

NANOGEN INC  
Form 424B3  
January 03, 2005  
Table of Contents

Filed pursuant to Rule 424(b)(3)

File No. 333-121511

**PROSPECTUS**

**202,001 Shares**

**NANOGEN, INC.**

**Common Stock**

---

This prospectus relates to the offer and sale of up to 202,001 shares of common stock of Nanogen, Inc. ( *Nanogen* ) issuable by us upon exercise of options to acquire shares of our common stock by certain former optionholders of Epoch Biosciences, Inc. ( *Epoch* ) in connection with our acquisition of Epoch. We assumed the options pursuant to the terms of the Agreement and Plan of Merger and Reorganization dated September 7, 2004, by and among Nanogen, Epoch, and Empire Acquisition Corp. (the *Merger Agreement* ). Pursuant to the terms of the Merger Agreement, these options were converted into options to purchase 202,001 shares of Nanogen common stock.

**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 3-15 of this prospectus.**

Our common stock trades on the Nasdaq National Market under the symbol NGEN. On December 30, 2004, the last reported sale price of our common stock on the Nasdaq National Market was \$7.52.

---

**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.**

---

The date of this prospectus is January 3, 2005.

**Table of Contents**

**TABLE OF CONTENTS**

	<b>Page</b>
<u>ABOUT THIS PROSPECTUS</u>	1
<u>ABOUT NANOGEN, INC.</u>	2
<u>RISK FACTORS</u>	3
<u>STATEMENTS REGARDING FORWARD-LOOKING INFORMATION</u>	15
<u>USE OF PROCEEDS</u>	16
<u>PLAN OF DISTRIBUTION</u>	16
<u>LEGAL MATTERS</u>	16
<u>EXPERTS</u>	16
<u>WHERE YOU CAN FIND MORE INFORMATION</u>	17
<u>INCORPORATION OF CERTAIN DOCUMENTS BY REFERENCE</u>	17

**Table of Contents**

**ABOUT THIS PROSPECTUS**

This prospectus is part of a registration statement that we filed with the Securities and Exchange Commission using a shelf registration process. This prospectus relates to the issuance of 202,001 shares of our common stock upon the exercise of options to purchase shares of our common stock, which options were assumed by us in the merger of Empire Acquisition Corp., our wholly owned subsidiary, with and into Epoch Biosciences, Inc.

You should rely only on the information contained in or specifically incorporated by reference into this prospectus or a supplement. 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.

**Table of Contents**

**ABOUT NANOGEN, INC.**

**General**

Nanogen was founded on the vision of integrating multiple scientific disciplines to develop diagnostic products. Through advances in genomic and pharmaceutical research, Nanogen believed that diagnostics and therapeutics would become closely linked. Further, Nanogen believed that by using electronics, Nanogen could develop a highly accurate and flexible set of products that would facilitate the analysis of complex genetic relationships and the correlation to disease and therapies. This vision in turn led to the definition of Nanogen's mission: to become a leading provider of high quality innovative advanced diagnostic products and services to patients, providers and pharmaceutical companies.

Nanogen currently develops and commercializes molecular diagnostics products and tests for the gene-based testing market for sale primarily in the United States, Europe and the Pacific Rim. By integrating microelectronics and molecular biology into a core proprietary technology platform, Nanogen seeks to establish the unique, open-architecture design of its primary products, the NanoChip<sup>®</sup> Molecular Biology Workstation and the NanoChip<sup>®</sup> Cartridge (collectively, the NanoChip<sup>®</sup> System), as a standard platform for molecular identification and analysis. In furtherance of its mission to become a leading supplier of advanced diagnostics testing products, Nanogen is developing a broad menu of Analyte Specific Reagents (ASRs) and other commercial applications for the NanoChip<sup>®</sup> System. Nanogen continually conducts research and development by itself and with third parties, to improve the NanoChip<sup>®</sup> System and to extend its technology to other applications such as biodefense, forensics, drug discovery and pharmacogenomics. Nanogen has several ASRs and other applications of its proprietary technology under development and is developing a pipeline of point-of-care tests, including tests for congestive heart failure, stroke and traumatic brain injury.

