

GENTA INC DE/
Form 424B5
December 16, 2004
PROSPECTUS Supplement
(To Prospectus dated May 11, 2004)

15,000,000 Shares

GENTA INCORPORATED

Common Stock

We are offering 15,000,000 shares of our common stock to certain purchasers pursuant to this prospectus supplement.

Our common stock is quoted on the Nasdaq National Market under the symbol [GNTA.] On December 14, 2004, the reported last sale price of our common stock on Nasdaq was \$1.85 per share.

	<u>Per Share</u>	<u>Total</u>
Public Price	\$ 1.500	\$ 22,500,000
Placement Agency Fees	\$ 0.056	\$ 843,750
Proceeds to Genta Incorporated before expenses	\$ 1.444	\$ 21,656,250

Before deciding whether to invest in our common stock, you should consider carefully the risks that we have described on page S-2 of this prospectus supplement.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or passed upon the accuracy or adequacy of this prospectus supplement or the accompanying prospectus. Any representation to the contrary is a criminal offense.

Rodman & Renshaw, LLC is acting as placement agent and will receive the placement agency fees referred to in the above table. We will also reimburse Rodman & Renshaw, LLC for a portion of its out-of-pocket expenses.

The date of this prospectus supplement is December 14, 2004.

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ABOUT THIS PROSPECTUS SUPPLEMENT

This prospectus supplement and the accompanying prospectus dated May 11, 2004 relate to the offer by us of 15,000,000 shares of our common stock. In the accompanying prospectus, we provide you with a general description of our common stock that we are offering. These documents contain important information you should consider when making your investment decision. This prospectus supplement may add, update or change information in the accompanying prospectus. You should read both this prospectus supplement and the accompanying prospectus as well as the additional information described under "Information Incorporated by Reference" on page S-2 of this prospectus supplement and "Where You Can Find More Information" on page 2 of the accompanying prospectus before investing in our common stock.

You should rely only on the information contained or incorporated by reference in this prospectus supplement and the accompanying prospectus that is also part of this document. We have not authorized anyone to provide information different from that contained or incorporated in this prospectus supplement and the accompanying prospectus. We are offering to sell shares of common stock only in jurisdictions where offers and sales are permitted. The information contained or incorporated in this prospectus supplement and the accompanying prospectus is accurate only as of the date of such information, regardless of the time of delivery of this prospectus supplement and the accompanying prospectus or of any sale of our common stock.

In this prospectus supplement, unless the context otherwise indicates, the terms "we," "our," "us," "the company" and "Genta" refer to Genta Incorporated.

INFORMATION INCORPORATED BY REFERENCE

The Securities and Exchange Commission (the "SEC") allows us to incorporate by reference the information we file with them, which means that we can disclose important information to you by referring you to those documents. The information incorporated by reference is an important part of this prospectus, and information that we file later with the SEC will automatically update and supersede this information. We incorporate by reference the documents listed below and any future filings we make with the SEC under Sections 13(a), 13(c), 14 or 15(d) of the Securities Exchange Act of 1934 until all of the securities that we may offer with this

prospectus supplement and the accompanying prospectus are sold:

- Annual Report on Form 10-K for the year ended December 31, 2003.
- Quarterly Reports on Form 10-Q for the quarters ended March 31, 2004, June 30, 2004 and September 30, 2004.
- Current Reports on Form 8-K filed on May 3, 2004, May 13, 2004, May 14, 2004, June 1, 2004, June 7, 2004, November 9, 2004 (excluding information furnished pursuant to Item 2.02), November 29, 2004 and December 6, 2004.

You may request a copy of these filings at no cost, by writing or telephoning Controller, Genta Incorporated, Two Connell Drive, Berkeley Heights, NJ 07922, (908) 286-9800.

