NANOGEN INC
Form 10-Q
November 09, 2005
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UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

FORM 10-Q

x QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the quarterly period ended September 30, 2005

OR

¨ TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the transition period from _____ to _____

Commission File Number 000-23541

NANOGEN, INC.

(Exact name of Registrant as specified in its charter)

Delaware	33-0489621
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
10398 Pacific Center Court, San Diego, CA	**92121**
(Address of principal executive offices)	**(Zip code)**

(858) 410-4600

(Registrant s telephone number, including area code)

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. YES x NO ¨

Indicate by check mark whether the registrant is an accelerated filer (as defined in Rule 12b-2 of the Exchange Act). YES x NO ¨

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). YES ¨ NO x

As of October 18, 2005, 54,177,670 shares of the Registrant s Common Stock were outstanding.

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PART I. FINANCIAL INFORMATION

ITEM 1. CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (UNAUDITED)

NANOGEN, INC.

CONDENSED CONSOLIDATED BALANCE SHEETS

(in thousands, except par value and share data)

	As of September 30, 2005 (unaudited)	As of December 31, 2004
ASSETS		
Current assets:		
Cash and cash equivalents	$ 27,670	$ 15,372
Short-term investments	12,989	36,562
Receivables, net	2,416	2,023
Inventories, net	3,372	1,744
Other current assets	1,850	1,741
Total current assets	48,297	57,442
Property and equipment, net	8,037	8,500
Acquired technology rights, net	10,043	11,819
Restricted cash	1,897	1,411
Other assets, net	1,928	780
Goodwill	96,178	96,072
Total assets	$ 166,380	$ 176,024
LIABILITIES AND STOCKHOLDERS EQUITY		
Current liabilities:		
Accounts payable and accrued liabilities	$ 7,274	$ 9,923
Deferred revenue	539	420
Common stock warrants	166	1,112
Current portion of debt obligations	727	988
Total current liabilities	8,706	12,443
Debt obligations, less current portion	774	610
Debt obligation resulting from the consolidation of a variable interest entity (note 9)	7,006	
Other long-term liabilities	6,246	5,455
Total long-term liabilities	14,026	6,065
Commitments and contingencies		
Stockholders equity:		
Convertible preferred stock, $0.001 par value, 5,000,000 shares authorized; no shares issued and outstanding at September 30, 2005 and December 31, 2004		
	55	48

Common stock, $0.001 par value, 135,000,000 shares authorized at September 30, 2005 and December 31, 2004; 54,677,859 and 47,765,581 shares issued and 54,177,670 and 47,265,392 outstanding at September 30, 2005 and December 31, 2004, respectively		
Additional paid-in capital	396,017	374,910
Accumulated other comprehensive loss	(83)	(174)
Deferred compensation	(2,490)	(1,184)
Capital deficit in consolidated variable interest entity (note 9)	(6,951)	
Accumulated deficit	(241,978)	(215,162)
Treasury stock, at cost, 500,189 shares at September 30, 2005 and December 31, 2004, respectively	(922)	(922)
Total stockholders equity	143,648	157,516
Total liabilities and stockholders equity	$ 166,380	$ 176,024

See accompanying notes.

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NANOGEN, INC.

CONSENSED CONSOLIDATED STATEMENTS OF OPERATIONS

(unaudited)

(in thousands, except per share data)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2005	2004	2005	2004
Revenues:				
Product sales	$ 1,060	$ 671	$ 3,348	$ 2,280
License fees and royalty income	1,748	25	5,071	214
Sponsored research				500
Contracts and grants	363	386	1,063	1,365
Total revenues	3,171	1,082	9,482	4,359
Costs and expenses:				
Cost of product sales	799	1,298	3,073	4,150
Research and development	5,701	4,514	15,773	12,901
Selling, general and administrative	5,326	4,811	17,703	12,626
Charge for acquired in-process research and development				3,758
Amortization of purchased intangible assets	393		1,178	
Total costs and expenses	12,219	10,623	37,727	33,435
Loss from operations	(9,048)	(9,541)	(28,245)	(29,076)
Other income (expense):				
Interest income, net	110	187	598	433
Other expense	(8)	(73)	(118)	(256)
Warrant valuation adjustment	109		946	
Gain (loss) on foreign currency translation	(1)	(15)	3	1,190
Total other income	210	99	1,429	1,367
Net loss	$ (8,838)	$ (9,442)	$ (26,816)	$ (27,709)
Net loss per share basic and diluted	$ (0.18)	$ (0.28)	$ (0.56)	$ (0.89)
Number of shares used in computing net loss per share basic and diluted	48,018	33,336	47,859	31,034

See accompanying notes.

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NANOGEN, INC.

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

(unaudited)

(in thousands)

	Nine months ended September 30,	
	2005	**2004**
Operating activities:		
Net loss	$ (26,816)	$ (27,709)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	4,197	2,678
Charge for acquired in-process research and development		3,758
Inventory reserves	(183)	2,429
Impairment charges	167	
Foreign currency translation gain		(1,190)
Other non-cash charges		47
Loss on disposal of fixed assets	31	43
Accretion related to short-term investments	186	175
Stock-based compensation expense	806	505
Warrant valuation adjustment	(946)	
(Decreases) increase in cash caused by changes in operating assets and liabilities, excluding the effects of acquisitions:		
Receivables	(393)	706
Inventories	(2,243)	(118)
Other current and long-term assets	(378)	(753)
Accounts payable and accrued liabilities	(1,074)	(2,090)
Deferred revenue and other long-term liabilities	119	(53)
Net cash used in operating activities	(26,527)	(21,572)
Investing activities:		
Purchase of short-term investments	(22,541)	(61,809)
Proceeds from sale and maturities of short-term investments	45,993	34,956
Strategic investments	(1,259)	
Acquisition of businesses, net of cash acquired	(1,681)	(2,669)
Purchase of equipment	(1,271)	(397)
Net cash provided by (used in) investing activities	19,241	(29,919)
Financing activities:		
Principal payments on long-term obligations	(842)	(420)
Issuance of equity, net	19,002	48,956
Equity transactions in variable interest entity	697	
Proceeds from development partner		441

Proceeds from restricted cash balances		14
Proceeds from long-term obligations	700	
Net cash provided by financing activities	19,557	48,991
Effect of exchange rate changes	27	13
Net increase (decrease) in cash and cash equivalents	12,298	(2,487)
Cash and cash equivalents at beginning of period	15,372	8,550
Cash and cash equivalents at end of period	$ 27,670	$ 6,063

See accompanying notes.

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NANOGEN, INC.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (UNAUDITED)

September 30, 2005

1. Basis of Presentation

The accompanying unaudited consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America for interim financial information and with the instructions to Form 10-Q and Article 10 of Regulation S-X. Accordingly, they do not include all of the information and disclosures required by accounting principles generally accepted in the United States of America for complete financial statements. The consolidated balance sheet as of September 30, 2005, consolidated statements of operations for the three and nine months ended September 30, 2005 and 2004, and the consolidated statements of cash flows for the nine months ended September 30, 2005 and 2004 are unaudited, but include all adjustments (consisting of normal recurring adjustments, except for charges for obsolete inventory and the entries related to the acquisition of SynX Pharma Inc., a $3.8 million charge to in-process research and development, and the consolidation of Jurilab, LTD, a variable interest entity which are discussed herein) which in the opinion of management are considered necessary for a fair presentation of the financial position, results of operations and cash flows for the periods presented. The results of operations for the three and nine months ended September 30, 2005 shown herein are not necessarily indicative of the results that may be expected for the year ending December 31, 2005.

For more complete financial information, these financial statements, and notes thereto, should be read in conjunction with the audited consolidated financial statements for the year ended December 31, 2004 included in the Nanogen, Inc. Annual Report on Form 10-K for the year ended December 31, 2004 filed with the Securities and Exchange Commission on March 15, 2005.

Certain reclassifications have been made to prior period balances in order to conform to the current period presentation.

When we refer to we, our, us or Nanogen in this document, we mean the current Delaware corporation Nanogen, Inc. and its California predecessor, as well as all of our consolidated subsidiaries.

Basis of Consolidation

Our consolidated financial statements include the assets, liabilities and operating results of majority-owned subsidiaries and other subsidiaries controlled by us. Effective July 1, 2003, we adopted Financial Accounting Standards Board Interpretation (FIN) No. 46, *Consolidation of Variable Interest Entities, an Interpretation of ARB No. 51*, for VIEs formed prior to February 1, 2003. In December 2003, the FASB issued FIN 46R, which revised FIN 46, in order to clarify the provisions of the original interpretation. Therefore, we have consolidated a material VIE

of which we are the primary beneficiary beginning July 20, 2005 the date of our initial investment in the VIE. The liabilities recognized as a result of consolidating the VIE do not represent additional claims on our general assets; rather, they represent claims against the specific assets of the consolidated VIE. Conversely, assets recognized as a result of consolidating this VIE do not represent additional assets that could be used to satisfy claims against our general assets. All significant intercompany accounts and transactions are eliminated.

Use of Estimates

The preparation of financial statements in conformity with accounting principles generally accepted in the United States requires management to make estimates and assumptions that affect the reported

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amounts of assets and liabilities and related disclosures at the date of the financial statements, and the amounts of revenues and expenses reported during the period. Actual results could differ from those estimates.

Long-Lived Assets

In accordance with Statement of Financial Accounting Standards (SFAS) No. 144, *Accounting for Impairment or Disposal of Long-Lived Assets*, we periodically assess certain of our long-lived assets, such as property and equipment and intangible assets other than goodwill, for potential impairment when there is a change in circumstances that indicates the carrying values of the assets may not be recovered. An impairment occurs when the undiscounted cash flows expected to be generated by an asset are less than its carrying amount. The loss is measured as the amount by which the asset s carrying value exceeds its fair value, and is recorded as a reduction in the carrying value of the related asset and a charge to operating expense. During the three and nine months ended September 30, 2005 we had approximately $167,000 in impairment losses. We had no impairment losses in the three and nine months ended September 30, 2004.

Goodwill

We have elected to perform our analysis of goodwill during the fourth quarter this year. In addition, we will perform an analysis whenever events and changes in circumstances suggest that the carrying amount may not be recoverable. No such events or changes were identified in the nine months ended September 30, 2005.

Net Loss per Share

We compute net income (loss) per share in accordance with SFAS No. 128, *Earnings per Share*. We compute basic net income (loss) per share by dividing the net income (loss) available to common stockholders for the period by the weighted average number of common shares outstanding during the period. Diluted net income (loss) per share is computed by dividing the net income (loss) for the period by the weighted average number of common shares outstanding during the period, and in the periods they are dilutive, common equivalent shares for outstanding stock options and warrants computed using the treasury stock method. The weighted average common shares outstanding during the period does not include those shares issued pursuant to the exercise of stock options prior to vesting. In loss periods, common stock equivalents are excluded from the computation of diluted net loss per share as their effect would be anti-dilutive.

Cash and Cash Equivalents and Short-Term Investments

We consider all highly liquid investments with maturity of three months or less from the date of purchase to be cash equivalents. We invest excess cash in highly liquid debt instruments of financial institutions and corporations with strong credit ratings and in United States government obligations. We have established guidelines relative to diversification and maturities that maintain safety and liquidity. These guidelines are periodically reviewed and modified to take advantage of trends in yields and interest rates.

We have evaluated our investments in accordance with the provisions of SFAS No. 115, *Accounting for Certain Investments in Debt and Equity Securities*, and we have determined that all of our investment securities are properly classified as available-for-sale. Based on our intent, investment policies and our ability to liquidate debt securities, we classified such short-term investment securities

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within current assets. Available-for-sale securities are carried at fair value, with unrealized gains and losses included in accumulated other comprehensive loss within stockholders equity. The amortized cost basis of debt securities is periodically adjusted for amortization of premiums and accretion of discounts to maturity. Such amortization is included as a component of interest income (expense). The amortized cost basis of securities sold is based on the specific identification method and all such realized gains and losses are recorded as a component within other income (expense), net.

