GENTA INC DE/ Form S-1/A May 29, 2009

As filed with the Securities and Exchange Commission on May [\_\_], 2009

Registration No. 333-153278

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

AMENDMENT NO. 2 TO

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 Heights, 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.  $\pounds$ 

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.  $\pounds$ 

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	Accelerated filer £	Non-accelerated filer R	Smaller reporting company $f$
filer £	(Do :	not check if a smaller reporting compan	y)

### CALCULATION OF REGISTRATION FEE

Title of each class of securities to be registered	Proposed maximum aggregate offering price		Amount of registration fee(1)
Units (consisting of Convertible Debt Securities(2) and Shares			
of Common Stock (par value \$0.001 per share))		—(3)	—(3)
Shares of Common Stock (par value \$0.001 per share)			
underlying convertible debt securities	\$[	] \$	[ ]
Convertible Debt Securities issuable as payment of interest			
under the Convertible Debt Securities	\$	[—] \$	[—]
Warrants			—(3)
Shares of Common Stock (par value \$0.001 per share)			
underlying Warrants	\$[	] \$	[ ]
Total	\$ 23,000,00	00 \$	905(4)

(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, based on the average of the high and low sale prices of the Registrant's common stock on March 2, 2009, as reported by the Over-the-Counter bulletin board. In accordance with Rule 416 under the Securities Act of 1933, in order to prevent dilution, a presently indeterminable number of shares of common stock are registered hereunder which may be issued in the event of a stock split, stock dividend or similar transaction. No additional registration fee has been paid for these shares of common stock.

Pursuant to Rule 457(g), no separate registration fee is required for the Convertible Debt Securities or the Warrants because we are registering those securities in the same registration statement as the underlying common stock.

(3) A registration fee of \$905.00 was previously paid in connection with the initial filing of this Registration Statement on Form S-1 (File No. 333-153278), which was filed by the Company on August 29, 2008.

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.

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 Securities and Exchange Commission 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.

# PROSPECTUS

Subject to completion, dated May [\_\_], 2009

### GENTA INCORPORATED

Up to [\_\_\_] of Units consisting of [ ] Convertible Debt Securities and [ ] shares of Common Stock

[\_\_\_] shares of Common Stock underlying the Convertible Debt Securities

[\_\_\_] Convertible Debt Securities issuable as payment of interest on the Convertible Debt Securities

Warrants to purchase [\_\_\_] shares of Common Stock

[\_\_\_] shares of Common Stock underlying the Warrants

We are offering units consisting of convertible debt securities convertible into [\_\_\_] shares of our common stock, [\_\_\_] shares of common stock underlying the convertible debt securities, [\_\_\_] convertible debt securities convertible into [\_\_\_] shares of common stock issuable as payment of interest on the convertible debt securities, warrants to purchase [\_\_\_] shares of our common stock and [\_\_\_] shares of common stock underlying the warrants collectively referred to as the securities. All costs associated with this registration will be borne by us.

On May [\_\_\_], 2009, the closing price of our common stock was \$[\_\_\_] per share. Our common stock is quoted on the OTC Bulletin Board under the symbol "GNTA.OB".

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 [16].

	Placement Agent					
	Discounts and Proceeds to Genta,					
	Price	e to Publ	icCon	nmissions	befo	re expenses
Per Share	\$	[]	\$	[]	\$	[]
Total	\$	[]	\$	[]	\$	[]

We have retained Rodman & Renshaw, LLC as placement agent to use its reasonable best efforts to solicit offers to purchase our securities in this offering in one or more closings. We have agreed to indemnify the placement agent against some liabilities, including liabilities under the Securities Act of 1933, as amended, or the Securities Act, and to contribute to payments that the placement agent may be required to make in respect thereof.

None of the proceeds from the sale of securities will be placed in escrow, trust or any similar account, and all of the subscription monies will be immediately available for our use. There is no minimum amount of securities that must be sold.

Neither the Securities and Exchange Commission nor any state Securities Commission has approved or disapproved of these securities, or determined if this prospectus is truthful or complete. Any representation to the contrary is a criminal offense.

We expect to deliver the securities to purchasers pursuant to this prospectus on or about [\_\_\_].

The date of this prospectus is [\_\_\_], 2009.

Rodman & Renshaw, LLC

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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 the securities, and seeking offers to buy the securities, 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 the placement agent has 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.

#### PROSPECTUS SUMMARY

This summary does not contain all of the information you should consider before buying our securities. 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 our securities.

#### 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 convertible debt securities convertible into [\_\_\_] shares of our common stock, [\_\_\_] shares of common stock underlying the convertible debt securities [\_\_\_] warrants to purchase shares of our common stock and [\_\_\_] shares of common stock issuable upon exercise of the warrants.

#### Overview

We are a biopharmaceutical company engaged in pharmaceutical, or drug, research and development. 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" (which includes our lead oncology drug, Genasense®); and "Small Molecules" (which includes our marketed product, Ganite®, and the investigational compounds tesetaxel and G4544).

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®, an oblimersen sodium injection. Genasense® is designed to block the production of a protein known as Bcl-2. Current science suggests that Bcl-2 is a fundamental, although not the sole, cause of the inherent resistance of cancer cells to anticancer treatments, such as chemotherapy, radiation, and monoclonal antibodies. While Genasense® has displayed some anticancer activity when used by itself, we are developing the drug primarily as a means of amplifying the cytotoxic effects of other anticancer treatments.

Genasense® has been studied in combination with a wide variety of anticancer drugs in a number of different cancer indications. We have reported results from randomized trials of Genasense® in a number of diseases. Under our own sponsorship or in collaboration with others, 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; chronic lymphocytic leukemia, referred to herein as CLL; and non-Hodgkin's lymphoma, referred to herein as NHL.

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

#### Melanoma

The initial NDA for Genasense® in melanoma was withdrawn in 2004 after an advisory committee to the Food and Drug Administration (FDA) failed to recommend approval. A negative decision was also received for a similar application in melanoma from the European Medicines Agency (EMEA) in 2007. Data from the 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 (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. LDH had also been previously described by others as the single most important prognostic factor in advanced melanoma.

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Based on these data, in August 2007 we initiated a new Phase 3 trial of Genasense® plus chemotherapy in advanced melanoma. This 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 (PFS) and overall survival.

AGENDA is designed to expand evidence for the safety and efficacy of Genasense® when combined with dacarbazine for patients who have not previously been treated with chemotherapy. The study prospectively targets patients who have low-normal levels of LDH. We have completed accrual of patient enrollment into AGENDA with 315 patients from the U.S., Canada, Western Europe, and Australia. In May 2009, a final analysis by an independent Data Monitoring Committee for both safety and futility informed us that the study passed its final futility analysis for progression-free survival (PFS). Accordingly, the Committee recommended that the study should continue to completion. We expect to release results on the final assessment of PFS in the fourth quarter of 2009. If those data are positive, we currently expect our regulatory submissions will be based upon confirmation that the addition of Genasense® to chemotherapy results in a statistically significant and clinically meaningful improvement in PFS. Approval by FDA and EMEA will allow Genasense® to be commercialized by us in the U.S. and in the European Union. Genasense® in melanoma has been designated an Orphan Drug in Australia and the United States, and the drug has received Fast Track designation in the United States.

Given our belief in the activity of Genasense® in melanoma, we have initiated additional clinical studies in this disease. One such study is a Phase 2 trial of Genasense® plus a chemotherapy regimen consisting of Abraxane® (paclitaxel protein-bound particles for injectable suspension) (albumin bound) plus temozolomide (Temodar®). 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.

### CLL

As noted above, 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 > 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®.

We submitted our NDA to the FDA in December 2005 in which we 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 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 FDA that indicated additional confirmatory evidence would be required to

support approval of Genasense® in CLL. In that communication, FDA recommended one option was to collect additional information regarding the clinical course and progression of disease in patients from the completed trial.

Subsequently, we obtained information regarding long-term survival on patients who had been accrued to our completed Phase 3 trial. In June 2008, we announced results from 5 years of follow-up These data showed that patients treated with Genasense® plus chemotherapy who achieved either a complete response (CR) or a partial response (PR) had also achieved a statistically significant increase in survival.

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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 (CR+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 (45%) responders in the Genasense® group were alive compared with 13 of 54 (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 (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.

These data were again submitted to FDA in the second quarter of 2008, and the application was again denied in December 2008. Genta re-appealed the denial, and in March 2009, CDER decided that available data were still not adequate to support approval of Genasense® in chronic lymphocytic leukemia, and the Agency recommended conducting a confirmatory clinical trial. We have not yet made a decision whether to conduct this study.

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.

### NHL

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 IV infusions, provide an opportunity to re-examine the drug's activity in some of these indications.

### Tesetaxel

In March 2008, we obtained from Daiichi Sankyo Company Ltd. 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 in June 2008. In January 2009, we announced initiation of a new clinical trial with tesetaxel to examine the clinical pharmacology of the drug over a narrow dosing range around the established Phase 2 dose.

We have also submitted applications to FDA for designation of tesetaxel as an Orphan Drug for treatment of patients with advanced gastric cancer and for patients with advanced melanoma. Both of these designations have been granted. We have submitted a proposed protocol to FDA for Special Protocol Assessment (SPA). A SPA is intended to secure agreement on the design, size, and endpoints of clinical trials that are intended to form the primary basis of an efficacy claim in a NDA. We also expect to seek Scientific Advice from the EMEA for this study to support a Marketing Authorization Application (MAA). The protocol proposes to examine the safety and efficacy of tesetaxel in patients with advanced gastric cancer whose disease has progressed after receiving first-line chemotherapy. Maintenance of

the license from Daiichi Sankyo requires certain payments that include amortization of licensing fees and milestones. If such payments are not made, Daiichi Sankyo may elect to terminate the license; however, a portion of the licensing fees may still be due even in the event of termination. We are currently in discussions with Daiichi Sankyo regarding the timing of these payments.