RISK FACTORS

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

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

We may be unsuccessful in our efforts to obtain FDA approval for 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 approval. Our financial condition and results of operations have been and will continue to be significantly affected by FDA action with respect to Genasense®. In late 2003, we filed our first new drug application, or NDA, with the FDA for Genasense® as a treatment combined with chemotherapy for patients with advanced malignant melanoma. On May 3, 2004, the FDA Oncology Drugs Advisory Committee voted not to recommend Genasense® for marketing approval. As a result, on May 13, 2004 we announced that we withdrew our NDA.

Genasense® is being studied in a number of clinical trials for other indications. Together with our collaborators, we have completed or are currently conducting randomized clinical trials in six different cancer indications. On November 8, 2004, we announced the results of our Phase 3 clinical trial of Genasense® in patients with relapsed or refractory chronic lymphocytic leukemia (CLL). We plan to discuss the feasibility of submitting a NDA based on these data with the FDA. However, we cannot assure you that we will submit a NDA for Genasense® as a treatment for patients with CLL, or that a NDA, even if submitted, will result in FDA approval of Genasense®. On November 26, 2004, we announced that our Phase 3 clinical trial of Genasense® in patients with advanced multiple myeloma did not meet its primary endpoint. 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.

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.

We intend to be a direct marketer of some products in the United States. Currently we do not have a sales force, as we have eliminated it in 2004, after our decision to withdraw the NDA for Genasense® for the treatment of advanced malignant melanoma. Our need to build a sales force capable of marketing our pharmaceutical products may adversely affect our sales and limit the commercial success of our products.

On November 8, 2004, we received from Aventis Pharmaceutical Inc., part of sanofi-aventis Group (Aventis), a notice of termination of the agreements between Genta and Aventis regarding the development and commercialization of Genasense®. We will lose a significant source of funding for Genasense® as a result of this termination.

In April 2002, we entered into a series of agreements relating to the development and commercialization of Genasense®, to which we refer collectively as the collaborative agreement, with Aventis and its affiliates. On November 8, 2004, we received from Aventis a notice of termination of the collaborative agreement. The key financial aspects of the collaborative agreement were the following:

- Aventis committed to provide up to \$476.9 million in initial payments, milestone payments and for the purchase from us of equity and convertible notes.
- If Genasense® received marketing approval from the FDA, we would have been entitled to royalties on Aventis' exclusive worldwide net sales of Genasense®.
- Aventis agreed to pay 75% of the development costs related to any U.S. NDA incurred by either us or Aventis subsequent to the execution of our collaborative agreement, and substantially all other development, marketing, and sales costs incurred worldwide.

- Aventis agreed to reimburse a portion of our expenses in building our sales force to market in the United States.

As of September 30, 2004, we had received a total of \$266.8 million in initial and near-term funding pursuant to the collaborative agreement, which included a \$10.0 million licensing fee and \$40.0 million in development funding, \$10.0 million in convertible debt proceeds, \$71.9 million pursuant to an at-market equity investment in our common stock, \$115.9 million in paid expense reimbursements and \$19.0 million in line of credit proceeds. As a result of the termination of the collaborative agreement, Aventis will continue to support the development of Genasense® for a six-month period lasting until May 8, 2005. After May 8, 2005, we will be responsible for all Genasense® costs. In addition, we are required to repay by June 30, 2005, \$19.0 million outstanding under the line of credit with Aventis. No further amounts may be borrowed under this line of credit. As a result of the termination of the collaborative agreement, Aventis was obligated to forgive the \$10.0 million of convertible debt issued to them in connection with the collaboration.

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

We 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 or if our collaborative arrangements are not successful in developing and commercializing products.

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

We also seek strategic alliances with corporate partners, primarily pharmaceutical and biotechnology companies, to help us develop and commercialize drugs. Various problems can arise in strategic alliances. A partner responsible for conducting clinical trials and obtaining regulatory approval may fail to develop a marketable drug. A partner may decide to pursue an alternative strategy or focus its efforts on alliances or other arrangements with third parties. A partner that has been granted marketing rights for a certain drug within a geographic area may fail to market the drug successfully. Consequently, strategic alliances that we may enter into may not be scientifically or commercially successful. In this regard, we have received from Aventis a notice of termination of the collaborative agreement and Genta Jago Technologies B.V., a joint venture we entered into with SkyePharma PLC to develop oral controlled-release drugs, has not resulted in any commercial products, and we plan to seek to terminate our involvement in this joint venture.