We review the carrying values of our investments and write down investments to their estimated fair value by a charge to operations when we determine the decline in value of an investment is considered to be other than temporary. The cost of investments sold is based on the average cost method and is recorded on the settlement date.

At September 30, 2005, the excess of carrying cost over the fair value of our short-term investments that are below carrying cost is immaterial and considered to be temporary.

Segment Information

SFAS No. 131, *Disclosures about Segments of an Enterprise and Related Information*, establishes standards for reporting information on operating segments in interim and annual financial statements. We operate in one segment, which is the business of development, manufacturing and commercialization of advanced diagnostic products. Our chief operating decision-makers review our operating results on an aggregate basis and manage our operations as a single operating segment.

Revenue Recognition

Product revenue is generated by the sale of commercial products and services under various sales programs to the end user and through distribution channels. The Securities and Exchange Commission (SEC) Staff Accounting Bulletin (SAB) No. 104, provides guidance on the recognition, presentation, and disclosure of revenue in financial statements. SAB No. 104 establishes the SEC s view that it is not appropriate to recognize revenue until all of the following criteria are met: persuasive evidence of an arrangement exists; delivery has occurred or services have been rendered; the seller s price to the buyer is fixed or determinable; collectibility is reasonably assured, and requires that both title and the risks and rewards of ownership be transferred to the buyer before revenue can be recognized. The Emerging Issues Task Force (EITF) Issue No. 00-21, *Accounting for Revenue Arrangements with Multiple Deliverables* addresses the determination of whether an arrangement involving more than one deliverable contains more than one unit of accounting and how the arrangement s consideration should be measured and allocated to the separate units of accounting. We believe that our revenue recognition policies are in compliance with SAB 104 and EITF Issue No. 00-21.

Product sales

We sell NanoChip Molecular Biology Workstations (NanoChip Systems) and related consumables including NanoChip Cartridges, and Analyte-Specific Reagents (ASRs), real time PCR reagent products, real time ASRs and point-of-care diagnostic tests (diagnostic tests) to end users and distributors in the research and clinical diagnostic fields.

Revenue from product sales that require no ongoing obligations are recognized as revenue when shipped to the customer (f.o.b. shipping point in the United States or Delivery Duty Paid at the customer s site in Europe) and title has passed and collection is reasonably assured. In transactions where a right-of-return exists, revenue is deferred until acceptance has occurred and the period for the right-of-return has

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lapsed. As of September 30, 2005, we have not entered into any sales transactions where rights-of-return exist.

We sell NanoChip Systems either as (i) direct sales or (ii) reagent rental/cost per test agreements.

(i) Direct sales

Revenue from the direct sales of NanoChip Systems and related consumables to an end user or a distributor is recognized following receipt of a purchase order, shipment of the product and when title has passed. In transactions where a right-of-return exists, revenue is deferred until acceptance has occurred and the period for the right-of-return has lapsed. The cost of sales related to the system and consumables is recorded in the period in which the corresponding revenue is recognized.

We provide product warranty coverage for NanoChip® Systems. The NanoChip® System s warranty periods are generally for one year under direct sales and over the period of the contract for a cost per test agreement. NanoChip® System s sold to distributors are typically sold without warranty coverage. The fair value of the warranty is recorded as deferred revenue. The revenue is recognized ratably over the warranty period. The fair value of the warranty is determined by the renewal price for a maintenance contract on similar equipment and is consistent for all customers.

Workstations sold to distributors are sold outright with title transferring at point of shipment (f.o.b. shipping point in the United States or Ex Works at the customer s site in Europe).

(ii) Reagent rental/cost per test agreements

Revenue from fee per test agreements results when a NanoChip System is provided to a customer in return for the customer paying a premium on consumable products over a contractual number of years. When the fee per test agreement is consummated, the value of the NanoChip® System is reclassified from inventory to fixed assets and the cost of the system is amortized to the cost of product sales over the period of the contractual arrangement. Revenues and the cost of product sales for consumables are recognized when they are shipped.

License and royalty fees

We recognize royalty revenue when the amounts are earned and determinable, which is generally when the cash payment is received. We are able to recognize minimum required payments on an accrual basis, as they are determinable under contract. Royalty payments that are based on product sales by the licensees are generally not finalized until the licensee has completed their internal computations of the royalties due and/or remitted their cash payment.

We will recognize revenue tied to third party sales on an accrual basis if information is available to enable us to estimate the royalty due to us. However, we could experience materially different revenues and results of operations when we receive actual royalty reports and the related cash payments.

In certain situations we may not be able to receive information on licensee product sales on a timely basis that will allow us to reasonably estimate the amount of royalty revenue to be recognized in the quarter the third party sales took place. We will not recognize this royalty revenue until we are able to ensure that we have reliable information, which may be in a subsequent period. Therefore, we could experience fluctuations in revenues from quarter to quarter depending on the timing of receipt of third party reports or cash payments.

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Sponsored research, contract and grants revenue

We earn revenue for performing tasks under research agreements with both commercial enterprises and governmental agencies. Sponsored research and contract and grants revenue is generally recorded as the costs and expenses to perform the research are incurred. Continuation of certain sponsored research and contracts and grants are dependent upon our achievement of specific contractual milestones. Milestone payments are recognized as revenue upon meeting the following criteria: i) we have achieved a specified milestone and have earned the milestone payment, ii) the milestone is substantive in nature and the achievement of the milestone was not reasonably assured at the inception of the agreement, iii) the fees are non-refundable, and iv) the collection of the payment is reasonably assured. In circumstances where funding is provided on a contractually scheduled basis, revenue is recorded ratably over the term of the arrangement. Payments received in advance are recorded as deferred revenue until the expenses are incurred. Any payments received prior to satisfying our revenue recognition criteria are recorded as deferred revenue in the balance sheet.

Recent Accounting Pronouncements

In December 2004, the FASB issued SFAS No. 123R, *Share-Based Payment*, that addresses the accounting for share-based payment transactions in which an enterprise receives employee services in exchange for either equity instruments of the enterprise or liabilities that are based on the fair value of the enterprise s equity instruments or that may be settled by the issuance of such equity instruments. The statement eliminates the ability to account for share-based compensation transactions, as we do currently, using the intrinsic value method as prescribed by Accounting Principles Board, or APB, Opinion No. 25, *Accounting for Stock Issued to Employees,* and generally requires that such transactions be accounted for using a fair-value-based method and recognized as expenses in our consolidated statement of operations. The statement requires companies to assess the most appropriate model to calculate the value of the options. We currently use the Black-Scholes option pricing model to value options; however, we are currently assessing which model we may use in the future under the new statement. The use of a different model to value options may result in a different fair value than the use of the Black-Scholes option pricing model. In addition, there are a number of other requirements under the new standard that would result in a different accounting treatment than is currently required. These differences include, but are not limited to, the accounting for the tax benefit on employee stock options and for stock issued under our employee stock purchase plan, and the presentation of tax benefits within the consolidated statement of cash flows. In addition, we will also be required to determine the transition method to be used at the date of adoption. The transition methods include modified prospective and modified retroactive adoption options. The modified prospective method requires that compensation expense be recorded for all unvested stock options and restricted stock at the beginning of the first quarter of adoption of FAS 123R, while the retroactive method would record compensation expense for all unvested stock options and restricted stock beginning with the first period restated.

In April 2005, the SEC announced the adoption of Release No. 33-8568, *Amendment to Rule 4-01(a) of Regulation S-X Regarding the Compliance Date for Statement of Financial Standard No. 123 (Revised 2004), Share-Based Payment*, that amends the effective date of FAS 123R to January 1, 2006 for fiscal year end companies such as ours. The adoption of FAS 123R will have a significant impact on our consolidated financial statements in the first quarter of 2006 as we will be required to expense the fair value of the stock option grants and stock purchases under our employee stock purchase plan rather than disclose the impact on the consolidated net results of operations within the footnotes, as is our current practice.

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In November 2004, the FASB issued SFAS No. 151, *Inventory Costs An Amendment of ARB No. 43, Chapter 4.* SFAS No. 151 clarifies that abnormal amounts of idle facility expense, freight, handling costs and spoilage should be expensed as incurred and not included in overhead. Further, FAS 151 requires that the allocation of fixed and production facilities overhead to conversion costs should be based on normal capacity of the production facilities. The provisions in FAS 151 are effective for inventory costs incurred during fiscal years beginning after June 15, 2005. We do not believe that the adoption of FAS 151 will have a significant effect on our financial statements.

In March 2005, the SEC released SAB No. 107, *Share-Based Payment* . SAB 107 provides the SEC staff position regarding the application of SFAS No. 123R. SAB 107 contains interpretive guidance related to the interaction between SFAS No. 123R and certain SEC rules and regulations, as well as provides the Staff s views regarding the valuation of share-based payment arrangements for public companies. SAB 107 also highlights the importance of disclosures made related to the accounting for share-based payment transactions. We are currently reviewing the effect of SAB 107 on our consolidated financial statements as we prepare to adopt SFAS 123R.

In June 2005, FASB issued SFAS 154, *Accounting Changes and Error Corrections* , a replacement of APB 20, *Accounting Changes*, and SFAS 3, *Reporting Accounting Changes in Interim Financial Statements*. This statement applies to all voluntary changes in accounting principle, and changes the requirements for accounting for and reporting of a change in accounting principle. SFAS 154 requires retrospective application to prior periods financial statements of a voluntary change in accounting principle unless it is impracticable. It is effective for accounting changes and corrections of errors made in fiscal years beginning after December 15, 2005. Earlier application is permitted for accounting changes and corrections of errors made occurring in fiscal years beginning after June 1, 2005. We do not believe that the adoption of SFAS 154 will have a significant effect on our financial statements.

2. Stock-Based Compensation

We apply the intrinsic value-based method of accounting as prescribed by APB Opinion No. 25, *Accounting for Stock Issued to Employees*, and related interpretations including FASB Interpretation No. 44, *Accounting for Certain Transactions involving Stock Compensation an interpretation of APB Opinion No. 25* to account for our stock option plans. Under the intrinsic value method, compensation expense is measured on the date of grant only if the then current market price of the underlying stock exceeded the exercise price and is recorded on a straight-line basis over the applicable vesting period. SFAS No. 123, *Accounting for Stock-Based Compensation*, established accounting and disclosure requirements using a fair value-based method of accounting for stock-based employee compensation plans. As allowed by SFAS No. 123, we have elected to continue to apply the intrinsic value-based method of accounting described above, and have adopted the disclosure requirements of SFAS No. 123, as amended by SFAS No. 148, *Accounting for Stock-Based Compensation Transition and Disclosure*.

The pro forma effects of stock-based compensation on net loss and net loss per common share have been estimated at the date of grant using the Black-Scholes option-pricing model. The Black-Scholes option-pricing model was developed for use in estimating the fair value of traded options that have no restrictions and are fully transferable and negotiable in a free trading market. Black-Scholes does not consider the employment, transfer or vesting restrictions that are inherent in our employee options. The use of an option valuation model, as required by SFAS No. 123, includes highly subjective assumptions based on long-term predictions, including the expected stock price volatility and average life of each option grant. Because our employee stock options have characteristics significantly different from those of freely traded options, and because the assumptions underlying the Black-Scholes model involve substantial judgment, our estimate of the fair value of our awarded stock options may differ materially from the ultimate value realized by the recipient employee.

