred Stock***

We are authorized to issue 600,000 shares of Series A Convertible Preferred Stock. At August 22, 2008, we had 7,700 shares of Series A Convertible Preferred Stock issued and outstanding.

Each share of Series A Convertible Preferred Stock is immediately convertible, into shares of our common stock, at a rate determined by dividing the aggregate liquidation preference of the series A convertible preferred stock by the conversion price. The conversion price is subject to adjustment for antidilution.

In the event of a liquidation of Genta, the holders of Series A Convertible Preferred Stock are entitled to a liquidation preference equal to \$50.00 per share.

### ***Series G Participating Cumulative Preferred Stock***

Two million shares of our Preferred Stock have been designated as Series G Participating Cumulative Preferred Stock, none of which are issued and outstanding. The Series G Participating Cumulative Preferred Stock are subject to the Stockholder Rights Plan described above.

### ***15% Senior Secured Convertible Notes***

On June 5, 2008, we entered into a securities purchase agreement with certain institutional and accredited investors, to place up to \$40 million of senior secured convertible notes, referred to herein as the notes, with such investors. On June 9, 2008, we placed \$20 million of such notes in the initial closing. The notes will bear interest at an annual rate of 15% payable at quarterly intervals in stock or cash at our option, and will be convertible into shares of our common stock at a conversion rate of 100,000 shares of common stock for every \$1,000.00 of principal. Until June 9, 2009, the holders of the notes have the right, but not the obligation, to purchase in whole or in part up to an additional \$20 million of notes. We have the right to force conversion of the notes in whole or in part if the closing bid price of our common stock exceeds \$0.50 for a period of 20 consecutive trading days. Certain members of our senior management participated in the initial closing.

The issuance of common stock upon conversion of the convertible notes may adversely affect the voting power of remaining holders of common stock and could result in a change in control of Genta without further action by the stockholders.

### ***Delaware Anti-Takeover Law***

Under Section 203 of the Delaware General Corporation Law certain business combinations between a Delaware corporation, whose stock generally is publicly traded or held of record by more than 2,000 stockholders, and an interested stockholder are prohibited for a three-year period following the date that such stockholder became an interested stockholder, unless:

the corporation has elected in its certificate of incorporation not to be governed by Section 203 (we have not made such an election);



either the business combination or the transaction which resulted in the stockholder becoming an interested stockholder was approved by the board of directors of the corporation before the other party to the business combination became an interested stockholder;

upon consummation of the transaction that made it an interested stockholder, the interested stockholder owned at least 85% of the voting stock of the corporation outstanding at the commencement of the transaction excluding voting stock owned by directors who are also officers or held in employee benefit plans in which the employees do not have the right to determine confidentially whether shares held subject to the plan will be tendered in a tender or exchange offer;

## **Table of Contents**

on or subsequent to such date the business combination is approved by the board of directors and authorized at an annual or special meeting of stockholders by the affirmative vote of at least 66<sup>2</sup>/<sub>3</sub>% of the outstanding voting stock which is not owned by the interested stockholder.

The three-year prohibition also does not apply to certain business combinations proposed by an interested stockholder following the announcement or notification of certain extraordinary transactions involving the corporation and a person who had not been an interested stockholder during the previous three years or who became an interested stockholder with the approval of a majority of the corporation's directors. A "business combination" is defined to include mergers, asset sales and other transactions resulting in financial benefit to a stockholder. In general, an "interested stockholder" is a person who, together with affiliates and associates, owns (or within three years, did own) 15% or more of a corporation's voting stock.

The statute could prohibit or delay mergers or other takeover or change in control attempts with respect to us and, accordingly, may discourage attempts to acquire us even though such a transaction may offer our stockholders the opportunity to sell their stock at a price above the prevailing market price.

