

NANOGEN INC  
Form 424B3  
October 10, 2003  
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Filed pursuant to Rule 424(b)(3)

File No. 333-109508

PROSPECTUS

## Nanogen, Inc.

### 4,228,791 Shares of Common Stock

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The security holders of Nanogen, Inc. identified in this prospectus under Selling Security Holders, or their respective pledgees or assignees may offer from time to time up to 4,228,791 shares of our common stock, of which 2,121,211 shares are issued and outstanding and 2,107,580 shares are issuable upon the exercise of outstanding warrants.

We will not receive any part of the proceeds from the sale of the shares covered by this prospectus. We will bear all expenses relating to registration of the shares.

The selling security holders have not advised us of any specific plans for the distribution of the shares covered by this prospectus, but it is anticipated that the shares will be sold from time to time in negotiated transactions and in transactions (which may include short sales and block transactions) on Nasdaq at the market price then prevailing, although sales may also be made as described in this prospectus under Plan of Distribution. The selling security holders and the broker-dealers through whom sale of the shares may be made may be deemed to be underwriters within the meaning of the Securities Act of 1933, as amended, and commissions or discounts paid to broker-dealers in connection with the sales and other compensation may be regarded as underwriters' compensation. See Plan of Distribution.

**An investment in the shares offered under this prospectus involves a high degree of risk. You should carefully consider the risk factors described on pages 2-11 of this prospectus.**

Our common stock trades on the Nasdaq National Market under the symbol NGEN. On October 9, 2003, the last reported sale price of our common stock on the Nasdaq National Market was \$3.86.

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

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The date of this prospectus is October 10, 2003.

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**ABOUT THIS PROSPECTUS**

You should rely only on the information contained in or specifically incorporated by reference into this prospectus. No dealer, sales person or other individual has been authorized to give any information or to make any representations not contained in this prospectus. If given or made, such information or representations must not be relied upon as having been authorized by us.

This prospectus does not constitute an offer to sell or a solicitation of an offer to buy, the common stock offered hereby in any jurisdiction where, or to any person to whom, it is unlawful to make such offer or solicitation.

The information contained in this prospectus is accurate only as of the date of this prospectus, regardless of the time of delivery of this prospectus or of any sale of common stock. Neither the delivery of this prospectus nor any sale made hereunder shall, under any circumstances, create an implication that there has not been any change in the facts set forth in this prospectus or in our affairs since the date of this prospectus.

Our principal offices are located at 10398 Pacific Center Court, San Diego, California 92121, and our telephone number is (858) 410-4600.

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**ABOUT NANOGEN, INC.**

Nanogen is a Delaware corporation with a goal to become a leading provider of molecular diagnostic tests and services. We integrate advanced microelectronics and molecular biology into a core technology platform with potentially broad and diverse commercial applications. Our primary areas of focus have been in genomics and biomedical research, medical diagnostics, biodefense, forensics and drug discovery. Our current commercially available products include:

the NanoChip® Molecular Biology Workstation, an automated, multi-purpose instrument used primarily for DNA-based analyses;

the NanoChip® Cartridge, which incorporates the NanoChip® Electronic Microarray and provides a flexible tool for the rapid identification and precise analysis of biological test samples containing charged molecules;

various Analyte Specific Reagents ( ASRs ) for detecting gene mutations associated with diseases such as cystic fibrosis, Alzheimer s disease and hereditary hemochromatosis; and

the Assay Toolbox, a product designed to help customers develop their own assays on the NanoChip® System.

In addition, we are developing several other ASRs and applications of our proprietary technology, as well as new instrumentation products. We also provide technical support and field applications assistance to our customers.

We commenced operations in 1993, and introduced our first two products into the marketplace in 2000. While we recognized revenue from product sales during the six months ended June 30, 2003 and the years ended December 31, 2002, 2001 and 2000, our main sources of revenues during these periods were payments under our sponsored research agreements, contracts and grants and, in 2002, a license fee valued at \$10.8 million received from a litigation settlement. We believe that in future periods, however, our revenue base will shift to being more product driven as our sales efforts continue to shift to clinical research laboratories, new products are introduced by us to the marketplace and market acceptance for our products increases. In addition, our research collaboration agreement with Hitachi, Ltd. is scheduled to expire during the second quarter of 2004 and certain of our government grants will also expire in 2004.

We incorporated in California in November 1991 and reincorporated in Delaware in November 1997. Our principal offices are located at 10398 Pacific Center Court, San Diego, California 92121, and our telephone number is (858) 410-4600.

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**RISK FACTORS**

An investment in the shares of common stock offered by this prospectus involves a high degree of risk. You should carefully consider the information set forth below before investing in our common stock. The trading price of our common stock could decline due to any of these risks, and you may lose some or all of your investment.

*If our products are not successfully developed or commercialized, we could be forced to curtail or cease operations.*

We are at an early stage of development. As of October 2, 2003, we had only a limited product offering that includes our NanoChip® System (which consists of our NanoChip® Molecular Biology Workstation and NanoChip® Cartridge), NanoChip® Cartridge, five ASRs, Assay Toolbox and a product available only in Europe solely for research use for beta thalassemia. All of our other platforms and ASRs and other potential products are under development. Our NanoChip® System, ASRs or our other products may not be successfully developed or commercialized on a timely basis, or at all. If we are unable, for technological or other reasons, to complete the development, introduction or scale-up of manufacturing of our new products, or if our products do not achieve a significant level of market acceptance, we would be forced to curtail or cease operations.

Since inception and through the period ended June 30, 2003, we have sold a total of 49 NanoChip® Systems. We also placed instruments at various customer sites under development site agreements whereby title of the NanoChip® Molecular Biology Workstation did not pass to the customer and therefore no revenue was recognized.