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### Pipeline

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 and through the first quarter of 2009 due to financial constraints.

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. 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.

### Ganite

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

#### 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. Information on our website is not part of this prospectus. Our website address is included in this prospectus as an inactive technical reference only.

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# SUMMARY OF THE OFFERING

The securities	We are offering:
	• up to \$[12] million in aggregate principal amount of units consisting of (i) [50]% senior secured convertible notes (the "2009 Notes") and (ii) [50]% common stock, par value \$0.001 (the "2009 Shares") (the "Units");
	• [ ] shares of common stock issuable upon conversion of or otherwise in respect of the 2009 Notes;
	• \$[ ] 2009 Notes issuable as payment of interest on the 2009 Notes;
	• warrants to purchase [ ] shares of common stock; and
	• [ ] shares of common stock issuable upon exercise of warrants.
The offering	Initial Sale
	Commencing upon the effectiveness of the registration statement of which this prospectus forms a part, we will offer and sell Units in the aggregate principal amount of \$[12] million consisting of 2009 Notes and 2009 Shares. We refer to this initial closing of the offering as the "initial sale." Each purchaser of Units in the initial sale will also receive a [2]-year warrant to purchase a number of shares of our common stock equal to 25% of the number of shares of our common stock underlying the 2009 Note purchased by such purchaser having the terms outlined in this prospectus. The offer and sale of the initial \$[12] million in Units are expected to occur in a single closing as soon as practical following the effectiveness of the registration statement.
Consent Required	We cannot undertake the transactions described in this prospectus without the consent of certain of the holders of our outstanding 15% Senior Secured Convertible Notes due 2010, which we refer to in this prospectus as the "2008 Notes."
	Concurrently with the closing of the initial sale, we will enter into a consent and amendment agreement with each holder of the 2008 Notes. Under the terms of these agreements, each holder of 2008 Notes will agree to provide such holder's consent to and approval of the transactions described in this prospectus, and will agree to certain amendments to the 2008 Notes necessary to permit the transactions described in this prospectus.
	In addition, the holders of the 2008 Notes and the holders of our outstanding 8% Senior Secured Convertible Notes due 2012 (the "April 2009 Notes") agree that the anti-dilution adjustment to the 2008 Notes and April 2009 Notes, as set forth in the form of 2008 Note and in the form of April 2009 Note, as a result of the transactions described herein, shall cause the conversion price in the 2008 Notes and April 2009 Notes to be reset to \$[]. As a result, the 2008 Notes and April 2009 Notes outstanding as of the date of this prospectus will be convertible into [] shares of our common stock upon the issuance of the 2009 Notes.

Use of proceeds	The proceeds will be used to advance our product candidates through clinical trials and clinical development, and general corporate purposes, including working capital needs and potential acquisition or licenses to intellectual property. See "Use of Proceeds."
Fees and expenses	We estimate that the total fees and expenses of this offering will be approximately \$[].
Material US federal income tax consequences	For a discussion of material U.S. federal income tax considerations relating to the purchase, ownership and disposition of the Units, shares of common stock into which the 2009 Notes are convertible, additional 2009 Notes issuable as payment of interest on the 2009 Notes, warrants and shares of common stock into which the warrants are exercisable, see "Material U.S. federal income tax consequences."
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Trading	Our common stock is traded on the OTC Bulletin Board under the symbol "GNTA.OB." We do not intend to list the Units or warrants on any national securities exchange or automated quotation system.
Placement agent	Rodman & Renshaw, LLC will act a placement agent for the placement for the securities being offered pursuant to this prospectus.
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 our Units and warrants.

The number of shares of our common stock that will be outstanding prior to this offering is 1,014,111,706 shares of common stock outstanding as of March 31, 2009. This amount excludes:

•1,878,670 shares of common stock issuable upon exercise of stock options outstanding or restricted stock units under our 1998 Stock Incentive Plan as of March 31, 2009 at a weighted average exercise price of \$25.33 per share, of which, options to purchase 1,341,011 shares were exercisable;

•102,267 shares of common stock issuable upon exercise of stock options outstanding under our 1998 Non-Employee Directors Stock Incentive Plan as of March 31, 2009 at a weighted average exercise price of \$22.61 per share, of which, options to purchase 102,267 shares were exercisable;

•153,541 shares of common stock available for future grant under our 1998 Non Employee Directors Stock Incentive Plan as of March 31, 2009;

•40,000,000 shares of common stock issuable upon exercise of warrants outstanding as of March 31, 2009 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 March 31, 2009; and

•1,065,345,148 shares of common stock issuable upon the conversion of our 15% Senior Secured Convertible Notes due 2010 as of March 31, 2009.

The share numbers above do not include the notes and warrants issued in the April 2009 financing.

Unless otherwise indicated, all information in this prospectus assumes there is no over-allotment option, no conversion of convertible notes or preferred stock and no exercise of stock options or warrants after March 31, 2009.

# SUMMARY OF THE TERMS OF THE 2009 NOTES

Issuer	Genta Incorporated.
Notes	Up to \$[6] million aggregate principal amount of [8]% Senior Secured Convertible Notes due 2013, which we refer to herein as the 2009 Notes.
Maturity	The notes will mature on [ ], 2013, unless earlier converted.
Interest payment dates	We will pay [8.00]% interest per annum on the principal amount of the 2009 Notes, payable [semi-annually in arrears on March and September of each year, starting on September, 2009, to holders of record at the close of business on the preceding March 1 and September 1 respectively]. Accrued but unpaid interest shall also be paid in the event of any conversion and at maturity of the 2009 Notes. Interest will accrue on the 2009 Notes from and including their original issue date, or from and including the record date with respect to the previous interest payment date, to, but excluding, the current record date, conversion date or maturity date, as applicable. Interest will accrue on the basis of a 360-day year consisting of twelve 30-day months. Interest on the 2009 Notes will be paid in additional 2009 Notes having a face value equal to the accrued interest.
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Ranking	The 2009 Notes will be:
	• secured on a second-priority lien basis by all of our assets;
	• pari passu to the 2008 Notes and April 2009 Notes; and
	• senior to any existing and future indebtedness.
Collateral	The 2009 Notes are secured by a second-priority lien on all of our assets.
	For more details, see "Description of notes—Security."
Sharing of liens	[We may secure additional indebtedness incurred after the date of issuance of the 2009 Notes by granting liens upon any or all of the collateral securing the 2009 Notes, including on a senior basis, which may be on an equal basis with the first-priority liens securing the 2008 Notes, or on a pari passu or junior basis.]
No restrictions on additional indebtedness	[The indenture does not limit the amount of additional indebtedness, including secured indebtedness, which we can create, incur, assume or guarantee, nor does the indenture limit the amount of indebtedness or other liabilities that our subsidiaries can create, incur, assume or guarantee. To the extent we incur additional secured indebtedness, the liens securing the 2009 Notes would be senior to the liens securing such additional secured indebtedness only to the extent that the liens securing the 2009 Notes have been perfected prior to, and have priority over, the liens securing such additional secured indebtedness.]
Conversion rights	The 2009 Notes will be convertible at any time, [subject to prior maturity,] into shares of our common stock, based on an initial conversion rate, subject to adjustment, of [500,000] shares per \$1,000 in principal amount of the 2009 Notes (which represents an initial conversion price of \$[0.002] per share).
Mandatory conversion	Subject to the limitations set forth below and under "Provisional limitation on the right to convert notes" and "Permanent limitation on the right to convert notes", at any time or from time to time, we may elect to cause the conversion, in whole or in part, of the 2009 Notes by providing thirty (30) days written notice of the date on which such conversion is to occur, which we refer to as a mandatory conversion date. Any such conversion shall be made pro-rata among all holders of 2009 Notes.
	We will only be permitted to cause the conversion on a mandatory conversion date if, on the proposed mandatory conversion date (i) the Daily VWAP is equal to or greater than \$[0.20] (as appropriately adjusted for stock splits, stock dividends, reorganizations, recapitalizations, stock combinations and the like) for each of the twenty (20) consecutive prior trading days ending on the trading day immediately prior to the notice date, (ii) the common stock issuable upon the mandatory conversion would, immediately upon issuance, be freely tradable without restrictions and (iii) we have sufficient authorized shares for full conversion of the 2009 Notes.
	See "Description of notes-Conversion rights-Mandatory conversion."