### **Advance Notice Requirements for Stockholder Proposals**

Our amended and restated bylaws provide that stockholders seeking to bring business before an annual meeting of stockholders, or to nominate candidates for election as directors at an annual meeting of stockholders, must provide timely notice thereof in writing. To be timely, a stockholder's notice must be delivered to the secretary at our principal executive offices not less than 50 calendar days nor more than 75 calendar days prior to the meeting; provided, that if less than 65 days' notice or prior public disclosure of the date of the meeting is given or made to stockholders, notice by the stockholder to be timely must be received not later than the close of business on the 15th day following the day on which notice of the date of the annual meeting was mailed or such public disclosure was made. Our amended and restated bylaws also specify requirements as to the form and content of a stockholder's notice. These provisions may discourage stockholders from bringing matters before an annual meeting of stockholders or from making nominations for directors at an annual meeting of stockholders.

### **Transfer Agent Information**

Our transfer agent is BNY Mellon Securities LLC.

**Table of Contents****UNDERWRITERS**

Under the terms and subject to the conditions contained in an underwriting agreement dated the date of this prospectus, the underwriters named below, for whom [ ] are acting as representatives, have severally agreed to purchase, and we have agreed to sell to them, the number of shares indicated below:

<b>Name</b>	<b>Number of Shares</b>
[ ]	[ ]
Total	[ ]

The underwriters are offering the shares of common stock subject to their acceptance of the shares from us and subject to prior sale. The underwriting agreement provides that the obligations of the several underwriters to pay for and accept delivery of the shares of common stock offered by this prospectus are subject to the approval of specified legal matters by their counsel and to other conditions. The underwriters are obligated to take and pay for all of the shares of common stock offered by this prospectus if any such shares are taken. However, the underwriters are not required to take or pay for the shares covered by the underwriters' over-allotment option described below.

The underwriters initially propose to offer part of the shares of common stock directly to the public at the public offering price listed on the cover page of this prospectus and part to certain dealers at a price that represents a concession not in excess of \$[ ] a share under the public offering price. After the initial offering of the shares of common stock, the offering price and other selling terms may from time to time be varied by the representatives.

We have granted to the underwriters an option, exercisable for 30 days from the date of this prospectus, to purchase up to an aggregate of [ ] additional shares of common stock at the public offering price listed on the cover page of this prospectus, less underwriting discounts and commissions. The underwriters may exercise this option solely for the purpose of covering over-allotments, if any, made in connection with the offering of the shares of common stock offered by this prospectus. To the extent the option is exercised, each underwriter will become obligated, subject to certain conditions, to purchase about the same percentage of the additional shares of common stock as the number listed next to the underwriter's name in the preceding table bears to the total number of shares of common stock listed next to the names of all underwriters in the preceding table. If the underwriters' option is exercised in full, the total price to the public would be \$[ ], the total underwriters' discounts and commissions would be [ ] and the total proceeds to us would be \$[ ].

We and each of our directors and executive officers have agreed that, without the prior written consent of [ ] on behalf of the underwriters, we and they will not, during the period ending 90 days after the date of this prospectus:

offer, pledge, sell, contract to sell, sell any option or contract to purchase, purchase any option or contract to sell, grant any option, right or warrant to purchase, lend or otherwise transfer or dispose of directly or indirectly, any shares of our common stock or any securities convertible into or exercisable or exchangeable for common stock; or

enter into any swap or other arrangement that transfers to another, in whole or in part, any of the economic consequences of ownership of our common stock,

whether any transaction described above is to be settled by delivery of our common stock or such other securities, in cash or otherwise.

These restrictions do not apply to:

the sale of shares to the underwriters;

the issuance by us of shares of our common stock upon the exercise of an option or a warrant or the conversion of a security outstanding on the date of this prospectus of which the underwriters have been advised in writing;

the issuance by us of shares or options to purchase shares of our common stock pursuant to our stock incentive plans, provided that the recipient of the shares agrees to be subject to the restrictions described in the immediately preceding paragraph;

**Table of Contents**

transactions by any person other than us relating to shares of common stock or other securities acquired in open market transactions after the completion of the offering of the shares;

transfers of shares as a gift or charitable contribution, or by will or intestacy;

transfers of shares to any trust the sole beneficiaries of which are the transferee and/or its immediate family members; or

transfers to certain entities or persons affiliated with the stockholder;

provided that in the case of each of the last three transactions, each donee, distributee, transferee and recipient agrees to be subject to the restrictions described in the immediately preceding paragraph, no filing under Section 16 of the Exchange Act is required in connection with these transactions, other than a filing on a Form 5 made after the expiration of the 90-day period, and no transaction includes a disposition for value.

