GENTA INC DE/ Form POS AM April 02, 2004

As filed with the Securities and Exchange Commission on April 2, 2004

Registration No. 333-110238

## SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

# Post-Effective Amendment No. 1 on FORM S-3

REGISTRATION STATEMENT UNDER THE SECURITIES ACT OF 1933

## GENTA INCORPORATED

(Exact Name of Registrant as Specified in Its Charter)

#### **Delaware**

(State or Other Jurisdiction of Incorporation or Organization)

#### 2836

(Primary Standard Industrial Classification Code Number)

#### 33-0326866

(I.R.S. Employer Identification Number)

## Two Connell Drive Berkeley Heights, NJ 07922 (908) 286-9800

(Address, Including Zip Code, and Telephone Number, Including Area Code, of Registrant□s Principal Executive Offices)

#### William P. Keane

Vice President, Chief Financial Officer and Corporate Secretary Genta Incorporated Two Connell Drive Berkeley Heights, NJ 07922 (908) 286-9800

(Name, Address, Including Zip Code, and Telephone Number, Including Area Code, of Agent For Service)

#### Copy to:

Richard A. Drucker Davis Polk & Wardwell 450 Lexington Avenue New York, New York 10017 (212) 450-4000

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

If the only securities being registered on this form are being offered pursuant to dividend or interest reinvestment plans, please check the following box. o

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. x

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.		
If delivery of the prospectus is expected to be made pursuant to Rule 434, please check the following box. 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		
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 filed to register additional securities for an offering pursuant to Rule 462(b) 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		

The information in this preliminary prospectus is not complete and may be changed. These securities may not be sold until the registration statement filed with the Securities and Exchange Commission is effective. This preliminary prospectus is not an offer to sell nor does it seek an offer to buy these securities in any jurisdiction where the offer or sale is not permitted.

SUBJECT TO COMPLETION DATED

, 2004.

#### **PRELIMINARY PROSPECTUS**

671,412 Shares

## **Genta Incorporated**

Common Stock

The selling stockholders of Genta Incorporated listed on page 15 of this prospectus are offering and selling a total of 671,412 shares of Genta common stock under this prospectus. These shares were originally issued to the selling stockholders in connection with Genta s acquisition of Salus Therapeutics, Inc. in August 2003. Genta will not receive any of the proceeds from the sale of the shares sold by these selling stockholders and is not offering any shares for sale under this prospectus. See Plan of Distribution for a description of sales of the shares by the selling stockholders.

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

See Risk Factors beginning on page 1 to read about certain factors you should consider before buying shares of the common stock.

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. Any representation to the contrary is a criminal offense.

. 2004.

Prospectus dated

We were incorporated in Delaware in 1988. In 1997, our company underwent a recapitalization, and a new management team was put in place, including our current chief executive officer, in late 1999. Our principal executive offices are located at Two Connell Drive, Berkeley Heights, New Jersey 07922 and our telephone number is (908) 286-9800. Our website address is

The terms Genta , the Company , we , us and our refer to Genta Incorporated.

www.genta.com. The information contained on our website is not a part of this prospectus.

Ganite is a trademark of Genta. In the United States Genasense is the property of Genta. Outside of the United States Gensasense is the property of Aventis Pharmaceuticals Inc. Service marks, trademarks and trade names referred to in this prospectus are the property of their respective owners.

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### **RISK FACTORS**

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

## **Risks Related to Our Business**

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 U.S. Food and Drug Administration, or FDA, approval in the time frame we expect or at all. We have 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. We filed and received priority designation, which increased the probability that the review by the FDA will be concluded within six months from the date of the completed application. The FDA may not complete its review within the time it has targeted. In addition, the action it takes may be to request further data or to disapprove the application. If Genasense is not approved by the FDA for melanoma, if the review time is substantially prolonged or if the FDA requires further clinical studies prior to approval, we have no short-term alternative for generating substantial revenue or income. Genasense may not be approved because the FDA may find our efficacy and safety data deficient or for other reasons. While we have completed enrollment in Phase 3 trials for other indications (including multiple myeloma and chronic lymphocytic leukemia, or CLL), we do not yet know whether the results of these clinical trials will warrant submission of a NDA. Moreover, preparation of NDAs for either or both of these indications would entail significant delay relative to the melanoma application, and there can be no assurance that either or both of these applications would suffice for Genasense approval. Failure to obtain approval or a substantial delay in approval of Genasense would have a material adverse effect on our results of operations and financial condition.