We are also party to transactions known as reagent rentals and cost-per-test agreements. Under these types of transactions, we place a Workstation at a customer site with no upfront cost to the customer. The value of the instrument is typically recaptured through a contracted stream of future reagent sales, sold at a premium to cover the cost of the system. Many of our reagent rentals and cost-per-test agreements entered into as of October 2, 2003 require customer acceptance of our CFTR ASRs as a pre-condition to the customer's commitment to purchase the instrument. Our CFTR ASRs may be utilized by customers to develop and validate tests for the detection of mutations in the CFTR gene associated with cystic fibrosis. These reagent rentals and cost-per-test agreements might have an adverse impact on our short-term instrument sales revenue and cash flow as the revenues and cash received under these agreements are over the life of the contract, as reagents are shipped to the customer. Our success will depend upon our ability to continue to overcome significant technological challenges and successfully introduce our products into the marketplace. A number of applications envisioned by us may require significant enhancements to our basic technology platform. There can be no assurance that we can successfully develop such enhancements.

For the six months ended June 30, 2003, product sales totaled \$890,000 which included the sale of four and one-half (a partial unit) NanoChip® Molecular Biology Workstations as well as sales of NanoChip® Cartridges, reagents and warranty revenue.

*Lack of market acceptance of our technology would harm us.*

Although we have developed a number of products as discussed above, we may not be able to further develop these products or to develop other commercially viable products. Even if we develop a product, it may not be accepted in the marketplace. If we are unable to achieve market acceptance, we will not be able to generate sufficient product revenue to become profitable. We may also be forced to carry greater inventories of our products for longer periods than we may have anticipated. If we are unable to sell the inventory of our products in a timely fashion and at

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anticipated price levels, we may not become profitable. In addition, we may have to take accounting charges and reduce the value of our product inventory to its net realizable value. Market acceptance will depend on many factors, including our ability to:

convince prospective strategic partners and customers that our technology is an attractive alternative to other technologies;

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manufacture products in sufficient quantities with acceptable quality and at an acceptable cost; and

sell, place and service sufficient quantities of our products.

In addition, our technology platform could be harmed by limited funding available for product and technology acquisitions by our customers, internal obstacles to customer approvals of purchases of our products and market conditions in general.

*Commercialization of some of our potential products depends on collaborations with others. If our collaborators are not successful or if we are unable to find collaborators in the future, we may not be able to develop these products.*

Our strategy for the research, development and commercialization of some of our products requires us to enter into contractual arrangements with corporate collaborators, joint venture partners, licensors, licensees and others. Our success depends in part upon the performance by these collaboration partners and potential collaboration partners of their responsibilities under these arrangements. Some collaborators may not perform their obligations as we expect, and we may not derive any revenue or other benefits from these arrangements.

In August 2003, Hitachi, Ltd. exercised its right to terminate the research collaboration agreement it has with us. The agreement is scheduled to terminate during the second quarter of 2004. Until the agreement terminates, we and Hitachi expect to continue to work on the development of a new clinical instrument. Our manufacturing and distribution agreements with Hitachi remain in place. In June 2001, we formed a new company, Nanogen Recognomics GmbH, with Aventis Research and Technologies & Co. KG, in which we own 60% of the stock of Nanogen Recognomics and Aventis R&T owns the remaining 40%. Nanogen Recognomics seeks to combine our NanoChip® technology and Aventis R&T's intellectual property and expertise in synthetic oligonucleotide chemistry and advanced molecular biology to develop new products and applications for the NanoChip® System. We do not know whether our collaborations will successfully develop and market any products under our respective agreements. Moreover, some of our collaborators are also researching competing technologies targeted by our collaborative programs.

We may be unsuccessful in entering into other collaborative arrangements to develop and commercialize our products. In addition, disputes may arise over ownership rights to intellectual property, know-how or technologies developed with our collaborators.

*We have a history of net losses. We expect to continue to incur net losses and we may not achieve or maintain profitability.*

Since our inception, we have incurred cumulative net losses which, as of June 30, 2003, total approximately \$163.2 million. Moreover, our negative cash flow and losses from operations will continue for the foreseeable future. We may never generate sufficient product revenue to become profitable. We also expect to have quarter-to-quarter fluctuations in revenues, expenses and losses, which fluctuations could be significant. The amount and timing of product revenue recognition and cash flow may depend on whether potential customers for the NanoChip® System choose to enter into sales, reagent rentals, cost-per-test or development site transactions.

To develop and sell our products successfully, we may need to increase our spending levels in research and development, as well as in selling, marketing and administration. We may have to incur these increased spending levels before knowing whether our products can be sold successfully.

*We will need additional capital in the future. If additional capital is not available, we may have to curtail or cease operations.*

We will need to raise more money to continue the research and development necessary to further develop our current products to bring our products to market and to further our manufacturing and marketing capabilities. We may seek additional funds through public and private stock offerings, arrangements with corporate partners, borrowings under lease lines of credit or other sources. If we cannot raise more money, we will have to reduce



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our capital expenditures, scale back our development of new products, reduce our workforce and seek to license to others products or technologies that we otherwise would seek to commercialize ourselves. The amount of money we will need will depend on many factors, including among others:

the progress of our research and development programs;

the commercial arrangements we may establish;

the time and costs involved in:

scaling up our manufacturing capabilities;

meeting regulatory requirements, including meeting necessary Quality System Regulations or QSRs and obtaining necessary regulatory clearances or approvals;

filing, prosecuting, defending and enforcing patent claims and litigation; and

the scope and results of our future clinical trials, if any.

Additional capital may not be available on terms acceptable to us, or at all. Any additional equity financing would likely be dilutive to stockholders, and debt financing, if available, may include restrictive covenants and require significant collateral.

*Competing technologies may adversely affect us.*

We expect to encounter intense competition from a number of companies that offer products in our targeted application areas. We anticipate that our competitors in these areas will include:

health care and other companies that manufacture laboratory-based tests and analyzers;

diagnostic and pharmaceutical companies;

companies developing drug discovery technologies; and

companies developing molecular diagnostic tests.

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If we are successful in developing products in these areas, we will face competition from established companies and numerous development-stage companies that continually enter these markets. In many instances, our competitors have substantially greater financial, technical, research and other resources and larger, more established marketing, sales, distribution and service organizations than us. Moreover, these competitors may offer broader product lines and have greater name recognition than us and may offer discounts as a competitive tactic.

In addition, several development-stage companies are currently making or developing products that compete with or will compete with our potential products. Our competitors may succeed in developing, obtaining approval from the U.S. Food and Drug Administration or marketing technologies or products that are more effective or commercially attractive than our current or potential products or that render our technologies and current or potential products obsolete.