Covenant to increase our authorized shares

We do not have a sufficient number of shares of our common stock currently authorized and available for issuance to allow for full conversion of the 2009 Notes, payment of interest in shares of our common stock or exercise of the warrants, and are required to seek stockholder approval at our next annual meeting of stockholders, or, alternatively, at a special meeting of stockholders, of, and to effect no later than the date that is 105 days from the date on which the first 2009 Note is issued:

	6,000,000,000 to at least [_ sufficient to permit full cor pay interest on all such 200	of shares of our authorized common stock from ] and to reserve for issuance shares of our common stock version of all 2009 Notes that may be issued, to allow us to 9 Notes in shares of our common stock and to allow exercise issue in conjunction with the issuance of 2009 Notes; and
	(2) a 1	reverse stock split of our common stock.
	of shares of our authorized authorization date. An ever effect the increase in autho	to the date of the latest to occur of the increase in the number stock and the effectiveness of the reverse stock split as the t of default will occur under the 2009 Notes if we fail to ized stock and the reverse stock split by the date that is 105 n the first 2009 Note is issued.
Limitations on transfers of the 2009 Notes	-	2009 Notes will be required to agree not to transfer, sell or 09 Notes until the Release Date.
Provisional limitation on right to convert notes		he earlier of (1) the date 105 days following the date on issued, and (2) the authorization date, as the release date.
	holder) or by us in any mar all prior conversions under converted does not exceed 2009 Notes held by such ho partial calendar weeks sinc holder) may only convert s holder's) pro rata allocation authorized and available fo have authorized and available	a 2009 Note may only be converted by a holder (or beneficial datory conversion on any day to the extent that, together with such note, the total amount of such note that has been he product of (A) 10% of the original principal amount of lder (or beneficial holder), and (B) the number of whole or e the date of the initial sale; and (ii) a holder (or beneficial ach 2009 Notes to the extent of such holder's (or beneficial of the number of shares of common stock we have r issuance. As of the date hereof, the number of shares we ble for issuance is [] shares of common stock.
Permanent limitation on rig to convert notes	htWe cannot effect a convers the holder (or beneficial ho such conversion would res	on of the 2009 Notes, whether voluntary or mandatory, and der) may not request a conversion of such 2009 Notes, if It in the beneficial holder and the beneficial holder's affiliates of our outstanding common stock after conversion.
	See "Description of notes-	-Conversion rights—Permanent limitation on right to convert notes."
Sinking fund	None.	
Events of default	amount of the 2009 Notes j	2009 Notes has occurred and is continuing, the principal lus any accrued and unpaid interest may become le. These amounts automatically become due and payable alt.
	See "Description of 2009 N	otes—Events of default."

DTC eligibility	The 2009 Notes will be issued in registered form without interest coupons, in denominations of integral multiples of \$1,000 principal amount, in the form of global securities and will be represented by one or more global certificates, deposited with, or on behalf of, DTC and registered in the name of a DTC or a nominee of DTC. Beneficial interests in the global securities will be shown on, and transfers will be effected only through, records maintained by DTC and its direct and indirect participants. Except in limited circumstances, holders may not exchange interests in their 2009 Notes for certificated securities.
	See "Description of notes-Form, denomination and registration of notes."
Listing and trading	The 2009 Notes are a new issue of securities, and there is currently no established trading market for the 2009 Notes. An active or liquid market may not develop for the 2009 Notes or, if developed, be maintained. We have not applied, and do not intend to apply, for the listing of the 2009 Notes on any securities exchange. Our common stock is listed on the OTC Bulletin Board under the symbol "GNTA.OB."

# SUMMARY OF THE TERMS OF THE WARRANTS

Issuer	Genta Incorporated.
Warrants	Warrants to purchase an aggregate of up to [ ] shares of our common stock.
Term	The warrants are exercisable during the period commencing on the date six months from the date of their issuance and ending on the date that is five years from the date of their issuance.
Exercise Price	The exercise price of the warrants is \$[ ] per share of common stock.
Net Exercise	In lieu of paying the exercise price for the shares of common stock issuable upon exercise of the warrants, at any time when the shares of common stock deliverable upon exercise of the warrants would not upon such exercise be freely tradable without restriction, the holder of the warrants may elect to convert the warrant into a number of shares of common stock equal to the value of the shares of common stock as to which the holder of the warrant is electing to exercise the warrant, less the exercise price otherwise payable upon exercise of such number of shares.
Adjustments	The exercise price and number and type of securities or other property issuable upon exercise of the warrants will be subject to adjustment for stock splits, stock dividends, recapitalizations, reclassifications and other events effecting the shares of our common stock.
Permanent limitation on right The warrants cannot be exercised or converted if such exercise or conversion would result in the holder and the holder's affiliates owning more than 4.999% of our outstanding common stock after conversion.	
Listing and trading	The warrants are a new issue of securities, and there is currently no established trading market for the warrants. An active or liquid market is not expected to develop for the warrants or, if developed, be maintained. We have not applied, and do not intend to apply, for the listing of the warrants on any securities exchange. Our common stock is listed on the OTC Bulletin Board under the symbol "GNTA.OB."

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#### 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 convertible debt securities, warrants to purchase shares of our common stock and the consent rights in this offering, at an assumed public offering price of [] per share, after deducting placement agent discounts and commissions and estimated offering expenses.

	Three months ended March 31, (in thousands except per share amounts) (unaudited) 2009		Year ended December 31, (in thousands except per share amounts) 2008			2007		2006
Consolidated Statements of Operations								
Data:	¢	()	¢	2(2	¢	500	¢	700
Product sales — net	\$	62	\$	363	\$	580	\$	708
Total revenues		62		363		580		708
Costs of goods sold		-		102		90		108
Operating expenses		4,470		33,410		26,116		59,764
Amortization of deferred financing costs		(6,287)		(11,229)		_	-	
Fair value — conversion feature liability		-		(460,000)			-	
Fair value — warrant liability		-		(2,000)		_	-	
All other (expense)/income -net		(372)		(1,435)		836		1,454
Loss before income taxes		(11,067)		(507,813)		(24,790)		(57,710)
Income tax benefit		-		1,975		1,470		929
Net loss	\$	(11,067)	\$	(505,838)	\$	(23,320)	\$	(56,781)
Net loss per basic and diluted common								
share *	\$	(0.01)	\$	(9.10)	\$	(0.79)	\$	(2.52)
Common shares used in computing net loss per basic and diluted share *		899,963		55,576		29,621		22,553

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

	March 31, 2009							
			March 31, 2009		December 31, 2008			
	adjusted)			(unaudited, as reported)(as re			eported)	
Balance Sheet Data:								
Cash and cash equivalents	\$	[_	_]	\$	598	\$	4,908	
Working capital deficiency		[_	_]		(9,510)		(5,220)	
Total assets		[_	_]		7,137		12,693	

Total stockholders' deficit	[]	(10,585)	(4,864)
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### **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 our securities. 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

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

Our operations to date have required significant cash expenditures. Our future capital requirements will depend on the results of our research and development activities, preclinical studies and clinical trials, competitive and technological advances, and regulatory activities of the FDA and other regulatory authorities. In order to commercialize our products, seek new product candidates and continue our research and development programs, we will need to raise additional funds.

On June 9, 2008, we placed \$20 million of senior secured convertible notes, or the 2008 Notes, with certain institutional and accredited investors. The notes bear interest at an annual rate of 15% payable at quarterly intervals in other senior secured convertible promissory notes to the holder, and are presently convertible into shares of Genta common stock at a conversion rate of 500,000 shares of common stock for every \$1,000.00 of principal. Certain members of our senior management participated in this offering. The notes are secured by a first lien on all of our assets.

On April 2, 2009, we entered into a securities purchase agreement with certain accredited institutional investors to place up to \$12 million of senior secured convertible notes, or the April 2009 Notes, and corresponding warrants to purchase common stock. We closed on approximately \$6 million of such notes and warrants on April 2, 2009. The April 2009 Notes bear interest at an annual rate of 8% payable semi-annually in other senior secured convertible promissory notes to the holder, and will be convertible into shares of our common stock at a conversion rate of 500,000 shares of common stock for every \$1,000.00 of principal amount outstanding. In addition, the April 2009 Notes include certain events of default, including a requirement that we effect a reverse stock split of our Common Stock within 105 days of April 2, 2009. There are currently not enough shares of our Common Stock authorized under our certificate of incorporation to cover the shares underlying the April 2009 Notes and warrants and the 2008 Notes.

A special meeting of our stockholders will be held on June 26, 2009. We have recommended to our stockholders that they provide authorization to our Board of Directors to effect a reverse split in any ratio from 1:2 to 1:100.

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

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

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

•

attempt to sell our company;

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cease operations; or
declare bankruptcy.

Presently, with no further financing, we will run out of funds in June 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.

If our stockholders do not approve authorizing our Board of Directors to effect a reverse split in a ratio of any ratio from 1:2 to 1:100, we will be in default on our April 2009 Notes.

As noted above, the April 2009 Notes include certain events of default, including a requirement that we effect a reverse stock split of our Common Stock within 105 days of April 2, 2009. There are currently not enough shares of our Common Stock authorized under our certificate of incorporation to cover the shares underlying the April 2009 Notes and warrants and the 2008 Notes.

A special meeting of our stockholders will be held on June 26, 2009. We have recommended to our stockholders that they provide authorization to our Board of Directors to effect a reverse split in any ratio from 1:2 to 1:100.

If our stockholders do not provide authorization to our Board of Directors to effect a reverse split within 105 days of April 2, 2009, we will be in default on our April 2009 Notes, and the principal amount of the notes plus accrued interest will be immediately due to our noteholders.

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

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

- our ability to demonstrate clinically that our products are useful and safe in particular indications;
  - delays or refusals by regulatory authorities in granting marketing approvals;
  - our limited financial resources and sales and marketing experience relative to our competitors;
    - actual and perceived differences between our products and those of our competitors;
    - the availability and level of reimbursement for our products by third-party payors;
      - incidents of adverse reactions to our products;
    - side effects or misuse of our products and the unfavorable publicity that could result; and
      - the occurrence of manufacturing, supply or distribution disruptions.

We cannot assure you that Genasense® will receive FDA or EMEA approval. For example, the NDA for Genasense® in melanoma was withdrawn in 2004 after an advisory committee to the FDA failed to recommend approval. A

negative decision was also received for a similar application in melanoma from the EMEA in 2007. Our initial NDA for the use of Genasense® plus chemotherapy in patients with relapsed or refractory CLL was also unsuccessful. In March 2009, the FDA Center for Drug Evaluation and Research (CDER) decided that available data were still not adequate to support approval of Genasense® for treatment of patients in chronic lymphocytic leukemia, and the Agency has recommended conducting a confirmatory clinical trial.

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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.

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, 2008 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.

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.

