NANOGEN INC Form 424B5 September 29, 2005 Table of Contents

Filed Pursuant to Rule 424(b)(5)

Registration Statement No. 333-125975

Prospectus Supplement

(To Prospectus dated June 28, 2005)

Nanogen, Inc.

6,802,721 Shares of Common Stock

and Warrants to Purchase 1,020,408 Shares of Common Stock

We are offering 6,802,721 shares of our common stock and warrants to purchase 1,020,408 shares of common stock (and the shares of common stock issuable upon exercise of those warrants) to one or more selected institutional investors pursuant to this prospectus supplement and the accompanying prospectus. Purchasers will receive warrants to purchase 0.15 shares of common stock at an exercise price of \$4.00 per share for each share of common stock they purchase in this offering. The shares of common stock and warrants will be purchased at the negotiated price of \$2.94 per unit. Units will not be issued or certificated. The shares of common stock and warrants are immediately separable and will be issued separately.

Our common stock is listed on the Nasdaq National Market under the symbol NGEN. On September 27, 2005, the last reported sale price of the common stock on the Nasdaq National Market was \$3.20 per share.

Before deciding whether to invest in our common stock and warrants, you should consider carefully the risks that we have described under the heading Risk Factors beginning on page S-4 of this prospectus supplement and on page 2 of the accompanying prospectus.

Seven Hills Partners LLC and Stonegate Securities, Inc. have agreed to act as agents for us in connection with the arrangement of this transaction on a best efforts basis. We have agreed to pay Seven Hills Partners LLC and Stonegate Securities, Inc. the aggregate placement agent fees set forth in the table below.

Maximum

Per Unit

Offering

Price to the public	\$ 2.94	\$ 20,000,000
Placement agent fees	\$ 0.14	\$ 960,000
Proceeds, before expenses, to Nanogen	\$ 2.80	\$ 19,040,000

All of the shares of common stock and warrants are being sold on an any or all basis. There can be no assurance that we will be successful in selling any or all of the shares and warrants offered hereby. We have not fixed a minimum number of shares and warrants to be sold pursuant to this offering. Therefore, we may sell less than all of the shares and warrants offered hereby, which may significantly reduce the amount of proceeds we receive.

We expect to deliver the shares and warrants on or about September 28, 2005.

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

STONEGATE SECURITIES, INC.

As Placement Agents

The date of this prospectus supplement is September 28, 2005.

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PROSPECTUS

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FORWARD-LOOKING STATEMENTS

This prospectus supplement, the accompanying prospectus, and the documents incorporated herein by reference include—forward-looking statements—within the meaning of Section 27A of the Securities Act and Section 21E of the Exchange Act. All statements other than statements of historical fact are—forward-looking statements—for purposes of these provisions, including any projections of earnings, revenues or other financial items, any statements of the plans and objectives of management for future operations, any statements concerning proposed new products or services, any statements regarding future economic conditions or performance, any statements relating to future regulatory action, and any statement of assumptions underlying any of the foregoing. In some cases, forward-looking statements can be identified by the use of terminology such as may , should , could , would , will , believes , intends , expects , plans , anticipates , estimates , potential , o negative thereof or other comparable terminology. Although we believe that the expectations reflected in the forward-looking statements contained in this prospectus and in the incorporated documents are reasonable, we cannot assure you that such expectations or any of the forward-looking statements will prove to be correct, and actual results could differ materially from those projected or assumed in the forward-looking statements. Our future financial condition and results of operations, as well as any forward-looking statements, are subject to inherent risks and uncertainties, including but not limited to those set forth herein under the heading—Risk Factors—and those discussed in documents we incorporate by reference into this prospectus and for the reasons described elsewhere in this prospectus.

We will not update these forward-looking statements, whether as a result of new information, future events or otherwise. You should, however, review additional disclosures we make in our quarterly reports on Form 10-Q, current reports on Form 8-K and annual reports on Form 10-K filed with the SEC.

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ABOUT THIS PROSPECTUS SUPPLEMENT

This prospectus supplement and the accompanying prospectus dated June 28, 2005 are part of a registration statement on Form S-3 we filed with the Securities and Exchange Commission using a shelf registration process. Under this shelf registration process, we may from time to time sell any combination of securities described in the accompanying prospectus in one or more offerings up to a total of \$60,000,000.

These documents contain important information you should consider when making your investment decision. The accompanying prospectus provides you with a general description of the securities we may offer. This prospectus supplement contains information about the shares and warrants offered hereby. This prospectus supplement may add, update or change information in the accompanying prospectus. You should rely only on the information provided in this prospectus supplement, the accompanying prospectus or incorporated by reference in this prospectus supplement or the accompanying prospectus. We have not authorized anyone to provide you with any other information.

This prospectus supplement does not constitute an offer to sell or a solicitation of an offer to buy the shares and warrants 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 the prospectus and the prospectus supplement is accurate only as of the date of the prospectus and the prospectus supplement, regardless of the time of delivery of this prospectus supplement or of any sale of the shares and warrants.

SUMMARY

This summary highlights information contained elsewhere or incorporated by reference in this prospectus supplement and the accompanying prospectus. This summary does not contain all of the information that you should consider before deciding to invest in the shares and warrants. You should read this entire prospectus supplement and the accompanying prospectus carefully, including the Risks Related to this Offering section contained on page S-4 of this prospectus supplement and the Risk Factors section on page S-4 of this prospectus supplement, and our consolidated financial statements and the related notes and the other documents incorporated by reference in this prospectus supplement and the accompanying prospectus.

Nanogen was founded with a vision to improve the quality of healthcare by introducing advanced human diagnostic products that will provide higher quality of information in a shorter period of time to our customers in the research, clinical laboratory or point-of-care markets. We intend to turn this vision into reality by continuing to develop new diagnostic products or by acquiring other companies and complementary products that will expand and accelerate our entry into rapidly growing diagnostic markets. We began a targeted acquisition strategy during 2004 that is expected to result in a broad product line of advanced diagnostic products. The combination of internally developed products plus acquired products addressing large markets should provide the stimulus for significant revenue acceleration in 2005 and beyond.

We were incorporated under the laws of the State of Delaware and our stock is listed on the Nasdaq National Market under the symbol NGEN. Our corporate offices are located at 10398 Pacific Center Court, San Diego, California 92121. Our main telephone number is 858-410-4600.

For further information regarding us and our financial information, you should refer to our recent filings with the SEC. See Where You Can Find More Information and Incorporation of Certain Documents by Reference.

Recent Developments

On July 19, 2005, we made an equity investment in Jurilab Ltd., a Finnish company focused on the discovery and identification of new genes and gene markers associated with the root cause of common diseases and drug response. We have initially invested 1.25 million Euros (about \$1.5 million) for a less than 20% equity interest, and we have agreed to invest another 1.25 million Euros in January 2006. In connection with our investment, we have the right to appoint two directors to Jurilab s four-member board of directors, one of which shall be the chairman. We have designated Howard C. Birndorf, our Chairman and Chief Executive Officer, as the chairman of Jurilab s board of directors, and David Ludvigson, our President and Chief Operating Officer, as a second member of Jurilab s board of directors. The investment agreement also grants us the option to acquire full ownership of Jurilab at agreed upon prices in the future.