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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 have a limited number of sales personnel. Our inability to build a sales force capable of marketing our pharmaceutical products will adversely affect our sales and limit the commercial success of our products.

#### We anticipate that we will incur additional losses and we may never be profitable.

We have not 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 December 31, 2003, we have incurred a cumulative net loss of \$323.3 million. We may never achieve revenue sufficient for us to

attain profitability. Achieving profitability is unlikely before Genasense becomes an approved drug and we receive at least a full year of royalties from Aventis Pharmaceuticals Inc., or Aventis, on worldwide sales pursuant to the development and commercialization agreements which we have entered into with Aventis.

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

Our operations to date have required significant cash expenditures. Our future capital requirements will depend on the results of our research and development activities, pre-clinical studies and clinical trials, competitive and technological advances, and regulatory activities of the FDA and other regulatory authorities. Our credit line with Aventis terminates with respect to new borrowings upon the earlier of December 31, 2004 or the first FDA approval of Genasense (which triggers a milestone payment from Aventis), and amounts borrowed under the credit line are due six months after termination. 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.

If we are unable to raise additional financing, 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.

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### Our business depends heavily on a small number of products.

We are currently marketing one product, Ganite, and we are actively seeking FDA approval of Genasense for advanced malignant melanoma. 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.

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.

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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 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,

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complexity and novelty of the product. While limited trials of some of our products have produced favorable results, 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. We cannot assure you that the FDA or other regulatory agencies will ever approve the use of our products that are under development. If the patient populations for which our products are approved are not sufficiently broad, or if approval is accompanied by unanticipated labeling restrictions, the commercial success of our products could be limited and our business, results of operations and financial condition could consequently be materially adversely affected.

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. The loss of any of these collaborative relationships could have a material adverse effect on our business. In addition, 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, 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. Moreover, we may be unable to negotiate advantageous strategic alliances in the future. Our failure to enter into strategic alliances, or the failure of a current or future strategic alliance to achieve its goals, could harm our efforts to develop and commercialize our drugs.

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.

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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.

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.

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## 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 services are provided and paid for in the United States. In particular, these third-party payors are increasingly attempting to contain health care costs by limiting both coverage and the level of reimbursement for new therapeutic products. In the future, it is possible that the government may institute price controls and further limits on Medicare and Medicaid spending. These controls and limits could affect the payments we collect from sales of our products. Internationally, medical reimbursement systems vary significantly, with some countries requiring application for, and approval of, government or third-party reimbursement. In addition, some medical centers in foreign countries have fixed budgets, regardless of levels of patient care. Even if we succeed in bringing therapeutic products to market, uncertainties regarding future health care policy, legislation and regulation, as well as private market practices, could affect our ability to sell our products in quantities, or at prices that will enable us to achieve profitability.

## Our business exposes us to potential product liability that may have a negative effect on our financial performance and our business generally.

The administration of drugs to humans, whether in clinical trials or commercially, exposes us to potential product and professional liability risks, which are inherent in the testing, production, marketing and sale of human therapeutic products. Product liability claims can be expensive to defend and may result in large judgments or settlements against us, which could have a negative effect on our financial performance and materially and adversely affect our business. We maintain product liability insurance (subject to various deductibles), but our insurance coverage may not be sufficient to cover claims. Furthermore, we cannot be certain that we will always be able to maintain or increase our insurance coverage at an affordable price. Even if a product liability claim is not successful, the adverse publicity and time and expense of defending such a claim may interfere with or adversely affect our business and financial performance.

We are dependent on our collaborators and cannot be sure that our collaborators will perform as expected. Moreover, collaborations might produce conflicts that could delay or prevent the development or commercialization of our potential product candidates and negatively impact our business and financial condition.

We have agreed to commercialize Genasense, if and when it is approved by the FDA, jointly with Aventis. Aventis will sell the product and pay us a royalty, and we and Aventis will cooperate on various aspects of commercialization. We have entered into an

agreement under which Avecia Biotechnology, Inc., or Avecia, will manufacture Genasense if and when it is approved. We cannot control the resources that Aventis, Avecia or any future 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.