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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 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 March 31, 2009, we have incurred a cumulative net deficit of \$955.2 million. We may never achieve revenue sufficient for us to attain profitability. Achieving profitability is unlikely unless Genasense® receives approval from the FDA or EMEA for commercial sale in one or more indications.

Our business depends heavily on a small number of products.

We currently market and sell one product, Ganite<sup>®</sup> and the principal patent covering its use for the approved indication expired in April 2005. If Genasense<sup>®</sup> is not approved, if approval is significantly delayed, or if in the event of approval the product is commercially unsuccessful, then we will 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.

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

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

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

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

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

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

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

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

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

investigations are not necessarily indicative of results that will be obtained in extended human clinical trials. Our products may prove to have undesirable and unintended side effects or other characteristics that may prevent our obtaining FDA or foreign regulatory approval for any indication. In addition, it is possible that research and discoveries by others will render our oligonucleotide technology obsolete or noncompetitive.

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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.

Between 2004 and 2007, we reported that randomized trials of Genasense® in patients with myeloma, acute myeloid leukemia, (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:

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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.

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.

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

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

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

The raw materials that we require to manufacture our drugs, particularly oligonucleotides, are available from only a few suppliers. If these suppliers cease to provide us with the necessary raw materials or fail to provide us with an adequate supply of materials at an acceptable price and quality, we could be materially adversely affected.

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

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

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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 to our products and services;
  - additional expense associated with amortization of acquired assets;
  - maintenance of uniform standards, controls, procedures and policies; and
- impairment of existing relationships with employees, suppliers and customers as a result of the integration of new management personnel.

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

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

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

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

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

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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 litigation are uncertain.

In November 2008, a complaint against us and our transfer agent, BNY Mellon Shareholder Services, was filed in the Supreme Court of the State of New York by an individual stockholder. The complaint alleges that we and our transfer agent caused or contributed to losses suffered by the stockholder. We deny the allegations of the complaint and intend to vigorously defend this lawsuit.

Risks Related to Our Common Stock

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

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

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

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.

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:

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- 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;

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- government regulation;
- developments in patent or other proprietary rights by us or our competitors, including litigation;
  - fluctuations in our operating results; and

market conditions for biopharmaceutical stocks in general.

At March 31, 2009, our outstanding convertible notes were convertible into 5.3 billion shares of common stock. On April 2, 2009 we sold additional notes and warrants, convertible into 3.9 billion shares of common stock. Future sales of shares of our common stock by existing stockholders, holders of preferred stock who might convert such preferred stock into common stock, holders of convertible notes who might convert such convertible notes 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.

As our convertible noteholders convert their notes into shares of our common stock, our stockholders will be diluted.

On June 9, 2008, we placed \$20 million of senior secured convertible notes, or the 2008 Notes, with certain institutional and accredited investors. The notes bear interest at an annual rate of 15% payable at quarterly intervals in other senior secured convertible promissory notes to the holder, and are presently convertible, after adjusting for the April 2009 note offering, into shares of our common stock at a conversion rate of 500,000 shares of common stock for every \$1,000.00 of principal. Certain members of our senior management participated in this offering. The notes are secured by a first lien on all of our assets. At March 31, 2009, our outstanding convertible notes were convertible into 5.3 billion shares of our common stock.

On April 2, 2009, we entered into a securities purchase agreement with certain accredited institutional investors to place up to \$12 million of senior secured convertible notes, or the April 2009 Notes, and corresponding warrants to purchase common stock. We closed on approximately \$6 million of such notes and warrants on April 2, 2009. The April 2009 Notes bear interest at an annual rate of 8% payable semi-annually in other senior secured convertible promissory notes to the holder, and will be convertible into shares of our common stock at a conversion rate of 500,000 shares of common stock for every \$1,000.00 of principal amount outstanding. In addition, the April 2009 Notes include certain events of default, including a requirement that we effect a reverse stock split of our Common Stock within 105 days of April 2, 2009. The notes and warrants are convertible into approximately 3.9 billion shares. There are currently not enough shares of Common Stock authorized under our certificate of incorporation to cover the shares underlying the April 2009 Notes and warrants and the 2008 Notes.

The conversion of some or all of our notes 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 notes or others.

If there is significant downward pressure on the price of our common stock, it may encourage holders of 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.

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Our common stock is considered a "penny stock" and does not qualify for exemption from the "penny stock" restrictions, which may make it more difficult for you to sell your shares.

Our common stock is classified as a "penny stock" by the SEC and is subject to rules adopted by the SEC regulating broker-dealer practices in connection with transactions in "penny stocks." The SEC has adopted regulations which define a "penny stock" to be any equity security that has a market price of less than \$5.00 per share, or with an exercise price of less than \$5.00 per share, subject to certain exceptions. For any transaction involving a penny stock, unless exempt, these rules require delivery, prior to any transaction in a penny stock, of a disclosure schedule relating to the penny stock market. Disclosure is also required to be made about current quotations for the securities and commissions payable to both the broker-dealer and the registered representative. Finally, broker-dealers must send monthly statements to purchasers of penny stocks disclosing recent price information for the penny stock held in the account and information on the limited market in penny stocks. As a result of our shares of common stock being subject to the rules on penny stocks, the liquidity of our common stock may be adversely affected.

#### Risks Related to this Offering

We have a significant amount of debt. Our substantial indebtedness could adversely affect our business, financial condition and results of operations and our ability to meet our payment obligations under the notes and our other debt.

We have a significant amount of debt. As of March 31, 2009, we had a total outstanding debt balance of \$4.6 million, consisting solely of 2008 Notes. As adjusted to give effect to this offering, on March 31, 2009, we estimate we would have had approximately \$[ ] million of outstanding debt.

Our aggregate level of debt could have significant consequences on our future operations, including:

•making it more difficult for us to meet our payment and other obligations under our outstanding debt, including the April 2009 Notes;

resulting in an event of default if we fail to comply with the restrictive covenants contained in our debt agreements, which could result in all of our debt becoming due and payable and, in the case of an event of default under our secured debt, could permit the lenders to foreclose on our assets securing such debt;

reducing the availability of our cash on hand by approximately \$[ ] million, including estimated expenses incurred in connection with the offering, and reducing cash flow to fund working capital, capital expenditures, acquisitions and other general corporate purposes and limiting our ability to obtain additional financing for these purposes;

limiting our flexibility in planning for, or reacting to, and increasing our vulnerability to, changes in our business, the industry in which we operate and the general economy; and

• placing us at a competitive disadvantage compared to our competitors that have less debt or are less leveraged.

Any of the above-listed factors could have an adverse effect on our business, financial condition and results of operations and our ability to meet our payment obligations under the notes and our other debt.

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Our substantial amount of secured debt may prevent us from obtaining additional financing in the future or make the terms of securing such additional financing more onerous to us.

The 2008 Notes are secured by a first priority lien on our assets, the April 2009 Notes are secured by a second-priority lien on our assets and the 2009 Notes are expected to be secured by a second-priority lien on our assets. While the terms or availability of additional capital is always uncertain, should we need to obtain additional financing in the future, because of the existing liens on our assets, it may be even more difficult for us to do so. Potential future lenders may be unwilling to provide financing on an unsecured basis and may not agree to share the collateral with our existing secured debt. Alternatively, if we are able to raise additional financing in the future, the terms of any such financing may be onerous to us. This potential inability to obtain borrowings or our obtaining borrowings on unfavorable terms could negatively impact our operations and impair our ability to maintain sufficient working capital.

The market value of the notes and warrants may be exposed to substantial volatility.

A number of factors, including factors specific to us and our business, financial condition and liquidity, the price of our common stock, economic and financial market conditions, interest rates, unavailability of capital and financing sources, volatility levels and other factors could lead to a decline in the value of the 2009 Notes, 2009 Shares and warrants and a lack of liquidity in the market, if any, for the 2009 Notes and 2009 Shares. As has recently been evident in the current turmoil in the global financial markets, the present economic slowdown and the uncertainty over its breadth, depth and duration, the entire convertible note market can experience sudden and sharp price swings and changes in liquidity, which can be exacerbated by large or sustained sales by major investors in the convertible notes, a default by a high-profile issuer, regulatory changes, or simply a change in the market's psychology regarding convertible notes. Moreover, if one or more of the rating agencies rates the 2009 Notes, the price of the notes would likely decline.

Declines in the market price of our common stock may depress the trading price of the 2009 Notes and warrants.

The market price of our common stock has experienced, and may continue to experience, significant volatility. From January 1, 2007 through May 7, 2008, the trading price of our common stock on the NASDAQ Global Market ranged from a low of \$0.15 per share to a high of \$3.36 per share. From May 7, 2008 through March 2, 2009, the trading price of our common stock on the OTC Bulletin Board has ranged from a low of \$0.0027 per share to a high of \$0.75 per share. Because the 2009 Notes are convertible into, and the warrants are exercisable for, shares of our common stock, declines in the price of our common stock may depress the trading price of the 2009 Notes and warrants. The risk of depressed prices of our common stock also applies to holders who receive shares of common stock upon conversion of their 2009 Notes or exercise of their warrants.

Numerous factors, including many over which we have no control, may have a significant impact on the market price of our common stock, including, among other things:

- our operating and financial performance and prospects;
  - our ability to repay our debt;
  - quarterly variations in operating results;
- investor perceptions of us and the industry and markets in which we operate;
- changes in earnings estimates or buy/sell recommendations by analysts; and

general financial, domestic, international, economic and other market conditions.