As these companies develop their technologies, they may develop proprietary positions that may prevent us from successfully commercializing products.

Also, we may not have the financial resources, technical expertise or marketing, distribution or support capabilities to compete successfully in the future.

*The uncertainty of patent and proprietary technology protection may adversely affect us.*

Our success will depend in part on obtaining and maintaining meaningful patent protection on our inventions, technologies and discoveries. Our ability to compete effectively will depend on our ability to develop and maintain proprietary aspects of our technology, and to operate without infringing the proprietary rights of

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others, or to obtain rights to third-party proprietary rights, if necessary. Our pending patent applications may not result in the issuance of patents. Our patent applications may not have priority over others' applications, and even if issued, our patents may not offer protection against competitors with similar technologies. Any patents issued to us may be challenged, invalidated or circumvented, and the rights created thereunder may not afford us a competitive advantage.

We also rely upon trade secrets, technical know-how and continuing inventions to develop and maintain our competitive position. Others may independently develop substantially equivalent proprietary information and techniques or otherwise gain access to our trade secrets or disclose our technology and we may not be able to meaningfully protect our trade secrets, or be capable of protecting our rights to our trade secrets. We seek to protect our technology and patents, in part, by confidentiality agreements with our employees and contractors. Our employees may breach their existing Proprietary Information, Inventions, and Dispute Resolution Agreements and these agreements may not protect our intellectual property. This could have a material adverse effect on us.

*Our products could infringe on the intellectual property rights of others, which may subject us to future litigation and cause us to be unable to license technology from third parties.*

Our commercial success also depends in part on us neither infringing valid, enforceable patents or proprietary rights of third parties, nor breaching any licenses that may relate to our technologies and products. We are aware of other third-party patents that may relate to our technology. It is possible that we may unintentionally infringe these patents or other patents or proprietary rights of third parties. We may in the future receive notices claiming infringement from third parties as well as invitations to take licenses under third-party patents. Any legal action against us or our collaborative partners claiming damages and seeking to enjoin commercial activities relating to our products and processes affected by third-party rights may require us or our collaborative partners to obtain licenses in order to continue to manufacture or market the affected products and processes. In addition, these actions may subject us to potential liability for damages. We or our collaborative partners may not prevail in an action and any license required under a patent may not be made available on commercially acceptable terms, or at all.

There are many U.S. and foreign patents and patent applications held by third parties in our areas of interest, and we believe that there may be significant other litigation in the industry regarding patent and other intellectual property rights. Additional litigation could result in substantial costs and the diversion of management's efforts regardless of the result of the litigation. Additionally, the defense and prosecution of interference proceedings before the U.S. Patent and Trademark Office, or USPTO, and related administrative proceedings would result in substantial expense to us and significant diversion of effort by our technical and management personnel. We may in the future become subject to USPTO interference proceedings to determine the priority of inventions. In addition, laws of some foreign countries do not protect intellectual property to the same extent as do laws in the U.S., which may subject us to additional difficulties in protecting our intellectual property in those countries.

We are aware of U.S. and European patents and patent applications owned by Oxford Gene Technologies. We have opposed one allowed European patent that had broad claims to array technology for analyzing a predetermined polynucleotide sequence. Oxford Gene's position with respect to the opposed patent is that the claims relate to what it terms the "diagnostic mode." Those claims have now been narrowed before the Opposition Division of the European Patent Office to the point that, if these claims remain final before the European Patent Office, we believe they would not be infringed by our technology. In the oral proceedings before the Opposition Division on November 13, 14, and 15, 2001, the Division determined that the claims' language must be limited to arrays with "smooth, impermeable" surfaces. The case is currently on appeal. If the decision of the Opposition Division is successfully appealed by Oxford Gene and the original claims are reinstated, or if an application relating to arrays is issued in another country with claims as broad as the original European patent, we could be subject to infringement accusations that could delay or preclude sales of some or all of our anticipated diagnostic products.

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*We are involved in intellectual property litigation that may be costly, time-consuming and may impact our competitive position.*

In December 2002, Oxford Gene Technologies filed a complaint against us in the United States District Court for the District of Delaware claiming that we infringe U.S. Patent No. 6,054,270 entitled Analytical Polynucleotide Sequences. We filed an answer to the complaint that denies that we infringe this patent. Nevertheless, if the litigation continues, significant attorneys' costs and fees could result. Although it is our position that Oxford Gene's assertions of infringement have no merit, neither the outcome of the litigation nor the amount and range of potential fees can yet be assessed. No assurances can be given that we will prevail in the lawsuit or that we can successfully defend ourselves against the claim. We may not prevail in the action, which could have a material adverse effect on us.

*The regulatory approval process is expensive, time consuming, uncertain and may prevent us from obtaining required approvals for the commercialization of our products.*

The manufacturing, labeling, distribution and marketing of any diagnostic products we may develop will be subject to regulation in the U.S. and other countries. These regulations could subject us to several problems such as:

failure to obtain necessary regulatory approvals or clearances for our products on a timely basis, or at all;

delays in receipt of or failure to receive approvals or clearances;

the loss of previously received approvals or clearances;

limitations on intended uses imposed as a condition of approvals or clearances; or

failure to comply with existing or future regulatory requirements.

In the U.S., the Food and Drug Administration, or FDA, regulates as medical devices most test systems, kits and reagents that are marketed for human in vitro diagnostic use. Pursuant to the Federal Food, Drug, and Cosmetic Act, the FDA regulates the preclinical and clinical testing, design, safety, effectiveness, manufacture, labeling, distribution and promotion of medical devices. We will not be able to commence marketing or commercial sales in the U.S. of these products until we receive an exemption, clearance or approval from the FDA, which can be a lengthy, expensive and uncertain process. We have not applied for FDA or other regulatory approvals with respect to any of our current products or products under development. We may experience difficulties that could delay or prevent the successful development, introduction and marketing of proposed products. Regulatory clearance or approval of any proposed products may not be granted by the FDA or foreign regulatory authorities on a timely basis, if at all. Noncompliance with applicable FDA requirements can result in:

criminal prosecution, civil penalties, other administrative sanctions or judicially imposed sanctions, such as injunctions;

recall or seizure of products;

total or partial suspension of production; and

failure of the government to grant premarket clearance or premarket approval for devices or withdrawal of marketing clearances or approvals once granted.