Our commercialization agreement with Aventis may be terminated by Aventis with six months prior notice. Recently Aventis has been the subject of acquisition proposals. If Aventis is acquired, it may undergo strategic or managerial changes that could reduce its commitment to Genasense or lead it to terminate our collaborative agreement. The agreement contains provisions that allow for assignment to a successor in the event of a merger of Aventis, such that the terms of the agreement remain unchanged.

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

An important part of our strategy involves conducting multiple product development programs. We may pursue opportunities in fields that conflict with those of our collaborators. In addition, disagreements with our collaborators could develop over rights to our intellectual property. The resolution of such conflicts and disagreements may require us to relinquish rights to our intellectual property that we believe we are entitled to. In addition, any disagreement or conflict with our collaborators could reduce our ability to obtain future collaboration agreements and negatively impact our relationship with existing collaborators. Such a conflict or disagreement could also lead to delays in collaborative research, development, regulatory approval or commercialization of various products or could require or result in litigation or arbitration, which would be time consuming and expensive and could have a significant negative impact on our business, financial condition and results of operations.

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

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

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

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

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

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

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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.

# The nature of the business activities or positions of our principal stockholders and present and future officers and directors may involve conflicts of interest.

One of our principal stockholders is Paramount Capital Asset Management, Inc. The sole stockholder and chairman of Paramount Capital Asset Management, Inc. is also the chairman of Paramount Capital Inc. and of Paramount Capital Investment LLC. These three companies, together with their affiliates, are collectively referred to as the Paramount Companies. The Paramount Companies beneficially own approximately 22% of our common stock, including beneficial ownership by Aries Select I, LLC, Aries Select II, LLC, and Aries Select, Ltd., of which Paramount Capital Asset Management, Inc. is the investment manager. The Paramount Companies have been distributing shares of Genta Incorporated to their fundholders and these distributions have lowered Paramount Companies beneficial ownership from approximately 41% as of May 1, 2003 to approximately 22% as of February 29, 2004. In the regular course of business, the Paramount Companies evaluate and pursue investment opportunities in biomedical and pharmaceutical products, technologies and companies. We cannot assure you that these other companies will not have interests in conflict with ours. In addition, some of our current or future officers and directors may from time to time serve as officers or directors of other biopharmaceutical or biotechnology companies in which Paramount has an investment.

### **Risks Related to Our Common Stock**

### Concentration of ownership of our stock could delay or prevent a change of control.

Our directors, executive officers and principal stockholders the Paramount Companies and the Aries Funds and Garliston Limited, a subsidiary of Aventis, beneficially own approximately 38% of our outstanding common stock. As a result, these stockholders, if acting together, have the ability to significantly influence the outcome of corporate actions requiring stockholder

approval. This concentration of ownership may have the effect of delaying or preventing a change in control of Genta.

In addition, Garliston Limited has agreed not to participate in hostile takeover attempts and to vote its shares in ways that may have anti-takeover effects.

## 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

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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.

## 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. We currently have an open search for a Senior Vice President, Research. If we are unable to fill this position or others that open, our business may be harmed.

#### Our stock price is volatile.

The market price of our common stock, like that of the common stock of many other biopharmaceutical companies, has been and likely will continue to be highly volatile. Factors that could have a significant impact on the future price of our common stock include but are not limited to:

- the results of 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 December 31, 2003, we had 75,927,033 shares of common stock outstanding and options, warrants, convertible preferred stock and convertible debt outstanding exercisable for or convertible into 19,047,612 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.

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#### **DESCRIPTION OF GENTA**

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 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.

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#### WHERE YOU CAN FIND MORE INFORMATION

We are required by federal securities laws to file certain information with the SEC. You can access this material on the SEC s Internet website at http://www.sec.gov. You can also read and copy this material at the SEC s public reference room, located at 450 Fifth Street, N.W., Washington, DC 20549. Please call the SEC at (800) 732-0330 for information on how the public reference room operates. The reference to the Uniform Resource Locator of the SEC s website is intended to be an inactive textual reference only.

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 the Controller, Genta Incorporated, Two Connell Drive, Berkeley Heights, NJ 07922, (908) 286-9800.