Notwithstanding the foregoing, if:

during the last 17 days of the 90-day period, we issue an earnings release; or

prior to the expiration of the 90-day period, we announce that we will release earnings results during the 16-day period beginning on the last day of the 90-day period,

the above restrictions shall continue to apply until the expiration of the 18-day period beginning on the issuance of the earnings release.

The following table shows the underwriting discounts and commissions that we are to pay to the underwriters in connection with this offering. These amounts are shown assuming both no exercise and full exercise of the underwriters' option to purchase additional shares of our common stock.

	<b>Paid by Genta</b>		<b>Total</b>	
	<b>No Exercise</b>	<b>Full Exercise</b>	<b>No Exercise</b>	<b>Full Exercise</b>
Per share	\$	\$	\$	\$
Total	\$	\$	\$	\$

In addition, we estimate that the expenses of this offering other than underwriting discounts and commissions payable by us will be \$[ ].

In order to facilitate the offering of the common stock, the underwriters may engage in transactions that stabilize, maintain or otherwise affect the price of the common stock. Specifically, the underwriters may sell more shares than they are obligated to purchase under the underwriting agreement, creating a short position. A short sale is covered if the short position is no greater than the number of shares available for purchase by the underwriters under the over-allotment option. The underwriters can close out a covered short sale by exercising the over-allotment option or purchasing shares in the open market. In determining the source of shares to close out a covered short sale, the underwriters will consider, among other things, the open market price of shares compared to the price available under the over-allotment option. The underwriters may also sell shares in excess of the over-allotment option, creating a

naked short position. The underwriters must close out any naked short position by purchasing shares in the open market. A naked short position is more likely to be created if the underwriters are concerned that there may be downward pressure on the price of our common stock in the open market after pricing that could adversely affect investors who purchase in this offering. In addition, to stabilize the price of our common stock, the underwriters may bid for, and purchase, shares of common stock in the open market. Finally, the underwriting syndicate may reclaim selling concessions allowed to an underwriter or a dealer for distributing our common stock in this offering, if the syndicate repurchases previously distributed common stock in transactions to cover syndicate short positions or to stabilize the price of our common stock. Any of these activities may stabilize or maintain the market price of the common stock above independent market levels. The underwriters are not required to engage in these activities, and may end any of these activities at any time.

Our common stock is listed on the OTC Bulletin Board under the symbol GNTA.OB .

In connection with this offering, some underwriters and any selling group members who are qualified market makers on the OTC Bulletin Board may engage in passive market making transactions in our common stock on the

## **Table of Contents**

OTC Bulletin Board in accordance with Rule 103 of Regulation M under the Securities Exchange Act of 1934, as amended, during the business day before the pricing of this offering, before the commencement of offers or sales of the common stock. Passive market makers must comply with applicable volume and price limitations and must be identified as passive market makers. In general, a passive market maker must display its bid at a price not in excess of the highest independent bid for the security; if all independent bids are lowered below the passive market maker's bid, however, the bid must then be lowered when purchase limits are exceeded.

We and the underwriters have agreed to indemnify each other against certain liabilities, including liabilities under the Securities Act.

## **LEGAL MATTERS**

The validity of the shares offered herein will be opined on for us by Morgan, Lewis & Bockius, LLP, which has acted as our outside legal counsel in relation to certain restricted tasks.