**Recent Developments**

On December 16, 2004, Nanogen completed its acquisition of Epoch Biosciences, Inc. ( Epoch ), a biotechnology company based in Bothell, Washington, pursuant to the Agreement and Plan of Merger and Reorganization dated September 7, 2004, among Nanogen, Epoch, and Empire Acquisition Corp. Under the terms of the Merger Agreement, Nanogen issued 0.4673 of a share of its common stock for each outstanding share of Epoch common stock. In addition, Nanogen assumed all of the outstanding warrants and options of Epoch, and those securities became exercisable or convertible into Nanogen common stock, with appropriate adjustments to reflect the application of the exchange ratio in the merger.

Nanogen was originally incorporated in California and reincorporated in Delaware in 1997. References herein to Nanogen refer to Nanogen, Inc. and its subsidiaries. Nanogen's headquarters are located at 10398 Pacific Center Court, San Diego, CA 92121, and Nanogen's telephone number is (858) 410-4600. Additional information about Nanogen is available on Nanogen's website at [www.nanogen.com](http://www.nanogen.com), which does not constitute a part of this prospectus.

---

**Table of Contents**

**RISK FACTORS**

An investment in our common stock involves a high degree of risk. Our business, financial condition or results of operations could be harmed by any of these risks. The risks and uncertainties described below are not the only ones we face. Additional risks not presently known to us or other factors not perceived by us to present significant risks to our business at this time also may impair our business operations.

*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 September 30, 2004, we had only a limited product offering that includes our NanoChip<sup>®</sup> System (which consists of our NanoChip<sup>®</sup> Molecular Biology Workstation and NanoChip<sup>®</sup> Cartridge), NanoChip<sup>®</sup> Cartridge, various ASRs for detection of gene mutations associated with diseases such as cystic fibrosis, general purpose reagents and accessories to facilitate assay and protocol development and validation on the NanoChip Platform and, through our acquisition of SynX, point-of-care diagnostic tests for myocardial infarction and drugs of abuse. We announced our second-generation instrument, the NanoChip<sup>®</sup> 400, in October 2004. This new instrument will begin shipping in 2005. All of our other platforms and ASRs and other potential products are under development. Our NanoChip<sup>®</sup> 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.

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 September 30, 2004 require customer acceptance of our CFTR ASRs as a pre-condition to the customer's commitment to purchase reagents. 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.

*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 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. In September 2004, June 2004 and September 2003 we took accounting charges of approximately \$904,000, \$1.5 million and \$829,000, respectively, to reduce product inventory to its estimated net realizable value. If actual future demand or market conditions are less favorable than those projected by us, additional inventory write-downs may be required. 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;



## Table of Contents

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.

Performance issues with our products may also harm market acceptance of our products and reduce our revenues. During the nine months ended September 30, 2004, we experienced performance issues with our CFTR ASR which negatively impacted our revenue. Certain of the clinical research laboratories using our CFTR ASR experienced validation rates and repeat rates which were not satisfactory, increasing their costs and labor associated with the tests. We are in the process of making improvements to our CFTR ASR to address these issues. Nonetheless, we may not be able to address these issues to the satisfaction of our clinical laboratory customers and they may decide to adopt alternative products or may not resume purchases of our CFTR ASR.

*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. 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.

In August 2003, Hitachi, Ltd. exercised its right to terminate the research collaboration agreement it has with us. The agreement terminated during the second quarter of 2004. Our manufacturing and distribution agreements with Hitachi remain in place. In October 2001, SynX entered into a development and manufacturing agreement with Princeton BioMeditech Corporation ( PBM ) which granted PBM exclusive rights to develop and manufacture certain point-of-care products of SynX, as well as rights to share in the profits of such products. As a result, our success in the point-of-care market is dependent upon PBM 's ability to perform under the agreement. 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. In February 2004, the shareholders of Nanogen Recognomics decided to convert Nanogen Recognomics into a non-operating holding company to attempt to commercialize its intellectual property through licensing and sales transactions.

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 recently announced our second-generation instrument system. The transition to new products subjects us to risks and uncertainties, including increased risks of excess or obsolete inventory and inventory related write-downs.*

## Edgar Filing: NANOGEN INC - Form 424B3

In October 2004, we announced our second-generation instrument system, the NanoChip® 400. This new instrument will begin shipping next year. Risks inherent in the transition to our second-generation system and other new products we may release in the future include:

potential delays in initial shipments of new products;

4



**Table of Contents**

the possibility that new products may erode demand for our current products, including those under reagent rental agreements, causing a decline in sales of current products and an excessive, obsolete supply of inventory;

potential delays in customer purchases in anticipation of new product releases or a decision by customers to evaluate new products for longer periods of time before making a purchase;

uncertainties in product pricing and market acceptance;

additional costs related to providing customer support and service for both first generation and second generation systems; and

unexpected technical or operational problems with the new products.