Through our investment, we will acquire certain rights to develop diagnostic products based on genes and gene markers discovered by Jurilab. We also may become a distributor of Jurilab s pharmacogenomic products and services and offer business development infrastructure and other resources to further the Jurilab business.

We are currently evaluating whether we will be required under applicable accounting rules to consolidate the financial statements of Jurilab with our own financial statements commencing from July 19, 2005. Currently, Jurilab has a negative equity position. If we are required to consolidate our financial statements with Jurilab s financial statements in future periods, we are unable to determine what the impact on our financial statements would be at this time. However, any losses incurred by Jurilab would impact our consolidated statement of operations. See Risks Related to Our Business Our relationship with Jurilab subjects us to numerous risk and uncertainties.

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THE OFFERING

Common stock offered by us 6,802,721 shares

Warrants to purchase common stock offered by 1,020,408

us

Common stock to be outstanding after this

offering

54,177,670 shares

Use of proceeds We intend to use the net proceeds from this offering for working capital, acquisitions and other

general corporate purposes, including the development and support of our sales and marketing organization, support for our continuing research and development efforts and, if opportunities arise, to acquire businesses, products, technologies or licenses that are complementary to our business and make strategic investments in businesses complementary to our business. See Use

of Proceeds on page S-20.

Warrant terms Each warrant is exercisable for the purchase of 0.15 shares of our common stock at an exercise

price of \$4.00 per share. The warrants will be exercisable at any time on or prior to September

28, 2010.

Dividend policy We have never declared or paid any cash dividends on our capital stock. We intend to retain

any future earnings to finance the growth and development of our business and do not

anticipate paying any cash dividends in the foreseeable future.

Nasdaq National Market symbol NGEN

The number of shares of common stock to be outstanding after this offering is based on 47,374,949 shares outstanding on September 27, 2005. It excludes:

7,792,513 shares of common stock issuable upon exercise of options outstanding as of September 27, 2005, of which 4,521,359 are exercisable under our stock option plans, at a weighted average exercise price of \$5.96 per share;

1,020,408 shares of common stock issuable upon the exercise of the warrants, with an exercise price of \$4.00 per share, which are being offered by this prospectus supplement;

1,475,642 shares of common stock issuable upon the exercise of warrants outstanding as of September 27, 2005, at a weighted average exercise price of \$7.20;

1,164,767 shares available for grant as of September 27, 2005 under our stock option plans; and

178,390 shares available for grant as of September 27, 2005 under our stock bonus plan.

Unless otherwise stated, outstanding share information throughout this prospectus supplement excludes such outstanding options or warrants to purchase shares of common stock, including the warrants issued in this offering.

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RISK FACTORS

An investment in the shares of common stock 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.

Risks Related to this Offering

Management will have broad discretion as to the use of the proceeds from this offering, and we may not use the proceeds effectively.

We have not designated the amount of net proceeds we will use for any particular purpose. Accordingly, our management will have broad discretion as to the application of the net proceeds and could use them for purposes other than those contemplated at the time of this offering. Our stockholders may not agree with the manner in which our management chooses to allocate and spend the net proceeds. Moreover, our management may use the net proceeds for corporate purposes that may not increase our profitability or our market value. See Use of Proceeds at page S-20 for a description of our management s intended use of the proceeds from this offering.

You will experience immediate dilution in the book value per share of the common stock you purchase.

Because the price per share of our common stock being offered is substantially higher than the book value per share of our common stock, you will suffer substantial dilution in the net tangible book value of the common stock you purchase in this offering. Based on the public offering price of \$2.94 per share, if you purchase shares of common stock in this offering, you will suffer immediate and substantial dilution of \$1.98 per share in the net tangible book value of the common stock. You may incur additional dilution of net tangible book value if holders of the warrants offered in this prospectus supplement exercise their warrants to purchase shares of our common stock. See Dilution at page S-21 for a more detailed discussion of the dilution you will incur in this offering.

We are offering the shares and warrants on a best efforts basis and we cannot be certain that we will raise the full amount contemplated in this offering.

We have retained Seven Hills Partners LLC and Stonegate Securities under a placement agency agreement to act as our exclusive placement agents in connection with this offering. The placement agents are not obligated and do not intend to purchase any of the shares and warrants offered hereby. The closing of this offering is not conditioned on the sale of all of the shares and warrants offered hereby, and we may sell all or any portion of such shares and warrants. Accordingly, we cannot be certain of the number of shares and warrants that will be purchased by investors. We currently anticipate that the closing will take place on September 28, 2005, but we cannot be certain that this will be the case. See Plan of Distribution.

Risks Related to our Business

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 June 30, 2005, 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, various ASRs for detection of gene mutations associated with diseases, general purpose reagents and accessories to facilitate assay and protocol development and validation on the NanoChip Platform, real-time ASRs that are platform independent for providing diagnosis of infectious and genetic diseases and, point-of-care diagnostic tests for myocardial infarction and drugs of abuse. We have announced our second-generation instrument, the NanoChip® 400, and a congestive heart failure point of care test, CHF test. This new instrument and product are expected to begin shipping later this year. All of our other platforms and ASRs and other potential products are under development. Our NanoChip® System, ASRs or our

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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. 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 products and 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 the six months ended June 30, 2005, we did not incur any charge to reduce our inventory to its net realizable value; however, in the years ended December 31, 2004, 2003, and 2002, we took accounting charges of approximately \$3.7 million, \$908,000 and \$424,000, respectively, to reduce product inventory to its estimated net realizable value. If actual future demand or market conditions are less favorable than those currently 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;

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 year ended December 31, 2004, certain clinical laboratories experienced performance issues with our cystic fibrosis analyte specific reagent, CFTR ASR, which negatively impacted our revenue. We are not currently offering our CFTR ASRs for sale in the United States. We are developing new reagents for the NC400. However, we may not be able to address product 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

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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.

Our NanoChip® System instruments, including Molecular Biology Workstation and the second-generation NanoChip® 400, are manufactured by Hitachi. As such our success in the micro-array based diagnostics market is largely dependent upon Hitachi s ability to perform under our manufacturing agreement. 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.

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.

The transition to new products subjects us to risks and uncertainties including undetected defects or unexpected technical or operational problems which could adversely affect our business.

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

potential delays in initial shipments of new products;

undetected defects or unexpected technical or operational problems with the new products;

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; and

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

The occurrence of any one of the foregoing factors could negatively impact our financial results, delay market acceptance of our products, divert our development resources, or otherwise have an adverse effect on our business.

If our acquisitions are unsuccessful, our business may be harmed.