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The weighted average estimated fair values of stock options granted during the three and nine months ended September 30, 2005 was $4.37 and $4.42 per share, respectively and the three and nine months ended September 30, 2004 was $4.64 and $5.70 per share. Fair value under SFAS No. 123 is determined using the Black-Scholes option-pricing model with the following assumptions:

	Three months ended September 30,		Nine months ended September 30,	
	2005	2004	2005	2004
Expected term	5 years	5 years	5 years	5 years
Interest rate	4.2%	3.8%	4.2%	3.8%
Volatility	47%	84%	62%	91%
Dividends				

Had compensation expense been recorded based on the fair value method prescribed by SFAS No. 123, our pro forma net loss, and pro forma loss per share would have been as follows:

	Three months ended September 30,		Nine months ended September 30,	
	2005	2004	2005	2004
Net loss:				
As reported	$ (8,838)	$ (9,442)	$ (26,816)	$ (27,709)
Add: Stock based employee compensation expense included in reported net loss, net of related tax effects	280		280	
Deduct: Total stock based employee compensation expense determined under Black-Scholes method for all awards, net of related tax effects	(1,288)	(1,222)	(4,111)	(3,122)
Pro forma	$ (9,846)	$ (10,664)	$ (30,647)	$ (30,831)
Basic and diluted loss per share:				
Basic and diluted loss per common share:				
As reported	$ (0.18)	$ (0.28)	$ (0.56)	$ (0.89)
Pro forma	$ (0.21)	$ (0.32)	$ (0.64)	$ (0.99)

The amounts disclosed above are not necessarily indicative of the amounts that will be expensed upon adoption of FAS No. 123R *Share-Based Payment*. Compensation expense calculated under FAS No. 123R may differ from amounts currently disclosed within these footnotes based on changes in the fair value of our common stock, changes in the number of options granted or the terms of such options, the treatment of tax benefits and changes in interest rates or other factors. In addition, upon adoption of FAS No. 123R, we may choose to use a different valuation model to value the compensation expense associated with employee stock options and stock purchases under our employee stock purchase plan, as discussed under Recent Accounting Pronouncements.

Periodically, we issue options to non-employees. The options are recorded at their fair values (using the Black-Scholes model) as determined in accordance with SFAS No. 123 and periodically re-measured in accordance with EITF 96-18 *Accounting for Equity Instruments That Are Issued To Other Than*

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Employees for Acquiring, or in Conjunction with Selling, Goods, or Services and are recognized over the related service period.

3. Business Combination

On April 21, 2004, we acquired all the outstanding common stock of SynX Pharma Inc. (SynX) in an all-stock transaction by way of a court-approved plan of arrangement. Based in Toronto, Canada, SynX leverages proteomic and biomarker research to develop a line of point-of-care diagnostic tests. Through this acquisition we gained access to SynX s point-of-care technologies. Consistent with our strategy to broaden our product lines we gained access to a world wide license to the congestive heart failure (CHF) marker NT-proBNP to develop a test for the point-of-care market. Also, by combining our companies, we were able to consolidate operational and administrative functions. These factors were among those that contributed to a purchase price resulting in the recognition of $10.5 million in goodwill.

The total purchase price of approximately $16.0 million was a result of us issuing SynX stockholders 0.123 shares of our common stock for each share of their common stock. The market value of our common stock on April 21, 2004 of $7.60 was used to determine the fair value of the shares exchanged. SynX debenture holders received our common stock based upon (i) the aggregate principal amount plus accrued and unpaid interest owed on the debenture, (ii) the currency exchange rate on April 21, 2004, and (iii) the average best bid and best ask price for our stock on April 21, 2004. SynX s stockholders and debenture holders received approximately 1.6 million shares of our common stock or 5% of our common stock immediately following the acquisition. We also assumed all of SynX s options and warrants outstanding at the effective date of the merger and they are now exercisable for 0.123 of our common stock. The exercise prices of the options and warrants were adjusted accordingly. The fair value of assumed options and warrants were determined using the Black-Scholes option pricing model using a stock price of $7.63 and the following assumptions:

	Options	Warrants
Expected term	2 years	2 years
Interest rate	1.47%	1.47%
Volatility	90%	90%
Dividends		

The results of operations of SynX have been included in the accompanying consolidated financial statements from the date of acquisition. The actual cost of the acquisition has been recorded as follows (in thousands):

Nanogen common stock exchanged	$ 12,493
Fair value of options and warrants assumed	1,237
Direct transaction costs	2,279
Total purchase price	$ 16,009

The allocation of the above purchase price is as follows (in thousands):

Tangible assets acquired	$ 5,818

In Process Research & Development	
Congestive Heart Failure Diagnostic	2,677
Traumatic Brain Injury Diagnostic	504
Diabetes Diagnostic	577
Intangible assets not subject to amortization	294
Goodwill	10,452
Total assets acquired	20,322
Liabilities assumed	(4,313)
Net assets acquired	$ 16,009

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We used an independent third party to perform a valuation analysis of our purchased intangibles and in-process research and development (IPR&D) and we reviewed their assumptions, calculations and conclusions for reasonableness. We primarily used the income approach to value these assets based on the assumption that the value of an asset can be determined by estimating the present value of the expected cash flows generated by an investment in that asset. Based on the valuation we allocated $294,000 to trade names that is not subject to amortization and allocated $3.8 million of the purchase price to IPR&D related to congestive heart failure (CHF), traumatic brain injury (TBI) and diabetes diagnostic products. The research and development underlining these applications was unique to our current research and development projects involving microarray technology. The IPR&D asset was expensed at the date of acquisition in accordance with FASB Interpretation No. 4 *Applicability of FASB Statement No. 2 to Business Combinations Accounted for by the Purchase Method*. The value assigned to acquired IPR&D was determined by estimating the expenses required to develop the acquired IPR&D into commercially viable products, estimating the resulting cash flows from the products and discounting the net cash flows to their present values and to reflect the risks associated with the development of the products. The discount rates used ranged from 30% to 40% reflecting the inherent risks involved in launching complex diagnostic products. The calculations of value were adjusted to reflect the creation efforts which were made prior to the close of the acquisition. The IPR&D expense resulting from these calculations allocated $2.7 million in fair value to CHF, $504,000 in fair value to TBI and $577,000 in fair value for diabetes diagnostics. At the time of the acquisition, the CHF product was the closest to completion, and is currently expected to be launched in the second half of 2005. The TBI and diabetes products are still in the early stages of the development cycle. The amount assigned to acquired in-process research and development was recorded as an expense in the statement of operations for the year ended December 31, 2004. Approximately $10.5 million has been allocated to goodwill which is not subject to amortization. Goodwill represents the excess purchase price over the fair value of the net tangible and intangible assets acquired, and is not deductible for tax purposes.

In addition, as part of the acquisition, we acquired certain real estate commitments approximating current market lease rates for comparable properties to SynX averaging $917,000 per year for a total of approximately $6.6 million on a building lease through 2012.

Pro Forma Information

The following unaudited pro forma information assumes that the April 21, 2004 and December 16, 2004 acquisition of SynX and Epoch Bioscience, Inc., respective occurred on January 1, 2004. The unaudited pro forma results have been prepared for comparative purposes only and do not purport to be indicative of the results of operations that would have actually resulted had the acquisition been in effect as of the periods indicated, or of future results of operations. The unaudited pro forma results for the three and nine months ended September 30, 2004, are as follows (in thousands, except per share data):

	Three months ended September 30, 2004	Nine months ended September 30, 2004
	(unaudited)	(unaudited)
Revenues	$ 3,552	$ 9,836
Net loss [1]	(10,657)	(34,296)
Loss per share (basic and diluted)	$ (0.23)	$ (0.76)

[1] Includes $3.8 million for the write-off of IPR&D costs for the three and nine months ended September 30, 2004.

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4. Warranty

Our products are generally sold without a warranty. However, we provide product warranty coverage for NanoChip® Systems. The NanoChip® System s warranty periods are generally for one year under direct sales and over the period of the contract for a cost per test agreement. NanoChip® System s sold to distributors are typically sold without warranty coverage.

We are required to estimate our warranty obligations incurred by reference to historical product warranty return rates, material usage. The estimated warranty obligation is recognized at the time of sale and amortized over the service period. Should actual costs differ from our estimated warranty obligations, revisions to the estimated warranty liability would be required. In addition, we have costs associated with an in-house service function that is charged to cost of products sales in the period it is incurred.

Changes in our warranty liability were as follows (in thousands):

	Balance at January 1,	Warranty additions (charges to expense)	Costs for warranty service	Balance at September 30,
2005:				
Warranty reserve	$ 17	$ 20	$ (19)	$ 18
2004:				
Warranty reserve	$ 159	$ 327	$ (308)	$ 178

5. Comprehensive Loss

SFAS No. 130, *Reporting Comprehensive Income*, requires us to report, in addition to net loss, comprehensive loss and its components. A summary is as follows (in thousands):

	Three months ended September 30,		Nine month ended September 30,	
	2005	2004	2005	2004
Comprehensive loss:				
Net unrealized gain / (loss) on short-term investments	$ 29	$ 25	$ 64	$ (120)
Foreign currency translation adjustment	3	78	27	(1,319)
Net loss	(8,838)	(9,442)	(26,816)	(27,709)
Comprehensive loss	$ (8,806)	$ (9,339)	$ (26,725)	$ (28,968)

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6. Common Stock Warrant Liability

As a result of our acquisition of Epoch Bioscience, we assumed warrants representing 381,317 shares of our common stock with an exercise price of $8.32 per share with an expiration date in early 2009. These warrants contain a provision whereby, under certain circumstances pertaining to a change of control of Nanogen, the warrant holders have the right to redeem their warrant for cash equal to the estimated fair value of the warrant using the Black Scholes method. The volatility factor to be used in this calculation is limited to the lesser of 50% or our actual historical volatility. As a result, and in accordance with EITF 00-19, *Accounting for Derivative Financial Instruments Indexed To, and Potentially Settled In a Company s Own Stock*, the fair value of the cash redemption portion of the warrants, measured in accordance with the terms of the warrant agreements, is recorded as a current liability on our balance sheet. The decrease in the market price of our common stock and other changes in the valuation assumptions from December 31, 2004 to September 30, 2005 resulted in a decrease in the value of the warrants between these dates of $946,000. Therefore, we reported an other income of $946,000 as a warrant valuation adjustment in our statement of operations for the nine months ended September 30, 2005.

The assumptions used in the Black-Scholes pricing model were:

	September 30, 2005	December 31, 2004
Expected term	3.4 years	4.2 years
Interest rate	4.2%	3.6%
Volatility	50%	50%
Dividends		

Until the warrants are exercised or expire, the valuation of the warrants and the corresponding liability will be re-measured quarterly and the financial statements will reflect a non-cash valuation adjustment based on the change in the calculated value of the warrants during each reporting period.

7. Commitments and Contingencies

Long-term debt obligations

In March 2005, we extended our $2.0 million December 2003 equipment funding agreement to provide financing for equipment purchases through February 2006. We have approximately $745,000 in financing available under this equipment funding agreement.

In March 2005, we issued a promissory note under this agreement in an aggregate principal amount of approximately $219,000. This note is secured by equipment with a cost of $219,000. This note bears interest at 10.86% per annum with principal and interest due in monthly payments of approximately $7,000 for 36 months.

In June 2005, we issued another promissory note under this agreement in an aggregate principal amount of approximately $261,000. This note is secured by equipment with a cost of $261,000. This note bears interest at 10.56% per annum with principal and interest due in monthly payments of approximately $8,500 for 36 months.

In September 2005, we issued another promissory note under this agreement in an aggregate principal amount of approximately $220,000. This note is secured by equipment with a cost of $220,000. This

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note bears interest at 10.90% per annum with principal and interest due in monthly payments of approximately $7,100 for 36 months.

As of September 30, 2005, the future contractual principal payments on all of our promissory notes are as follows (in thousands):

For the years ended December 31,	
2005 (three months)	$ 284
2006	662
2007	431
2008	124
Total	$ 1,501

The interest expense for the three and nine months ended September 30, 2005 was $32,000 and $94,000, respectively.

Purchase Commitment

In June 2003, we committed to a manufacturing agreement with Hitachi, Ltd. (Hitachi) that requires us to provide annual purchase commitments to Hitachi for the second-generation workstation, the NanoChip® 400. As of September 30, 2005, we had commitments to purchase $1.2 million of the NanoChip® 400 instruments from Hitachi through November 2005.

Investment agreement

Our investment agreement with Jurilab states that if they meet certain conditions we have the obligation to invest an additional $1.5 million in cash by January 31, 2006.