If any of these risks occur, our revenues could decline and our financial condition could be harmed.

During the three and nine months ended September 30, 2004, we increased our reserve related to our inventory of NanoChip<sup>®</sup> Molecular Biology Workstations and accessory items by approximately \$900,000 and \$2.4 million respectively, due in part to our announcement of the NanoChip<sup>®</sup> 400. If actual future demand for our first-generation products is less favorable than management's projections, additional inventory write-downs may be required, and would be reflected in cost of sales in the period the revision is made.

*Past and future mergers and acquisitions could be difficult to integrate, disrupt our business, dilute the ownership interests of our stockholders and harm our operating results. We may never realize the anticipated benefits of our acquisitions.*

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. On December 16, 2004, we completed our acquisition of Epoch Biosciences, Inc., a biotechnology company based in Bothell, Washington in an all-stock transaction. In April 2004 we completed our acquisition of SynX Pharma Inc., a point-of-care diagnostic company. The process of integrating Epoch, SynX or any other acquired business, technology, service or product requires significant efforts and expenditures, including the coordination of information technologies, research and development, sales and marketing, administration and manufacturing. Additionally, Epoch is located in Washington and SynX is located in Canada and because our facilities are physically separated, it may be difficult for us to communicate effectively with, manage and integrate these employees and operations with the rest of the Company. If we are not able to integrate the operations of acquired companies and businesses successfully, we may not be able to meet our expectations of future results of operations. Future acquisitions could also 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.

Factors that will affect the success of our mergers and acquisitions include:

presence or absence of adequate internal controls and/or significant fraud in the financial systems of acquired companies;

the ability to retain key employees;

## Edgar Filing: NANOGEN INC - Form 424B3

competitive factors, including technological advances attained by competitors and patents granted to, or contested by competitors, which would result in increased efficiency in their ability to compete against us;

the ability of the combined company to increase sales of all such companies' products; and

the ability of the combined company to operate efficiently and achieve cost savings.

## Table of Contents

Even if we are able to successfully integrate our acquired operations, we may never realize the anticipated benefits of the Epoch acquisition, the SynX acquisition, or any other acquisition. Our failure to achieve synergies could have a material adverse effect on the business, results of operations and financial condition of the combined company. In addition, to the extent that the economic benefits associated with any of our acquisitions diminish in the future, we may be required to record additional write downs of goodwill, intangible assets or other assets associated with such acquisitions, which would adversely affect our operating results.

*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 September 30, 2004, total approximately \$204 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<sup>®</sup> System choose to enter into sales, reagent rentals, cost-per-test or development site transactions. We believe our future operating results may be subject to quarterly fluctuations due to a variety of factors, including, but not limited to, market acceptance of the NanoChip<sup>®</sup> System, including the NanoChip<sup>®</sup> 400, and potential other products under development, including the CHF product and diagnostics related to infectious disease, the type of acquisition program our potential customers may choose, whether and when new products are successfully developed and introduced by us or our competitors, and the achievement of milestones under our collaborative agreements with Hitachi and various government agencies. The recognition of revenue under contracts, grants and sponsored research agreements will be subject to significant fluctuations in both timing and amount and therefore our results of operations for any period may not be comparable to the results of operations for any other period.

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 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;

## Edgar Filing: NANOGEN INC - Form 424B3

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.

## **Table of Contents**

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;

companies developing molecular diagnostic tests; and

companies developing point-of-care diagnostic tests.

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 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.

## **Table of Contents**

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. One such interference has recently been declared between U. S. Patent 6,461,828 owned by our Canadian subsidiary, SYN-X Pharma, and a patent application owned by Biosite Incorporated ( Biosite ). The count of the interference is directed to a method for predicting cardiac mortality in a patient using pairs of biological markers. Among the markers within the scope of the count are pro-BNP and troponin I, markers which are the basis of a product being developed by SYN-X for the prognosis of congestive heart failure. Even though Biosite is the senior party in the interference because of its earlier filing date, the Company believes that it will be able to prove an earlier date of invention and thus prevail in the interference. However, if Biosite prevails it may obtain a patent having claims corresponding exactly or closely to the count of the interference. If that were to occur, the Company would be precluded from marketing in the United States a product for predicting cardiac mortality using the markers within the scope of any claim obtained by Biosite. We may in the future become subject to other 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.