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In addition, the stock market in recent months has experienced extreme price and trading volume fluctuations that often have been unrelated or disproportionate to the operating performance of individual companies. These broad market fluctuations may adversely affect the price of our common stock, regardless of our operating performance. In addition, sales of substantial amounts of our common stock in the public market, or the perception that those sales may occur, could cause the market price of our common stock to decline. Furthermore, stockholders may initiate securities class action lawsuits if the market price of our stock drops significantly, which may cause us to incur substantial costs and could divert the time and attention of our management.

These factors, among others, could significantly depress the trading price of the 2009 Notes and warrants and the price of our common stock issued upon conversion of the 2009 Notes and exercise of the warrants.

The conversion rate of the 2009 Notes may not be adjusted for certain dilutive events that may occur.

As described more fully herein, we will adjust the conversion rate of the 2009 Notes for certain events, including, among others:

the issuance of stock dividends on our common stock;

the issuance of certain rights or warrants;

certain subdivisions and combinations of our capital stock;

the distribution of capital stock, indebtedness, cash or other assets; and

certain tender or exchange offers.

We will not adjust the conversion rate for other events, such as an issuance of common stock for cash or in connection with an acquisition, that may adversely affect the trading price of the notes or our common stock. If we engage in any of these types of transactions, the value of the common stock into which your notes may be convertible may be diluted. An event that adversely affects the value of the notes, but does not result in an adjustment to the conversion rate, may occur.

We may not be able to provide you with all of the shares of our common stock that you would otherwise be entitled to receive upon a conversion of the 2009 Notes, upon payment of interest in shares of our common stock or upon exercise of the warrants because the 2009 Notes and warrants contain a cap on the shares we may issue to any holder.

You will not be entitled to convert the 2009 Notes or exercise the warrants to the extent (and only to the extent) that such conversion or exercise would cause you (including your affiliates) to become, directly or indirectly, a "beneficial owner" (as defined within the meaning of Section 13(d) of the Exchange Act and the rules and regulations promulgated thereunder) of more than 4.999% of the shares of our common stock outstanding at such time. This limitation also applies to our ability to pay interest in shares of our common stock. We refer to this limitation as the "issuance cap."

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We may not be able to provide you with all of the shares of our common stock that you would otherwise be entitled to receive upon a conversion of the 2009 Notes, upon payment of interest in shares of our common stock or upon exercise of the warrants because we do not have a sufficient number of shares of our common stock currently authorized and available for issuance.

We do not have a sufficient number of shares of our common stock currently authorized and available for issuance to allow for full conversion of the 2009 Notes, payment of interest in shares of our common stock or exercise of the warrants, and are required to seek stockholder approval at our next annual meeting of stockholders, or, alternatively, at a special meeting of stockholders, of, and to effect not later than the date that is 105 days from the date on which the first 2009 Note is issued:

(1) an increase the number of shares of our authorized common stock from 6,000,000,000 to at least [ ] and to reserve for issuance shares of our common stock sufficient to permit full conversion of all 2009 Notes that may be issued, to allow us to pay interest on all such 2009 Notes in shares of our common stock and to allow exercise of all warrants that we may issue in conjunction with the issuance of 2009 Notes; and

(2) a 1- reverse stock split of our common stock.

We cannot assure you that we will be successful in obtaining approval to increase the authorized shares of our common stock or to effect a 1- reverse stock split. If we fail to obtain approval for both of these proposals, you may not be able to fully convert the 2009 Notes or exercise the warrants. In addition, the failure to effect the increase in our authorized shares and the reverse stock split will trigger a default under the indenture governing the 2009 Notes.

We may not have the ability to pay principal or interest on the 2009 Notes when due.

The 2009 Notes mature on [], 2013 and bear interest semi-annually at a rate of [8.00]% per annum. Absent additional financing, we will likely not have sufficient funds to pay the principal upon maturity or upon any acceleration thereof. In addition, we may not have sufficient funds to pay interest on the 2009 Notes. If we fail to pay principal or interest on the 2009 Notes when due, we will be in default under the indenture governing the 2009 Notes.

We are subject only to limited covenants in the indenture for the 2009 Notes, and these limited covenants may not protect your investment.

The indenture for the 2009 Notes does not:

require us to maintain any financial ratios or specific levels of net worth, revenues, income, cash flows or liquidity and, accordingly, does not protect holders of the notes in the event that we experience significant adverse changes in our financial condition or results of operations;

restrict our ability to repurchase our securities; or

restrict our ability to make investments or to pay dividends or make other payments in respect of our common stock or other securities.

Furthermore, the indenture governing the 2009 Notes will not restrict our ability to incur additional indebtedness, including additional secured indebtedness, or our ability to designate any secured indebtedness as senior to, or pari-passu with, the 2009 Notes. We could engage in many types of transactions, such as incurring additional indebtedness or engaging in acquisitions, refinancings or recapitalizations, which could substantially affect our capital structure and the value of the 2009 Notes and warrants and our common stock. For these reasons, you should not

consider the covenants in the indenture as a significant factor in evaluating whether to invest in the 2009 Notes and warrants.

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If an active and liquid trading market for the 2009 Notes and warrants does not develop, the market price of the 2009 Notes and warrants may decline and you may be unable to sell your 2009 Notes and warrants.

The 2009 Notes and warrants are a new issue of securities for which there is currently no public market. We do not intend to list the 2009 Notes and warrants on any national securities exchange. An active trading market is not expected to develop for the 2009 Notes and warrants. Even if a trading market for the 2009 Notes and warrants develops, the market may not be liquid. If an active trading market does not develop, you may be unable to resell your 2009 Notes and warrants or may only be able to sell them at a substantial discount.

Future issuances of common stock and hedging activities may depress the trading price of our common stock and the 2009 Notes and warrants.

Any issuance of equity securities by us after this offering, including the issuance of shares upon conversion of the 2009 Notes and warrants, could dilute the interests of our existing stockholders, including holders who have received shares upon conversion of their 2009 Notes or exercise of the warrants, and could substantially decrease the trading price of our common stock and the 2009 Notes and warrants. We may issue equity securities in the future for a number of reasons, including to finance our operations and business strategy, for acquisitions, to adjust our ratio of debt to equity, to satisfy our obligations upon the exercise of outstanding warrants or options, in order to satisfy obligations under debt that remains outstanding, or for other reasons. In addition, the price of our common stock could also be affected by possible sales of our common stock by investors who view our convertible notes as a more attractive means of equity participation in our company and by hedging or arbitrage trading activity that we expect to develop involving our common stock. This hedging or arbitrage could, in turn, affect the trading price of the notes and any common stock that holders receive upon conversion of the notes.

Provisions in the indenture for the 2009 Notes, our charter documents and Delaware law could discourage an acquisition of us by a third party, even if the acquisition would be favorable to you.

The indenture for the 2009 Notes prohibits us from engaging in certain mergers or acquisitions unless, among other things, the surviving entity assumes our obligations under the 2009 Notes. These and other provisions, including the provisions of our charter documents and Delaware law described under "Description of capital stock" could prevent or deter a third party from acquiring us even where the acquisition could be beneficial to you. In addition, 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.

An adverse rating of the 2009 Notes may cause their trading price to fall.

We do not intend to seek a rating of the 2009 Notes. However, if a rating agency rates the 2009 Notes, it may assign a rating that is lower than investors' expectations. Ratings agencies also may lower ratings on the 2009 Notes in the future. If rating agencies assign a lower-than-expected rating to the 2009 Notes or to our credit ratings in general or reduce, or indicate that they may reduce, their ratings in the future, the trading price of the 2009 Notes could significantly decline, the liquidity of any market for the 2009 Notes could be adversely impacted, our cost of financing could increase and our access to the capital markets could be limited. A rating is based upon information furnished by us or obtained by the rating agency from its own sources and is subject to revision, suspension or withdrawal by the

rating agency at any time. Rating agencies may review the ratings assigned to the 2009 Notes due to developments that are beyond our control. We cannot assure you that any ratings on the 2009 Notes will not be downgraded in the near future.

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You may have to pay US taxes if we adjust the conversion rate in certain circumstances, even if you do not receive any cash.

We will adjust the conversion rate of the 2009 Notes for stock splits and combinations, stock dividends, cash dividends and certain other events that affect our capital structure. If we adjust the conversion rate, you may be treated as having received a constructive distribution from us, resulting in taxable income to you for US federal income tax purposes, even though you would not receive any cash in connection with the conversion rate adjustment and even though you might not exercise your conversion right.

As a holder of 2009 Notes or warrants, you will not be entitled to any rights with respect to our common stock, but you will be subject to all changes made with respect to our common stock.

If you hold 2009 Notes or warrants, you will not be entitled to any rights with respect to our common stock (including, without limitation, voting rights and rights to receive any dividends or other distributions on our common stock), but you will be subject to all changes affecting our common stock. You will have the rights with respect to our common stock only when we deliver shares of common stock to you upon conversion of your 2009 Notes or exercise of your warrants. For example, in the event that an amendment is proposed to our Certificate of Incorporation or code of regulations requiring stockholder approval and the record date for determining the stockholders of record entitled to vote on the amendment occurs prior to the date you are deemed to have received common stock upon conversion, you will not be entitled to vote on the amendment, although you will nevertheless be subject to any changes in the powers, preferences or special rights of our common stock.

Recent actions taken by the SEC to address abusive short selling may not effectively prevent security holders from engaging in short sales, which could further contribute to downward pressure on the trading price of our common stock. At the same time, these actions may also make it more difficult and/or expensive to hedge positions in convertible securities.