Restricted Cash

We have pledged under a security agreement long-term certificates of deposit and a letter of credit, in lieu of cash deposits, to secure operating lease obligations which are reflected as restricted cash in the accompanying consolidated balance sheet. We had approximately $1.9 million and $1.4 million in long-term certificates of deposit and a letter of credit at September 30, 2005 and December 31, 2004, respectively.

Litigation

We may be subject to potential liabilities under various claims and legal actions that may be asserted. These matters have arisen in the ordinary course and conduct of our business, as well as through acquisitions, and some may be covered, at least partly, by insurance. Claim estimates that are probable and can be reasonably estimated are reflected as liabilities. The ultimate resolution of these matters is subject to many uncertainties. It is reasonably possible that some of the matters, which are pending or may be asserted, could be decided unfavorably to us. Although the amount of liability at September 30, 2005, with respect to these matters cannot be ascertained, we believe that any resulting liability should not materially affect our consolidated financial position, results of operation or cash flows.

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8. Financial Statement Details

Receivables

Receivables are comprised of the following (in thousands) as of:

	September 30, 2005	December 31, 2004
	(Unaudited)	
Product	$ 800	$ 721
License fees	1,646	1,375
Contract and grant	40	103
	2,486	2,199
Allowance for doubtful accounts	(70)	(176)
	$ 2,416	$ 2,023

Inventories

Inventories include the cost of material, labor and overhead, and are stated at the lower of average cost, determined on the first-in, first-out method, or market. We periodically evaluate our on-hand inventories and make appropriate provisions for any inventories deemed excess or obsolete.

Inventories consist of the following (in thousands) as of:

	September 30, 2005	December 31, 2004
	(Unaudited)	
Raw materials	$ 2,788	$ 1,924
Work in process (materials, labor and overhead)	2,229	2,398
Finished goods (materials, labor and overhead)	3,983	3,282
	9,000	7,604
Reserve for excess and obsolescence	(5,628)	(5,860)
	$ 3,372	$ 1,744

During the three months and nine months ended September 30, 2004, we increased our reserves related to our inventory NanoChip® Molecular Biology Workstation and accessory items by $900,000 and $2.4 million, respectively. This charge is reflected as additional cost of sales during the period.

Property and Equipment

Property and equipment consist of the following (in thousands) as of:

	Estimated Useful Life (years)	September 30, 2005	December 31, 2004
		(Unaudited)	
Scientific equipment	5	$ 10,818	$ 9,338
Office furniture and equipment	3 5	4,507	4,061
Manufacturing equipment	5	1,220	1,858
Leasehold improvements	(lesser of lease term or life of improvements)	7,327	7,247
		23,872	22,504
Less accumulated depreciation and amortization		(15,835)	(14,004)
		$ 8,037	$ 8,500

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For the three and nine months ended September 30, 2005, depreciation and amortization expense related to property and equipment totaled $856,000 and $2.5 million, respectively.

Acquired Technology Rights

Acquired technology rights consist of the following (in thousands) as of:

	Estimated Useful Life(years)	September 30, 2005		December 31, 2004	
		Gross Carrying Amount	Accumulated amortization	Gross Carrying Amount	Accumulated amortization
		(Unaudited)			
In-licensed technology rights	3 10	$ 6,024	$ (5,409)	$ 6,111	$ (4,897)
Customer contracts acquired	7	1,211	(129)	1,210	
Completed technology acquired	3 10	9,395	(1,049)	9,395	
Total acquired technology rights		$ 16,630	$ (6,587)	$ 16,716	$ (4,897)
Intangible assets not subject to amortization:					
Trademarks & trade names		$ 294		$ 294	

The amortization expense of intangibles for the three and nine months ended September 30, 2005 was $433,000 and $1,690,000, respectively. In the three months ended September 30, 2005 we recognized $167,000 of impairment charges related to in-licensed technology rights.

Estimated amortization of intangibles (in thousands) for the years ended:

2005 (Three months)	$ 430
2006	1,689
2007	1,682
2008	1,534
2009	1,489
Thereafter	3,219
	$ 10,043

Accounts Payable and Accrued Liabilities

Accounts payable and accrued liabilities are comprised of the following (in thousands) as of:

	September 30, 2005	December 31, 2004
	(Unaudited)	
Accounts payable	$ 1,907	$ 918
Accrued compensation and benefits	1,331	2,443
Accrued legal fees	403	944
Accrued acquisition costs		2,329
Accrued warrant rescission		598
Other	3,633	2,691
	$ 7,274	$ 9,923

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9. Variable Interest Entity

On July 20, 2005, we purchased approximately $1.5 million in stock of Jurilab LTD (Jurilab), a development stage research and development company focused on technology related to certain gene markers. This investment represents approximately 16.7% of their outstanding stock. We have the obligation to increase our equity investment by approximately $1.5 million by January 31, 2006 if Jurilab meets certain conditions within our investment agreement. In addition, we have the option to purchase the entire company at not-to-exceed prices through December 31, 2007. Based on our analysis of the investment agreement, we are the primary beneficiary under FIN 46R *Consolidation of Variable Interest Entities.* We are the primary beneficiary because our equity investment at risk is not sufficient to permit Jurilab to finance its activities without additional support, we have the direct ability through control of Jurilab s Board of Directors to make decisions about the entity s activities and our equity interest is not proportional to the losses we will take from the research and development expenses. In addition substantially all of the entity s activities are conducted on our behalf despite our disproportionate ownership percentage.

Jurilab s creditors have no recourse against us and our maximum exposure to loss is the extent of our investment in the entity. Conversely, assets recognized as a result of consolidating do not represent additional assets that could be used to satisfy claims against our general assets.

Included in our consolidated balance sheet at September 30, 2005 were the net liabilities (in thousands) of Jurilab:

	September 30, 2005
	(Unaudited)
Cash	$ 529
Restricted cash	486
Other assets	722
Debt obligations	(7,006)
Other long-term liabilities	(730)
Net liabilities	$ (5,999)

Consolidation of Jurilab s results of operations included the following:

	Three months ended September 30, 2005	Nine months ended September 30, 2005
	(Unaudited)	(Unaudited)
Net sales	$ 58	$ 58
Cost of product sales	(28)	(28)
Research and development expense	(689)	(689)
Other income	(42)	(42)
Net loss	$ (701)	$ (701)

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10. Investment

On July 5, 2005, we purchased $350,000 in common stock of Pharmacogenetics Diagnostic Laboratory, LLC (PGx) a development stage research and development company to provide us access to certain technology related to pharmacogenetics. We may increase our equity investment to approximately $500,000 if PGx reaches certain agreed upon milestones. We conducted a sensitivity analysis that considered both the qualitative and quantitative factors of our initial and potential additional investments in PGx to consider if we should consolidate PGx as a VIE under FIN 46. We did not consider PGx a VIE because we believe it is likely PGx will obtain additional and operating funding from other third parties, the fact their creditors have no recourse against us and our maximum exposure to their loss is the extent of our investment. Therefore, we will expense PGx s net losses to research and development. Once our investment, which is carried as other long-term assets, is reduced to zero, we will stop recording the results of operations of PGx in our financials. We believe this appropriately reflects the substance of this transaction, which is to fund research and development.

11. Related Party Transaction

In June 2005, we signed a letter of agreement with FasTraQ, Inc. (FasTraQ) for the development of certain future product. Our Chief Executive Officer and Chairman of the Board, Mr. Birndorf, is a director and an investor in FasTraQ. Mr. Birndorf abstained from the discussions and votes regarding FasTraQ at the meetings of our Board of Directors. We made an initial non-refundable payment of $500,000 to FasTraQ to begin the initial development of this product. We have been expensing the $500,000 payment over approximately six months, which is the estimated time required to perform the related development. As of September 30, 2005, $250,000 has been expensed.

12. Stock Transaction

In September 2005, we sold to institutional investors 6.8 million shares of common stock at $2.94 per share and a million warrants exercisable at $4.00 per share for five years and received approximately $18.8 million, net of expenses, in cash. This offering was conducted under a shelf registration statement filed with the Securities and Exchange Commission in June 2005 that allowed us to raise up to $60.0 million in equity transactions. We are subject to certain restrictions under the stock purchase agreement which limits our ability to raise additional equity until December 31, 2005 unless it is in connection with merger and acquisition activity. After December 31, 2005, we may raise an additional $36.0 million, under the June 2005 shelf registration statement, by issuing some combination of common stock, preferred stock, debt securities or warrants.

13. Subsequent Event

On October 18, 2005 we signed an addendum to the June 2005 letter of agreement with FasTraQ, a related party, to continue to research certain aspects of our technology and to supply materials at no cost to be used in the development of this technology. We will pay FasTraQ up to $100,000 based on meeting research milestones. In November 2005, we paid FasTraQ $25,000 under the addendum.

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Item 2. Management s Discussion and Analysis of Financial Condition and Results of Operations

Forward Looking Statement

This report contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995 which provides a safe harbor for these types of statements. To the extent statements in this report involve, without limitation, our expectations for growth, estimates of future revenue, expenses, profit, cash flow, balance sheet items or any other guidance on future periods, these statements are forward-looking statements. Forward-looking statements are not guarantees of performance. They involve known and unknown risks, uncertainties and assumptions that may cause actual results, levels of activity, performance or achievements to differ materially from any results, level of activity, performance or achievements expressed or implied by any forward-looking statement. These risks and uncertainties include those included herein under the caption Factors That May Affect Results below. We assume no obligation to update any forward-looking statements. Results of Operations should be read in conjunction with the Management s Discussion and Analysis of Financial Condition and Results of Operations, Consolidated Financial Statements and Notes thereto for the year ended December 31, 2004 in our Annual Report on Form 10-K.

Summary:

During the nine months ended September 30, 2005, the following significant business developments occurred:

We continue to implement our strategy to deliver a broader range of revenue generating products for the advance diagnostics market. In the last nine months we have made steady progress towards the introduction of several new products and believe they present opportunities for Nanogen to grow revenues substantially in 2006. These new product launches represent important milestones in the progress of our company and the implementation of a sustainable, multi-product business model that over time will demonstrate improved financial performance. We began shipments of our second generation molecular biology workstation system, the NanoChip® 400, shortly after the end of the third quarter. The NanoChip® 400 will generate revenue from research and clinical customers. Additionally, in the future we expect that clinical laboratory customers will purchase our ASRs to develop tests for respiratory viral conditions, thrombosis, and for the detection of mutations potentially related to Cystic Fibrosis. In addition, our point-of-care test for congestive heart failure (CHF) remains under development as we seek regulatory approval to begin distribution. However, due to the nature of the regulatory approval process, which is not within our control, we are uncertain whether we can achieve this approval by the end of this year.

The costs associated with the development of unique solutions for the clinical, research and point-of-care markets and the execution of our multi-product commercialization strategy continues to require a significant investment and use of our cash. We believe we will continue to use cash and have quarterly net losses for at least the next year until our product offerings gain traction in the market place and generate a return on investment. To continue to fund our commercialization strategy, in September, we received approximately $18.8 million, net of expenses, by issuing to institutional investors a combination of 6.8 million shares of common stock at $2.94 per share and a million warrants exercisable at $4.00 per share for five years. This offering was conducted under a shelf registration statement filed with the Securities and Exchange Commission in June

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2005 that allows us to raise up to $60.0 million in registered equity transactions. We are subject to certain restrictions under the placement agency agreement which limits our ability to raise additional equity until December 31, 2005 unless it is in connection with merger and acquisition activity. After December 31, 2005, we may raise an additional $36.0 million, under the June 2005 shelf registration statement, by issuing some combination of common stock, preferred stock, debt securities or warrants. We will continue to evaluate our cash position as it relates to our strategic business requirements and may in the future conduct additional offerings that balances our cash requirements with the interest of our stockholders.

Epoch Bioscience, whose acquisition was completed on December 16, 2004, was integrated into our operations during the first half of this year.