This prospectus is part of a registration statement on Form S-3 we filed with the SEC. This prospectus omits some information contained in the registration statement in accordance with SEC rules and regulations. You should review the information and exhibits in the registration statement for further information on us and our common stock. Statements in this prospectus concerning any document we filed as an exhibit to the registration statement or that we otherwise filed with the SEC are not intended to be comprehensive and are qualified by reference to these filings. You should review the complete document to evaluate these statements. The registration statement, including the exhibits and schedules thereto, are also available for reading and copying at the offices of Nasdag Operations, 1735 K Street, N.W., Washington, D.C. 20006.

We make available free of charge on our internet website (http://www.genta.com) our annual report on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K and amendments to these reports filed or furnished pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934 as soon as reasonably practicable after we electronically file such material with, or furnish it to, the Securities and Exchange Commission. Our website and the information contained therein or connected thereto shall not be deemed to be incorporated into this prospectus or the registration statement of which it forms a part.

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#### SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

We have made statements under the caption Risk Factors and in other sections of or incorporated by reference in this prospectus that are forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934. We intend that all forward-looking statements be subject to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. In some cases, you can identify these statements by forward-looking words such as may , might , will , should , expects , plans , anticipates , believes , estimates , predicts , continue , the negative of these terms and other comparable terminology.

These forward-looking statements reflect our views as of the date they are made with respect to future events and financial performance, but are subject to many risks and uncertainties, which could cause actual results to differ materially from any future results expressed or implied by such forward-looking statements. Factors that may cause actual results to differ materially from those contemplated by the forward-looking statements include, among others, those listed under the caption entitled Risk Factors and the following:

- FDA approval or failure to approve Genasense;
- our ability to develop, manufacture and sell our products or to 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;

- 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.

Although we believe the expectations reflected in the forward-looking statements are reasonable, we cannot guarantee future results, level of activity, performance or achievements. Moreover, neither we nor any other person assumes responsibility for the accuracy and completeness of any of these forward-looking statements. We are under no duty to update any of these forward-looking statements after the date of this prospectus to conform our prior statements to actual results or revised expectations.

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#### **USE OF PROCEEDS**

We will not receive any of the proceeds from the sale of common stock by the selling stockholders. All sale proceeds will be received by the selling stockholders.

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#### **SELLING STOCKHOLDERS**

The selling stockholders may offer and sell up to a total of 671,412 shares of Genta common stock under this prospectus. The shares that may be offered under this prospectus were originally issued to the selling stockholders in connection with Genta s acquisition of Salus Therapeutics, Inc. in August 2003. In connection with this acquisition, we agreed to register these shares under the Securities Act.

The selling stockholders will determine the actual number of shares, if any, that they will sell. Because the selling stockholders may sell all, some or none of the shares of common stock that they hold and offer, we are unable to estimate the amount or percentage of shares of common stock that they will hold after completion of the offering.

The following table sets forth, to the best of our knowledge, based on information provided to us by the selling stockholders:

- the number of shares of Genta common stock owned by each selling stockholder; and
- the number of shares that may be offered by each selling stockholder under this prospectus.

All information with respect to share ownership has been provided by the selling stockholders. Except as described below, none of the selling stockholders holds any position or office with, or has otherwise had a material relationship with, Genta for the past three years. Since the date on which the selling stockholders provided this information, they may have sold, transferred or otherwise disposed of all or a portion of their shares of common stock in transactions exempt from the registration requirements of the Securities Act.

None of the selling stockholders beneficially owns 1% or more of our outstanding common stock.

Name	Number of Shares of Common Stock Beneficially Owned (1)	Number of Shares of Common Stock That May Be Offered
Orrin Grant Hatch	1,311	852
Gary R. Hooper	889	889
Richard K. Koehn(2)	27,972	13,632
Thomas N. Parks	5,297	3,443
Dinesh Patel(3)	28,183	18,319
Ramesh Prakash, Ph.D.(4)	18,089	11,758
Paradigm Resources, L.C.	17,142	11,142
John J. Rossi	889	889
Duane E. Ruffner(5)	28,658	18,319
Willem Spiegel	2,759	1,832
Cy A. Stein(6)	10,889	889
University of Utah Research Foundation(7)	7,864	5,112
Utah Ventures II, L.P.	680,432	442,281
vSpring, L.P.	170,350	110,731
vSpring Partners, L.P.	21,701	14,106
Wright Ventures, L.C.	21,193	13,775
WS Investment Company, LLC	5,297	3,443
Total	1,048,915	671,412

<sup>(1)</sup> Beneficial ownership is determined in accordance with the rules of the SEC and generally includes voting or investment power with respect to securities.