The FDA also has the authority to request the recall, repair, replacement or refund of the cost of any regulated device that may eventually be manufactured or distributed by us. Any devices manufactured or distributed by us pursuant to FDA clearance or approvals are subject to thorough and continuing regulation by the FDA and certain state agencies, including the California Department of Health Services.

*Our dependence on suppliers for materials could impair our ability to manufacture our products.*

Outside vendors provide key components and raw materials used by us and Hitachi in the manufacture of our products. Although we believe that alternative sources for these components and raw materials are available, any supply interruption in a limited or sole source component or raw material would harm our and Hitachi's ability to manufacture our products until a new source of supply is identified and qualified, including

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qualification under applicable FDA regulations. In addition, an uncorrected defect or supplier's variation in a component or raw material, either unknown to us or Hitachi or incompatible with our or Hitachi's manufacturing processes, could harm our or Hitachi's ability to manufacture products. We or Hitachi may not be able to find a sufficient alternative supplier in a reasonable time period, or on commercially reasonable terms, if at all. If we or Hitachi fail to obtain a supplier for the manufacture of components of our potential products, we may be forced to curtail or cease operations.

*If we are unable to manufacture products on a commercial scale, our business may suffer.*

Hitachi manufactures our NanoChip® System, and we manufacture our NanoChip® Cartridges, our ASRs and most of our other products. We and Hitachi rely on subcontractors to manufacture the limited quantities of microchips and other components we require for use by and sale to our customers, as well as for internal and collaborative purposes. Manufacturing, supply and quality control problems may arise as we or Hitachi either alone, together or with subcontractors, attempt to further scale up manufacturing procedures or to manufacture new products. We or Hitachi may not be able to scale-up in a timely manner or at a commercially reasonable cost. Problems could lead to delays or pose a threat to the ultimate commercialization of our products and cause us to fail.

We or Hitachi or any of our contract manufacturers could encounter manufacturing difficulties, including those relating to:

the ability to scale up manufacturing capacity;

production yields;

quality control and assurance; or

shortages of components or qualified personnel.

Our manufacturing facilities and those of Hitachi and any other of our contract manufacturers are or will be subject to periodic regulatory inspections by the FDA and other federal, state and international regulatory agencies and these facilities are or may become subject to Quality System Regulation, or QSR, requirements of the FDA. If we, Hitachi or our third-party manufacturers, fail to maintain facilities in accordance with QSR regulations, other international quality standards or other regulatory requirements, then the manufacture process could be suspended or terminated which would harm us.

*Lead times for obtaining materials and components for our products and the manufacturing and introduction of our products may vary significantly which could lead to excess inventory levels as well as shortages of critical components and products if our supply and demand forecasts are inaccurate.*

We anticipate that our products, including our ASRs and most of our other products will be manufactured and introduced by us and third parties, if any, based on forecasted demand and that we will seek to purchase components and materials in anticipation of the actual receipt of purchase orders from our customers. Lead times for materials and components to be included in our products vary significantly and may depend on factors such as the business practices of each specific supplier and the terms of the particular contracts, as well as the overall market demand for such materials and components at any given time. Also, we often rely on our own and third party forecasted demand for various products and the

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accuracy of such forecasts may depend on a number of factors, including but not limited to, government reports and recommendations for certain genetic testing, regulatory burdens, competitive products, the nature and effectiveness of our products, the timing and extent of the introduction of our products into the marketplace and other factors. If the forecasts are inaccurate, we could experience fluctuations in excess inventory of our products, or shortages of critical components or products, either of which could cause our business to suffer.

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*We currently rely on one manufacturer of our Workstation and for certain future generations of the Workstation and other hardware products, and only we manufacture our NanoChip® Cartridges, and our ASRs and most of our other products, which may delay the manufacture and shipment of our products to customers.*

We have signed an exclusive manufacturing agreement with Hitachi to manufacture our NanoChip® Workstation and a collaboration agreement to exclusively manufacture certain of our other second generation Workstations and other hardware products to be developed, subject to certain terms and conditions in each agreement. We have retained exclusive rights pursuant to each agreement to manufacture the NanoChip® Cartridges. Pursuant to the manufacturing agreement and the collaboration agreement, each party is obligated to provide the other with certain notice periods if such party determines to curtail or terminate the manufacturing relationship. Nevertheless, while alternative manufacturers of our Workstation and other products currently exist, a lengthy process would be required to negotiate and begin work under a manufacturing agreement with a new manufacturer which could disrupt our manufacturing process and harm our business.

*The number of our sales and marketing employees may not result in corresponding numbers of sales or placements of the NanoChip® System or sale of ASRs or other Nanogen products.*

As of October 2, 2003, we had 32 total employees in our worldwide sales and marketing group. In July 2000, we incorporated a subsidiary, Nanogen Europe B.V. in The Netherlands as our European sales office. As of October 2, 2003, this office employed 7 European-based sales executives and support personnel in the United Kingdom, Germany and The Netherlands.

Developing, training and monitoring this sales and marketing force has required and will further require capital and time expenditures by us and certain of our employees. The size of our sales and marketing force may not result in corresponding numbers of sales or placements of the NanoChip® System nor increased product revenues associated with such sales or placements or our ASRs or other products. We may be required to increase or decrease the size of this sales and marketing force as deemed necessary and such increases or decreases in staff will require additional capital and time expenditures by us and our employees.

*Failure to expand our international sales as we intend would reduce our ability to become profitable.*

We expect that a portion of our sales will be made outside the United States. A successful international effort will require us to develop relationships with international customers and partners. We may not be able to identify, attract or retain suitable international customers and distribution partners. As a result, we may be unsuccessful in our international expansion efforts. Furthermore, expansion into international markets will require us to continue to establish and expand foreign sales and marketing efforts, hire additional sales and marketing personnel and maintain good relations with our foreign customers and distribution partners.