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

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

An important part of our strategy involves conducting multiple product development programs. We may pursue opportunities in fields that conflict with those of our collaborators. In addition, disagreements with our collaborators could develop over rights to our intellectual property. The resolution of such conflicts and disagreements may

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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 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 operating losses associated with ongoing research and development activities, pre-clinical testing, clinical trials, regulatory submissions and manufacturing activities. From the period since our inception to September 30, 2004, we incurred a cumulative net loss of \$370.6 million. We may never achieve revenue sufficient for us to attain profitability. Achieving profitability is unlikely before Genasense® becomes an approved drug.

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

Our operations to date have required significant cash expenditures. As a result of Aventis's termination of the collaborative agreement, after May 8, 2005, we will be responsible for all Genasense® costs. Our future capital requirements will depend on the results of our research and development activities, pre-clinical studies and clinical trials, competitive and technological advances, and regulatory activities of the FDA and other regulatory authorities. In order to commercialize our products, we will need to raise additional funds. We may obtain those funds through public and private offerings of our securities, including debt or equity financing, or through collaborations or other arrangements with research institutions and corporate partners. 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.

As of September 30, 2004, we had \$36.7 million in cash, cash equivalents and marketable securities. We will receive approximately \$21.7 million in net proceeds from this offering before deducting expenses. We will need additional funding after this offering to meet our cash requirements and such funding may not be available to us on satisfactory terms or at all.

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

- delay, scale back or eliminate some or all of our research and product development programs;
- license third parties to develop and commercialize products or technologies that we would otherwise seek to develop and commercialize ourselves;
- attempt to sell our company;
- cease operations; or declare bankruptcy.

Our business depends heavily on a small number of products.

We are currently marketing one product, Ganite®. We do not expect to expand our marketed product portfolio significantly in the short term. If Genasense® is not approved, or is commercially unsuccessful, we do not expect significant sales of other products to offset this loss of potential revenue.

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

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

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

- obtain U.S. and foreign patent or other proprietary protection for our technologies, products and processes;
- preserve trade secrets; and
- operate without infringing the patent and other proprietary rights of third parties.

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

We hold numerous U.S., foreign and international patents covering various aspects of our technology, which include novel compositions of matter, use, methods of large-scale synthesis and methods of controlling gene expression. 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 sufficiently broad 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 any 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 expensive, 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 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 patent covering the use of Ganite® for its approved indication will expire in 2005. Genta has filed and continues to file patent applications seeking intellectual property protection for Ganite®. If these applications are unsuccessful, competition from generic drugs may adversely affect the profitability of Ganite®.

Many 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

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the activity of antisense oligonucleotide technology in model systems in vitro and in animals, among our products, 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 pre-clinical testing. Results obtained in pre-clinical 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.

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

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

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

- inability to obtain sufficient quantities of materials for use in clinical trials;
- inability to adequately monitor patient progress after treatment;
- unforeseen safety issues;

- the failure of the products to perform well during clinical trials;
- and government or regulatory delays.

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

The FDA and comparable regulatory agencies in foreign countries impose substantial pre-market approval requirements on the introduction of pharmaceutical products. These requirements involve lengthy and detailed pre-clinical 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 pre-clinical 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. On May 3, 2004, the FDA Oncology Drugs Advisory Committee voted not to recommend Genasense® for marketing approval for the treatment of advanced malignant melanoma. As a result, on May 13, 2004 we announced that we withdrew our NDA. We cannot assure you that the FDA or other regulatory agencies will ever approve the use of our products that are under development. In addition, 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.

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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 before it can manufacture Genasense®. Failure of the facility to be approved could delay the approval of Genasense®.

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

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

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

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

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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 price and quality.

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 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.