In July 2005, we made an equity investment of approximately $1.5 million in Jurilab LTD (Jurilab), a Finnish company that has assembled a large database of genetic markers by studying the genetic patterns of a founder population in East Finland. Uniquely, this database was constructed over the last twenty years providing novel insights to the correlation of genetic patterns as a prognosticator of disease. Our investment in Jurilab is an example of our desire to add proprietary content on top of our advanced diagnostic tools and thereby creating unique solutions to evaluate and diagnose disease. We expect to make another equity investment of approximately $1.5 million early next year to help cover their operating expenses. The investment agreement provides us with an option to purchase the entire company over the next several years after we understand the potential of their genetic marker database in greater detail.

We signed five European distributors for our congestive heart failure (CHF) test. When we complete development and receive regulatory approval for our test, our distribution network will provide access to 28 European nations and an exposure to a potential customer base of over 7,500 hospitals, 4,000 clinical laboratories and almost 11,000 cardiac specialists. Our European distributors will be responsible for the distribution and marketing of our CHF tests. We did not receive any payments or require purchase commitments from these distributors.

Our business:

We are headquartered in San Diego, California and were founded on the vision of providing a higher quality of healthcare through advanced medical diagnostic products. As disease is increasingly understood at a patient-specific level, we provide the tests that will allow physicians or researchers to make informed decisions based on specific proteins or genes specific to the individual patient or person. Our goal is to become a leader in providing the advanced diagnostic technology that will enable the application of medical care to shift from reactive to proactive. With this vision, we have developed a product portfolio and pipeline that renders molecular biology information accessible to researchers and clinicians.

Products:

In 2004 and 2005, we raised approximately a combined $62.7 million in capital and with this funding we continue to broaden our product portfolio to expand our sources of revenues. Our platform technologies will meet the needs of a large and underserved range of customers in the advanced diagnostic market. These technologies include the microarray platform (e.g. NanoChip®), real-time PCRs and anticipated point-of-care products, each providing us greater revenue potential and the opportunity to increase our critical mass and future growth.

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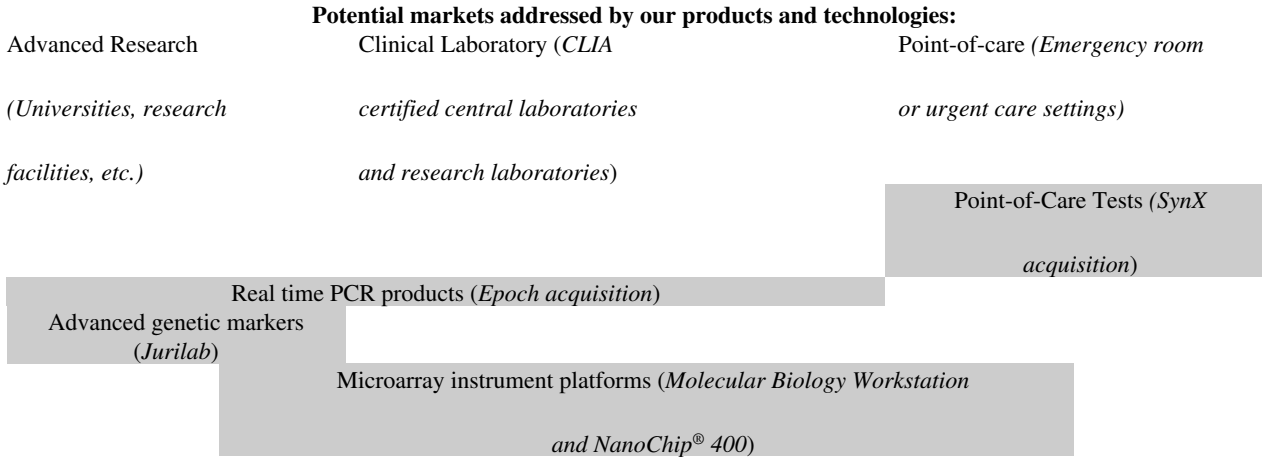
Below illustrates how our platform technologies address the market for advanced molecular diagnostic tools:



As illustrated above we have four categories of advanced diagnostic products: 1) real-time ASRs, 2) microarray instrument platforms, 3) point-of-care tests and 4) advanced genetic markers.

1) Real-time PCR products

Our real-time PCR products include both custom designed products for the research market and Analyte Specific Reagents ASRs which are sold to clinical laboratories. These products are advanced molecular probes that amplify disease specific genetic sequences for analysis or identification in a simple test with rapid turn around. The customers for this product line are primarily advanced research and clinical laboratories that test for single markers or mutations in genes. An advantage of our real-time PCR products is its platform independence providing us a broader market and customer base. In addition, we believe these products provide us name recognition and compliment our current sales and marketing efforts with a wider array of solutions for our customers.

2.) Microarray instrument platforms and related ASRs

For our customers that require more complex testing than is available with real-time instruments, we have developed the Molecular Biology Workstation and the second generation NanoChip®400 system. These systems are based on our proprietary microarray-based or lab on a chip testing technology that allows testing for multiple gene markers or mutations on one test site. Our second generation system, released in October 2005, offers customers a smaller footprint, faster throughput and simpler operating procedures than the current system.

3) Point-of-care

Our point-of-care pipeline consists of highly specific tests for identifying protein markers that play a role in diseases. By identifying these proteins, doctors can more accurately diagnose and monitor the progress of specific diseases. Our researchers are developing products that focus on congestive heart failure, diagnosis of stroke and traumatic brain injury. We believe our technology will help to move many of these tests from the clinical reference lab to the point-of-care settings such as the emergency room. We are currently in the final stages of seeking regulatory approval to begin distribution of our congestive heart failure product, which will test for levels of the protein NT-proBNP.

4) Advanced genetic markers

With our investment in Jurilab we gained access to a large database of advanced genetic markers created by studying the genetic patterns of a founder population in East Finland. This database provides insights to the correlation of genetic patterns as a prognosticator of disease. We expect this technology to

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feed the development and commercialization of our real-time PCR or Microarray instrument platforms by adding proprietary solutions to evaluate and diagnose disease. In addition, we expect to pursue license and royalty opportunities related to technologies that we do not wish to commercialize.

Other sources of revenue:

License fee and royalty income

We own 132 issued U.S. patents as of September 30, 2005. We receive significant royalty payments from Applied Biosystems pursuant to an agreement between Applied Biosystems and Epoch Biosciences. This agreement provided us minimum quarterly royalties through the end of this quarter. Beginning October 1, 2005, we will receive royalty payments based on actual sales which may result in a significant reduction in the amount of royalties we receive. In addition, because we are not receiving minimum quarterly royalty payments, in certain situations, until we are able to ensure that we have reliable information, we may not recognize this revenue until a subsequent period. Although we expect our relationship with Applied Biosystems to continue into the foreseeable future this contract can be terminated with a 180 day notice.

We do not currently receive significant royalty payments from our patent portfolio with the exception of the Applied Biosystems agreement. We are evaluating our intellectual property position and may choose to license portions of our patent portfolio in the future, if we believe the terms and conditions are acceptable in relationship to our future product pipeline.

Contracts and grants

We fund some of our research and development efforts through contracts and grants awarded by various federal and state agencies. Revenue is recognized under these contracts and grants as expenses are incurred. We do not believe these grants will be our primary source of on-going revenue but provide us additional revenue while offsetting our research and development costs. We will continue to seek new contracts and grants that are aligned with our internal research and development goals.

Other:

Acquisitions and goodwill valuation:

We actively and selectively seek to acquire companies with complementary products and strong intellectual property positions to allow us to expand our product offerings and penetrate emerging markets. In July 2005, we strategically invested approximately $1.5 million in cash into Jurilab to acquire 16.7% of the outstanding stock and obtain effective control of the board of directors. Our investment agreement states that if they meet certain conditions we have the obligation to invest an additional $1.5 million in cash by January 31, 2006. In addition, we have the option to purchase the entire company (in cash or stock) at not-to-exceed prices through December 31, 2007. We believe that this investment strategy is an effective use of our cash, because it provides us approximately two years to evaluate Jurilab s technology for potential commercialization and integration into our product lines before we commit to purchasing the entity.

Based on our analysis of the Jurilab investment agreement we are considered the primary beneficiary under FIN 46R *Consolidation of Variable Interest Entities.* We are the primary beneficiary because our equity investment at risk is not sufficient to permit Jurilab to finance its activities without additional support, we have the direct ability through the Board of Directors to make decisions about their activities and our equity interest is not proportional to the losses we will take from the research and development expenses. In addition, substantially all of their activities are conducted on our behalf despite our disproportionate ownership percentage. Therefore, we have consolidated the operation of Jurilab s operations into our financial results, however, their creditors have no recourse against us and our maximum exposure to loss is the extent of our investment in the entity. Conversely, assets recognized as

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a result of consolidating do not represent additional assets that could be used to satisfy claims against our general assets.

During 2004, we identified SynX and Epoch as two businesses operating in market niches that were complementary to our existing business and products and which we believed would offer us the ability to broaden our product line. We acquired in all stock transactions, SynX and Epoch to obtain new product lines for the proteomics technology pipeline (e.g. point-of-care) and real-time ASR diagnostic markets, respectively. We believe that these acquisitions are important to our long-term strategy and are an example of our ongoing efforts to build a stronger company with products to serve the advanced diagnostic marketplace.

The factors that contributed to a purchase price resulting in the recognition of goodwill was our belief that our existing sales and marketing infrastructure would allow us to market and sell the current and future products of these companies within our current sales and marketing organization. Finally, we identified numerous operational and administrative functions which could be consolidated within the combined company.

We utilized an independent third party to perform a valuation analysis related to intangible assets of SynX and Epoch as of their respective acquisition dates. We reviewed the assumptions, calculations and conclusions of this valuation analysis for accuracy and reasonableness. We recognized identified intangible assets in our acquisitions if we could identify an asset from contractual or other legal rights or if the asset is separable from the business. We considered an asset separable if it (a) was capable of being sold, transferred, licensed, rented or exchanged or (b) can be transferred in combination with a related asset or liability. We then identified the intangible assets in SynX and Epoch in the following areas: marketing, customer relationships, artistic creation, contracts and technologies. For technologies acquired, we considered the guidelines set forth in SFAS No.2 *Accounting for Research and Development Expense* and FASB Interpretation No. 4 *Applicability of FASB Statement No.2 to Business Combinations Accounted for by the Purchase Method* to determine whether a technology is classified as complete or in-process research and development (IPR&D). Pursuant to the above guidelines, we assessed the value and future applications of technology assets to be used in IPR&D projects. We expensed technologies determined to have no alternative future use. Completed technology was recorded at its fair value and will be amortized over its estimated remaining useful life.

In-process research and development

Based upon a valuation by an independent third party, we allocated $3.8 million of the purchase price of SynX to IPR&D related to congestive heart failure (CHF), traumatic brain injury (TBI) and diabetes diagnostic products. The research and development underlining these applications was unique to our current research and development projects involving microarray technology. The IPR&D asset was expensed at the date of acquisition in accordance with FIN 4. The value assigned to the acquired IPR&D was determined by estimating the expenses required to develop the acquired IPR&D into commercially viable products, estimating the resulting cash flows from the products and discounting the net cash flows to their present values and to reflect the risks associated with the development of the products. The discount rates used ranged from 30% to 40% reflecting the inherent risks involved in launching complex diagnostic products. The calculations of value were adjusted to reflect the creation efforts which were made prior to the close of the acquisition. The IPR&D expense resulting from these calculations allocated $2.7 million in fair value to CHF, $504,000 in fair value to TBI and $577,000 in fair value for diabetes diagnostics. At the time of the acquisition, the CHF product was the closest to completion, and is currently expected to be launched in the second half of 2005. The TBI and diabetes products are still in the early stages of the development cycle.

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The development of medical diagnostic devices is subject to a number of risks, including development, regulatory and marketing risks. There can be no assurance our development stage products will overcome these hurdles and become commercially viable products or gain commercial acceptance. We did not have accurate estimates as to the resource requirements needed to launch new products in research and development at the time of the acquisition. We fund these products with our working capital. As of September 30, 2005, none of these products has been commercialized.