As part of our business strategy, we have acquired companies, technologies and product lines to complement our internally developed products. We expect that acquisitions will remain a part of our growth strategy going forward. Acquisitions involve numerous risks, including the following:

The possibility that we will pay more than the value we derive from the acquisition, which could result in future non-cash impairment charges;

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Difficulties in integration of the operations, technologies, and products of the acquired companies, which may require significant attention of our management that otherwise would be available for the ongoing development of our business;

The assumption of certain known and unknown liabilities of the acquired companies; and

Difficulties in retaining key relationships with employees, customers, partners and suppliers of the acquired company.

Any of these factors could have a negative impact on our business, results of operations or financing position.

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. Further, any additional equity financing, debt financing, or credit facility used for such acquisition may not be on satisfactory terms, and any such financing or facility may place restrictions on our business. 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 may not realize the benefits that we anticipate from our recent acquisitions of Epoch Biosciences, Inc. and SynX Pharma Inc. or other acquisitions due to integration and other challenges.

We completed two significant acquisitions in 2004: the acquisition of SynX Pharma Inc. in April 2004 and Epoch Biosciences, Inc. in December 2004. We expect that the SynX product line will accelerate our entry into the point-of-care market and we expect that the acquisition of Epoch will result in a material increase in revenues during 2005. However, we cannot be certain that we will achieve these and other benefits which we currently expect from these acquisitions. The process of integrating these and other acquired companies requires, and will require, significant efforts and expenditures, including the coordination of information technologies, research and development, sales and marketing, administration and manufacturing. Combining our product offerings with those of acquired companies is a complex and lengthy process involving a number of steps in which we will seek to achieve increasing degrees of integration of our products. Additionally, SynX is located in Canada and Epoch is located in Washington, and because our San Diego facilities are or may be physically separated from facilities of other companies we acquire, 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 these acquired companies and businesses successfully, we may not be able to meet our expectations of future results of operations.

Factors that will affect the success of these acquisitions and any future acquisitions include the following:

our ability to manage a more complex corporate structure that requires additional resources for such responsibilities as tax planning, foreign currency management, financial reporting and risk management;

our ability to retain key employees of acquired companies; and

our ability to increase revenues due to the integration of the products and technologies of the acquired companies; and

our ability to operate efficiently following the completion of acquisitions and to achieve cost savings.

Even if we are able to successfully integrate our acquired operations, we may never realize the anticipated benefits of the SynX and Epoch acquisitions, or any other acquisition. Our failure to achieve these benefits and synergies could have a material adverse effect on our business, results of operations and financial condition.

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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, 2005, total approximately \$233.1 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. 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 second generation NanoChip® 400 System, acquisitions, 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.

Changes in financial accounting standards related to stock option expenses are expected to have a significant effect on our reported results.

The FASB recently issued a revised standard that requires that we record compensation expense in the statement of operations for employee stock options using the fair value method. The adoption of the new standard is expected to have a significant effect on our results of operations, although it will not affect our cash flows, and could adversely impact our ability to provide accurate guidance on our future reported financial results due to the variability of the factors used to establish the value of stock options. As a result, the adoption of the new standard in the first quarter of fiscal 2006 could negatively affect our stock price and our stock price volatility.

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 can not 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:

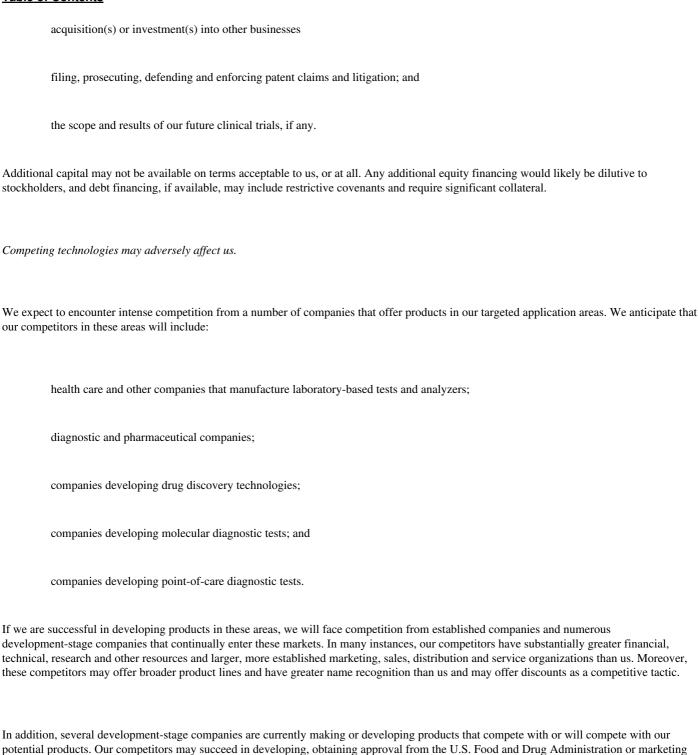
scaling up our manufacturing capabilities;

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

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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.

technologies or products that are more effective or commercially attractive than our current or potential products or that render our technologies

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, maintaining and enforcing 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. Budgetary concerns may cause us to not file, or continue, litigation against known infringers of our patent rights, or may cause us not to file for, or pursue, patent protection for all of our inventive technologies in jurisdictions where they may have value.

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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. In the past, we and the companies we have acquired have received, and may in the future receive, notices claiming infringement from third parties as well as invitations to take licenses under third-party patents which have, in some instances, resulted in litigation, settlement of litigation and our licensing of third party intellectual property rights. In particular, the receipt of infringement notices by us may subject us to costly litigation, divert management resources and result in the invalidation of our intellectual property rights. These claims may require us to pay significant damages, cease production of infringing products, terminate our use of infringing technologies or develop non-infringing technologies. Further, 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. These actions may also subject us to liability for damages. Although in the past we and the companies we have acquired have succeeded in settling some third party claims concerning alleged infringement of intellectual property rights, which settlements have involved the payment of royalties by us or such companies we have acquired, there can be no assurance that in the future we would be successful in settling such claims. In addition, there can be no assurance that, even if such settlements are achieved, that they would be on commercially reasonably terms or would not otherwise have a material adverse impact on the company s business. 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 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 have opposed one allowed European patent granted to Oxford Gene Technology that had broad claims to array technology for analyzing a predetermined polynucleotide sequence. We opposed the grant of that European patent, and Oxford Gene Technology subsequently narrowed its claims. However, we are still opposing such narrower claims before the European Patent Office's Opposition Division. Even if Oxford Gene Technology successfully defends its current, narrower claims, and even if a patent is subsequently granted for such claims, we do not believe that our product will infringe upon such claims. Nonetheless, Oxford Gene Technology may still later assert that some of our products infringe upon its patents that Oxford Gene Technology may obtain from time to time. If the decision of the Opposition Division is successfully appealed by Oxford Gene and the original

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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.

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 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 tolling agreement with Oxford Gene pursuant to which the lawsuit was dismissed by Oxford Gene without prejudice. Under the tolling agreement, we are obligated to give Oxford Gene notice if we determine that we desire to commercialize DNA arrays for use in certain assay formats. If that notice is given, we and Oxford Gene are obliged to discuss in good faith for 30 days whether we wish to acquire, and whether Oxford Gene is willing to grant, a license under the patent involved in the litigation. If we and Oxford Gene are unable to enter into such a license or other agreement within such 30 days, Oxford is free to re-initiate the litigation.