The SEC recently adopted various rules and rule amendments to address potentially manipulative short selling activities, including adopting new anti-fraud rule, Rule 10b-21 under the Exchange Act to address naked short selling, amending Rule 203 of Regulation SHO to eliminate an exception for certain options market makers, and adopting new Rule 204T of Regulation SHO, which generally mandates that a sales transaction for common stock be closed out on the fourth day following the trade's date. In particular, Rule 10b-21 specifically provides that it is a manipulative or deceptive device or contrivance for any seller of equity securities of a public company to deceive its brokers about its intention or ability to deliver the relevant securities in time for settlement and to fail to deliver shares by the close of business on the trade's settlement date. As a result of the SEC's focus on closing out failures to deliver securities in connection with sales transactions, a holder of 2009 Notes may find it more difficult and/or expensive to hedge its investment. However, the full effects of the recent SEC actions, if any, are not clear, including whether such actions will deter short selling and the effect these rule changes will have on the market for convertible securities generally and on the market for the 2009 Notes.

Your rights in the collateral may be adversely affected by the failure to create, attach or perfect security interests in collateral.

Applicable law requires that a security interest in certain tangible and intangible assets can only be properly created, attached to collateral and perfected, and its priority retained, through certain actions undertaken by the secured party. The liens on or against the collateral securing the 2009 Notes may not be properly created or attached, or perfected with respect to the claims of the notes, if the collateral agent is not able to take the actions necessary to create, attach or perfect any of these liens in a timely manner. In addition, applicable law requires that certain property and rights acquired after the grant of a general security interest, such as real property, can only be perfected at the time such property and rights are acquired and identified. We have limited obligations to create, attach and perfect the security

interest of the holders of the notes in specified collateral. We cannot assure you that the trustee or the collateral agent for the notes will monitor, or that we will inform such trustee or collateral agent of, the future acquisition of property and rights that constitute collateral, and that the necessary action will be taken to properly create, attach and perfect the security interest in such after-acquired collateral. The collateral agent for the 2009 Notes has no obligation to monitor the acquisition of additional property or rights that constitute collateral or the creation, attachment or perfection of any security interest. Such failure may result in the loss of the security interest in the collateral or the priority of the security interest in favor of the 2009 Notes against third parties.

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In the event of our bankruptcy, the ability of the holders of the 2009 Notes to realize upon the collateral will be subject to certain bankruptcy law limitations.

The ability of holders of the 2009 Notes to realize upon the collateral will be subject to certain bankruptcy law limitations in the event of our bankruptcy. Under federal bankruptcy law, secured creditors are prohibited from repossessing their security from a debtor in a bankruptcy case, or from disposing of security repossessed from such a debtor, without bankruptcy court approval, which may not be given. Moreover, applicable federal bankruptcy laws generally permit the debtor to continue to use and expend collateral, including cash collateral, and to provide liens senior to the liens of the collateral agent for the 2009 Notes, to secure indebtedness incurred after the commencement of a bankruptcy case, provided that the secured creditor either consents or is given "adequate protection." "Adequate protection" could include cash payments or the granting of additional security, if and at such times as the presiding court in its discretion determines, for any diminution in the value of the collateral as a result of the stay of repossession or disposition of the collateral during the pendency of the bankruptcy case, the use of collateral (including cash collateral) and the incurrence of such senior indebtedness. In view of the lack of a precise definition of the term "adequate protection" and the broad discretionary powers of a US bankruptcy court, we cannot predict whether or when the collateral agent under the indenture for the notes could foreclose upon or sell the collateral, and the holders of the notes will not be compensated for any delay in payment or loss of value of the collateral through the provision of "adequate protection," except to the extent of any grant of additional liens that are junior to the first-priority obligations.

The value of the collateral may not be sufficient to secure the full amount of your claims or entitle you to post-petition interest.

The 2009 Notes are secured by a second priority lien on our assets. However, as of December 31, 2008, we had approximately \$15.5 million principal amount of 2008 Notes outstanding, which are [senior] to the 2009 Notes and have a first priority security interest in our assets, and approximately \$6.0 million principal amount of April 2009 Notes outstanding. In addition, the indenture does not restrict our ability to issue additional secured indebtedness. [Under the proposed terms of the intercreditor agreement, the 2009 Notes would not receive any proceeds from the collateral until the 2008 Notes and any other senior secured indebtedness has been paid in full. Furthermore, the 2009 Notes may be required to share in any remaining proceeds from the collateral with any future secured debt that is pari-passu with the 2009 Notes. If the proceeds from the sale of our assets are insufficient to pay all amounts due under the senior secured debt and the 2009 Notes, then the holders of 2009 Notes would only have an unsecured claim against our remaining assets, subordinated to the claims of any senior creditors and pari-passu with the claims of our trade creditors and other unsecured and unsubordinated indebtedness.

In any bankruptcy proceeding with respect to us, it is possible that the bankruptcy trustee, the debtor-in-possession or competing creditors will assert that the fair market value of the collateral with respect to the notes on the bankruptcy filing date was, after allowing for the satisfaction of the claims of senior creditors with respect thereto, less than the then-current principal amount of the notes. Upon a finding by the bankruptcy court that the notes are under-collateralized, the claims in the bankruptcy proceeding with respect to the notes would be bifurcated between a secured claim and an unsecured claim, and the unsecured claim would not be entitled to the benefits of security in the collateral. Other consequences of a finding of under-collateralization would be, among other things, a lack of entitlement on the part of the notes to receive post-petition interest and a lack of entitlement on the part of the unsecured other "adequate protection" under federal bankruptcy laws. In addition, if any payments of post-petition interest had been made at the time of such a finding of under-collateralization, those payments could be recharacterized by the bankruptcy court as a reduction of the principal amount of the secured claim with respect to the notes.

No fair market value appraisal of the collateral was prepared in connection with this offering and we therefore cannot assure you that the note holders' interest value in the collateral equals or exceeds the principal amounts of the notes,

and we believe it is likely that such value of the collateral is less than the principal amounts of the notes. In addition, some or all of our assets may be illiquid and difficult to sell for full value and the ability of the holders of the 2009 Notes or the trustee to realize on the collateral may be subject to bankruptcy law limitations. Accordingly, the holders of the 2009 Notes would likely receive less than the amount of their investment upon our liquidation or reorganization.

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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. If we only raise three million dollars, our expenses will comprise approximately [7]% of the aggregate offering proceeds. There is a substantial likelihood that we would need to raise additional funds within the next two months. If we only raise ten million dollars, our expenses will comprise approximately [2]% of the aggregate offering proceeds. There is a substantial likelihood that we would need to raise additional funds before the end of 2009.

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 [\_\_\_], 2009, 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 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 statemet 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. 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.

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#### USE OF PROCEEDS

We estimate that the net proceeds to us from our sale of convertible debt securities in an aggregate principal amount of \$[], common stock in an aggregate principal amount of \$[\_\_] and warrants to purchase [] shares of our common stock in this offering will be approximately \$[] million, assuming a public offering price of \$[] per share and after deducting estimated placement agent 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 aggregate principal amount of convertible debt securities and warrants to purchase shares of our common stock offered by us, as set forth above, remains the same and after deducting placement agent discounts 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:

- •[65]% to advance our lead product candidate Genasense® through clinical trials, especially for the long-term follow-up of patients entered into our Phase 3 trial of Genasense® in melanoma, known as AGENDA;
- •[15]% of the proceeds will be reserved to further advance 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. 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
- •[20]% of the proceeds will be spent for general corporate purposes, including working capital needs, payment of accrued liabilities and potential acquisitions or licenses to intellectual property 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.

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#### CAPITALIZATION

The following table describes our capitalization as of March 31, 2009:

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on an actual basis; and

•on an as adjusted basis to give effect to our sale of convertible debt securities in an aggregate principal amount of \$[], [] shares of our common stock issuable as payment for interest on the convertible debt securities and warrants to purchase [] shares of our common stock in this offering at an assumed public conversion price of \$[] per share, after deducting estimated placement agent 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.

	Ma Ac	As of March 31, 200 Actual (unaudited) (in the		)9 As Adjusted (unaudited) busands)	
Convertible notes due June 7, 2010, \$10,654 outstanding net of debt discount of (\$5,991)	\$	4,663	\$	[	]
Common stock, \$.001 par value; 6,000,000,000 shares authorized, 1,014,111 shares issued and outstanding at March 31, 2009 and [] shares issued and outstanding at March 31, 2009 (as adjusted)		1,014	[		]
Preferred stock, 5,000 authorized:					
Series A convertible preferred stock, \$.001 par value; 8 shares issued and outstanding, liquidation value of \$385 at December 31, 2008 (actual and as adjusted)					
Series G participating cumulative preferred stock, \$.001 par value; 0 shares issued					
and outstanding at March 31, 2009 (actual and as adjusted) Additional paid-in capital		943,594	- [		]
Accumulated deficit		(955,193)		(955,19	93)
Total stockholders' deficit		(10,585)	[		]
Total capitalization	\$	(5,922)	\$ [		]

The number of shares of our common stock that will be outstanding after this offering is 1,014,111,706 shares of common stock outstanding as of March 31, 2009. This amount excludes:

- •1,878,670 shares of common stock issuable upon exercise of stock options outstanding and restricted stock units under our 1998 Stock Incentive Plan as of March 31, 2009 at a weighted average exercise price of \$25.33 per share, of which, options to purchase 1,341,011 shares were exercisable;
- •102,267 shares of common stock issuable upon exercise of stock options outstanding under our 1998 Non-Employee Directors Stock Incentive Plan as of March 31, 2009 at a weighted average exercise price of \$22.61 per share, of which, options to purchase 102,267 shares were exercisable;
- •153,541 shares of common stock available for future grant under our 1998 Non Employee Directors Stock Incentive Plan as of March 31, 2009;

•40,000,000 shares of common stock issuable upon exercise of warrants outstanding as of March 31, 2009 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 March 31, 2009; and

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• 1,065,345,148 shares of common stock issuable upon the conversion of our 15% Senior Secured Convertible Notes due 2010 as of March 31, 2009.