Manufacturing:

Except for our oligonucleotide genomics services and specialized manufacturing production businesses, which are make-to-order businesses, we principally manufacture products for inventory and ship products shortly after the receipt of orders, and anticipate that we will continue to do so in the future. We do not currently have a significant backlog and do not anticipate we will develop a material backlog in the near future. In addition, we rely on third-party manufacturers to supply many of our raw materials, product components, and in some cases, entire products.

Hitachi manufactures our NanoChip® systems and we manufacture the majority of our consumable products in our manufacturing facilities in San Diego, California and Bothell, Washington.

Development and manufacturing agreement with Princeton BioMeditech Corporation (PBM):

Through SynX we are a party to a 2001 development and manufacturing agreement between SynX Pharma and PBM to jointly develop and market various point-of-care tests for certain biomarkers and protein targets. Under this arrangement PBM worked to develop, produce, and distribute rapid assay diagnostic point-of-care products (POC Rapid Assay) utilizing reagents supplied by SynX. SynX agreed to pay a portion of the development costs for a POC reader prior to our acquisition. There were no remaining funding obligations at the time we acquired SynX. Any revenue generated by jointly developed products is required to be shared between the parties. As of September 30, 2005, we did not have any significant revenue under this agreement.

We are currently in continuing discussions with PBM to clarify and modify various terms within this agreement. Although this agreement is unclear on certain terms and is subject to change in the near future, our current agreement defines PBM as responsible for procuring the CHF reader, manufacturing the CHF consumables, and marketing, selling and distributing the CHF readers and tests within the United States. We are responsible for providing certain reagents for the CHF consumable product and for marketing, selling and distributing the CHF readers and tests outside of the United States. Further, the parties will share revenues with the majority of revenues being allocated to the party responsible for selling, marketing and distributing the CHF product within a specific geographic territory. Each party will be responsible for its own manufacturing, sales and marketing expenses.

Other than the revenue stream payments and shared funds of the reader development, there are no material purchase minimums.

In the year ended December 31, 2004 there were no payments between the parties. In the nine months ended September 30, 2005, we ordered and paid approximately $200,000 of CHF readers from PBM.

FDA regulations:

Many of our products are used for research purposes or by CLIA-certified laboratories to develop and validate their own tests. When we begin to distribute and manufacture products for non-CLIA laboratory customers and point-of-care customers, we are subject to additional FDA requirements such as pre-market applications. Additionally, some of these same sites and products are intended to comply with certain voluntary quality programs such as ISO 9001 or ISO 13485:2003.

In the third quarter of 2005, we received an untitled letter from the Office of In Vitro Diagnostic Devise Evaluation and Safety (OIVD), a division of the FDA. The letter described the OIVD s concerns

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that the NanoChip® systems and certain related ASRs might be construed as a closed system and therefore a medical device that requires a pre-market application. We believe that our NanoChip® systems and the related ASRs are independent and are not marketed or intended as a closed system. If there is an unfavorable decision in this matter it could delay sales of our NanoChip400® to clinical laboratories in the United States. During 2006, we plan to submit the NanoChip 400® with one or more assays to the FDA for clearance. Our decision as to the exact timing of this submission is related to our ongoing discussions with the FDA in regard to the testing requirements of the system.

Fluctuations:

We anticipate that our results of operations will fluctuate on a quarterly and annual basis and will be difficult to predict. The timing and degree of fluctuation will depend upon several factors, including those discussed under Risk Factors That May Affect Future Results. In addition, our results of operations could be affected by the timing of orders from distributors and the mix of sales between distributors and our direct sales force. We cannot assure you that we will be able to achieve revenue growth or profitability on a quarterly or annual basis.

Results of operations three and nine months ended September 30, 2005 compared to the three and nine months ended September 30, 2004

Revenues

The following table summarizes our revenues (in thousands):

	For the three months ended September 30,			For the nine months ended September 30,		
	2005	2004	Difference	2005	2004	Difference
Product sales	$ 1,060	$ 671	$ 389	$ 3,348	$ 2,280	$ 1,068
License fees and royalty income	1,748	25	1,723	5,071	214	4,857
Sponsored research					500	(500)
Contracts and grants	363	386	(23)	1,063	1,365	(302)
Total	$ 3,171	$ 1,082	$ 2,089	$ 9,482	$ 4,359	$ 5,123

Product sales include revenue from our three product lines of advanced diagnostic products: real-time PCR products that include both custom designed products for the research market and ASRs which are sold to clinical laboratories, microarray instrument platforms and related ASRs consumables (NanoChip® system) and point-of-care tests. Product sales rose during the three and nine months ended September 30, 2005 as compared to the same periods in the prior year primarily due to additional revenue from real-time PCR products acquired through the acquisition of Epoch in December 2004. Revenue from the NanoChip® system fell by approximately 46% in the nine months ended September 30, 2005 when compared to the same period in 2004, due primarily to price reductions on the NanoChip® systems sold in anticipation of the second generation product, the Nanochip400®, which began shipping in October 2005.

The future: In the last quarter of 2005, we are expecting additional sales revenue with the release of our second generation NanoChip® 400 which is more focused on our customer s requirements than the first generation system. However, in the third quarter of 2005, we received an untitled letter from the Office of In Vitro Diagnostic Devise Evaluation and Safety (OIVD), a division of the FDA. The letter described the OIVD s concerns that the NanoChip® systems and certain related ASRs might be construed as a closed system therefore a medical device that requires a pre-market application. We believe that our NanoChip® systems and the related ASRs are independent and are not marketed or

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intended as a medical device. If there is an unfavorable decision in this matter it could delay sales of our NanoChip400® in the United States.

Our congestive heart failure products remain in development in the fourth quarter of 2005, due to the uncertainties regarding the timing of the regulatory approval process. We do not expect significant, if any, revenues from our congestive heart failure products in the fourth quarter of 2005.

License fees and royalty income includes non-refundable fees generated from the licensing of our technology with third parties. License fees and royalty income increased in the three and nine months ended September 30, 2005 as compared to the same periods in 2004 due to the royalty bearing licensing agreement with Applied Biosystems for the TaqMan® 5 -nuclease real-time PCR assays.

The future: We continually evaluate additional licensing opportunities for our intellectual property and plan to commit more resources in early 2006 to develop potential future income streams either through direct development or licensing arrangements. Our contractual minimums for the TaqMan® 5 -nuclease real-time PCR assay with Applied Biosystems ended September 30, 2005. In the fourth quarter of 2005, we will begin to receive royalty payments based on actual sales and expect our license revenue to decrease based on our analysis of historic sales of the product. In addition, because we are not receiving minimum quarterly royalty payments, in certain situations, until we are able to ensure that we have reliable information, we may not recognize this revenue until a subsequent period. Although we expect our relationship with Applied Biosystems to continue into the foreseeable future this contract can be terminated with a 180 day notice.

Sponsored research revenue is nonrefundable money generated through the development agreement with Hitachi. We did not recognize any sponsored research revenue in 2005 due to the termination of the Hitachi collaborative research agreement in August 2003. Funding through this agreement was completed in the second quarter of 2004.

The future: With the conclusion of our sponsored research agreement with Hitachi in the second quarter of 2004, we do not expect any revenue from Hitachi in 2005 or thereafter. We may enter into additional sponsored research projects in the future.

Contracts and grants revenue is nonrefundable payments by various federal agencies, state agencies and private foundations for our research and development efforts awarded through contracts and grants. Contracts and grants revenue is recorded as the costs and expenses to perform the research are incurred, if the amount is reasonably commensurate with the effort expended and collection of the payment is reasonably assured. Under certain arrangements where funding is provided for contractually on a scheduled basis, revenue is recorded ratably over the term of the arrangement. Payments received in advance under these arrangements are recorded as deferred revenue until the expenses are incurred. The decrease in contract and grant revenue in the nine months ended September 30, 2005 as compared to the same period in the prior year is primarily related to the completion in the first quarter of 2005 of certain grants with no additional grants to replace the ones that were completed. In the second quater, we entered into several new contracts and grants that began to offset our decrease in revenue in the three months ended September 30, 2005 as compared to the same period in the prior year.

The future: The recognition of revenue under contracts and grants may vary from quarter to quarter and may result in significant fluctuations in operating results from year to year depending on the timing and quantity of contracts and grants. In the future, we expect contract and grant revenue to become a

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decreasing portion of our overall revenues. We expect the majority of our revenue growth to be generated through an increase in product revenue.

Cost and expenses

Cost of product sales (in thousands):

	For the three months ended September 30,			For the nine months ended September 30,		
	2005	2004	Difference	2005	2004	Difference
Cost of product sales	$ 799	$ 1,298	$ (499)	$ 3,073	$ 4,150	$ (1,077)

Cost of product sales includes the material, manufacturing labor, overhead costs and inventory impairment charges related to our products. In the three and nine months ended September 30, 2005, the cost of product sales included costs related to the sale of the NanoChip® system (which were significantly offset by reserves taken prior to 2005, see below), the cost of delivering real-time ASRs and other various diagnostic products from our SynX operations as compared to the same period in 2004, where the cost of product sales primarily related to the NanoChip® system. The decrease in cost of product sales in the three and nine months ended September 30, 2005 as compared to the same period in 2004, was primarily due to inventory reserves taken in 2004 for the first generation NanoChip® system.

As of September 30, 2005, we had an inventory reserve of $5.6 million primarily related to our first generation NanoChip® system as compared to $5.0 million as of September 30, 2004. This inventory reserve was accumulated throughout 2004 and 2003 during our quarterly evaluations of anticipated sales for the next twelve months. After our announcement of a second generation system in October 2004 and evaluating actual sales during the year, we reserved (expensed) the net remaining carrying value of all first generation NanoChip® systems without purchase orders as of December 31, 2004. In the three and nine months ended September 30, 2005, we sold approximately $50,000 and $183,000 of NanoChip® systems that had been fully reserved. Going forward, future sales of our first generation system are highly uncertain in light of our release of a second generation system in October of 2005. Future sales of first generation NanoChip® systems, if any, will have a minimal cost of product sales.

The future. We are still in the early stages of commercialization of our real-time ASRs product line and are working to build in efficiencies into our manufacturing processes and expect to see improved gross margins in the future. We anticipate the second generation NanoChip® System will have a lower selling price per unit; therefore, our gross margins will depend on the number of units sold or rented to absorb our fixed capacity costs.

Research and development expenses (in thousands):

	For the three months ended September 30,	For the nine months ended September 30,

	2005	2004	Difference	2005	2004	Difference
Research and development expenses	$ 5,701	$ 4,514	$ 1,187	$ 15,773	$ 12,901	$ 2,872

Research and development expenses include the costs associated with the development of our technology. The increase in research and development expenditures in the three and nine months

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ended September 30, 2005 as compared to the same period in 2004, primarily related to product development expenses of real time ASR products related to our acquisition of Epoch and consolidation of Jurilab with no comparable expenses in 2004.

The future. We expect our research and development expenditures to remain at a similar level for the remainder of the year as we continue to control our development costs. However, we may incur additional costs if we acquire additional businesses or enter into significant development agreements in the last quarter of the year. We will continue to focus our research and development expenditures in our current technology platforms (microarray, real time ASRs, advanced genetic markers and point-of-care applications) in the advanced diagnostic market.