On June 30, 2005, we gave Oxford Gene notice that we desired to commercialize DNA arrays for use in such assay formats. Oxford Gene is now free to re-initiate the litigation against us under the tolling agreement. 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 clearances and approvals required to manufacture, market and sell our products are uncertain, and our failure to comply with such clearances and approvals could have a material adverse effect on our company.

Unless otherwise exempt, medical devices require FDA approval or clearance prior to marketing in the United States. We believe our currently marketed products, including general laboratory instruments and as analyte specific reagents well as certain of those products we intend to market in the future, other than our CHF test, are not subject to 510(k) clearance or premarket approval requirements. As a result, to date we have not applied for FDA or any other regulatory approvals or clearances with respect to any of our products other than with respect to our CHF test. Obtaining 510(k) clearance and premarket approval may be time-consuming, expensive and uncertain. The regulatory approval or clearance process required to manufacture, market and sell our existing and future products is currently uncertain. If the FDA or other regulatory authorities assert that our products are subject to 510(k) clearance and premarket approval requirements or other similar procedures, our business may experience incremental costs, increased regulatory risks and production delays. In addition, we could be subject to:

the recall or seizure of our products;

total or partial suspension of the production of our products;

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

substantial delay in the manufacture or sale of our current or future products;

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

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

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We received a letter from the FDA on August 12, 2005, regarding the NanoChip® Molecular Biology Workstation, the NanoChip® Microarray, and certain of our analyte specific reagents (ASRs) in which the FDA stated that the Workstation, Microarray, and ASRs appear to be promoted to work together as an integrated system and that there are inconsistencies with the labeling and the representations of the intended use of our products. The FDA further stated that these products as labeled are considered medical devices and subject to the requirements of the premarket approval or clearance process. The FDA requested that we respond within 30 days and indicated that we could request a meeting with the FDA to discuss the matter. We have submitted a written response to the FDA in which we have outlined our position that these products are not intended to be and do not need to be linked together. We also stated in our written response that we will revise certain of our marketing materials to address the FDA s concerns regarding the labeling and representations of intended use of our products. We have requested a meeting with the FDA to discuss the matter. To date, we have not received a response to our submission.

There can be no assurance that the FDA will agree with our position that with these revisions our products are not subject to 510(k) clearance or the premarket approval process. The FDA may ultimately require, or we may determine it appropriate, to submit our existing or future products to the premarket approval process or the 510(k) clearance process, either of which may be time-consuming, expensive and uncertain. In addition, if we submit our current products to the premarket approval process or the 510(k) clearance process, it is unclear what the impact would be on our products that have been or are being sold without such approvals. We may be allowed to continue to market our current products pending the outcome of the clearance or approval process for each product, but there can be no assurance that the FDA would not require us to withdraw one or more of our products from the marketplace pending receipt of such approvals or clearances.

Furthermore, the FDA could determine that other products we manufacture or sell or intend to manufacture or sell, including the second-generation NanoChip® 400, also are subject to the premarket approval process or the 510(k) clearance process. If the FDA makes any such determination or otherwise disagrees with our position, the FDA could preclude us from manufacturing or shipping the NanoChip® 400 until we have received FDA marketing authorization. The FDA could also revise its definition of analyte specific reagents in a manner that might cause our current or future analyte specific reagents to be subject to the 510(k) clearance process. In addition, the FDA could subject us to any of the penalties described above, including administrative or judicially imposed sanctions and the recall or seizure of our products. Any such result could substantially delay the release of our current and future products. Furthermore, any such result would have a material adverse effect on our business, financial position and results of operations, and the market value of our common stock could decline.

The regulatory approval process for our products may be expensive, time-consuming and uncertain.

To the extent that our products require FDA or other regulatory approval or clearance prior to marketing, such regulatory approval process may be expensive, time-consuming, uncertain and may prevent us from obtaining or maintaining required approvals for the commercialization of our products, which may have a significant impact on our business. It generally takes at least three to six months from the time of submission or more to obtain 510(k) clearance, but the process may take longer if the FDA requests more data or research. The premarket approval process takes between one and two years from the time of submission. Regulatory clearance or approval of any of our products may not be granted by the FDA or foreign regulatory authorities for several years, if at all. Our failure to obtain required approvals from regulatory authorities could have a material adverse effect on our business, results of operations and financial condition. In other countries, the manufacture or sale of our products may require approval by local government agencies with missions comparable to the FDA s. The process of obtaining any such approval may also be lengthy, expensive and uncertain.

We expect to submit some of our products in the future to the 510(k) clearance process or premarket approval process and, as such, expect to incur significant expenses in order to receive such clearances or approvals. We also cannot predict the likelihood of obtaining such clearances or approvals. The failure to obtain such clearances or approvals could prevent the successful development, introduction and marketing of certain of our products, and could cause the market price for our stock to decline.

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In addition, whether or not our products are subject to 510(k) clearance or premarket approval, we will be subject to certain FDA regulations covering, among other things, manufacturing, promotions and medical device reporting. For instance, manufacturing facilities are required to adhere to the FDA s current Quality System Regulations, including extensive record keeping and reporting and periodic inspections of our manufacturing facilities. Similar requirements are imposed by foreign governmental agencies. Compliance with these regulations requires substantial expenditures of time, money and effort in such areas as production and quality control to ensure full compliance. Failure to comply with such regulations at one of our manufacturing facilities could result in an enforcement action brought by the FDA, which could include withholding the approval of products manufactured at that facility.

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; PBM manufactures our point-of-care products; and we manufacture our NanoChip® Cartridges, our ASRs and most of our other 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.

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 or PBM 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.

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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 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 NanoChip® 400 as well as our Workstation and other hardware products, and we currently rely on another manufacturer for our point-of-care products, and such reliance 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 by us. In addition, with the acquisition of SynX, we acquired an exclusive manufacturing agreement with PBM for the manufacture of our future point-of-care products.

Because we are solely dependent on these other companies for the manufacture of these products, any disruption in either of these companies businesses or in our relationship with such companies may have a material adverse effect on our business. To the extent we have adverse developments in our relationship with Hitachi or PBM, or to the extent we develop contractual disputes, it may have an adverse impact on our business, our ability to implement existing products or launch new products. In particular, to the extent we seek to amend, modify or extend or otherwise change aspects of our contractual relationship with either of these parties, we may experience manufacturing delays associated with negotiating the terms of those arrangements and other related complications. If we determine to curtail or terminate our manufacturing relationship with either of these parties, 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. Furthermore, the manufacturing of our point-of-care products depends on certain intellectual property owned by PBM and licensed by PBM from third parties, and we may not be able to manufacture or find an alternative manufacturer of the design of these products without this intellectual property, which would severely impact our point-of-care products.

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 August 31, 2005, we had 44 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

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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;

political and economic instability, including the war on terrorism; and

difficulties in staffing and managing foreign offices.