The share numbers above do not include the notes and warrants issued in the April 2009 financing.

Unless otherwise indicated, all information in this prospectus assumes there is no over-allotment option, no conversion of convertible notes or preferred stock and no exercise of stock options or warrants after March 31, 2009.

#### DILUTION

Our net tangible book value as of March 31, 2009 was approximately \$[(10.6)] million, or \$[(0.01)] 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 convertible debt securities in an aggregate principal amount of \$[], [] shares of our common stock issuable as payment for interest on the convertible debt securities and warrants to purchase [] shares of our common stock in this offering at an assumed conversion price of \$[] per share, and after deducting estimated placement agent discounts and commissions and offering expenses payable by us, our net tangible book value as of [March 31, 2009] 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 March 31, 2009	\$	(0.01)		
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 conversion price per share paid by a new investor. If any shares are issued in connection with outstanding you will experience further dilution.

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#### DESCRIPTION OF BUSINESS

#### Overview

We are a biopharmaceutical company engaged in pharmaceutical (drug) research and development. 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" (which includes our lead oncology drug, Genasense®); and "Small Molecules" (which includes our marketed product, Ganite®, and the investigational compounds tesetaxel and G4544).

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

Genasense® has been studied in combination with a wide variety of anticancer drugs in a number of different cancer indications. We have reported results from randomized trials of Genasense® in a number of diseases. Under our own sponsorship or in collaboration with others, 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; chronic lymphocytic leukemia (CLL); and non-Hodgkin's lymphoma (NHL).

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

The initial NDA for Genasense® in melanoma was withdrawn in 2004 after an advisory committee to the Food and Drug Administration (FDA) failed to recommend approval. A negative decision was also received for a similar application in melanoma from the European Medicines Agency (EMEA) in 2007. Data from the 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 (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. LDH had also been previously described by others as the single most important prognostic factor in advanced melanoma.

Based on these data, in August 2007 we initiated a new Phase 3 trial of Genasense® plus chemotherapy in advanced melanoma. This 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 (PFS) and overall

survival.

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AGENDA is designed to expand evidence for the safety and efficacy of Genasense® when combined with dacarbazine for patients who have not previously been treated with chemotherapy. The study prospectively targets patients who have low-normal levels of LDH. We have completed accrual of patient enrollment into AGENDA with 315 patients from the U.S., Canada, Western Europe, and Australia. A final analysis by an independent Data Monitoring Committee for both safety and futility will be completed in May 2009. If the trial progresses to completion, we expect to release results on the final assessment of PFS in the fourth quarter of 2009. If those data are positive, we currently expect our regulatory submissions will be based upon confirmation that the addition of Genasense® to chemotherapy results in a statistically significant and clinically meaningful improvement in PFS. Approval by FDA and EMEA will allow Genasense® to be commercialized by us in the U.S. and in the European Union. Genasense® in melanoma has been designated an Orphan Drug in Australia and the United States, and the drug has received Fast Track designation in the United States.

Given our belief in the activity of Genasense® in melanoma, we have initiated additional clinical studies in this disease. One such study is a Phase 2 trial of Genasense® plus a chemotherapy regimen consisting of Abraxane® (paclitaxel protein-bound particles for injectable suspension) (albumin bound) plus temozolomide (Temodar®). 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.

As noted above, our initial NDA for the use of Genasense® plus chemotherapy in patients with relapsed or refractory CLL was not approved. We conducted a randomized Phase 3 trial in 241 patients with relapsed or refractory CLL who were treated with fludarabine and cyclophosphamide (Flu/Cy) with or without Genasense®. The trial achieved its primary endpoint: a statistically significant increase (17% vs. 7%; P=0.025) in the proportion of patients who achieved a complete response (CR), defined as a complete or nodular partial response. Patients who achieved this level of response also experienced disappearance of predefined disease symptoms. A key secondary endpoint, duration of CR, was also significantly longer for patients treated with Genasense® (median 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®.

We submitted our NDA to the FDA in December 2005 in which we 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 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 FDA that indicated additional confirmatory evidence would be required to support approval of Genasense® in CLL. In that communication, FDA recommended one option was to collect additional information regarding the clinical course and progression of disease in patients from the completed trial.

Subsequently, we obtained information regarding long-term survival on patients who had been accrued to our completed Phase 3 trial. In June 2008, we announced results from 5 years of follow-up These data showed that patients treated with Genasense® plus chemotherapy who achieved either a complete response (CR) or a partial response (PR) 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 (CR+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 (45%) responders in the Genasense® group were alive compared with 13 of 54 (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 (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.

These data were again submitted to FDA in the second quarter of 2008, and the application was again denied in December 2008. Genta re-appealed the denial, and in March 2009, CDER decided that available data were still not adequate to support approval of Genasense® in chronic lymphocytic leukemia, and the Agency recommended conducting a confirmatory clinical trial. We have not yet made a decision whether to conduct this study.

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Lastly, several trials have shown definite evidence of clinical activity for Genasense® in patients with non-Hodgkin's lymphoma (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, acute myeloid leukemia, (AML), hormone-refractory prostate cancer (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.

In March 2008, we obtained from Daiichi Sankyo Company Ltd. 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 in June 2008. In January 2009, we announced initiation of a new clinical trial with tesetaxel to examine the clinical pharmacology of the drug over a narrow dosing range around the established Phase 2 dose.

We have also submitted applications to FDA for designation of tesetaxel as an Orphan Drug for treatment of patients with advanced gastric cancer and for patients with advanced melanoma. Both of these designations have been granted. We have submitted a proposed protocol to FDA for Special Protocol Assessment (SPA). A SPA is intended to secure agreement on the design, size, and endpoints of clinical trials that are intended to form the primary basis of an efficacy claim in a NDA. We also expect to seek Scientific Advice from the EMEA for this study to support a Marketing Authorization Application (MAA). The protocol proposes to examine the safety and efficacy of tesetaxel in patients with advanced gastric cancer whose disease has progressed after receiving first-line chemotherapy. Maintenance of the license from Daiichi Sankyo requires certain payments that include amortization of licensing fees and milestones. If such payments are not made, Daiichi Sankyo may elect to terminate the license; however, a portion of the licensing fees may still be due even in the event of termination. We are currently in discussions with Daiichi Sankyo regarding the timing of these payments.

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 and 2009 due to financial constraints.

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. 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®, our sole marketed product. Our financial constraints have prevented us from investing in adequate commercial support for Ganite®, and the intellectual property that provided us with an exclusive position in the United States has expired.

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:

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

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

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

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

Research and Development Programs

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#### **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, micro-RNA, 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 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, 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.

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

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

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

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

#### Genasense®

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

Overview of Preclinical and Clinical studies of Genasense®

### Preclinical Studies

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

#### **Clinical Studies**

Genasense® has been in clinical trials since 1995. We currently have efficacy and safety data on over 2,000 patients in Phase 1, Phase 2 and Phase 3 clinical trials that have been conducted in the U.S., Europe, South America and Australia. These studies have included patients with a wide variety of tumor types, including advanced melanoma, several types of acute and chronic leukemia, NHL, multiple myeloma and cancers of the prostate, colon, lung, breast and other tumor types. Since 2001, Genta and its collaborators have jointly initiated approximately twenty clinical trials. Results of these clinical trials 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/or published in peer-reviewed scientific journals.

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

In the first quarter of 2007, we completed a trial using a concentrated solution of Genasense® administered by bolus subcutaneous injection. This trial showed that a total dose of 225 mg could be administered as a single subcutaneous injection, which is approximately equivalent to the daily dose used in the Phase 3 trial of Genasense® in CLL. The limiting reaction in this study was a localized and reversible skin rash. In 2007, we began a new Phase 1 trial of Genasense® administered as an IV infusion over 2 hours. This trial showed that the maximally tolerable dose was 900 mg, and we have now advanced that study into a trial at that dose administered twice per week. We have also continued to escalate the single dose of Genasense® up to a total of 1200 mg over 2 hours. The pharmacokinetic and pharmacodynamic data from these trials may be useful for determining whether the prior requirement for treatment by continuous IV infusion can ultimately be eliminated by these more convenient dosing regimens.

For additional background information on the drug application process and clinical trials, see "Government Regulation."

### Ganite®

Ganite® as a Treatment for Cancer-Related Hypercalcemia

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

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

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

In May 2004, we eliminated our sales force and significantly reduced our marketing support for Ganite®. Since then, we have continued only minimal marketing support of the product. On March 2, 2006, we announced publication of a randomized, double blind, Phase 2 trial that showed Ganite® was highly effective when compared with Aredia® (pamidronate disodium; Novartis, Inc.) in hospitalized patients with cancer-related hypercalcemia.

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

Based on previously published data, Ganite® showed clear anticancer activity in patients with certain types of cancer, particularly NHL. Due to patent expirations previously described, we do not plan further clinical trials for Ganite® as an anticancer drug.

### Other Pipeline Products and Technology Platforms

### Oral Gallium-Containing Compounds

We have sought to develop novel formulations of gallium-containing compounds that can be taken orally and that will have extended patent protection. 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. In March 2006, Genta and Emisphere Technologies, Inc. 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. In August 2007, we announced submission of 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®. Results of the initial clinical trial were presented at a scientific meeting in the second quarter of 2008. In January 2009, we announced that two new patents related to the Company's franchise in gallium-containing products have issued in the United States. Applications similar to these patents are pending worldwide, and several additional applications that address other compositions and uses have been filed in the U.S. and other territories. These patents and filings provide for claims of compositions and uses of gallium compounds that can be taken by mouth over extended periods for treatment of skeletal diseases as well as other indications. Progress in the clinical development of G4544 program was delayed in 2008 due to financial constraints, but we currently expect to continue our program when our financial condition improves.