Selling, general and administrative expenses (in thousands):

	For the three months ended September 30,			For the nine months ended September 30,		
	2005	2004	Difference	2005	2004	Difference
Selling, general and administrative expenses	$ 5,326	$ 4,811	$ 515	$ 17,703	$ 12,626	$ 5,077

Selling, general and administrative expenses include sales and marketing personnel, tradeshows, promotional activities and materials, administrative personnel, legal, other professional expenses and general corporate expenses. We had a $1.7 million increase in general and administrative expenses in the nine months ended September 30, 2005 as compared to the same period in 2004 that related to expenses we incurred managing a more complex and diverse business, costs associated with the Sarbanes-Oxley Act compliance and the integration of Epoch and SynX. In addition, in the nine months ended September 30, 2005 as compared to the same period in 2004 we had an additional $2.3 million in expenses associated with Epoch s operations. In anticipation of future product releases of the NanoChip® 400 and point-of-care product lines we had a $1.0 million increase related to our sales and marketing expenditures. The narrowing of the difference between selling, general and administrative expenses in the third quarter 2005 as compared to the same in 2004 is reflective of our efforts to integrate Epoch, contain costs and eliminate redundant operations.

The future. In future quarters we expect selling, general and administrative expenses to remain consistent as we continue to recognize savings from the consolidation of our acquisitions. However, the savings from consolidation of general and administrative activities are expected to be offset by increased sales and marketing expenses required to support the various new product launches expected later in 2005. Expenses may also be further impacted by potential future business combinations or corporate development transactions.

Charge for acquired in-process research and development (in thousands):

	For the three months ended September 30,			For the nine months ended September 30,		
	2005	2004	Difference	2005	2004	Difference
Charge for acquired in-process research and development	$	$	$	$	$ 3,758	$ (3,758)

We incurred a non-cash charge of $3.8 million related to the expensing of acquired in-process research and development (IPR&D), related to the SynX acquisition in the second quarter of

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2004 with no comparable charges in the same period of 2005. The IPR&D asset was expensed at the date of acquisition in accordance with FASB Interpretation No. 4 *Applicability of FASB Statement No.2 to Business Combinations Accounted for by the Purchase Method.* The estimated fair value of $3.8 million in IPR&D expense was related to $2.7 million for congestive heart failure (CHF), $504,000 for traumatic brain injury (TBI) and $577,000 for diabetes diagnostic products. These products as of the acquisition date in April 2004, had not reached technological feasibility and had no alternative future uses.

The future. The development of these diagnostic products is subject to a number of risks, including development, regulatory and marketing risks. As of September 30, 2005 none of these products has been commercialized; however, our CHF product is closest to commercialization. We do not currently have a schedule for the commercialization of the TBI or diabetes diagnostic products. The primary risk associated with not completing this technology as anticipated is the delay in recovery or non-recovery of our investment in this area of research and development. We do not expect to incur any additional charges for acquired IPR&D related to the SynX or Epoch acquisitions. However, if we acquire other companies in the future, we may incur additional material in-process research and development charges. Costs associated with the completion of IPR&D are recorded as research and development expenses in the period incurred.

Amortization of purchased intangible assets (in thousands):

	For the three months ended September 30,			For the nine months ended September 30,		
	2005	2004	Difference	2005	2004	Difference
Amortization of purchased intangible assets	$ 393	$	$ 393	$ 1,178	$	$ 1,178

Amortization of purchased intangible assets relates to our acquisition of Epoch in 2004 where we acquired the rights to certain completed technology and customer contracts valued at approximately $10.6 million. We are amortizing (expensing) these intangible assets over periods ranging from 3 to 10 years.

The future. We expect this amortization expense to remain consistent at its current level. However, amortization expense may also be impacted by potential future business combinations or our periodic impairment evaluations.

Other income

The following table summarizes our other income (in thousands):

	For the three months ended September 30,			For the nine months ended September 30,		
	2005	2004	Difference	2005	2004	Difference
Interest income, net	$ 110	$ 187	$ (77)	$ 598	$ 433	$ 165
Other expense	(8)	(73)	65	(118)	(256)	138

Warrant valuation adjustment	109		109	946		946
Gain (loss) on foreign currency translation	(1)	(15)	14	3	1,190	(1,187)
Total other income	$ 210	$ 99	$ 111	$ 1,429	$ 1,367	$ 62

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Interest income, net

Interest income primarily relates to the interest we receive on our cash, cash equivalents, and short-term investments netted against the interest expense we incur from debt obligations. Our interest income increased in the nine months ended September 30, 2005 as compared to the same period in 2004 due to higher interest rates on our short-term investments. The decrease in the three months ended September 30, 2005 as compared to the same period in 2004 primarily relates to our consolidation of Jurilab s interest expense.

Warrant valuation adjustment

Warrant valuation adjustment relates to our acquisition of Epoch in 2004 where we assumed warrants convertible into 381,317 shares of our common stock that contain a cash redemption feature which may be triggered under certain conditions. We accounted for the fair value of these warrants in our purchase accounting, with a portion of the value assigned to the cash redemption liability, and the remaining portion recorded as additional paid-in capital. We are required to revalue the cash redemption liability related to these warrants quarterly using the Black-Scholes valuation model with the changes in value accrued in the balance sheet and the associated non-cash income or expense recorded in the statement of operations. This revaluation adjustment occurred due to a decrease in our stock price during the quarter thereby decreasing the implied value of the warrant. Should our stock price increase in future quarters, this non-cash warrant valuation adjustment will become a loss rather than an income as it was in the current quarter.

Gain on Foreign Currency Translation

The decrease in foreign currency translation income in the nine months ended September 30, 2005 primarily relates to the first quarter of 2004 decision to reorganize and discontinue all business activities of our majority owned subsidiary, Nanogen Recognomics GmbH. In accordance with Statement of Financial Accounting Standards No. 52, *Foreign Currency Translation*, and its related interpretations, when the business activity at this entity was discontinued we were required to recognize a one time gain of $1.2 million related to previously unrealized gains from foreign currency translation.

Liquidity and capital resources

Short-term and long-term liquidity

The following is a summary of our key liquidity measures as of September 30, 2005 and December 31, 2004 (in thousands):

	September 30, 2005	December 31, 2004	Difference
Cash and cash equivalents	$ 27,670	$ 15,372	$ 12,298
Short-term investments, available for sale	12,989	36,562	(23,573)
Total cash and cash equivalents and short-term investment, available for sale	$ 40,659	$ 51,934	$ (11,275)

Current assets	$ 48,297	$ 57,442	(9,145)
Current liabilities	(8,706)	(12,443)	3,737
Working capital	$ 39,591	$ 44,999	$ (5,408)

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Our cash and cash equivalents and short-term investments, available for sale and working capital decreased $11.3 million and $5.4 million, respectively, in the nine months ended September 30, 2005. These decreases were due to the early stages of our products life cycle that requires us to expend cash as we bring products to market, expand our product pipeline and manage this activity. We believe we will continue to consume cash and have quarterly net losses during the next several years. We have incurred negative cash flows from operations since inception and do not expect to generate positive cash flows to fund our operations until we generate significant revenues from our product offerings and/or begin generating a return on our intellectual property.

We expect that our existing capital resources, combined with anticipated product revenues, license fees, contract and grant funding and access to financing, will be sufficient to support our planned operations, at least through September 30, 2006. This estimate is a forward-looking statement that involves risks and uncertainties, and actual results may differ materially. In September, to continue to fund our commercialization strategy, we received approximately $18.8 million in cash by issuing to institutional investors a combination of 6.8 million shares of common stock at $2.94 per share and a million warrants exercisable at $4.00 per share for five years. This offering was conducted under a shelf registration statement filed with the Securities and Exchange Commission in June 2005 that allowed us to raise up to $60.0 million in equity transactions. We are subject to certain restrictions under the placement agency agreement in our September 2005 offering, which limits our ability to sell additional equity until December 31, 2005 unless it is in connection with to merger and acquisition activity. Subject to these restrictions, we may raise an additional $36.0 million, under the June 2005 shelf registration statement, by selling some combination of common stock, preferred stock, debt securities or warrants. We will continue to evaluate our cash position as it relates to our strategic business requirements and may in the future conduct additional offerings that balances our cash requirements with the interest of our stockholders. Without access to financing (on terms acceptable to us), we may have to cease or curtail operations that may materially alter our current business strategy and certain product development.

From inception to September 30, 2005, we have financed our operations primarily by:

- Issuing our stock
- Generating revenues
- Cash obtained through our acquisition of Epoch
- Using proceeds from our litigation settlement with CombiMatrix
- Obtaining a modest amount of capital equipment long-term financing

We believe that our near-term borrowing requirements and debt repayments will continue to involve a relatively small amount of cash.

We invest excess funds in short-term investments that are classified as available-for-sale. We believe that it is important to maintain a significant amount of cash and short-term investments on hand to ensure that we have adequate resources to fund future research and development, provide working capital and assuage legal risks and challenges to our business model.

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Cash provided by (used in) operating, investing and financing activities of the nine months ended September 30, 2005 and 2004 are as follows (in thousands):

	September 30, 2005	September 30, 2004
Net cash used in operating activities	$ (26,527)	$ (21,572)
Net cash provided by (used in) investing activities	19,241	(29,919)
Net cash provided by financing activities	$ 19,557	$ 48,991

Operating activities

Net cash used in operating activities for the nine months ended September 30, 2005 and 2004 primarily related to our net losses and changes in working capital due to the build up of our NanoChip®400 inventory and payments of liabilities. The net loss in both periods was primarily related to the costs associated with commercializing our products that includes broadening our product lines, the development and support of our sales and marketing organization, continuing research and development efforts on existing products and the administration of this activity.

Investing activities

Net cash provided by investing activities in the nine months ended September 30, 2005 primarily related to net proceeds from the sale of short-term investments, which was offset by the purchase of fewer short-term investments (i.e. we utilized short-term investments to fund our operating activities). In addition, we had approximately $1.7 million in payments related to our December 2004 acquisition of Epoch and approximately $1.3 million of payments, net of cash consolidated related to our July 2005 purchases of equity in Jurilab and PGx. Net cash used in investing activities in the nine months ended September 30, 2004 primarily related to reinvesting the cash we realized from our common stock sale into purchasing available-for-sale short-term investments in order to enhance our yield on our cash balances. In addition, we used $2.1 million related to the acquisition of SynX, including the payment of transaction costs and a bridge funding made to SynX prior to completion of the acquisition.

Capital spending is essential to our product innovation initiatives and maintaining our operational capabilities. In the nine months ended September 30, 2005 and 2004, we used cash to purchase $1,271,000 and $397,000, respectively, in equipment to support the development of our product lines. The additional capital spending in the nine months ended September 30, 2005 was primarily due to the purchase of additional scientific equipment related to our more diversified development activities.

Financing activities

Net cash provided by financing activities in the nine months ended September 30, 2005 related to proceeds of $18.8 million from selling to institutional investors a combination of 6.8 million shares of common stock at $2.94 per share and a million warrants exercisable at $4.00 per share for five years. We received an additional $202,000 from the exercise of employee stock options. Jurilab had approximately $697,000 in net equity transactions related to financing activities. To offset the cost of purchasing equipment, we issued $700,000 in promissory notes secured by the equipment. We currently have approximately $745,000 of funding available under our financing line as of September 30, 2005.

Net cash provided by financing activities in the nine months ended September 30, 2004 related to the $39.5 million in gross proceeds from sale of common stock, $4.4 million in gross proceeds from the exercise of warrants related to financing in September 2003, and approximately $5.0 million from the exercise of employee stock options. In addition, we received $441,000 under a development agreement with Hitachi that ended in 2004.

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In the nine months ended September 30, 2005 and 2004, net cash provided by financing activities was offset by payments related to our debt obligations of $842,000 and $420,000, respectively.

We have no significant contractual obligations not fully recorded on our Consolidated Balance Sheets or fully disclosed in the Notes to our Condensed Consolidated Financial Statements. We have no off-balance sheet arrangements other than VIE discussed in the footnotes and Critical Accounting Policies and Estimates.

Critical Accounting Policies and Estimates

We consider an accounting estimate and policy to be critical if: 1) the accounting estimate requires us to make assumptions about matters that were highly uncertain at the time the accounting estimate was made, and 2) changes in the estimate that are reasonably likely to occur from period to period, or use of different estimates that we reasonably could have used in the current period, would have a material impact on our financial condition or results of operations.