In addition, we expect increased costs in deploying the NanoChip® System, including the second-generation NanoChip® 400, ASRs, point-of-care diagnostics, and other products in foreign countries due to;

licenses, tariffs and other trade barriers;

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. In addition, we began a targeted acquisition strategy during 2004, and our due diligence of acquired companies may fail to reveal material risks relating to product liabilities of such companies. 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. We may be required to pay substantial damages in connection with any product liability claims. A successful product liability claim or series of claims could have an adverse

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effect on our business, financial condition and results of operations. Further, we may not be able to maintain adequate levels of product liability insurance at reasonable cost or reasonable terms. Excessive insurance costs or uninsured claims would add to our future operating expenses and adversely affect our financial condition.

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 six months ended June 30, 2005 and the years ended December 31, 2004, 2003 and 2002, we experienced turnover rates of 10%, 27%, 25% and 29%, respectively. Turnover at these rates may continue and, if they continue, will adversely affect us.

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 adversely affect our business.

In recent years, health care payors as well as federal and state governments have focused on containing or reducing health care costs. We cannot predict the effect that any of these initiatives may have on our business, and it is possible that they will adversely affect our business. Health care cost containment initiatives focused on genetic testing could cause the growth in the clinical market for diagnostic testing to be curtailed or slowed. In addition, health care cost containment initiatives could cause pharmaceutical companies to reduce research and development spending. In either case, our business and our operating results would be harmed. In addition, diagnostic testing in clinical settings is often billed to third-party payors, including private insurers and governmental organizations. If our current and future clinical products are not considered cost-effective by these payors, reimbursement may not be available to users of our products. In this event, potential customers would be much less likely to use our products, and our business and operating results could be seriously harmed.

In addition, sales of our future products may depend, in large part, on the availability of adequate reimbursement to users of those products from government insurance plans, managed care organizations and private insurance plans. Physicians recommendations to use our products may be influenced by the availability of reimbursement by insurance companies and other third-party payors. There can be no assurance that insurance companies or third-party payors will provide coverage for our products or that reimbursement levels will be adequate for the reimbursement of the providers of our products. In addition, outside the United States, reimbursement systems vary from country to country and there can be no assurances that third-party reimbursement will be made available at an adequate level, if at all, for our products under any other reimbursement system. Lack of or inadequate reimbursement by government or other third-party payors for our products could have a material adverse effect on our business, financial condition and results of operations.

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.

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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 diagnostic 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® 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;

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;

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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.

Investor confidence and share value may be adversely impacted if our independent auditors are unable to provide us with the attestation of the adequacy of our internal controls over financial reporting, as required by Section 404 of the Sarbanes-Oxley Act of 2002.

As directed by Section 404 of the Sarbanes-Oxley Act of 2002, the SEC adopted rules requiring public companies to include a report of management on our internal controls over financial reporting in our annual reports on Form 10-K and quarterly Form 10-Qs that contains an assessment by management of the effectiveness of our internal controls over financial reporting. In addition, our independent auditors must attest to and report on management s assessment of the effectiveness of our internal controls over financial reporting as of the end of the fiscal year. How companies are maintaining their compliance with these requirements including internal control reforms, if any, to comply with the requirements of Section 404, and how independent auditors are applying these requirements and testing companies internal controls, remain subject to uncertainty. We expect that our internal controls will continue to evolve as our business activities change. In addition, the acquisitions we made during 2004 and any future acquisitions we make may impact our ability to maintain effective internal controls over financial reporting. As permitted by SEC rules, we were not required to include our SynX and Epoch subsidiaries in our management s assessment of internal control over financial reporting for the year ended December 31, 2004. However, for the year ending December 31, 2005, we will be required to assess the effectiveness of the internal controls of these companies which we acquired in 2004, in addition to our existing business. Further, if, during any year, our independent auditors are not satisfied with our internal controls over financial reporting, including the internal controls over financial reporting of SynX and Epoch, or the level at which these controls are documented, designed, operated, tested or assessed, or if the independent auditors interpret the requirements, rules or regulations differently than we do, then they may decline to attest to management s assessment or may issue a report that is qualified. This could result in an adverse reaction in the financial marketplace due to a loss of investor confidence in the reliability of our financial statements, which ultimately could negatively impact the market price of our shares.

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 take some stockholder actions, including the amendment of any of the anti-takeover provisions contained in our certificate of incorporation or amendment of our bylaws.

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, the SEC and Nasdaq, have recently issued new requirements and regulations and continue to develop additional

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regulations and requirements in response to recent laws enacted by Congress, most notably the Sarbanes-Oxley Act of 2002. 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.

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.

We will be dependent upon our agreement with Applied Biosystems for a significant portion of our revenues for 2005 and future periods, and a reduction of sales under or early termination of this agreement would seriously harm our revenues and operating results and would likely cause our stock price to decline.

In January 1999, Epoch and Applied Biosystems entered into a License and Supply Agreement pursuant to which we licensed some of our technology to Applied Biosystems for use in its TaqMan® 5 - nuclease real-time PCR assays, (TaqMan is a registered trademark of Roche Molecular Systems, Inc.). In July 1999, Epoch licensed its proprietary software, which speeds the design of oligonucleotide probes used in the study of genes, to Applied Biosystems. In August 2000, the agreement was amended to, among other things, provide for Epoch manufacturing product for Applied Biosystems. In July 2002 this agreement was further amended to remove the manufacturing rights from the contract effective October 2002, redefine product categories, increase the minimum royalties and royalty rates, and establish that minimum royalties are measured and paid quarterly. We will depend upon product sales and royalties from Applied Biosystems sales of its TaqMan assays under this agreement for a significant portion of our revenues in 2005 and future periods.

The technology licenses and Applied Biosystem s obligation to pay us royalties on their sale of products that incorporate Epoch s technologies continue until the expiration of the underlying patents. Since the July 2002 amendment that increased the minimum royalty levels, quarterly royalties earned based on actual sales by Applied Biosystems have been less than the contractual minimum royalty levels. As a result, the royalty payments have been in the amount of the specified quarterly minimum level. The current agreement calls for quarterly royalty minimums through the third quarter of 2005. Thereafter, we expect to experience a near term reduction in royalties and increased variability in royalties thereafter under this arrangement.

Either party may terminate the agreement upon 180 days written notice. In the event that this agreement is terminated, our revenues, financial condition and operating results would be adversely affected and our stock price would likely decline.

Our relationship with Jurilab subjects us to numerous risk and uncertainties.

In July 2005 we acquired a minority equity interest in Jurilab of approximately 17% and we hold two of Jurilab s four board of director seats. Our relationship with Jurilab subjects us to numerous risk and uncertainties, including:

we have invested 1.25 million Euros (about \$1.5 million) in Jurilab and have committed to invest another 1.25 million Euros in January 2006 and we may lose all of our investment;

we may be required to consolidate Jurilab s financial statements with our own and, if we are so required, our operating results could be less predictable and subject to significant fluctuation beyond our control, and our operating results could be adversely affected by the results of Jurilab;

our relationship with Jurilab may require our management to devote substantial time and resources to Jurilab s business, which may adversely affect our business;

we have the right to acquire Jurilab, and if we exercise this right, it would entail significant risks, which risks would be even more acute because Jurilab is an early stage company;

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in the event we were to acquire Jurilab, we would likely be required to seek additional financing that may not be available to us on acceptable terms, or at all.