## **EXPERTS**

The consolidated financial statements as of December 31, 2007 and 2006, and for each of the three years in the period ended December 31, 2007, included in this Prospectus have been audited by Deloitte & Touche LLP, an independent registered public accounting firm, as stated in their report appearing herein and elsewhere in the Registration Statement (which report expresses an unqualified opinion on the consolidated financial statements and includes explanatory paragraphs relating to Genta Incorporated's ability to continue to as a going concern and the adoption of Statement of Financial Accounting Standards No. 123 (Revised 2004), Shared-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). Such consolidated financial statements have been so included in reliance upon the report of such firm given upon their authority as experts in accounting and auditing.

## **HOW TO GET MORE INFORMATION**

We have filed with the SEC a Registration Statement on Form S-1 under the Securities Act with respect to the securities offered by this prospectus. This prospectus, which forms a part of the Registration Statement, does not contain all the information set forth in the Registration Statement, as permitted by the rules and regulations of the SEC. For further information with respect to us and the securities offered by this prospectus, reference is made to the Registration Statement. Statements contained in this prospectus as to the contents of any contract or other document that we have filed as an exhibit to the Registration Statement are qualified in their entirety by reference to the exhibits for a complete statement of their terms and conditions. The Registration Statement and other information may be read and copied at the SEC's Public Reference Room at 100 F Street N.E., Washington, D.C. 20549. The public may obtain information on the operation of the Public Reference Room by calling the SEC at 1-800-SEC-0330. The SEC maintains a web site at <http://www.sec.gov> that contains reports, proxy and information statements, and other information regarding issuers that file electronically with the SEC.

We will also send you copies of the material we file with the SEC, free of charge, upon your request. Please call or write our Investor Relations department at:

Genta Incorporated  
Attention: Investor Relations  
200 Connell Drive  
Berkeley Heights, NJ 07922

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. Our website and the information contained therein or connected thereto shall not be deemed to be incorporated into this prospectus or the Registration Statement of which it forms a part.



**Table of Contents**

**INDEX TO FINANCIAL STATEMENTS**

**Genta Incorporated  
Index to Financial Statements**

<u>Report of Independent Registered Public Accounting Firm</u>	F-2
<u>Consolidated Balance Sheets as of December 31, 2007 and 2006</u>	F-3
<u>Consolidated Statements of Operations for the Years Ended December 31, 2007, 2006 and 2005</u>	F-4
<u>Consolidated Statements of Stockholders' Equity for the Years Ended December 31, 2007, 2006 and 2005</u>	F-5
<u>Consolidated Statements of Cash Flows for the Years Ended December 31, 2007, 2006 and 2005</u>	F-6
<u>Notes to Consolidated Financial Statements for the Years Ended December 31, 2007, 2006 and 2005</u>	F-7
<u>Consolidated Balance Sheets as of June 30, 2008 and December 31, 2007</u>	F-27
<u>Consolidated Statements of Operations for the Six Months Ended June 30, 2008 and 2007</u>	F-28
<u>Consolidated Statements of Cash Flows for the Three and Six Months Ended June 30, 2008 and 2007</u>	F-29
<u>Notes to Consolidated Financial Statements for the Three and Six Months Ended June 30, 2008 and 2007</u>	F-30

F-1

---

**Table of Contents**

**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

**Table of Contents****GENTA INCORPORATED****CONSOLIDATED BALANCE SHEETS  
AS OF DECEMBER 31, 2007 AND 2006**

	<b>December 31, 2007</b>	<b>December 31, 2006</b>
	<b>(In thousands, except par value data)</b>	
<b>ASSETS</b>		
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
<b>LIABILITIES AND STOCKHOLDERS EQUITY</b>		
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.

F-3

---

**Table of Contents**

**GENTA INCORPORATED**

**CONSOLIDATED STATEMENTS OF OPERATIONS**  
**FOR THE YEARS ENDED DECEMBER 31, 2007, 2006 AND 2005**

	<b>Years Ended December 31,</b>		
	<b>2007</b>	<b>2006</b>	<b>2005</b>
	<b>(In thousands, except per share data)</b>		
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.

Table of Contents**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
	Shares	Amount	Shares	Amount	Capital	Deficit	Compensation	(Loss)	Equity	
	(In thousands)									
<b>Balance at January 1, 2005</b>	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			2							