**Table of Contents**

*We may continue to be 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. In April 2003, we filed an answer to the complaint that denied that we infringe this patent. In October 2003, we entered into a settlement agreement with Oxford Gene Technologies pursuant to which the lawsuit was dismissed by Oxford Gene Technology without prejudice. If the litigation were to be reinitiated, 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 any further litigation nor the amount and range of potential fees can be assessed. No assurances can be given that we would prevail in any future lawsuits or that we could successfully defend ourselves against any future claims.

*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;



## Edgar Filing: NANOGEN INC - Form 424B3

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.

## **Table of Contents**

*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, Hitachi and PBM 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 qualification under applicable FDA regulations. In addition, an uncorrected defect or supplier's variation in a component or raw material, either unknown to us, Hitachi or PBM or incompatible with our, Hitachi or PBM's manufacturing processes, could harm our, Hitachi or PBM's ability to manufacture our products. We, Hitachi or PBM 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, Hitachi or PBM fail to obtain a supplier for the manufacture of components of our 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, including the second-generation NanoChip® 400, we manufacture our NanoChip® Cartridges, our ASRs and most of our other products, and PBM manufactures our point-of-care products. We, Hitachi and PBM 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, Hitachi or PBM either alone, together or with subcontractors, attempt to further scale up manufacturing procedures or to manufacture new products. We, Hitachi or PBM 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, Hitachi or PBM 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 PBM 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, PBM 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

## Table of Contents

party forecasted demand for various products and the 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.

*We currently rely on one manufacturer of our Workstation and for certain future generations of the Workstation and other hardware products, one manufacturer for our point-of-care 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 second generation NanoChip® 400 workstations and other hardware products to be developed. We have retained exclusive rights pursuant to each agreement to manufacture the NanoChip® Cartridges. Pursuant to the manufacturing agreements 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, the sale of ASRs, point-of-care diagnostic products or other Nanogen products*

As of September 30, 2004, we had 38 total employees in our worldwide sales and marketing group.

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, point-of-care diagnostic products or other products. We may be required to increase or decrease the size of the 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;

costs and risks of deploying the NanoChip® System, including the second-generation NanoChip® 400, ASRs, point-of-care diagnostics, and other products in foreign countries;

licenses, tariffs and other trade barriers;

**Table of Contents**

- 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.

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 product liability claim brought against us could be expensive to defend and could result in a diversion of management's attention from our core business. A successful product liability claim or series of claims could have an adverse effect on our business, financial condition and results of operations.

*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, 2003, the turnover rate at all levels at Nanogen was 25%. For the years ended December 31, 2002 and 2001 the turnover rates at Nanogen were 29% and 31%, respectively. During the nine month period ended September 30, 2004, we experienced a turnover rate equivalent to approximately 31% annualized. Turnover at these rates may, and if they continue, will adversely affect us.

## Edgar Filing: NANOGEN INC - Form 424B3

The turnover rates above exclude the impact of reductions in workforce. In April 2003, we reduced our workforce by approximately 20% and incurred a severance charge of approximately \$500,000 in the second quarter of 2003. Also, in October 2002, we reduced our workforce by approximately 10% and incurred severance charges of approximately \$290,000 during the fourth quarter of 2002. 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;

**Table of Contents**

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.

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;

**Table of Contents**

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

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

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;

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, nanotechnology stocks and other stocks in general;

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.

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

## Edgar Filing: NANOGEN INC - Form 424B3

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.

*Our business is subject to changing regulation of corporate governance and public disclosure that has increased both our costs and the risk of noncompliance.*

Because our common stock is publicly traded, we are subject to certain rules and regulations of federal, state and financial market exchange entities charged with the protection of investors and the oversight of companies whose securities are publicly traded. These entities, including the Public Company Accounting Oversight Board,

## **Table of Contents**

the SEC and Nasdaq, have recently issued new requirements and regulations and continue to develop additional regulations and requirements in response to recent laws enacted by Congress, most notably the Sarbanes-Oxley Act of 2002 ( SOX ). Our efforts to comply with these new regulations have resulted in, and are likely to continue to result in, increased general and administrative expenses and a diversion of management time and attention from revenue-generating activities to compliance activities.

In particular, our efforts to comply with Section 404 of SOX and the related regulations regarding our required assessment of our internal controls over financial reporting and our external auditors' audit of that assessment has required, and continues to require, the commitment of significant financial and managerial resources. Although we believe that the ongoing review of our internal controls will enable us to provide an assessment of our internal controls and our external auditors to provide their audit opinion as of December 31, 2004 as required by Section 404 of SOX, we can give no assurance that these efforts will be completed on a timely and successful basis.

Moreover, because these laws, regulations and standards are subject to varying interpretations, their application in practice may evolve over time as new guidance becomes available. This evolution may result in continuing uncertainty regarding compliance matters and additional costs necessitated by ongoing revisions to our disclosure and governance practices.

## **STATEMENTS REGARDING FORWARD-LOOKING INFORMATION**

Various statements made in this prospectus or incorporated by reference into 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 acquisitions of businesses and technologies, 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;

our ability to integrate Epoch Biosciences, Inc., SynX Pharma Inc. and any other acquired companies and to realize anticipated synergies from these acquisitions;

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 selling, general and administrative expenses and other expenses associated with our business;

## Edgar Filing: NANOGEN INC - Form 424B3

operating results of acquired companies, businesses, collaborations, joint ventures and other corporate partnering arrangements;

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

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

our product launch plans.

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

## **Table of Contents**

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**

The shares offered hereby are being offered by Nanogen. We currently intend to use the net proceeds from the exercise of the options for general corporate purposes. We will pay all of the expenses of the offering.

### **PLAN OF DISTRIBUTION**

We are registering 202,001 shares of our common stock issuable upon the exercise of options held by individuals who are not, and have not been, employees of Nanogen. The options were assumed by us in the merger of Empire Acquisition Sub, our wholly owned subsidiary, with and into Epoch Biosciences, Inc. The shares of our common stock offered by the prospectus will be quoted on The Nasdaq Stock Market.

### **LEGAL MATTERS**

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

### **EXPERTS**

Ernst & Young LLP, independent registered public accounting firm, have audited our consolidated financial statements included in our Annual Report on Form 10-K for the year ended December 31, 2003, as set forth in their report, which is incorporated by reference in this prospectus and elsewhere in the registration statement. Our financial statements are incorporated by reference in reliance on Ernst & Young LLP's report, given on their authority as experts in accounting and auditing.

## Edgar Filing: NANOGEN INC - Form 424B3

The financial statements of Epoch Biosciences, Inc. as of December 31, 2003 and 2002, and for each of the years in the three-year period ended December 31, 2003, appearing in Nanogen's Current Report on Form 8-K filed December 21, 2004 have been audited by KPMG LLP, independent registered public accounting firm, as set forth in their report included therein and incorporated by reference herein, and upon the authority of said firm as experts in accounting and auditing. The audit report containing the December 31, 2003 financial statements refers to the adoption of SFAS No. 142, Goodwill and Other Intangible Assets, effective January 2002.

The consolidated financial statements of SynX Pharma Inc. as of December 31, 2003 and 2002, and for each of the years in the two-year period ended December 31, 2003, have been incorporated by reference herein in reliance upon the audit report and the comments for US readers of KPMG LLP, chartered accountants, incorporated by reference herein, and upon the authority of said firm as experts in accounting and auditing.

**Table of Contents**

**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 by 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>.

**INCORPORATION OF CERTAIN DOCUMENTS BY REFERENCE**

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 (other than the portions thereof deemed to be furnished to the Commission) 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, 2003, filed with the Commission on March 30, 2004;

our quarterly reports on Form 10-Q for the quarters ended March 31, 2004, June 30, 2004 and September 30, 2004;

our current reports on Form 8-K filed with the Commission on February 10, 2004, March 4, 2004, March 9, 2004, May 6, 2004, June 3, 2004, July 6, 2004, August 13, 2004, September 8, 2004, December 8, 2004 and December 21, 2004; and

the description of our common stock contained in our registration statement on Form 8-A 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

10398 Pacific Center Court

San Diego, CA 92121

(858) 410-4600

Table of Contents

**202,001 SHARES**

**NANOGEN, INC.**

**COMMON STOCK**

---

**PROSPECTUS**

---

**January 3, 2005**