International operations involve a number of risks not typically present in domestic operations, including:

currency fluctuation risks;

changes in regulatory requirements;



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costs and risks of deploying the NanoChip® System, ASRs and other products in foreign countries;

licenses, tariffs and other trade barriers;

political and economic instability, including the war on terrorism;

difficulties in staffing and managing foreign offices;

costs and difficulties in establishing and maintaining foreign distribution partnerships;

potentially adverse tax consequences; and

the burden of complying with a wide variety of complex foreign laws and treaties.

Our international sales and marketing efforts will also be subject to the risks associated with the imposition of legislation and regulations relating to the import or export of high technology products. We cannot predict whether tariffs or restrictions upon the importation or exportation of our products will be implemented by the United States or other countries.

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We may lose money when we exchange foreign currency received from international sales into U.S. dollars. A portion of our business is expected to be conducted in currencies other than the U.S. dollar. We recognize foreign currency gains or losses arising from our operations in the period incurred. As a result, currency fluctuations between the U.S. dollar and the currencies in which we do business will cause foreign currency transaction gains and losses. We cannot predict the effects of exchange rate fluctuations upon our future operating results because of the number of currencies involved, the variability of currency exposure and the potential volatility of currency exchange rates. We currently do not engage in foreign exchange hedging transactions to manage our foreign currency exposure.

*We may have significant product liability exposure.*

We face an inherent business risk of exposure to product liability and other claims in the event that our technologies or products are alleged to have caused harm. These risks are inherent in the testing, manufacturing and marketing of our products. Any potential product liability claims could exceed the amount of our insurance coverage or may be excluded from coverage under the terms of the policy. Our insurance may not be renewed at a cost and level of coverage comparable to that then in effect.

*If we lose our key personnel or are unable to attract and retain additional personnel, we may not be able to pursue collaborations or develop our own products.*

We are highly dependent on the principal members of our scientific, manufacturing, marketing, administrative, management and executive personnel, the loss of whose services might significantly delay or prevent the achievement of our objectives. We face competition from other companies, academic institutions, government entities and other organizations in attracting and retaining personnel. For the year ended December 31, 2002, the turnover rate at all levels at Nanogen was 39%. For the years ended December 31, 2001 and 2000 the turnover rates at Nanogen were 31% and 19%, respectively. Turnover at these rates may, and if they continue, will adversely affect us.

In October 2002, we reduced our workforce by approximately 10% and incurred severance charges of approximately \$290,000 during the fourth quarter of fiscal 2002 related to this event. We also reduced our workforce in April 2003 by approximately 20%. A severance charge of approximately \$500,000 was recognized in the second quarter of fiscal year 2003 related to this event. Continued layoffs could have an adverse effect on us.

*Health care reform and restrictions on reimbursement may limit our returns on potential products.*

Our ability to earn sufficient returns on our products will depend in part on the extent to which reimbursement for our products and related treatments will be available from:

government health administration authorities;

private health coverage insurers;

managed care organizations; and

other organizations.

If appropriate reimbursement cannot be obtained, we could be prevented from successfully commercializing our potential products.

There are efforts by governmental and third party payors to contain or reduce the costs of health care through various means. We expect that there will continue to be a number of legislative proposals to implement government controls. The announcement of proposals or reforms could impair our ability to raise capital. The adoption of proposals or reforms could impair our business.

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Additionally, third party payors are increasingly challenging the price of medical products and services. If purchasers or users of our products are not able to obtain adequate reimbursement for the cost of using our products, they may forego or reduce their use. Significant uncertainty exists as to the reimbursement status of newly approved health care products, and whether adequate third party coverage will be available.

*If ethical and other concerns surrounding the use of genetic information become widespread, we may have less demand for our products.*

Genetic testing has raised ethical issues regarding confidentiality and the appropriate uses of the resulting information. For these reasons, governmental authorities may call for limits on or regulation of the use of genetic testing or prohibit testing for genetic predisposition to certain conditions, particularly for those that have no known cure. Any of these scenarios could reduce the potential markets for our products, which could seriously harm our business, financial condition and results of operations.

*We use hazardous materials in our business. Any claims relating to improper handling, storage or disposal of these materials could be time consuming and costly.*

Our research and development processes involve the controlled storage, use and disposal of hazardous materials including, but not limited to, biological hazardous materials and radioactive compounds. We are subject to federal, state and local regulations governing the use, manufacture, storage, handling and disposal of materials and waste products. Although we believe that our safety procedures for handling and disposing of these hazardous materials comply with the standards prescribed by law and regulation, the risk of accidental contamination or injury from hazardous materials cannot be completely eliminated. In the event of an accident, we could be held liable for any damages that result, and any liability could exceed the limits or fall outside the coverage of our insurance. We may not be able to maintain insurance on acceptable terms, or at all. We could be required to incur significant costs to comply with current or future environmental laws and regulations.

*Our stock price could continue to be highly volatile and our stockholders may not be able to resell their shares at or above the price they paid for them.*

The market price of our common stock, like that of many other life sciences companies, has been highly volatile and is likely to continue to be highly volatile. The following factors, among others, could have a significant impact on the market price of our common stock:

the results of our premarket studies and clinical trials or those of our collaborators or competitors or for DNA testing in general;

evidence of the safety or efficacy of our potential products or the products of our competitors;

the announcement by us or our competitors of technological innovations or new products;

the announcement by us of acquisitions by customers of our NanoChip<sup>®</sup> System, ASRs or our other products;

announcements by us of government grants or contracts or of failure to obtain such government grants or contracts;

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announcements by us of involvement in litigation;

developments concerning our patents or other proprietary rights or those of our competitors, including other litigation or patent office proceedings;

loss of key board, executive, management or other personnel or the increase or decrease in size of our sales and marketing staff;

governmental regulatory actions or the failure to gain necessary clearances or approvals;

the ability to obtain necessary licenses;

changes or announcements in reimbursement policies;

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developments with our subsidiaries and collaborators;

changes in or announcements relating to acquisition programs for our products, including the expiration or continuation of our development site agreements;

period-to-period fluctuations in sales, inventories and our operating results;

market conditions for life science stocks and other stocks in general;

purchases by Nanogen pursuant to our stock repurchase program;

changes in estimates of our performance by securities analysts and the loss of coverage by one or more securities analysts;

the announcement by us of any stock repurchase plan, any purchases made thereunder by us and any cessation of the program by us;

changes in the United States war on terrorism and other geopolitical and military situations in which the country is involved; and

changes in the price of petroleum, heating oil and any other raw materials that we use at our facilities.