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<sup>(2)</sup> From August 21, 2003 to February 17, 2004, Mr. Koehn was Senior Scientific Advisor at Genta.

<sup>(3)</sup> By virtue of his position as Managing Director of the general partner of vSpring, L.P. and vSpring Partners, L.P. Mr. Patel may be considered the beneficial owner of 170,350 shares of common stock held by, and 110,731 shares of common stock being offered by, vSpring, L.P. and 21,701 shares held by, and 14,106 shares of common stock being offered by, vSpring Partners, L.P.

- (4) From August 21, 2003 to September 25, 2003, Mr. Prakash was an employee of Genta.
- (5) Since August 21, 2003, Mr. Ruffner has been an employee of Genta.
- (6) The number of shares beneficially owned by Mr. Stein includes options to purchase 10,000 shares of common stock of Genta at \$8.50 per share. Mr. Stein serves on the Scientific Advisory Board of Genta and is a consultant and a research collaborator of Genta.
- (7) The University of Utah Research Foundation is the licensor of certain technology to Genta.

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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:

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- 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.

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#### 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 are registering the shares of Genta common stock offered under this prospectus on behalf of the selling stockholders. As used herein, selling stockholders includes donees and pledgees selling shares received from the selling stockholders after the date of this prospectus. We will pay all expenses of registration of the shares offered hereby, other than commissions, discounts and concessions of underwriters, dealers or agents. Brokerage commissions and similar selling expenses, if any, attributable to the sale of the shares will be borne by the selling stockholders. We will not receive any of the proceeds from the sale of the shares by the selling stockholders.

The shares may be sold from time to time by the selling stockholders. The selling stockholders may from time to time sell their shares directly to purchasers or, alternatively, through underwriters, broker-dealers or agents. These shares may be sold in one or more transactions at fixed prices, at prevailing market prices at the time of sale, at varying prices determined at the time of sale, or at negotiated prices. Such sales may be effected in transactions (which may involve crosses or block transactions) (a) on any national securities exchange or quotation service on which these shares may be listed or quoted at the time of sale, (b) in the over-the-counter market, (c) in transactions otherwise than on such exchanges or services or in the over-the-counter market or (d) through the writing of options. In connection with sales of these shares or otherwise, the selling stockholders may enter into hedging transactions with broker-dealers, which may in turn engage in short sales of these shares in the course of hedging the positions they assume. The selling stockholders may also sell their shares short and deliver their shares to close out such short positions, or loan or pledge their shares to broker-dealers that in turn may sell such securities.

If the selling stockholders effect these transactions by selling their shares through broker-dealers (which may act as agents or principals), these broker-dealers may receive compensation in the form of discounts, concessions or commissions from the selling stockholders and/or the purchasers of shares for whom these broker-dealers may act as agents or to whom they sell as principal, or both (which compensation as to a particular broker-dealer might be in excess of customary commissions).

The selling stockholders and any broker-dealers that act in connection with the sale of the shares might be deemed to be underwriters—within the meaning of Section 2(11) of the Securities Act. Consequently, any commissions received by these broker-dealers and any profit on the resale of the shares sold by them while acting as principals might be deemed to be underwriting discounts or commissions under the Securities Act. We have agreed to indemnify the selling stockholders against certain liabilities, including liabilities arising under the Securities Act, or to contribute to payments which the selling stockholders may be required to make in respect thereof.

Because the selling stockholders may be deemed to be underwriters within the meaning of Section 2(11) of the Securities Act, the selling stockholders will be subject to the prospectus delivery requirements of the Securities Act, which may include delivery through the facilities of the Nasdaq National Market pursuant to Rule 153 under the Securities Act. We have informed the selling stockholders that the anti-manipulation provisions of Regulation M under the Securities Exchange Act of 1934 may apply to their sales in the market.

The selling stockholders also may resell all or a portion of the shares in open market transactions in reliance upon Rule 144 under the Securities Act, provided that they meet the criteria and conform to the requirements of that rule.

