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

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

UNITED STATES SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549
Form S-1
REGISTRATION STATEMENT
UNDER
THE SECURITIES ACT OF 1933
GENTA INCORPORATED
(Exact name of registrant as specified in its charter)

Delaware	**2836**	**33-0326866**
(State or other jurisdiction of incorporation or organization)	*(Primary Standard Industrial Classification Code Number)*	*(I.R.S. Employer Identification Number)*

200 Connell Drive
Berkeley Heights, New Jersey 07922
(908) 286-9800
(Address, including zip code, and telephone number, including area code, of registrant s principal executive offices)

Raymond P. Warrell, Jr., M.D.
Chairman and Chief Executive Officer
Genta Incorporated
200 Connell Drive
Berkeley, New Jersey 07922
(Name, address, including zip code, and telephone number, including area code, of agent for service)

Copies to:

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

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

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

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. o

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. o

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. o

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of large accelerated filer, accelerated filer and smaller reporting company in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer o	Accelerated filer o	Non-accelerated filer þ (Do not check if a smaller reporting company)	Smaller reporting company o

CALCULATION OF REGISTRATION FEE

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

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

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

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

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

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

SUBJECT TO COMPLETION, DATED AUGUST 29, 2008

PROSPECTUS

GENTA INCORPORATED

[ ] shares of Common Stock

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

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

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

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

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

Please refer to Risk Factors beginning on page 7.

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

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

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

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

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

[UNDERWRITERS]

The date of this prospectus is [ ], 2008.

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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 shares of common stock, and seeking offers to buy shares of common stock, only in jurisdictions where offers and sales are permitted. The information contained in this prospectus is accurate only as of the date of this prospectus, regardless of when this prospectus is delivered or when any sale of our common stock occurs.

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

relating to this offering and the distribution of this prospectus.

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PROSPECTUS SUMMARY

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

Introduction

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

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

Overview

We are a biopharmaceutical company engaged in pharmaceutical, or drug, research and development, our sole reportable segment. We are dedicated to the identification, development and commercialization of novel drugs for the treatment of cancer and related diseases. Our research portfolio consists of two major programs: DNA/RNA Medicines and Small Molecules.

The DNA/RNA Medicines program includes drugs that are based on using modifications of either DNA or RNA as drugs that can be used to treat disease. These technologies include antisense, decoys, and small interfering or micro RNAs. Our lead drug from this program is an investigational antisense compound known as Genasense®, 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 Phase 3 trials of Genasense® in seven different diseases: melanoma; chronic lymphocytic leukemia, commonly known as CLL; multiple myeloma; acute myeloid leukemia, commonly known as AML; non small cell lung cancer; small cell lung cancer; and prostate cancer. Under our own sponsorship or in collaboration with the U.S. National Cancer Institute, or NCI, we are currently conducting additional clinical trials. We are especially interested in the development, regulatory approval, and commercialization of Genasense® in at least three diseases: melanoma; CLL; and non-Hodgkin s lymphoma, commonly known as NHL.

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

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

also received for a similar application in melanoma from the European Medicines Agency, or EMEA, in 2007. In 2006, data from the pivotal Phase 3 trial that comprised the primary basis for these applications were published in a peer-reviewed journal. These results showed that Genasense® treatment compared with chemotherapy alone in patients with advanced melanoma was associated with a statistically significant increase in overall response, complete response, durable response, and progression-free survival, or PFS. However, the primary endpoint of overall survival approached but did not quite reach statistical significance (P=0.077). Subsequently, our analysis of this trial showed that there was a significant treatment interaction effect related to levels of a blood enzyme known as LDH. When this effect was analyzed by treatment arm, survival was shown to be significantly superior for patients with a non-elevated LDH who received Genasense® (P=0.018; n=508). Moreover, this benefit was

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

Based on this data, in August 2007 we initiated a new Phase 3 trial of Genasense® plus chemotherapy in advanced melanoma. The trial, known as AGENDA, is a randomized, double-blind, placebo-controlled study in which patients are randomly assigned to receive Genasense® plus dacarbazine or dacarbazine alone. The study uses LDH as a biomarker to identify patients who are most likely to respond to Genasense®, based on data obtained from our preceding trial in melanoma. The co-primary endpoints of AGENDA are progression-free survival and overall survival.

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

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

As noted, our initial NDA for the use of Genasense® plus chemotherapy in patients with relapsed or refractory in CLL was also unsuccessful. In CLL, we conducted a randomized Phase 3 trial in 241 patients with relapsed or refractory disease who were treated with fludarabine and cyclophosphamide, commonly known as Flu/Cy, with or without Genasense®. The trial achieved its primary endpoint: a statistically significant increase (17% vs. 7%; P=0.025) in the proportion of patients who achieved a complete response, or CR, defined as a complete or nodular partial response. Patients who achieved this level of response also experienced disappearance of predefined disease symptoms. A key secondary endpoint, duration of CR, was also significantly longer for patients treated with Genasense® (median not reached but exceeding 36+ months in the Genasense® group, versus 22 months in the chemotherapy-only group).

Several secondary endpoints were not improved by the addition of Genasense®. The percentage of patients who experienced serious adverse events was increased in the Genasense® arm; however, the percentages of patients who discontinued treatment due to adverse events were equal in the treatment arms. The incidence of certain serious adverse reactions, including but not limited to nausea, fever and catheter-related complications, was increased in patients treated with Genasense®.

In December 2005, we completed submission of an NDA to the FDA that sought accelerated approval for the use of Genasense® in combination with Flu/Cy for the treatment of patients with relapsed or refractory CLL who had previously received fludarabine. In December 2006 we received a non-approvable notice on that application from FDA. However, we believed that our application had met the regulatory requirements for approval, and in April 2007, we filed an appeal of that notice using FDA s Formal Dispute Resolution process. In March, 2008, we received a formal notice from FDA that indicated additional confirmatory evidence would be required to support approval of

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

About Us

Genta was incorporated in Delaware on February 4, 1988. Our principal executive offices are located at 200 Connell Drive, Berkeley Heights, New Jersey 07922. Our telephone number is (908) 286-9800. The address of our website is www.Genta.com. 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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THE OFFERING

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

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

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

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

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

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

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

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

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

from the first closing of our convertible notes.

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

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SUMMARY OF SELECTED FINANCIAL INFORMATION

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

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

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

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

Six Months Ended June 30,

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

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* Includes fair value of the conversion feature liability in the amount of $740.0 an