There were no material changes in the critical accounting policies or estimates from those at December 31, 2004. However, we conducted a sensitivity analysis based on certain assumptions that considered both the qualitative and quantitative factors of our initial and potential additional investments in PGx to consider if we should consolidate PGx as a VIE under FIN 46. Based our analysis we did not consider PGx a VIE because we assumed it is likely PGx will obtain additional and operating funding from other third parties in the future. Therefore, we expensed PGx s net losses to research and development. Once our investment, which is carried as other long-term assets, is reduced to zero we will stop recording the results of operations of PGx in our financials. We believe this appropriately reflects the substance of this transaction which is to fund research and development.

Related Party Transaction:

In June 2005, we signed a letter of agreement with FasTraQ, Inc. (FasTraQ) for the development of certain future product. Our Chief Executive Officer and Chairman of the Board, Mr. Birndorf, is a director and an investor in FasTraQ. Mr. Birndorf abstained from the discussions and votes regarding FasTraQ at the meetings of our Board of Directors. We made an initial non-refundable payment of $500,000 to FasTraQ to begin the initial development of this product. We will expense the $500,000 over approximately six months which is the estimated time required to perform the development. As of September 30, 2005, $250,000 has been expensed.

On October 18, 2005 we signed an addendum to the June 2005 letter of agreement with FasTraQ to continue to research certain aspects of our technology and to supply materials at no cost to be used in the development of this technology. We will pay FasTraQ up to $100,000 based on meeting research milestone. In November 2005, we paid FasTraQ $25,000 under the addendum.

Future Accounting Requirements

In December 2004, the FASB issued Statement of Financial Accounting Standards No. 123 (revised 2004), *Share-Based Payment*, that addresses the accounting for share-based payment transactions in which an enterprise receives employee services in exchange for either equity instruments of the enterprise or liabilities that are based on the fair value of the enterprise s equity instruments or that may be settled by the issuance of such equity instruments. The statement eliminates the ability to account for share-based compensation transactions, as we do currently, using the intrinsic value method as prescribed by Accounting Principles Board, or APB, Opinion No. 25, *Accounting for Stock Issued to Employees*, and generally requires that such transactions be accounted for using a fair-value-based method and recognized as expenses in our consolidated statement of income. The statement requires companies to assess the most appropriate model to calculate the value of the options. We currently use the Black-Scholes option pricing model to value options and are currently assessing which model we may use in the future under the new statement and may deem an alternative model to be the most appropriate. The use of a different model to value options may result in a different fair value than the use of the Black-Scholes option pricing model. In addition, there are a number of other requirements under the new standard that would result in differing accounting treatment than currently required. These differences include, but are not limited to, the

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accounting for the tax benefit on employee stock options and for stock issued under our employee stock purchase plan, and the presentation of these tax benefits within the consolidated statement of cash flows. In addition to the appropriate fair value model to be used for valuing share-based payments, we will also be required to determine the transition method to be used at date of adoption. The allowed transition methods include modified prospective and modified retroactive adoption options. The modified prospective method requires that compensation expense be recorded for all unvested stock options and restricted stock at the beginning of the first quarter of adoption of FAS No. 123R, while the retroactive method would record compensation expense for all unvested stock options and restricted stock beginning with the first period restated.

In April 2005, the Securities and Exchange Commission announced the adoption of Release No. 33-8568, *Amendment to Rule 4-01(a) of Regulation S-X Regarding the Compliance Date for Statement of Financial Standard No. 123 (Revised 2004), Share-Based Payment*, that amends the effective date of FAS No. 123R. The effective date of the new standard under these new rules for our consolidated financial statements is January 1, 2006. Adoption of this statement will have a significant impact on our consolidated financial statements as we will be required to expense the fair value of our stock option grants and stock purchases under our employee stock purchase plan rather than disclose the impact on our consolidated net income within our footnotes, as is our current practice.

RISK FACTORS THAT MAY AFFECT FUTURE RESULTS

You should carefully consider the following risks, together with other matters described in this Form 10-Q or incorporated herein by reference in evaluating our business and prospects. If any of the following risks occurs, our business, financial condition or operating results could be harmed. In such case, the trading price of our securities could decline. The risks described below are not the only ones we face. Additional risks not presently known to us or that we currently deem immaterial may also impair our business operations. Certain statements in this Form 10-Q (including certain of the following factors) constitute forward-looking statements.

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

We are at an early stage of development. As of September 30, 2005, we had only a limited product offering that includes our NanoChip® System (which consists of our NanoChip400® and NanoChip® Cartridge), NanoChip® Cartridge, and various ASRs for detection of gene mutations associated with diseases and point-of-care diagnostic tests for myocardial infarction and drugs of abuse. We have announced our congestive heart failure point of care test, CHF tests which we expect to be released in early 2006. Our second generation instrument the NanoChip® 400 began shipping in October 2005. All of our ASRs and 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.

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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 nine months ended September 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 CFTR ASRs. However, we may not be able to address product issues to the satisfaction of our 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

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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 2005, we announced the release of our second-generation instrument system, the NanoChip® 400. 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.

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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;
- 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.

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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.

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

Since our inception, we have incurred cumulative net losses which, as of September 30, 2005, total approximately $242.0 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.

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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 (QSRs) and obtaining necessary domestic and international regulatory clearances or approvals;

acquisition(s) or investment(s) into other businesses

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

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

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

Competing technologies may adversely affect us.

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

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

diagnostic and pharmaceutical companies;

companies developing drug discovery technologies;

companies developing molecular diagnostic tests; and

companies developing point-of-care diagnostic tests.

If we are successful in developing products in these areas, we will face competition from established companies and numerous development-stage companies that continually enter these markets. In many

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instances, our competitors have substantially greater financial, technical, research and other resources and larger, more established marketing, sales, distribution and service organizations than us. Moreover, these competitors may offer broader product lines and have greater name recognition than us and may offer discounts as a competitive tactic.

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

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

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

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

Our success will depend in part on obtaining, 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.

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

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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 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

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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 analyte specific reagents as 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.

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

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meeting with the FDA to discuss the matter. We have submitted a written response to the FDA in which we have clarified that these products are not intended 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 also 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

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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.

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.

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

As of September 30, 2005, we had 47 total employees in our worldwide sales and marketing group.

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

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

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

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

- currency fluctuation risks;
- changes in regulatory requirements;
- 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.

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

We may have significant product liability exposure.

We face an inherent business risk of exposure to product liability and other claims in the event that our technologies or products are alleged to have caused harm. These risks are inherent in the testing, manufacturing and marketing of our products. 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 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 nine months ended September 30, 2005 and the years ended December 31, 2004, 2003 and 2002, we experienced turnover rates of 16%, 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

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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.

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;

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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;

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.

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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 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.

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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 are required to consolidate Jurilab s financial statements with our own and our operating results are less predictable and subject to significant fluctuation beyond our control, and our operating results maybe 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;

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- 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;

- 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.

Item 3. Quantitative and Qualitative Disclosures About Market Risk

We are exposed to market risk related to fluctuations in interest rates and in foreign currency exchange rates.

Interest rate exposure

Our exposure to market risk due to fluctuations in interest rates relates primarily to short-term investments. These short-term investments, reported at an aggregate fair market value of $13.0 million as of September 30, 2005, consist primarily of investments in debt instruments of financial institutions and corporations with strong credit ratings and United States government obligations. These securities are subject to market rate risk inasmuch as their fair value will fall if market interest rates increase. If market interest rates were to increase immediately and uniformly by 100 basis points from the levels prevailing at September 30, 2005, for example, the fair value of the portfolio would not decline by a material amount. We do not use derivative financial instruments to mitigate the risk inherent in these securities. However, we do attempt to reduce such risks by generally limiting the maturity date of such securities, diversifying our investments and limiting the amount of credit exposure with any one issuer. While we do not always have the intent, we do currently have the ability to hold these investments until maturity and, therefore, believe that reductions in the value of such securities attributable to short-term fluctuations in interest rates would not materially affect our financial position, results of operations or cash flows. Changes in interest rates would, of course, affect the interest income we earn on our cash balances after re-investment.

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Foreign Currency Exchange Rate Exposure

The functional currency for our Canadian and Netherlands subsidiaries is the U.S. dollar. The functional currency of our majority owned subsidiary in Germany is the euro. The German subsidiary s accounts are translated from the euro to the U.S. dollar using the current exchange rate in effect at the balance sheet date for balance sheet accounts, and using the average exchange rate during the period for revenues and expense accounts. The effects of translation are recorded in accumulated other comprehensive income in the consolidated financial statements included herein. In certain instances, our subsidiaries conduct business with customers and vendors in euros or in other local European currencies. Exchange gains and losses arising from these transactions are recorded using the actual exchange rate differences on the date of the transaction. We have not taken any action to reduce our exposure to changes in foreign currency exchange rates, such as options or futures contracts, with respect to transactions with our European customers and vendors. The net tangible assets of our foreign subsidiaries, excluding intercompany balances, was approximately $4.1 million at September 30, 2005.

Notwithstanding the foregoing, the indirect effect of fluctuations in interest rates and foreign currency exchange rates could have a material adverse effect on our business financial condition and results of operations. For example currency exchange rate fluctuations may affect international demand for our products. In addition, interest rates fluctuations may affect our customers buying patterns. Furthermore, interest rate and currency exchange rate fluctuations may broadly influence the United States and foreign economies resulting in a material adverse effect on our business, financial condition and results of operations.

Foreign currency exchange rates can be obtained from the website at www.oanda.com.

ITEM 4. CONTROLS AND PROCEDURES

(a) Evaluation of Disclosure Controls and Procedures.

We have carried out an evaluation, under the supervision and the participation of our management, including our principal executive officer and principal financial officer, of the effectiveness of the design and operation of our disclosure controls and procedures (as defined in Rule 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended (the Exchange Act), as of the end of the fiscal quarter covered by this report. Based upon that evaluation, our principal executive officer and principal financial officer concluded that our disclosure controls and procedures are effective that (a) the information required to be disclosed by us in the reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC s rules and forms, and (b) such information is accumulated and communicated to our management, including our principal executive officer and principal financial officer, as appropriate to allow timely decisions regarding required disclosure.

(b) Change in Internal Control over Financial Reporting.

In the third quarter of 2005, we continue to make minor improvements to our internal control processes; however, no material changes were made.

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PART II. OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

Litigation

In the normal course of business, we have been and will likely continue to be subject to routine litigation incidental to our business, such as claims related to customer disputes, employment practices, product liability, warranty or patent infringement. Responding to litigation, regardless of whether it has merit, can be expensive and disruptive to normal business operations. However, as litigation is inherently uncertain, we cannot predict the outcome of such matters. We can provide no assurance that the ultimate outcome, either individually or in the aggregate, will not have a material adverse effect on our financial statements.

ITEM 2. UNREGISTERED SALE OF EQUITY SECURITIES AND USE OF PROCEEDS

Not applicable

ITEM 3. DEFAULTS UPON SENIOR SECURITIES

Not applicable

ITEM 4. SUBMISSION OF MATTERS TO A VOTE OF SECURITY HOLDERS

Not applicable

ITEM 5. OTHER INFORMATION

Not applicable

ITEM 6. EXHIBITS

Exhibit No.	Description
31.1	Certifications of Chief Executive Officer Required by Rule 13a-14(a) of the Securities Exchange Act of 1934, as amended.

31.2	Certifications of Chief Financial Officer Required by Rule 13a-14(a) of the Securities Exchange Act of 1934, as amended.
32.1	Certifications of Chief Executive Officer Pursuant to Section 906 of the Sarbanes Oxley Act of 2002.
32.2	Certifications of Chief Financial Officer Pursuant to Section 906 of the Sarbanes Oxley Act of 2002.

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SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

NANOGEN, INC.

Date: November 9, 2005

/s/ HOWARD C. BIRNDORF
Howard C. Birndorf
Chairman of the Board and Chief Executive Officer

Date: November 9, 2005

/s/ ROBERT SALTMARSH
Robert Saltmarsh
Chief Financial Officer

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NANOGEN, INC.

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