Upon being notified by any selling stockholder that he has entered into any material arrangement with a broker-dealer for the sale of the shares through a block trade, special offering, exchange distribution or secondary distribution or a purchase by a broker or dealer, we will file a supplement or an amendment to this prospectus, if required, under the Securities Act, disclosing material terms of such arrangement, including but not limited to:

• the name of the selling stockholder and the participating broker-dealers;

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- the number of shares involved;
- the price at which the shares were sold;
- the commissions paid or discounts or concessions allowed to these broker-dealers, where applicable;
- that the broker-dealers did not conduct any investigations to verify the information set out or incorporated by reference in this prospectus; and
- other facts material to the transaction.

We have agreed with the selling stockholders to keep the registration statement of which this prospectus is a part effective for a period ending on the earlier of (i) the date on which all shares offered under this prospectus have been sold, or (ii) the date on which the shares offered hereby can be sold without volume limitations under Rule 144 under the Securities Act.

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

#### **LEGAL MATTERS**

Certain legal matters relating to the shares of common stock offered hereby have been passed upon for Genta by Davis Polk & Wardwell, New York, New York.

#### **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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No dealer, salesperson or other person is authorized to give any information or to represent anything not contained in this prospectus. You must not rely on any unauthorized information or representations. This prospectus is an offer to sell only the shares offered hereby, but only under circumstances and in jurisdictions where it is lawful to do so. The information contained in this prospectus is current only as of its date.

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671,412 Shares

## **Genta Incorporated**

Common Stock

# PART II INFORMATION NOT REQUIRED IN PROSPECTUS

#### Item 14. Other Expenses of Issuance and Distribution.

	Amount To Be Paid
Registration fee	\$ 581
Legal fees and expenses	100,000
Accounting fees and expenses	50,000
Miscellaneous	10,000
Total	\$ 160,581

Each of the amounts set forth above other than the Registration fee is an estimate.

#### Item 15. Indemnification of Directors and Officers.

Section 102(b)(7) of the Delaware General Corporation Law permits a corporation to provide in its certificate of incorporation that a director of the corporation shall not be personally liable to the corporation or its stockholders for monetary damages for breach of fiduciary duty as a director, except for liability (i) for any breach of the director s duty of loyalty to the corporation or its stockholders, (ii) for acts or omissions not in good faith or which involve intentional misconduct or a knowing violation of law, (iii) for unlawful payments of dividends or unlawful stock repurchases, redemptions or other distributions, or (iv) for any transaction from which the director derived an improper personal benefit.

Section 145 of the Delaware General Corporation Law provides that a corporation may indemnify any person, including a director or officer, who is, or is threatened to be made, a party to any threatened, pending or completed legal action, suit or proceeding, whether civil, criminal, administrative or investigative (other than an action by or in the right of such corporation), by reason of fact that such person is or was a director, officer, employee or agent of such corporation, or is or was serving at the request of such corporation as a director, officer, employee or agent of another corporation or other enterprise against expenses (including attorney s fees), judgments, fines and amounts paid in settlement actually and reasonably incurred by such person in connection with such action, suit or proceeding, provided such person acted in good faith and in a manner he reasonably believed to be in or not opposed to the corporation s best interests and, with respect to any criminal actions or proceedings, had no reasonable cause to believe that his conduct was unlawful. A Delaware corporation may provide similar indemnification in an action or suit by or in the right of the corporation, except that no indemnification is permitted if the director or officer is adjudged to be liable to the corporation unless and to the extent the Court of Chancery or the court in which such action was brought determines that such person is reasonably entitled to indemnify. Where a director or officer is successful on the merits or otherwise in the defense of any action referred to above, the corporation must indemnify him or her against the expenses which such director or officer actually and reasonably incurred.

Article VIII of Genta s restated certificate of incorporation, as amended, provides indemnification of directors and officers of Genta to the fullest extent permitted by the Delaware General Corporation Law.

Genta maintains liability insurance for each director and officer for certain losses arising from claims or charges made against them while acting in their capacities as directors or officers of the Registrant.

#### Item 16. Exhibits.

(a) The following exhibits are filed as part of this Registration Statement:

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Exhibit <u>Number</u>	<u>Description</u>
5	Opinion of Davis Polk & Wardwell (previously filed)
23.1	Consent of Deloitte & Touche LLP
23.2	Consent of Davis Polk & Wardwell (previously filed)
24.1	Power of Attorney (previously filed)
(b) The foll	owing financial statement schedule is filed as part of this Registration Statement:

None.