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

During the months of May and June 2004, numerous complaints were filed in the United States District Court for the District of New Jersey against us and certain of our principal officers on behalf of purported classes of our shareholders who purchased our securities during several class periods. The complaints generally allege that we and certain of our principal officers violated the federal securities laws by issuing materially false and misleading statements regarding Genasense® for the treatment of advanced melanoma that had the effect of artificially inflating the market price of our securities. The shareholder class action complaints in the various actions seek monetary damages in an unspecified amount and recovery of plaintiffs' costs and attorneys' fees. In addition, two shareholder derivative actions have been filed against our directors and certain officers in New Jersey state and federal courts. Based on facts substantially similar to those asserted in the shareholder class actions, the derivative plaintiffs claim that defendants have breached their fiduciary duties to the shareholders and other violations of New Jersey law. All of these actions are in their earliest stages and we intend to defend them vigorously.

We cannot predict with certainty the eventual outcome of such pending litigation. Furthermore, we may have to expend significant efforts and incur substantial expense in defending these lawsuits.

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

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maintain or increase our insurance coverage at an affordable price. Even if a product liability claim is not successful, the adverse publicity and time and expense of defending such a claim may interfere with or adversely affect our business and financial performance.

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

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

- difficulties in assimilating the operations and personnel of acquired companies;

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

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

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

In many cases, our products under development will be competing with existing therapies for market share. In addition, a number of companies are pursuing the development of antisense technology and controlled-release formulation technology and the development of pharmaceuticals utilizing such technologies. We compete with fully integrated pharmaceutical companies that have substantially greater 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 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 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 Genta.

We have not paid, and do not expect to pay in the future, 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 pre-clinical studies and clinical trials by us or our competitors;
 - announcements of technological innovations or new therapeutic products by us or our competitors;
 - government regulation;
 - developments in patent or other proprietary rights by us or our respective competitors, including litigation; and
 - fluctuations in our operating results, and market conditions for biopharmaceutical stocks in general.

As of September 30, 2004, we had 80,357,093 shares of common stock outstanding and options, warrants, convertible preferred stock and convertible debt outstanding exercisable for or convertible into 13.3 million additional shares. Future sales of shares of common stock by existing stockholders, holders of preferred stock who might convert such preferred stock into common stock and option and warrant holders who may exercise their options and warrants to purchase common stock also could adversely affect the market price of the common stock. Moreover, the perception that sales of substantial amounts of our common stock might occur could

adversely affect prevailing market prices.

DILUTION

The net tangible book value of our common stock on September 30, 2004 was \$(34.8) million, or approximately \$(0.43) per share. Net tangible book value per share represents the amount of our total tangible assets, less our total tangible liabilities, divided by the total number of shares of our common stock outstanding. Dilution in net tangible book value per share to new investors represents the difference between the amount per share paid by purchasers of shares of our common stock in this offering and the net tangible book value per share of our common stock immediately afterwards. Without taking into account any other changes in net tangible book value after September 30, 2004, other than the sale of the 15 million shares of common stock offered by us under this prospectus supplement at a price of \$1.50 per share and after deducting the estimated placement agent fees and estimated offering expenses payable by us, our net tangible book value would have been \$(13.2) million or approximately \$(0.14) per share. This represents an immediate accretion in net tangible book value of approximately \$0.29 per share to existing stockholders and an immediate dilution in net tangible book value of U.S. \$(1.64) per share to new investors.

Offering price per share		\$ 1.50
Net tangible book value as of September 30, 2004	(.43)	
Increase per share attributable to new investors	<u>.29</u>	
As adjusted net tangible book value per share after the offering		<u>(.14)</u>
Decrease in net tangible book value per share to new investors		\$ (1.64)

This table excludes shares of common stock issuable upon exercise of options, warrants and other rights, and the effect of shares of common stock issued, except as indicated above, since September 30, 2004.

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PLAN OF DISTRIBUTION

The shares of common stock offered hereby are being offered for sale directly by us to institutional investors.