*By increasing the number of shares of our common stock that may be sold into the market, this offering could cause the market price of our common stock to drop significantly, even if our business is doing well.*

Sales of substantial amounts of common stock in the public market as a result of this offering could reduce the market price of our common stock and make it more difficult to sell equity securities in the future. The 4,228,791 shares covered by this prospectus may be resold into the public market.

The number of shares covered by this prospectus represents approximately 16.3% of the total number of our shares of common stock that are issued and outstanding. Sales of these shares in the public market, or the perception that future sales of these shares could occur, could have the effect of lowering the market price of our common stock below current levels.

*Our anti-takeover provisions could discourage potential takeover attempts and make attempts by stockholders to change management more difficult.*

The approval of two-thirds of our voting stock is required to approve some transactions and to take some stockholder actions, including the calling of a special meeting of stockholders and the amendment of any of the anti-takeover provisions contained in our certificate of incorporation. Further, pursuant to the terms of our stockholder rights plan adopted in November 1998, as amended, we have distributed a dividend of one right for each outstanding share of common stock. These rights will cause substantial dilution to the ownership of a person or group that attempts to acquire us on terms not approved in advance by our board of directors and may have the effect of deterring unsolicited takeover attempts.

*If we make any acquisitions, we will incur a variety of costs and may never realize the anticipated benefits.*

If appropriate opportunities become available, we may attempt to acquire businesses, technologies, services or products that we believe are a strategic fit with our business. We currently have no commitments or agreements with respect to any material acquisitions. If we do undertake any transaction of this sort, the process of integrating an acquired business, technology, service or product may result in operating difficulties and expenditures and may absorb significant management attention that would otherwise be available for ongoing development of our business. Moreover, we may never realize the anticipated benefits of any acquisition. Future acquisitions could result in potentially dilutive issuances of equity securities, the incurrence of debt, contingent liabilities and/or amortization expenses related to certain intangible assets and increased operating expenses, which could adversely affect our results of operations and financial condition.

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**STATEMENTS REGARDING FORWARD-LOOKING INFORMATION**

Various statements made in this prospectus under the captions *About Nanogen, Inc.* and *Risk Factors*, and made elsewhere in this prospectus are forward-looking statements. Forward-looking statements provide our current expectations or forecasts of future events. This prospectus includes, without limitation, forward-looking information about the following:

the development of the markets and demand for our products and services;

our product development plans, including the introduction of new products, and anticipated activities designed to pursue these plans, including collaborations and other corporate partnering arrangements;

our ability to generate substantial revenues from sales of products and consumable cartridges and reagents and continuing revenues from reagent rental agreements;

the ability of our product platform to affect the market and become an industry standard;

our ability to generate license and other fee revenue in the future;

the amounts we invest in research and development activities in the future;

future levels of operating expenses associated with our business;

operating results of joint ventures and other corporate partnering arrangements;

competition that we may face from competitors;

the protection afforded to us by intellectual property law;

the outcome of a pending lawsuit against us;

the amounts and timing of our contractual obligations and capital commitments;

our future revenues and results of operations;

our future exposure to market risk; and

our future capital needs and our ability to fund those needs.



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When used in this prospectus, the words may, will, expect, anticipate, intend, plan, believe, seek, estimate, future, could, envision, potentially, and similar expressions are generally intended to identify forward-looking statements, but are not the exclusive expressions of forward-looking statements. Because forward-looking statements involve risks and uncertainties, there are important factors that could cause actual results to differ materially from those expressed or implied by these forward-looking statements, including those risks discussed in this prospectus and the documents incorporated herein by reference.

In addition, our performance and financial results could differ materially from those reflected in these forward-looking statements due to general financial, economic, regulatory and political conditions affecting the molecular diagnostics industry. Given these risks and uncertainties, any or all of these forward-looking statements may prove to be incorrect. Therefore, you are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date made. Furthermore, we undertake no obligation to publicly update any forward-looking statements. We claim the protections afforded by the Private Securities Litigation Reform Act of 1995, as amended, for our forward-looking statements.

### USE OF PROCEEDS

We will not receive any of the proceeds from the sale of common stock offered under this prospectus.

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The selling security holders identified in the following table, including their respective donees, transferees, pledgees or other successors-in-interest, are offering for sale 4,228,791 shares of common stock, of which 2,121,211 shares are issued and outstanding and 2,107,580 shares are exercisable upon the exercise of warrants. We previously issued the 2,121,211 outstanding shares and warrants to purchase 2,057,580 shares of common stock in a private placement transaction pursuant to Securities Purchase Agreements dated as of September 17, 2003, and we previously issued warrants to purchase 50,000 shares of common stock in a private placement transaction pursuant to a License Agreement with GeneType AG dated April 12, 2002.

The following table sets forth as of September 29, 2003 the number of shares beneficially owned by the selling security holders. Beneficial ownership is determined in accordance with the rules of the SEC and generally includes voting or investment power with respect to securities. The shares of common stock issuable upon the exercise of warrants exercisable within 60 days after September 29, 2003 are deemed outstanding and to be beneficially owned by the selling security holders holding such warrants. The percentage of ownership for the selling security holders disclosed in this table is based on 23,906,905 shares of common stock outstanding as of September 29, 2003. Both the number of shares listed as being offered by the selling security holders in the table and the holders' respective percentages of share ownership after the offering are based on the assumptions that all of the shares being offered are sold pursuant to this offering, and that no other shares of common stock are acquired or disposed of by the selling security holders prior to the termination of this offering. Because the selling security holders may sell all, some or none of their shares or may acquire or dispose of other shares of common stock, we cannot estimate the aggregate number of shares that will be sold in this offering or the number or percentage of shares of common stock that the selling security holders will own upon completion of this offering.

The selling security holders, including their respective donees, transferees, pledgees or other successors-in-interest, may offer their shares of common stock for sale from time to time at market prices prevailing at the time of sale or at negotiated prices.