#### Antisense and RNAi Research and Discovery

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

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

Patents and Proprietary Technology

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

We own or have licensed several patents and applications to numerous aspects of oligonucleotide technology, including novel compositions of matter, methods of large-scale synthesis, methods of controlling gene expression and methods of treating disease. 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 the composition of Genasense® and its backbone chemistry that expire between 2008 and 2015. The U.S. composition patents for Genasense may be eligible for extension under Waxman-Hatch provisions. Corresponding patent applications have been filed in three foreign countries. We also own five U.S. patent applications relating to methods of using Genasense® expected to expire in 2020 and 2026, with approximately 50 corresponding foreign patent applications and granted patents.

Included among 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® and methods employing them. Other related U.S. and corresponding foreign patent applications are still pending.

Tesetaxel, its potential uses, composition, and methods of manufacturing are covered under a variety of patents licensed exclusively from Daiichi Sankyo, Inc. We believe that composition-of-matter claims on tesetaxel extend to at least 2020 in the U.S. and Europe and to 2022 in Japan. A number of other patents have been filed worldwide for this compound.

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The principal patent covering the use of Ganite® for its approved indication, including extensions 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 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 above Risk Factor entitled "We may be unable to obtain or enforce patents, other proprietary rights and licenses to protect our business; we could become involved in litigation relating to our patents or licenses that could cause us to incur additional costs and delay or prevent our introduction of new drugs to market".

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 of \$20.0 million,

\$13.5 million and \$28.1 million during the years ended December 31, 2008, 2007 and 2006, respectively.

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### 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 and Chief Operating Officer, 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<sup>®</sup>. For international product sales, we may distribute our products through collaborations with third parties.

### Manufacturing and Raw Materials

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

We currently rely on third parties to manufacture our products. We have a manufacturing and supply agreement with Avecia Biotechnology, Inc., or Avecia, a leading multinational manufacturer of pharmaceutical products, to supply quantities of Genasense®. This agreement renews automatically at the end of each year, unless either party gives one-year notice. We are not obligated to purchase further drug substance from Avecia prior to approval of Genasense®. We believe this agreement is sufficient for our production needs with respect to Genasense®.

We have a manufacturing and supply agreement with Johnson Matthey Inc. that renews automatically at the end of each year, unless either party gives one-year notice. Under the agreement, we will purchase a minimum of 80% of our requirements for quantities of Ganite®; however, there are no minimum purchase requirements.

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

### Human Resources

As of March 31, 2009, we had [] employees, [] of whom hold doctoral degrees. As of that date, there were [] employees engaged in research, development and other technical activities and [] 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.

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

Clinical trials are generally categorized into four phases.

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

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

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

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

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

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

In circumstances where a company intends to develop and introduce a novel formulation of an active drug ingredient already approved by the FDA, clinical and preclinical testing requirements may not be as extensive. Limited

additional data about the safety and/or effectiveness of the proposed new drug formulation, along with chemistry and manufacturing information and public information about the active ingredient, may be satisfactory for product approval. Consequently, the new product formulation may receive marketing approval more rapidly than a traditional full new drug application; although no assurance can be given that a product will be granted such treatment by the FDA.

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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 from a European state may submit an application to the remaining member states. Within 90 days of receiving the applications and assessment report, each member state must decide whether to recognize approval.

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

### Competition

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

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

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

### Available Information

Our reports that have been filed with the Securities and Exchange Commission, or SEC, are available on our website free of charge, including our annual reports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K, Forms 3, 4 and 5 filed on behalf of directors and executive officers and any amendments to such reports filed pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended, or the Exchange Act. Copies of our Annual Report on Form 10-K may also be obtained without charge electronically or by paper by contacting the Company at (908) 286-9800.

In addition, we make available on our website (i) the charters for the committees of the Board of Directors, including the Audit Committee, Compensation Committee and Nominating and Corporate Governance Committee, (ii) the Company's Code of Business Conduct (the Code of Conduct) governing its directors, officers. Within the time period required by the SEC, we will post on our website any modifications to the Code of Business Conduct and Ethics, as required by the Sarbanes-Oxley Act of 2002.

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The public may also read and copy the materials we file with the SEC at its Public Reference Room at 100 F Street, N.E., Washington, DC 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 also maintains a web site at http://www.sec.gov that contains reports, proxy and information statements and other information regarding companies that file electronically with the SEC.

### LEGAL PROCEEDINGS

In September 2008, several shareholders of our Company, on behalf of themselves and all others similarly situated, filed a class action complaint against our Company, our Board of Directors, and certain of our executive officers in Superior Court of New Jersey, captioned Collins v. Warrell, Docket No. L-3046-08. The complaint alleged that in issuing convertible notes, our Board of Directors, and certain officers breached their fiduciary duties, and our Company aided and abetted the breach of fiduciary duty. On March 20, 2009, the Superior Court of New Jersey granted the motion of our Company to dismiss the class action complaint and dismissed the complaint with prejudice. The plaintiffs have filed a notice of appeal to the Appellate Division of the Superior Court from the order dismissing this case.

In November 2008, a complaint against our Company and its transfer agent, BNY Mellon Shareholder Services, was filed in the Supreme Court of the State of New York by an individual stockholder. The complaint alleges that our Company and our transfer agent caused or contributed to losses suffered by the stockholder. Our Company denies the allegations of this complaint and intends to vigorously defend this lawsuit.

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### 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.

	High*		Low*	
2007				
First Quarter	\$	3.36	\$	1.86
Second Quarter	\$	2.46	\$	1.68
Third Quarter	\$	1.80	\$	0.80
Fourth Quarter	\$	1.31	\$	0.52
2008				
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 to reflect a 1-for-6 reverse stock split effected 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.

	Hig	h	Lov	N
2008				
Second Quarter (from May 7, 2008)	\$	0.41	\$	0.10
Third Quarter	\$	0.75	\$	0.25
Fourth Quarter	\$	0.40	\$	0.0027
2009				
First Quarter	\$	0.00149	\$	0.0037
Second Quarter (through May 15, 2009)	\$	0.0232	\$	0.0054
First Quarter	-		-	

The closing price of our common stock on the OTC Bulletin Board on May 15, 2009 was \$0.0092 per share. There were 564 holders of record of our common stock as of May 15, 2009. We estimate that there are approximately 31,000 beneficial owners of our common stock.

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### 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.

	ende	ee Months ed March 31, 2009 naudited)	1, amounts 2005	2004					
Consolidated Statements	(01		2008		2007	2006	2000	2001	
of Operations Data:									
License fees & royalties	\$	— \$		- \$	—\$	—\$	5,241 \$	3,022	
Development funding			—				20,988	12,105	
Product sales — net		62	363		580	708	356	(512)	
Total revenues		62	363		580	708	26,585	14,615	
Costs of goods sold			102		90	108	52	170	
Provision for excess									
inventory				-				1,350	
Total cost of goods sold			102		90	108	52	1,520	
Operating expenses — gros	s	4,470	33,410		26,116	59,764	37,006	101,324	
sanofi-aventis									
reimbursement				_			(6,090)	(43,292)	
Operating expenses — net		4,470	33,410		26,116	59,764	30,916	58,032	
Gain on forgiveness of debt		_	_	_			1,297	11,495	
Amortization of deferred							-,_>,	11,170	
financing costs and debt									
discount		(6,287)	(11,229)						
Fair value — conversion		(-) )							
feature liability			(460,000)						
Fair value — warrant			( / /						
liability			(2,000)						
All other									
(expense)/income-net		(372)	(1,435)		836	1,454	502	(147)	
Loss before income taxes		(11,067)	(507,813)		(24,790)	(57,710)	(2,584)	(33,589)	
Income tax benefit			1,975		1,470	929	381	904	
Net loss	\$	(11,067) \$	(505,838)	\$	(23,320) \$	(56,781) \$	(2,203) \$	(32,685)	
Net loss per basic and								/	
diluted common share *	\$	(0.01) \$	(9.10)	\$	(0.79) \$	(2.52) \$	(0.13) \$	(2.46)	
			. ,					. ,	
Shares used in computing									
net loss per basic and									
diluted common share*		899,963	55,576		29,621	22,553	17,147	13,300	

<sup>\*</sup> 

all figures prior to July 2007 have been retroactively adjusted to reflect a 1-for-6 reverse stock split effected in July 2007

			At December 31,										
	At March 31, 2009 2			2008 2007			2006			2005		)04	
Balance Sheet Data:													
Cash, cash equivalents and marketable													
securities	\$	598	\$	4,908	\$	7,813	\$	29,496	\$	21,282	\$	42,247	
Working capital (deficit)		(9,510)		(5,220)		877		12,682		11,703		(4,269)	
Total assets		7,137		12,693		29,293		51,778		27,386		50,532	
Total stockholders' equity (deficit)		(10,585)		(4,864)		2,931		14,642		15,697		1,752	
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#### SUPPLEMENTARY FINANCIAL INFORMATION

The following table presents our condensed operating results for each of the eight (8) fiscal quarters through the period ended March 31, 2009. 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.

			Three Months Ended (unaudited) (in thousands except per share																						
			amou	amounts)																					
			Dec																						
	Ma	r 31	31												June										
	20	09	2008		Sep	o 30	Jur	e 30	Ma	r 31	Dee	c 31	Sep	<b>o</b> 30	30										
	(	1)	(1)		2008 (1)		2008 (1)		200	2008 (1)		2008 (1) 200		008 (1) 2008		08 (1) 2008		08 (1) 2008		008 20		)7	2007		2007
Total revenues	\$	62	\$		\$	115	\$	131	\$	117	\$	266	\$	115	\$										