Terrorist attacks, war, natural disasters and other catastrophic events may negatively impact aspects of our operations, revenue, costs and stock price.

Threats of terrorist attacks in the United States of America, as well as future events occurring in response to or in connection with them, including, without limitation, future terrorist attacks or threats against United States of America targets, rumors or threats of war, actual conflicts involving the United States of America or its allies, including the on-going U.S. conflicts in Iraq and Afghanistan, further conflicts in the Middle East and in other developing countries, or military or trade disruptions affecting our domestic or foreign suppliers of merchandise, may impact our operations. Our operations also may be affected by natural disasters or other similar events, including floods, hurricanes, earthquakes or fires. Our California and Washington facilities, including our corporate offices and principal product development facilities, are located near major earthquake faults. The potential impact of any of these events to our operations includes, among other things, delays or losses in the delivery of products by us and decreased sales of such products. Additionally, any of these events could result in increased volatility in the United States of America and worldwide financial markets and economies. Also, any of these events could result in economic recession in the United States of America or abroad. Any of these occurrences could have a significant impact on our operating results, revenue and costs and may result in the volatility of the future market price of our common stock.

USE OF PROCEEDS

We estimate that the net proceeds we will receive from this offering, excluding the proceeds, if any, from the exercise of the warrants issued in this offering, will be approximately \$18.9 million, after deducting the placement agent fees and estimated offering expenses.

We intend to use the net proceeds we receive from sales of the securities offered hereby for working capital, acquisitions and other general corporate purposes, including the development and support of our sales and marketing organization, support for our continuing research and development efforts and, if opportunities arise, to acquire businesses, products, technologies or licenses that are complementary to our business and make strategic investments in businesses complementary to our business. We periodically review acquisition and strategic investment opportunities that are related to our business and we believe that it is desirable to have funds on hand so as to be able to make acquisitions and strategic investments promptly. As of the date of this prospectus supplement, we have no specific agreements, understandings, commitments or arrangements with regard to any particular future acquisition or strategic investment (other than our commitment to invest an additional 1.25 million Euros in Jurilab in January 2006 as described elsewhere herein), and no assurance can be given that we will be able to consummate any such acquisitions or strategic investments or that, if consummated, such acquisitions or investments would be on terms that are favorable to

Pending these uses, we intend to invest the proceeds of this offering in short-term, investment grade interest-bearing securities.

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DILUTION

If you purchase our shares and warrants in this offering, your interest will be diluted to the extent of the difference between the public offering price per share and the net tangible book value per share of our common stock after this offering. We calculate net tangible book value per share by dividing the net tangible book value, tangible assets less total liabilities, by the number of outstanding shares of our common stock.

Our net tangible book value at June 30, 2005, was \$33.3 million, or \$0.70 per share, based on 47,374,949 shares of our common stock outstanding as of September 27, 2005. After giving effect to the sale of 6,802,721 shares of common stock by us at a public offering price of \$2.94 per share, less the placement agent discounts and commissions and our estimated offering expenses, our net tangible book value at June 30, 2005, would have been approximately \$52.2 million, or \$0.96 per share. For purposes of calculating dilution per share, we have assumed that no value was assigned to the warrants, which results in additional immediate dilution to the shares. This represents an immediate increase in the net tangible book value of \$0.26 per share to existing stockholders and an immediate dilution of \$1.98 per share to investors in this offering. The following table illustrates this per share dilution:

Public offering price per unit		\$ 2.94
Net tangible book value per share as of June 30, 2005	\$ 0.70	
Increase in net tangible book value per share after the offering	\$ 0.26	
Net tangible book value per share after this offering		\$ 0.96
Dilution per share to new investors		\$ 1.98

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DESCRIPTION OF WARRANTS

Each warrant represents the right to purchase 0.15 shares of common stock at an initial exercise price equal to \$4.00 per share. Each warrant may be exercised on or after September 28, 2005 through and including September 28, 2010.

Exercise. Holders of the warrants may exercise their warrants to purchase shares of our common stock for cash on or before the expiration date by delivering an exercise notice, appropriately completed and duly signed, and payment of the exercise price for the number of shares to which the warrant is being exercised. We provide certain buy-in rights to a holder if we fail to deliver the shares of common stock underlying the warrants by the third trading day after the date on which delivery of such stock certificate is required by the warrant. The buy-in rights apply if after such third trading day, but prior to cure by us, the holder purchases (in an open market transaction or otherwise) shares of our common stock to deliver in satisfaction of a sale by the holder of the warrant shares that the holder anticipated receiving from us upon exercise of the warrant. In this event, at the request of and in the holder s discretion, we will either:

pay cash to the holder in an amount equal to the buy-in price, meaning the holder s total purchase price (including brokerage commissions, if any) for the shares of common stock so purchased less the aggregate exercise price, at which point our obligation to deliver such stock certificate (and to issue such shares of common stock underlying the exercised warrants) terminates; or

promptly deliver to the holder a certificate or certificates representing the shares of common stock underlying the exercised warrant and pay cash to the holder in an amount equal to the excess (if any) of the buy-in price over the product of (A) such number of shares of common stock, times (B) the closing price of our common stock on the date of the event giving rise to our obligation to deliver such certificate.

In addition, the warrant holders are entitled to a cashless exercise option if, at any time of exercise, there is no effective registration statement registering, or no current prospectus available for, the issuance of the shares underlying the warrants. This option entitles the warrant holder to elect to receive fewer shares of common stock without paying the cash exercise price. The number of shares to be issued would be determined by a formula based on the total number of shares to which the warrant holder is entitled, the fair market value of the common stock on the date of exercise and the applicable exercise price of the warrants.

The shares of common stock issuable on exercise of the warrants will be, when issued in accordance with the warrants, duly and validly authorized, issued and fully paid and non-assessable. At all times that the warrants are outstanding, we agree to maintain the effectiveness of the registration statement of which this prospectus supplement and the accompanying prospectus form a part, covering the common stock to be issued upon exercise of the warrant, and will authorize and reserve at least that number of shares of common stock equal to the number of shares of common stock issuable upon exercise of all outstanding warrants.

Delivery of Certificates. Upon the holder s exercise of a warrant, we will promptly issue and deliver a certificate for the shares of common stock issuable upon exercise of the warrant, free of restrictive legends. We will, if the holder provides the necessary information to us, issue and deliver the shares electronically through The Depository Trust Corporation through its Deposit Withdrawal Agent Commission System.