Name of Selling Security Holder	Beneficial Ownership of Selling Security Holder Prior to Offering		Number of Shares Offered	Beneficial Ownership of Selling Security Holder After Offering	
	Number	Percentage		Number	Percentage
AIG DKR Soundshore Strategic Holding Fund Ltd.	298,485(1)	1.2%	298,485(1)	0	0%
Ariel Fund Limited	399,910(2)	1.7%	399,910(2)	0	0%
Cohanzyck Partners, L.P.	205,955(3)	*	205,955(3)	0	0%
Elliott Associates, L.P.(4)	260,000(5)	1.1%	197,000(5)	63,000	*
Elliott International, L.P.(4)	322,500(6)	1.3%	295,500(6)	27,000	*
Gabriel Capital, L.P.	289,590(7)	1.2%	289,590(7)	0	0%
GeneType AG	50,000(8)	*	50,000(8)	0	0%
JMB Capital Partners, L.P.	895,455(9)	3.7%	895,455(9)	0	0%
Langley Partners, L.P.	1,477,500(10)	6.0%	1,477,500(10)	0	0%
Truk Opportunity Fund, LLC	119,396(11)	*	119,396(11)	0	0%
<b>Total</b>			<b>4,228,791</b>		

\* Less than 1%.

(1) Includes shares issuable upon the exercise of warrants to purchase 78,788 shares at an exercise price of \$4.14 per share that expire on March 18, 2004, warrants to purchase 37,879 shares at an exercise price of \$4.75 per share that expire on September 20, 2004 and warrants to purchase 30,303 shares at an exercise price of \$4.75 per share, subject to certain adjustments, that expire on September 18, 2008.



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- (2) Includes shares issuable upon the exercise of warrants to purchase 105,560 shares at an exercise price of \$4.14 per share that expire on March 18, 2004, warrants to purchase 50,750 shares at an exercise price of \$4.75 per share that expire on September 20, 2004 and warrants to purchase 40,600 shares at an exercise price of \$4.75 per share, subject to certain adjustments, that expire on September 18, 2008.
- (3) Includes shares issuable upon the exercise of warrants to purchase 54,364 shares at an exercise price of \$4.14 per share that expire on March 18, 2004, warrants to purchase 26,137 shares at an exercise price of \$4.75 per share that expire on September 20, 2004 and warrants to purchase 20,909 shares at an exercise price of \$4.75 per share, subject to certain adjustments, that expire on September 18, 2008.
- (4) Elliott Associates, L.P. and Elliott International, L.P. are affiliates.
- (5) Includes shares issuable upon the exercise of warrants to purchase 52,000 shares at an exercise price of \$4.14 per share that expire on March 18, 2004, warrants to purchase 25,000 shares at an exercise price of \$4.75 per share that expire on September 20, 2004 and warrants to purchase 20,000 shares at an exercise price of \$4.75 per share, subject to certain adjustments, that expire on September 18, 2008.
- (6) Includes shares issuable upon the exercise of warrants to purchase 78,000 shares at an exercise price of \$4.14 per share that expire on March 18, 2004, warrants to purchase 37,500 shares at an exercise price of \$4.75 per share that expire on September 20, 2004 and warrants to purchase 30,000 shares at an exercise price of \$4.75 per share, subject to certain adjustments, that expire on September 18, 2008.
- (7) Includes shares issuable upon the exercise of warrants to purchase 76,440 shares at an exercise price of \$4.14 per share that expire on March 18, 2004, warrants to purchase 36,750 shares at an exercise price of \$4.75 per share that expire on September 20, 2004 and warrants to purchase 29,400 shares at an exercise price of \$4.75 per share, subject to certain adjustments, that expire on September 18, 2008.
- (8) Consists of shares issuable upon the exercise of warrants at an exercise price of \$4.10 per share, subject to certain adjustments.
- (9) Includes shares issuable upon the exercise of warrants to purchase 236,364 shares at an exercise price of \$4.14 per share that expire on March 18, 2004, warrants to purchase 113,637 shares at an exercise price of \$4.75 per share that expire on September 20, 2004 and warrants to purchase 90,909 shares at an exercise price of \$4.75 per share, subject to certain adjustments, that expire on September 18, 2008.
- (10) Includes shares issuable upon the exercise of warrants to purchase 390,000 shares at an exercise price of \$4.14 per share that expire on March 18, 2004, warrants to purchase 187,500 shares at an exercise price of \$4.75 per share that expire on September 20, 2004 and warrants to purchase 150,000 shares at an exercise price of \$4.75 per share, subject to certain adjustments, that expire on September 18, 2008. Each warrant contains a provision limiting the exercise of such warrant if such exercise would cause Langley Partners, L.P. to beneficially own more than 4.9999% of the issued and outstanding shares of the Company. Accordingly, Langley Partners, L.P. disclaims beneficial ownership of any shares otherwise issuable upon the exercise of its warrants in excess of such limitation.
- (11) Includes shares issuable upon the exercise of warrants to purchase 31,516 shares at an exercise price of \$4.14 per share that expire on March 18, 2004, warrants to purchase 15,152 shares at an exercise price of \$4.75 per share that expire on September 20, 2004 and warrants to purchase 12,122 shares at an exercise price of \$4.75 per share, subject to certain adjustments, that expire on September 18, 2008.

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**PLAN OF DISTRIBUTION**

We are registering the shares of common stock on behalf of the selling security holders. Sales of shares may be made by selling security holders, including their respective donees, transferees, pledgees or other successors-in-interest, from time to time on the Nasdaq National Market, any other exchange upon which our shares may trade in the future, in the over-the-counter market or otherwise, at market prices prevailing at the time of sale, at prices related to market prices, or at negotiated or fixed prices. The shares may be sold by one or more of, or a combination of, the following:

a block trade in which the broker-dealer so engaged will attempt to sell the shares as agent but may position and resell a portion of the block as principal to facilitate the transaction;

purchases by a broker-dealer as principal and resale by such broker-dealer for its account pursuant to this prospectus;

ordinary brokerage transactions and transactions in which the broker solicits purchases through options, swaps or derivatives;

in privately negotiated transactions;

through the settlement of short sales; and

put or call option transactions relating to the shares.

The selling security holders may effect these transactions by selling shares directly to purchasers or to or 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 security holders and/or the purchasers of shares for whom such broker-dealers may act as agents or to whom they sell as principals, or both (which compensation as to a particular broker-dealer might be in excess of customary commissions). The selling security holders may also sell shares of common stock short and deliver shares covered by this prospectus to close out short positions, provided that the short sale is made after the registration statement is declared effective and a copy of this prospectus is delivered in connection with the short sale. The selling security holders have advised us that they have not entered into any agreements, understandings or arrangements with any underwriters or broker-dealers regarding the sale of their securities.

The selling security holders may enter into hedging transactions with broker-dealers or other financial institutions. In connection with those transactions, the broker-dealers or other financial institutions may engage in short sales of the shares or of securities convertible into or exchangeable for the shares in the course of hedging positions they assume with the selling security holders. The selling security holders may also enter into options or other transactions with broker-dealers or other financial institutions which require the delivery of shares offered by this prospectus to those broker-dealers or other financial institutions. The broker-dealer or other financial institution may then resell the shares pursuant to this prospectus (as amended or supplemented, if required by applicable law, to reflect those transactions).

The selling security holders and any broker-dealers that act in connection with the sale of shares may be deemed to be underwriters within the meaning of Section 2(11) of the Securities Act of 1933, and any commissions received by broker-dealers or any profit on the resale of the shares sold by them while acting as principals may be deemed to be underwriting discounts or commissions under the Securities Act. The selling security holders may agree to indemnify any agent, dealer or broker-dealer that participates in transactions involving sales of the shares against liabilities, including liabilities arising under the Securities Act.

The selling security holders will be subject to the prospectus delivery requirements of the Securities Act. The selling security holders and any other person participating in the distribution of the shares will be subject to the applicable provisions of the Securities Exchange Act of 1934 and the rules and regulations thereunder, including, without limitation, Regulation M of the Exchange Act, which may limit the timing of purchases and

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sales of any of the shares by the selling security holders and any other participating person. Regulation M may also restrict the ability of any person engaged in the distribution of the shares to engage in market-making activities with respect to the shares of common stock.

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

Upon being notified by a selling security holder that a material arrangement has been entered into with a broker-dealer for the sale of 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 to this prospectus, if required pursuant to Rule 424(b) under the Securities Act, disclosing:

the name of the selling security holder and of the participating broker-dealer(s);

the number of shares involved;

the initial price at which the shares were sold;

the commissions paid or discounts or concessions allowed to the broker-dealer(s), where applicable;

that such broker-dealer(s) did not conduct any investigation to verify the information set out or incorporated by reference in this prospectus; and

other facts material to the transactions.

In addition, we will file a supplement to this prospectus when a selling security holder notifies us that a donee or pledgee intends to sell more than 500 shares of common stock.

*Expenses Associated with Registration.* We are paying all expenses and fees in connection with the registration of the shares. The selling security holders will bear all brokerage or underwriting discounts or commissions paid to broker-dealers in connection with the sale of the shares.

## **LEGAL MATTERS**

The legality of the common stock offered by this prospectus has been passed upon for us by Morgan, Lewis & Bockius LLP, Philadelphia, Pennsylvania.

**EXPERTS**

The consolidated financial statements of Nanogen, Inc. appearing in our Annual Report (Form 10-K) for the year ended December 31, 2002, have been audited by Ernst & Young LLP, independent auditors, as set forth in their report thereon included therein and incorporated herein by reference. Such consolidated financial statements are incorporated herein by reference in reliance upon such report given on the authority of such firm as experts in accounting and auditing.



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**WHERE YOU CAN FIND MORE INFORMATION**

This prospectus is part of a registration statement that we filed with the Securities and Exchange Commission. The registration statement that contains this prospectus, including the exhibits to the registration statement, contains additional information about us and the securities offered under this prospectus. We file annual, quarterly and special reports, proxy statements and other information with the Commission. You may read and copy any document we file at the Commission's Public Reference Room at 450 Fifth Street, N.W., Washington, D.C. 20549. Please call the Commission at 1-800-SEC-0330 for further information on the Public Reference Room. Our public filings, including reports, proxy and information statements, are also available on the Commission's web site at <http://www.sec.gov>.

The Securities and Exchange Commission allows us to incorporate by reference information from other documents that we file with them, which means that we can disclose important information by referring to those documents. The information incorporated by reference is considered to be part of this prospectus, and information that we file later with the Commission will automatically update and supersede this information. We incorporate by reference into this prospectus the documents listed below, and any future filings we make with the Commission under Sections 13(a), 13(c), 14 or 15(d) of the Securities Exchange Act of 1934 prior to the termination of this offering:

our annual report on Form 10-K for the year ended December 31, 2002, filed with the Commission on March 31, 2003;

our quarterly reports on Form 10-Q for the quarters ended March 31, 2003 and June 30, 2003;

our current reports on Form 8-K filed with the Commission on May 22, 2003 and September 22, 2003;

all other reports filed under Section 13(a) or 15(d) of the Securities Exchange Act of 1934 since December 31, 2002; and

the description of our common stock contained in our registration statement on Form 8-A12G filed under Section 12(g) of the Securities Exchange Act of 1934 with the Commission on April 7, 1998, including any amendment or reports filed for the purpose of updating such description.

To the extent that any statement in this prospectus is inconsistent with any statement that is incorporated by reference and that was made on or before the date of this prospectus, the statement in this prospectus shall supersede such incorporated statement. The incorporated statement shall not be deemed, except as modified or superceded, to constitute a part of this prospectus or the registration statement. Statements contained in this prospectus as to the contents of any contract or other document are not necessarily complete and, in each instance, we refer you to the copy of each contract or document filed as an exhibit to the registration statement.

We will furnish without charge to each person, including any beneficial owner, to whom a copy of this prospectus is delivered, upon written or oral request, a copy of the information that has been incorporated into this prospectus by reference (except exhibits, unless they are specifically incorporated into this prospectus by reference). You should direct any requests for copies to:

Nanogen, Inc.

Attn: General Counsel

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