In connection with this offering, we have agreed to pay a fee of \$843,750 to Rodman & Renshaw, LLC, which is acting as placement agent. We will also reimburse Rodman & Renshaw, LLC for a portion of its out-of-pocket expenses.

We have also agreed to indemnify Rodman & Renshaw, LLC against certain liabilities, including liabilities under the Securities Act of 1933, as amended.

LEGAL MATTERS

Certain legal matters in connection with the legality of the offering of the common stock hereby will be passed upon for us by Stefan C. Grant, M.D., Esq., our Vice President and Corporate Counsel.

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PROSPECTUS

15,000,000 Shares

GENTA INCORPORATED

COMMON STOCK

We may offer from time to time common stock. Specific terms of these securities will be provided in supplements to this prospectus. You should read this prospectus and any supplement carefully before you invest.

Our common stock is listed on the Nasdaq National Market under the symbol [GNTA].

Investing in our common stock involves certain risks, which we describe in our periodic reports and which we will describe in supplements to this prospectus.

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

The date of this prospectus is May 11, 2004

You should rely only on the information contained in or incorporated by reference in this prospectus. We have not authorized anyone to provide you with different information. We are not making an offer of these securities in any state where the offer is not permitted. You should not assume that the information contained in or incorporated by reference in this prospectus is accurate as of any date other than the date on the front of this prospectus. The terms [Genta,] [we,] [us,] and [our] refer to Genta Incorporated.

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THE COMPANY

Genta is a biopharmaceutical company dedicated to the identification, development and commercialization of novel drugs for cancer and related diseases. Our research portfolio consists of two major areas of focus:

DNA/RNA Medicines, which are drugs based on chemical modifications of either deoxyribonucleic acid, or DNA, or ribonucleic acid, or RNA; and

Small Molecules.

We began marketing our first commercial product, Ganite, which is part of our Small Molecule program, in October 2003. Ganite has been approved by the U.S. Food and Drug Administration, or FDA, for treatment of cancer-related hypercalcemia that is resistant to hydration. The drug is being marketed and sold exclusively by Genta in the United States by our dedicated sales force.

Our lead investigational antisense drug is called Genasense (oblimersen sodium), a molecule that is designed to block the production of a protein known as Bcl-2. Current science suggests that Bcl-2 is a fundamental (although not sole) cause of the inherent resistance of cancer cells to current anticancer treatments, such as chemotherapy, radiation, or monoclonal antibodies. While Genasense has displayed some anticancer activity when used by itself, we are developing the drug solely as a means of amplifying the effects of other anticancer therapy by pre-treating patients with Genasense.

WHERE YOU CAN FIND MORE INFORMATION

We file annual, quarterly and special reports, proxy statements and other information with the SEC. You may read and copy any document that we file at the Public Reference Room of the SEC at 450 Fifth Street, NW, Washington, D.C. 20549. You may obtain information on the operation of the Public Reference Room by calling the SEC at 1-800-SEC-0330. In addition, the SEC maintains an Internet site at <http://www.sec.gov>, from which interested persons can electronically access the registration statement including the exhibits and schedules thereto.

The SEC allows us to incorporate by reference the information we file with them, which means that we can disclose important information to you by referring you to those documents. The information incorporated by reference is an important part of this prospectus, and information that we file later with the SEC will automatically update and supersede this information. We incorporate by reference the documents listed below and any future filings we make with the SEC under Sections 13(a), 13(c), 14, or 15(d) of the Securities Exchange Act of 1934 until all of the securities offered by this prospectus have been sold:

Annual Report on Form 10-K for the year ended December 31, 2003.

You may request a copy of these filings at no cost, by writing or telephoning Controller, Genta Incorporated, Two Connell Drive, Berkeley Heights, NJ 07922, (908) 286-9800.