Certain Adjustments. The exercise price and the number of shares of common stock purchasable upon the exercise of the warrants are subject to adjustment upon the occurrence of specific events, including stock dividends, stock splits, and combinations of our common stock. If we are party to any reorganization, recapitalization, reclassification, consolidation or merger in which our common stock is converted into or exchanged for securities, cash or other property, then each holder s warrant will become the right to receive, upon exercise of such warrant, in lieu of our

common stock, the same kind and amount of securities, cash or other property as it would have been entitled to receive upon the occurrence of such transaction, if the warrant

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had been exercised immediately prior to such transaction. If we make or issue a dividend or other distribution payable in securities of the company other than share of common stock, or in cash or other property, then each holder s warrant will become the right to receive, upon exercise of such warrant, in addition to the number of shares of common stock issuable under the warrant, the same kind and amount of securities, cash or other property as it would have been entitled to receive upon the occurrence of such transaction, if the warrant had been exercised immediately prior to such transaction.

We will provide notice to holders of the warrants to provide such holders with a practical opportunity to exercise their warrants and hold common stock in order to participate in or vote on the following corporate events:

if we declare a dividend or distribution of cash, securities or other property in respect of our common stock;

if we authorize, approve, or enter into any agreement contemplating or soliciting approval for a merger, sale or similar transaction pursuant to which common stock is converted or exchanged for cash, securities or property; or

if we authorize our voluntary dissolution, liquidation or winding up of affairs.

Additional Provisions. The above summary of certain terms and provisions of the warrants is qualified in its entirety by reference to the detailed provisions of the warrants, the form of which will be filed as an exhibit to a current report on Form 8-K that will be incorporated herein by reference. We are not required to issue fractional shares upon the exercise of the warrants. No holders of the warrants will possess any rights as a shareholder under those warrants until the holder exercises those warrants. The warrants may be transferred independent of the common stock they were issued with, on a form of assignment, subject to all applicable laws.

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PLAN OF DISTRIBUTION

Seven Hills Partners LLC and Stonegate Securities, Inc., referred to as the placement agents, have entered into a placement agency agreement with us in which they have agreed to act as placement agents in connection with the offering. Seven Hills Partners LLC is serving as the lead placement agent and sole bookrunner, and Stonegate Securities is serving as co-placement agent. The placement agents are using their best efforts to introduce us to selected institutional investors who will purchase the shares and warrants. The placement agents have no obligation to buy any of the shares and warrants from us, nor are the placement agents required to arrange the purchase or sale of any specific number or dollar amount of the shares and warrants, but have agreed to use their best efforts to arrange the sale of all of the shares and warrants. There is no required minimum number of shares and warrants that must be sold as a condition to completion of the offering.

All investor funds will be deposited into an escrow account set up at Wells Fargo Bank, N.A. Wells Fargo Bank, acting as escrow agent, will invest all funds it receives in a non-interest bearing account. No investor funds will be accepted by us prior to the date of this prospectus supplement. Upon closing, we will deliver to each investor the number of shares purchased by such investor through the facilities of The Depository Trust Company, and we will deliver the warrants directly to the investors. The closing of the purchase of the shares and warrants will be on an any or all basis and, therefore, there may be more than one closing.

We have agreed to indemnify the placement agents and certain other persons against certain liabilities under the Securities Act of 1933, as amended. The placement agents have informed us that they will not engage in overallotment, stabilizing transactions or syndicate covering transactions in connection with this offering.

We have agreed to pay the placement agents a fee equal to 4.8% of the proceeds of this offering. The following table shows the per share and total fees we will pay to the placement agents assuming the sale of all of the shares and warrants offered pursuant to this prospectus supplement and the accompanying prospectus.

Per unit	\$ 0.14
Total	\$ 960,000

We have also agreed to pay to the placement agents a fee equal to 4.8% of the funds received by us upon the exercise, if any, of warrants. This fee is not reflected in the foregoing table. Because there is no minimum offering amount required as a condition to closing, the actual total fee may be less than the maximum amount set forth above.

We and Howard C. Birndorf, our Chairman and Chief Executive Officer, have agreed to a 30-day lock-up with respect to our common shares and other of our securities that Mr. Birndorf beneficially own, including securities convertible into our common shares and securities that are exchangeable or exercisable for our common shares. This means that, subject to certain exceptions, for a period of 30 days following the commencement of this offering, we and Mr. Birndorf may not offer, pledge, announce the intention to sell, sell, contract to sell, sell any option or contract to purchase, purchase any option or contract to sell, grant any option, right or warrant to purchase, lend, or otherwise transfer or dispose of, directly or indirectly, any shares of our common stock or any securities convertible into or exercisable or exchangeable for common stock; or (2) enter into any swap or other arrangement that transfers to another, in whole or in part, any of the economic consequences of ownership of our common stock, without the prior written consent of Seven Hills Partners, LLC.

In addition, we have further agreed that, without the prior written consent of Seven Hills Partners, LLC, we will not offer, announce the intention to offer, or sell any shares of common stock, any securities convertible into or exercisable or exchangeable for common stock or any of our other equity securities as part of an equity financing of the company from the date hereof until December 31, 2005, other than in connection with (i) a consolidation or merger of our company with or into any other corporation or other entity, provided that such consolidation or merger is not effected solely to merge or consolidate with a wholly-owned subsidiary of our

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company, or (ii) any acquisition of the capital stock or assets of any other corporation or other entity, provided that such other corporation or entity is not a wholly-owned subsidiary of our company. The foregoing offer restriction period shall end prior to December 31, 2005 if the average closing price for our common stock for 20 consecutive trading days during such period is equal to or exceeds \$4.00 per share.

This is a brief summary of the material provisions of the placement agency agreement and does not purport to be a complete statement of its terms and conditions. A copy of the placement agency agreement will be filed with the SEC and incorporated by reference into the Registration Statement of which this prospectus supplement forms a part. See Where You Can Find More Information on page 16 of the accompanying prospectus.

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LEGAL MATTERS

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

WHERE YOU CAN FIND MORE INFORMATION

This prospectus supplement is part of a registration statement that we filed with the Securities and Exchange Commission. The registration statement that contains this prospectus supplement, including the exhibits to the registration statement, contains additional information about us and the securities offered by this prospectus supplement.

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 100 F Street, N.E., 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.

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INCORPORATION OF CERTAIN DOCUMENTS BY REFERENCE

The SEC 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 supplement, and information that we file later with the SEC will automatically update and supersede this information. We incorporate by reference into this prospectus supplement the documents listed below, and any future filings (other than the portions thereof deemed to be furnished to the SEC pursuant to Item 9 or Item 12 of Form 8-K) we make with the SEC 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, 2004, filed with the SEC on March 15, 2005; our quarterly report on Form 10-Q for the quarter ended March 31, 2005, filed with the SEC on May 10, 2005; our quarterly report on Form 10-Q for the quarter ended June 30, 2005, filed with the SEC on August 9, 2005; our current report on Form 8-K filed with the SEC on September 28, 2005; our current report on Form 8-K filed with the SEC on August 19, 2005; our current report on Form 8-K filed with the SEC on June 10, 2005; our current report on Form 8-K filed with the SEC on January 11, 2005; our current report on Form 8-K filed with the SEC on December 21, 2004; and our current report on Form 8-K/A filed with the SEC on July 6, 2004.