#### Item 17. Undertakings.

The undersigned hereby undertakes:

- (a) (1) To file, during any period in which offers or sales are being made of securities registered hereby, a post-effective amendment to this registration statement:
  - (i) to include any prospectus required by Section 10(a)(3) of the Securities Act of 1933;
  - (ii) to reflect in the prospectus any facts or events arising after the effective date of the registration statement (or the most recent post-effective amendment thereof) which, individually or in the aggregate, represent a fundamental change in the information set forth in the registration statement. Notwithstanding the foregoing, any increase or decrease in volume of

securities offered (if the total dollar value of securities offered would not exceed that which was registered) and any deviation from the low or high end of the estimated maximum offering range may be reflected in the form of prospectus filed with the Securities and Exchange Commission pursuant to Rule 424(b) if, in the aggregate, the changes in volume and price represent no more than a 20 percent change in the maximum aggregate offering price set forth in the Calculation of Registration Fee table in the effective registration statement;

(iii) to include any material information with respect to the plan of distribution not previously disclosed in the registration statement or any material change to such information in the registration statement;

provided, however, that paragraphs (i) and (ii) above do not apply if the information required to be included in a post-effective amendment by those paragraphs is contained in periodic reports filed by the registrant pursuant to Section 13 or Section 15(d) of the Securities Exchange Act of 1934 that are incorporated by reference in this registration statement.

- (2) That, for the purpose of determining any liability under the Securities Act of 1933, each such post-effective amendment shall be deemed to be a new registration statement relating to the securities offered herein, and the offering of such securities at that time shall be deemed to be the initial *bona fide* offering thereof.
- (3) To remove from registration by means of a post-effective amendment any of the securities being registered which remain unsold at the termination of the offering.
- (b) The undersigned Registrant hereby undertakes that, for purposes of determining any liability under the Securities Act of 1933, each filing of the registrant s annual report pursuant to Section 13(a) or Section 15(d) of the Securities Exchange Act of 1934 (and, where applicable, each filing of an employee benefit plan s annual report pursuant to Section 15(d) of the Securities Exchange Act of 1934) that is incorporated by reference in the registration statement shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.
- (c) Insofar as indemnification for liabilities arising under the Securities Act of 1933 may be permitted to directors, officers and controlling persons of the registrant pursuant to the provisions referenced in Item 14 of this Registration Statement, or otherwise, the registrant has been advised that in the opinion of the Securities and Exchange Commission such indemnification is against public policy as expressed in the Act and is, therefore, unenforceable. In the event that a claim for indemnification against such liabilities (other than the payment by the registrant of expenses incurred or paid by a director, officer, or controlling person of the registrant in the successful defense of any action, suit or proceeding) is asserted by such director, officer or controlling person in connection with the securities being registered hereunder, the registrant will, unless in the opinion of its counsel the matter has been settled by controlling precedent, submit to a court of appropriate jurisdiction the question of whether such indemnification by it is against public policy as expressed in the Act and will be governed by the final adjudication of such issue.

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#### **SIGNATURES**

Pursuant to the requirements of the Securities Act of 1933, the Registrant has duly caused this Registration Statement to be signed on its behalf by the undersigned, thereunto duly authorized, in City of Berkeley Heights, State of New Jersey, on the 2nd day of April, 2004.

GENTA INCORPORATED

By:/s/ William P. Keane

Name: William P. Keane

Title: Vice President, Chief Financial Officer and Corporate Secretary

Pursuant to the requirements of the Securities Act of 1933, as amended, this Registration Statement has been signed by the following persons in the capacities and on the dates indicated.

Signature	Title	Date
* Raymond P. Warrell, Jr., M.D.	Chairman of the Board of Directors and Chief Executive Officer (Principal Executive Officer)	April 2, 2004
/s/ William P. Keane William P. Keane	Vice President, Chief Financial Officer and Corporate Secretary (Principal Accounting Officer)	April 2, 2004
Jerome E. Groopman, M.D.	Director	April 2, 2004
Betsy McCaughey, Ph.D.	Director	April 2, 2004
Peter T. Tattle	Director	
* Daniel D. Von Hoff, M.D.	Director	April 2, 2004
* Harlan J. Wakoff	Director	April 2, 2004

\*

	Douglas G. Watson	Director	April 2, 2004	
	*			
	Michael S. Weiss	Director	April 2, 2004	
*By:	/s/ William P. Keane	_		
	William P. Keane Attorney-in-fact			

## **EXHIBIT INDEX**

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