SPECIAL NOTE ON FORWARD-LOOKING STATEMENTS

This prospectus includes forward-looking statements. We have based these forward-looking statements on our current expectations and projections about future events. These forward-looking statements are subject to risks, uncertainties, and assumptions about our business, including, among other things:

- FDA approval or failure to approve Genasense;
- our ability to develop, manufacture and sell our products or enter into collaborative arrangements with third parties to manufacture or sell our products;
- the safety and efficacy of our products;
- the commencement and completion of pre-clinical and clinical trials;
- our ability to obtain necessary regulatory approvals;

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- our contractual collaborative arrangements;
- the adequacy of our capital resources;
- the ability to obtain sufficient financing to maintain our planned operations;
- the possibility and effect of patent infringement claims; and
- the impact of competitive products and market conditions.

We have no obligation to publicly update or revise any forward-looking statements, whether as a result of new information, future events or risks. New information, future events or risks may cause the forward-looking events we discuss in this prospectus not to occur.

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USE OF PROCEEDS

Unless otherwise indicated in a prospectus supplement, the net proceeds from the sale of the common stock will be used for research and development, for commercialization expenses, for potential licenses and acquisitions of complementary products, technologies or businesses and for general corporate purposes.

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DESCRIPTION OF CAPITAL STOCK

Our authorized capital stock consists of 120,000,000 shares of common stock, par value \$.001 per share, and 5,000,000 shares of preferred stock, par value \$.001 per share.

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

General

The authorized capital stock of Genta consists of 120,000,000 shares of common stock and 5,000,000 shares of preferred stock.

Common Stock

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

Preferred Stock

The Board of Directors has the authority, without further action by the stockholders, to issue up to 5,000,000 shares of preferred stock in one or more series and to fix the rights, preferences, privileges and restrictions thereof, including dividend rights, conversion rights, voting rights, terms of redemption, liquidation preferences and the number of shares constituting any series or the designation of such series. The issuance of preferred stock could adversely affect the voting power of holders of common stock and could have the effect of delaying, deferring or preventing a change in control of Genta without further action by the stockholders and may adversely affect the voting and other rights of the holders of our common stock.

Series A Convertible Preferred Stock

General

We are authorized to issue 600,000 shares of series A convertible preferred stock.

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

In the event of a liquidation of Genta, the holders of series A convertible preferred stock are entitled to a liquidation preference equal to \$50 per share.

Delaware Anti-Takeover Law

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

- the corporation has elected in its certificate of incorporation not to be governed by Section 203 (we have not made such an election);
- the business combination was approved by the board of directors of the corporation before the other party to the business combination became an interested stockholder;
- upon consummation of the transaction that made it an interested stockholder, the interested stockholder owned at least 85% of the voting stock of the corporation outstanding at the commencement of the transaction (excluding voting stock owned by directors who are also officers or held in employee benefit plans in which the employees do not have the right to determine confidentially whether shares held subject to the plan will be tendered in a tender or exchange offer; or
- on or subsequent to such date the business combination is approved by the board of directors and authorized at an annual or special meeting of stockholders by the affirmative vote of at least 66 % of the outstanding voting stock which is not owned by the interested stockholder. The three-year prohibition also does not apply to certain business combinations proposed by an interested stockholder following the announcement or notification of certain extraordinary transactions involving the corporation and a person who had not been an interested stockholder during the previous three years or who became an interested stockholder with the approval of a majority of the corporation's directors. A "business combination" is defined to include mergers, asset sales and other transactions resulting in financial benefit to a stockholder. In general, an "interested stockholder" is a person who, together with affiliates and associates, owns (or within three years, did own) 15% or more of a corporation's voting stock. The statute could prohibit or delay mergers or other takeover or change in control attempts with respect to Genta and, accordingly, may discourage attempts to acquire Genta even though such a transaction may offer Genta's stockholders the opportunity to sell their stock at a price above the prevailing market price.

Advance Notice Requirements for Stockholder Proposals

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

Limits on Special Meetings

Genta's restated certificate of incorporation and bylaws provide that special meetings of the stockholders of Genta may be called only by the Chairman of the Board or the Chief Executive Officer of Genta or by a resolution adopted by the affirmative vote of a majority of the Board of Directors.

Super-majority Requirements

We have specified provisions in our restated certificate of incorporation and bylaws that require a super-majority vote of the stockholders to amend, revise or appeal provisions that may have an anti-takeover effect.

Listing

Our common stock is listed on the Nasdaq National Market under the symbol "GNTA".

Transfer Agent and Registrar

The Transfer Agent and Registrar for the common stock is Mellon Investor Services.

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PLAN OF DISTRIBUTION

We may sell the common stock in any of three ways (or in any combination):

- through underwriters or dealers;
- directly to a limited number of purchasers or to a single purchaser; or
- through agents.

The prospectus supplement will set forth the terms of the offering of such common stock, including

- (a) the name or names of any underwriters, dealers or agents and the amounts of common stock underwritten or purchased by each of them,
- (b) the initial public offering price of the common stock and the proceeds to us and any discounts, commissions or concessions allowed or reallocated or paid to dealers, and
- (c) any securities exchanges on which the common stock may be listed.

Any initial public offering price and any discounts or concessions allowed or reallocated or paid to dealers may be changed from time to time.

If underwriters are used in the sale of any common stock, the common stock will be acquired by the underwriters for their own account and may be resold from time to time in one or more transactions, including negotiated transactions, at a fixed public offering price or at varying prices determined at the time of sale. The common stock may be either offered to the public through underwriting syndicates represented by managing underwriters, or directly by underwriters. Generally, the underwriters' obligations to purchase the common stock will be subject to certain conditions precedent. The underwriters will be obligated to purchase all of the common stock if they purchase any of the common stock. Such underwriters may include, among others, Goldman, Sachs & Co.

We may sell the common stock through agents from time to time. The prospectus supplement will name any agent involved in the offer or sale of the common stock and any commissions we pay to them. Generally, any agent will be acting on a best efforts basis for the period of its appointment.

We may authorize underwriters, dealers or agents to solicit offers by certain purchasers to purchase the common stock from us at the public offering price set forth in the prospectus supplement pursuant to delayed delivery contracts providing for payment and delivery on a specified date in the future. The contracts will be subject only to those conditions set forth in the prospectus supplement, and the prospectus supplement will set forth any commissions we pay for solicitation of these contracts.

Agents and underwriters may be entitled to indemnification by us against certain civil liabilities, including liabilities under the Securities Act, or to contribution with respect to payments which the agents or underwriters may be required to make in respect thereof. Agents and underwriters may be customers of, engage in

transactions with, or perform services for us in the ordinary course of business.

We may enter into derivative transactions with third parties, or sell common stock not covered by this prospectus to third parties in privately negotiated transactions. If the applicable prospectus supplement indicates, in connection with those derivatives, the third parties may sell common stock covered by this prospectus and the applicable prospectus supplement, including in short sale transactions. If so, the third party may use common stock pledged by us or borrowed from us or others to settle those sales or to close out any related open borrowings of stock, and may use common stock received from us in settlement of those derivatives to close out any related open borrowings of stock. The third party in such sale transactions will be an underwriter and, if not identified in this prospectus, will be identified in the applicable prospectus supplement (or a post-effective amendment).

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VALIDITY OF COMMON STOCK

The validity of the common stock in respect of which this prospectus is being delivered will be passed on for us by Davis Polk & Wardwell.

EXPERTS

The consolidated financial statements incorporated in this prospectus by reference from the Company's Annual Report on Form 10-K for the year ended December 31, 2003 have been audited by Deloitte & Touche LLP, independent auditors, as stated in their report, which is incorporated herein by reference, and have been so incorporated in reliance upon the report of such firm given upon their authority as experts in accounting and auditing.

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EXHIBIT INDEX

<u>Exhibit No.</u>	<u>Document</u>
1.1	Form of Underwriting Agreement*
5.1	Opinion of Davis Polk & Wardwell
23.1	Consent of Deloitte & Touche LLP
23.2	Consent of Davis Polk & Wardwell (included in Exhibit 5.1)
24.1	Power of Attorney (included on the signature page of the Registration Statement)

* To be filed by amendment or on Form 8-K.