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 SEC 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 supplement is inconsistent with any statement that is incorporated by reference and that was made on or before the date of this prospectus supplement, the statement in this prospectus supplement shall supersede such incorporated statement. The incorporated statement shall not be deemed, except as modified or superseded, to constitute a part of this prospectus supplement, the accompanying prospectus or the registration statement. Statements contained in this prospectus supplement 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 supplement or the accompanying prospectus is delivered, upon written or oral request, a copy of the information that has been incorporated into this prospectus supplement or the accompanying prospectus by reference (except exhibits, unless they are specifically incorporated into this prospectus supplement or the accompanying 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

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Table of Contents PROSPECTUS \$60,000,000 NANOGEN, INC. **Common Stock Preferred Stock Debt Securities Warrants to Purchase Common Stock** Warrants to Purchase Preferred Stock An investment in the securities offered under this prospectus involves a high degree of risk. You should carefully consider the <u>risk factors</u> described on pages 2-15 of this prospectus.

We may offer and sell from time to time shares of common stock, shares of preferred stock, debt securities or warrants to purchase shares of common or preferred stock. We may sell any combination of the above described securities, in one or more offerings in amounts, at prices and on terms determined at the time of the offering. The total aggregate public offering price of the securities offered under this prospectus is \$60,000,000.

We will provide the specific terms of the offer and sale of these securities in supplements to this prospectus. The prospectus supplements may also add, update or change information contained in this prospectus. You should read this prospectus and any supplements carefully before you

invest. The prospectus may not be used to offer and sell securities unless accompanied by a prospectus supplement.

Our common stock trades on the Nasdaq National Market under the symbol NGEN. Each prospectus supplement offering any other securities will state whether those securities are listed or will be listed on any national securities exchange or the Nasdaq Stock Market.
Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities of determined if this prospectus is truthful or complete. Any representation to the contrary is a criminal offense.

The date of this prospectus is June 28, 2005.

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FORWARD-LOOKING STATEMENTS

This prospectus and the documents incorporated herein by reference include forward-looking statements within the meaning of Section 27A of the Securities Act and Section 21E of the Exchange Act. All statements other than statements of historical fact are forward-looking statements for purposes of these provisions, including any projections of earnings, revenues or other financial items, any statements of the plans and objectives of management for future operations, any statements concerning proposed new products or services, any statements regarding future economic conditions or performance, and any statement of assumptions underlying any of the foregoing. In some cases, forward-looking statements can be identified by the use of terminology such as may , should , could , would , will , believes , intends , expects , plans , estimates , potential , or continue or the negative thereof or other comparable terminology. Although we believe that the expectations reflected in the forward-looking statements contained in this prospectus and in the incorporated documents are reasonable, we cannot assure you that such expectations or any of the forward-looking statements will prove to be correct, and actual results could differ materially from those projected or assumed in the forward-looking statements. Our future financial condition and results of operations, as well as any forward-looking statements, are subject to inherent risks and uncertainties, including but not limited to those set forth herein under the heading Risk Factors and those discussed in documents we incorporate by reference into this prospectus and for the reasons described elsewhere in this prospectus.

We will not update these forward-looking statements, whether as a result of new information, future events or otherwise. You should, however, review additional disclosures we make in our quarterly reports on Form 10-Q, current reports on Form 8-K and annual reports on Form 10-K filed with the SEC.

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ABOUT THIS PROSPECTUS

This prospectus is part of a registration statement on Form S-3 that we filed with the Securities and Exchange Commission, or the SEC, using a shelf registration process. Under this shelf process, we may from time to time sell any combination of securities described in this prospectus in one or more offerings, up to a total dollar amount of \$60,000,000. This prospectus provides you with a general description of the securities we may offer. Each time we sell securities, we will provide a prospectus supplement that will contain specific information about the terms of that offering. The prospectus supplement may, along with information that is incorporated by reference as described under the heading Where You Can Find More Information, also add, update or change information contained in this prospectus. You should read both this prospectus and any prospectus supplement together with additional information described below under the heading Where You Can Find More Information.

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 securities 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 securities. 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.

NANOGEN, INC.

The following is only a summary. We urge you to read the entire prospectus, including the more detailed financial statements, notes to the financial statements and other information incorporated by reference from our other filings with the SEC. Investing in our securities involves risk. Accordingly, please carefully consider the information provided under the heading Risk Factors on page 2.

Nanogen was founded with a vision to improve the quality of healthcare by introducing advanced human diagnostic products that will provide higher quality of information in a shorter period of time to our customers in the research, clinical laboratory or point-of-care markets. We intend to turn this vision into reality by continuing to develop new diagnostic products or by acquiring other companies and complementary products that will expand and accelerate our entry into rapidly growing diagnostic markets. We began a targeted acquisition strategy during 2004 that is expected to result in a broad product line of advanced diagnostic products. The combination of internally developed products plus acquired products addressing large markets should provide the stimulus for significant revenue acceleration in 2005 and beyond.

We were incorporated under the laws of the State of Delaware and our stock is listed on the Nasdaq National Market under the symbol NGEN. Our corporate offices are located at 10398 Pacific Center Court, San Diego, California 92121. Our main telephone number is 858-410-4600.

For further information regarding us and our financial information, you should refer to our recent filings with the SEC. See Where You Can Find More Information and Incorporation of Certain Documents by Reference.

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RISK FACTORS

An investment in our securities 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 March 31, 2005, 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, 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® 400, in October 2004. This new instrument is expected to begin shipping in 2005. 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.

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. 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 products and 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 the quarter ended March 31, 2005 we did not incur any charge to reduce our inventory to its net realizable value, however, in the years ended December 31, 2004, 2003, and 2002 we took accounting charges of approximately \$3.7 million, \$908,000 and \$1.1 million, respectively, to reduce product inventory to its estimated net realizable value. If actual future demand or market conditions are less favorable than those currently 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;

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

sell, place and service sufficient quantities of our products.

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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 year ended December 31, 2004, certain clinical laboratories experienced performance issues with our cystic fibrosis analyte specific reagent, CFTR ASR, which negatively impacted our revenue. We are not currently offering our CFTR ASRs for sale in the United States. We are developing new reagents for the NC400. However, we may not be able to address product 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.

Our NanoChip® System instruments, including Molecular Biology Workstation and the second-generation NanoChip® 400, are manufactured by Hitachi. As such our success in the micro-array based diagnostics market is largely dependent upon Hitachi s ability to perform under our manufacturing agreement. 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.

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.

In October 2004, we announced our second-generation instrument system, the NanoChip® 400. This new instrument is expected to begin shipping in 2005. Risks inherent in the transition to our second-generation system and other new products we may release in the future include the following:

potential delays in initial shipments of new products;

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;

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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.

If our acquisitions are unsuccessful, our business may be harmed.

As part of our business strategy, we have acquired companies, technologies and product lines to complement our internally developed products. We expect that acquisitions will remain a part of our growth strategy going forward. Acquisitions involve numerous risks, including the following: