

NANOGEN INC
Form 10-Q
November 09, 2006
Table of Contents

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 20549
FORM 10-Q

(Mark one)

QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the quarterly period ended September 30, 2006

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
(State or other jurisdiction of
incorporation or organization)

33-0489621
(I.R.S. Employer
Identification No.)

10398 Pacific Center Court, San Diego, California
(Address of principal executive offices)

92121
(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 twelve 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 ninety days. Yes No

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, or a non-accelerated filer. See definition of accelerated filer and large accelerated filer in Rule 12b-2 of the Exchange Act. (Check one):

Edgar Filing: NANOGEN INC - Form 10-Q

Large Accelerated Filer Accelerated Filer Non-Accelerated Filer

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

Indicate the number of shares outstanding of each of the issuer's classes of common stock, as of the latest practicable date.

The number of shares outstanding of each of the issuer's classes of common stock, as of the close of business on October 24, 2006, were as follows:

Class	Number of Shares
Common Stock, \$0.0001 per share par value	67,450,411

Table of Contents

NANOGEN, INC.

QUARTERLY REPORT ON FORM 10-Q

TABLE OF CONTENTS

	Page
PART I. FINANCIAL INFORMATION	
Item 1. Financial Statements	
<u>Condensed Consolidated Balance Sheets at September 30, 2006 (unaudited) and December 31, 2005</u>	3
<u>Condensed Consolidated Statements of Operations (unaudited) for the three months and nine months ended September 30, 2006 and 2005</u>	4
<u>Condensed Consolidated Statements of Cash Flows (unaudited) for the nine months ended September 30, 2006 and 2005</u>	5
<u>Notes to Condensed Consolidated Financial Statements (unaudited)</u>	6
Item 2. <u>Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	22
Item 3. <u>Quantitative and Qualitative Disclosure about Market Risk</u>	43
Item 4. <u>Controls and Procedures</u>	44
PART II. OTHER INFORMATION	
Item 1. <u>Legal Proceedings</u>	44
Item 1a. <u>Risk Factors</u>	44
Item 2. <u>Unregistered Sale of Equity Securities and Use of Proceeds</u>	57
Item 3. <u>Defaults Upon Senior Securities</u>	57
Item 4. <u>Submission of Matters to a Vote of Security Holders</u>	57
Item 5. <u>Other Information</u>	57
Item 6. <u>Exhibits</u>	58
<u>Signatures</u>	59
EXHIBITS	
Exhibit 10.1	
Exhibit 10.2	
Exhibit 10.3	
Exhibit 31.1	
Exhibit 31.2	
Exhibit 32.1	
Exhibit 32.2	

Table of Contents**PART I. FINANCIAL INFORMATION****ITEM 1. Financial Statements****NANOGEN, INC.****CONDENSED CONSOLIDATED BALANCE SHEETS**

(in thousands, except par value and share data)

	September 30, 2006 (unaudited)	December 31, 2005
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 26,761	\$ 6,194
Short-term investments	6,025	26,185
Receivables, net	7,779	2,141
Inventories, net	7,366	3,724
Other current assets	2,122	1,457
Total current assets	50,053	39,701
Property and equipment, net	9,424	7,590
Acquired intangibles, net	18,750	9,604
Restricted cash	4,341	1,794
Other assets	1,533	2,214
Goodwill	39,727	37,178
Total assets	\$ 123,828	\$ 98,081
LIABILITIES AND STOCKHOLDERS EQUITY		
Current liabilities:		
Accounts payable and accrued liabilities	\$ 11,388	\$ 7,728
Acquisition payable, secured by letter of credit	2,570	
Deferred revenue	775	535
Short-term assigned royalty interests	2,930	
Common stock warrants	13	86
Current portion of debt obligations	687	701
Total current liabilities	18,363	9,050
Debt obligations, less current portion	619	643
Debt obligation of variable interest entity (Note 6)	7,417	7,245
Sponsored research payable	4,852	4,854
Long-term assigned royalty interests	17,070	
Other long-term liabilities	2,407	1,794
Commitments and contingencies		
Stockholders' equity:		
Convertible preferred stock, \$0.001 par value, 5,000,000 shares authorized at September 30, 2006 and December 31, 2006; no shares issued and outstanding at September 30, 2006 and December 31, 2005		
Common stock, \$0.001 par value, 135,000,000 shares authorized at September 30, 2006 and December 31, 2005; 67,450,518 and 54,794,648 shares issued and outstanding at September 30, 2006 and December 31, 2005, respectively	67	55

Edgar Filing: NANOGEN INC - Form 10-Q

Additional paid-in capital	428,760	396,297
Accumulated other comprehensive loss	(553)	(189)
Deferred compensation	(54)	(2,218)
Initial capital deficit of consolidated variable interest entity, net	(4,839)	(6,856)
Accumulated deficit	(349,510)	(311,656)
Treasury stock, at cost, 416,027 shares at September 30, 2006 and 500,189 shares at December 31, 2005	(771)	(938)
Total stockholders' equity	73,100	74,495
 Total liabilities and stockholders' equity	 \$ 123,828	 \$ 98,081

See accompanying notes.

Table of Contents**NANOGEN, INC.****CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS****(unaudited)****(in thousands, except per share data)**

	Three Months Ended		Nine Months Ended	
	September 30, 2006	September 30, 2005	September 30, 2006	September 30, 2005
Revenues:				
Product sales	\$ 4,727	\$ 1,060	\$ 10,865	\$ 3,348
License fees	1,866	1,748	5,494	5,071
Contracts and grants	912	363	1,809	1,063
Total revenues	7,505	3,171	18,168	9,482
Costs and expenses (1):				
Cost of product sales	3,509	799	9,771	3,073
Research and development	6,242	5,701	19,054	15,773
Selling, general and administrative	8,441	5,326	24,738	17,703
Amortization of purchased intangible assets	869	393	2,159	1,178
Total costs and expenses	19,061	12,219	55,722	37,727
Loss from operations	(11,556)	(9,048)	(37,554)	(28,245)
Other income (expense):				
Interest income, net	32	110	310	598
Other expense	(93)	(8)	(490)	(118)
Warrant valuation adjustment	10	109	73	946
Provision for income tax	(150)		(150)	
Gain (loss) on foreign currency translation	(25)	(1)	(43)	3
Total other income (loss)	(226)	210	(300)	1,429
Net loss	\$ (11,782)	\$ (8,838)	\$ (37,854)	\$ (26,816)
Net loss per share basic and diluted	\$ (0.18)	\$ (0.18)	\$ (0.69)	\$ (0.56)
Number of shares used in computing net loss per share basic and diluted	66,839	48,018	54,587	47,859

(1) The effect of share based payments and the adoption of Statement of Financial Accounting Standards (SFAS) No. 123 (revised 2004), *Share Based Payment* (123R) on loss from operations is as follows:

Cost of product sales	\$ 30	\$	\$ 165	\$
Research and development	364		1,242	
Selling, general and administrative	818	194	2,831	806
Amortization of purchased intangible assets				

Edgar Filing: NANOGEN INC - Form 10-Q

Total stock-based compensation expense	\$ 1,212	\$ 194	\$ 4,238	\$ 806
--	----------	--------	----------	--------

See accompanying notes.

Table of Contents**NANOGEN, INC.****CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS****(unaudited)****(in thousands)**

	Nine Months Ended	
	September 30,	
	2006	2005
Operating activities:		
Net loss	\$ (37,854)	\$ (26,816)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	4,849	4,197
Other non-cash charges	105	(16)
Loss on disposal of fixed assets	370	31
Accretion related to short-term investments	79	186
Stock-based compensation expense	4,238	806
Warrant valuation adjustment	(73)	(946)
Increase (decreases) in cash caused by changes in operating assets and liabilities, excluding the effects of acquisitions:		
Receivables, net	(5,408)	(393)
Inventories, net	(947)	(2,243)
Other current and long-term assets	155	(378)
Accounts payable and accrued liabilities	203	(1,074)
Deferred revenue and other long-term liabilities	240	119
Net cash used in operating activities	(34,043)	(26,527)
Investing activities:		
Purchase of short-term investments	(18,600)	(22,541)
Proceeds from sale and maturities of short-term investments	38,780	45,993
Strategic investments		(1,259)
Acquisition of businesses	(6,461)	(1,681)
Purchase of equipment and technology rights	(1,543)	(1,271)
Net cash provided by investing activities	12,176	19,241
Financing activities:		
Principal payments on capital lease obligations	(577)	(842)
Proceeds received by variable interest entity from financing transactions	2,189	697
Proceeds from assignment of royalty interests	20,000	
Issuance of common stock, net	20,558	19,002
Issuance of treasury stock	167	
Proceeds from long-term obligations	538	700
Net cash provided by financing activities	42,875	19,557
Effect of exchange rate changes	(441)	27
Net increase in cash and cash equivalents	20,567	12,298
Cash and cash equivalents at beginning of period	6,194	15,372

Edgar Filing: NANOGEN INC - Form 10-Q

Cash and cash equivalents at end of period	\$ 26,761	\$ 27,670
--	-----------	-----------

See accompanying notes.

Table of Contents

NANOGEN, INC.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (UNAUDITED)

September 30, 2006

1. Summary of Significant Accounting Policies

Organization and Business Activity

When we refer to we, our, us or Nanogen in this document, we mean Nanogen, Inc. that was incorporated in California on November 6, 1991 and was reincorporated in Delaware in November 1997 as well as all of its consolidated subsidiaries. Our vision is to create an advanced diagnostic company with products aimed at the clinical, research and point-of-care markets.

Basis of Presentation

The accompanying unaudited condensed 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 condensed consolidated balance sheet as of September 30, 2006, condensed consolidated statements of operations for the three and nine months ended September 30, 2006 and 2005, and the condensed consolidated statements of cash flows for the nine months ended September 30, 2006 and 2005 are unaudited, but include all adjustments (consisting of normal recurring adjustments, except for the purchase of Spectral s and Amplimedical s assets which is 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. In addition, we adopted Statement of Financial Accounting Standards (SFAS) No. 123R, *Share-Based Payment (revised 2004)* on January 1, 2006, as discussed in this Note 1. The results of operations for the three and nine months ended September 30, 2006 shown herein are not necessarily indicative of the results that may be expected for the year ending December 31, 2006.

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, 2005 included in the Nanogen, Inc. Annual Report on Form 10-K for the year ended December 31, 2005 filed with the Securities and Exchange Commission on March 16, 2006.

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 (FASB) Interpretation No. 46 (FIN), *Consolidation of Variable Interest Entities, an Interpretation of ARB No. 51*, for Variable Interest Entities (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 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. We regularly evaluate estimates and assumptions related to allowances for doubtful accounts, sales returns and allowances, warranty reserves, inventory reserves, stock-based compensation expense, goodwill and purchased intangible asset valuations, strategic investments and other loss contingencies. We base our estimates and assumptions on current facts, historical experience and various other factors that we believe to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities and the accrual of costs and expenses that are not readily apparent from other sources. The actual results experienced by us may differ materially and adversely from our estimates. To the extent there are material differences between the estimates and the actual results, future results of operations will be affected.

Table of Contents

In addition, the accompanying financial statements have been prepared assuming the realization of assets and the satisfaction of liabilities in the normal course of business. As of September 30, 2006 we have approximately \$32.8 million in cash and short-term investments compared to the use of approximately \$34.0 million in cash in our operating activities in the nine months ending September 30, 2006. We do not expect to generate positive cash flow from our operating activities and will rely on our access to capital financing and other sources of non-dilutive financing to fund our on-going operations for, at least, the next twelve months. We have entered into an equity financing agreement with Azimuth Opportunity Ltd., that may provide up to approximately \$19.5 million in capital as of September 30, 2006 (see note 10). This agreement is subject to certain conditions and therefore, no assurance can be given that this financing will be realized or that we will be able to obtain additional financing in the future. These financial statements do not include any adjustments relating to the recoverability and classification of recorded asset amounts or the amounts and classification of liabilities that might be necessary if we are unable to raise additional capital.

Revenue Recognition

We generate revenue through our product sales, license and royalty fees, and sponsored research, contracts and grants with third parties. We recognize revenue only after all of the following criteria are met: i) there is persuasive evidence of an arrangement, ii) delivery has occurred or services have been rendered, iii) the price is fixed and determinable, iv) collectibility is reasonably assured, and v) both the title and the risks and rewards of ownership are transferred to an unrelated third party. In addition, we apply the prescribed methodology in Emerging Issue Task Force (EITF) Issue No. 00-21, *Accounting for Revenue Arrangements with Multiple Deliverables*, to evaluate our revenue arrangements to determine if it involves more than one deliverable and, if so, how the arrangement's consideration should be measured and allocated to revenue.

Product sales

We sell our commercial products under various sales programs directly to end users and through various distribution channels. Our product sales include our molecular testing platforms and related consumables, Analyte-Specific Reagents (ASRs), real time polymerase chain reaction (PCR) reagent products and point-of-care diagnostic tests.

We sell molecular testing platforms as either (i) a direct sale or (ii) under a reagent rental/cost per test arrangement.

(i) Direct sales

We recognize revenue from the direct sale of molecular testing platforms to end users or distributors after we receive a purchase order, have shipped the instrument and title has passed to the customer (f.o.b. shipping point in the United States or Delivery Duty Paid at the customer's site in Europe) 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 lapsed. The cost of product sales related to a sold instrument are recorded in the period in which the corresponding revenue is recognized. Through September 30, 2006, we have not entered into any molecular testing platform sales transaction where rights-of-return exist.

(ii) Reagent rental/cost per test arrangements

A reagent rental/cost per test arrangement occurs when we provide a customer a molecular testing platform in return for a contractual arrangement where the customer is required to purchase a minimum number of consumables, at set prices, within a certain time-frame. When the fee per test arrangement is consummated, the value of the molecular testing platform 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. We recognize revenue when the consumables are shipped under the terms of the arrangement.

We provide product warranty coverage for our molecular testing platforms. The warranty periods are generally for one year for direct sales. Molecular testing platforms sold to distributors are sold without warranty coverage. The fair value of the warranty is recorded as deferred revenue and 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.

Revenue from ASRs, real time PCR reagent products and point-of-care diagnostic tests is recognized when we receive a purchase order, have shipped the product and title has passed to the customer (f.o.b. shipping point in the United States or Delivery Duty Paid at the customer's site in Europe) and collection is reasonably assured. In transactions where a right-of-return exists, we defer our revenue recognition until the customer has accepted our product and the right-of-return period has lapsed.

Table of Contents*License and royalty fees*

We apply the prescribed methodology in EITF 00-21 to evaluate our license and royalty fee contracts to determine if these contracts involve more than one identifiable deliverable. We then determine the fair value of each identified deliverable in the contract. Any cash payments received before the identified deliverable is provided to the licensee are recorded as deferred revenue. As each deliverable is provided to the licensee, we recognize the fair value of the deliverable as revenue. Often the useful life of the technology transferred is not explicitly written in the license and royalty fee contract and we are required to estimate the useful life of the technology transferred to ratably recognize revenue over this period. We believe that cash payment streams are one of the primary indicators of our customer's perceived useful life of the technology transferred; therefore, we recognize revenue during this period of time unless there are other contrary indicators in the license and royalty contract. In addition, as they are determinable under contract we recognize minimum payments on an accrual basis.

Royalty payments that are based on product sales by the licensees are generally not determinable until the licensee has completed their internal computations of the royalties due and/or remitted their cash payment. Therefore, we will recognize revenue tied to third party sales on an accrual basis if information is available to enable us to accurately estimate the royalty due to us. 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 maybe in a subsequent period. Therefore, we could experience fluctuations in revenues from quarter to quarter depending on the timing of the receipt of third party sales reports or cash payments.

Sponsored research, contract and grant revenue

We earn revenue for performing tasks under research agreements with both private enterprises and governmental agencies. Sponsored research, contract and grant revenue is recorded as the costs and expenses to perform the research are incurred. Continuation of certain sponsored research, 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. Any payments received in advance or prior to satisfying our revenue recognition criteria are recorded as deferred revenue in the balance sheet.

Long-Lived Assets

In accordance with 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. We recorded \$29,000 in impairment losses in the three and nine months ended September 30, 2006. During the three and nine months ended September 30, 2005 we recorded approximately \$167,000 in impairment losses.

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 during the three and nine months ended September 30, 2006.

The following table summarizes the changes in the carrying amount of goodwill for the nine months ended September 30, 2006 (in thousands):

Balance as of December 31, 2005	\$ 37,178
Acquisition of Spectral	1,593
Acquisition of Amplimedical	1,227
Adjustment to purchase price of Epoch	(271)

Balance as of September 30, 2006

\$ 39,727

Table of Contents

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) 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, restricted stock and warrants is 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 maturities 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 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 specific identification method and is recorded on the settlement date.

At September 30, 2006, the excess of carrying cost over the fair value of our short-term investments that are below carrying cost is immaterial, considered to be temporary and we have the ability to hold the investments until their value is recovered.

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.

Research and Development

Cost incurred in research and development activities are expensed as incurred.

Adoption of SFAS 123(R), Share-Based Payment

Prior to January 1, 2006, we accounted for stock awards under the intrinsic value method, which followed the recognition and measurement principles of Accounting Principles Board (APB) Opinion No. 25, *Accounting for Stock Issued to Employees*, and its related Interpretations. The intrinsic value method of accounting resulted in compensation expense for restricted stock and restricted stock unit issuances to employees at their estimated fair value on the date of grant based on the number of shares granted and the quoted price of our common stock. The intrinsic value method resulted in compensation expense for stock options issue to employees to the extent the option's exercise price was set below the market price on the date of grant. Also, to the extent stock awards were subject to an exchange offer, other modifications, or performance criteria, such awards were subject to variable accounting treatment. To the extent stock awards were forfeited prior to vesting, the corresponding previously recognized expense was reversed as an offset to operating expenses. In addition, prior to our adoption of SFAS No. 123R, we did not record any compensation expense associated with our Employee Share Purchase Plan (ESPP).

Table of Contents

As of January 1, 2006, we adopted SFAS No. 123R, *Share-based Payment* (SFAS 123R) using the modified prospective method of recognition of compensation expense related to share-based payments. Our unaudited condensed consolidated statement of operations for the three months and nine months ended September 30, 2006 reflects the impact of adopting SFAS No. 123R. In accordance with the modified prospective transition method, our unaudited condensed consolidated statements of operations for the three and nine months ended September 30, 2005 have not been restated to reflect, and do not include, the impact of SFAS No. 123R.

We are required to measure the compensation cost for all stock awards at fair value on the date of grant and recognize the associated compensation expense over the service period for the awards that are expected to vest. The fair value of restricted stock and restricted stock unit grants are determined on the date of grant, based on the number of shares granted and the quoted price of our common stock. To determine the fair value of stock option awards SFAS No. 123R requires companies to use an option-pricing model. We determined the fair value of our stock option grants using the Black-Scholes valuation model, which is consistent with the valuation techniques utilized for our stock option footnote disclosures required under SFAS No. 123, *Accounting for Stock Based Compensation*, as amended by SFAS No. 148, *Accounting for Stock-Based Compensation Transition and Disclosure*. The associated fair value of the awards is recognized as an expense over the service period, net of estimated forfeitures. The estimation of stock awards that will ultimately vest requires significant judgment, and to the extent actual results or updated estimates differ from our current estimates, such amounts will be recorded as a cumulative adjustment in the period the estimates are revised. When estimating expected forfeitures we consider the type of awards and our historical experience. Actual results, and future changes in estimates, may differ substantially from our current estimates. In addition, we are required to calculate, as of the date of grant, the fair value of the ESPP shares issued to our employees and record this cost as compensation expense over the vesting period.

Prior to the adoption of SFAS No. 123R, we were required to account for cash retained as a result of tax deductions relating to stock-based compensation to be presented in operating cash flows, along with other tax cash flows, if any, in accordance with the provisions of the EITF Issue No. 00-15, *Classification in the Statement of Cash Flows of the Income Tax Benefit Received by a Company upon Exercise of a Nonqualified Employee Stock Option*. SFAS No. 123R supersedes EITF 00-15, amends SFAS No. 95, *Statement of Cash Flows*, and requires tax benefits relating to excess stock-based compensation deductions to be prospectively presented in the statement of cash flows as financing cash inflows. On November 10, 2005, the FASB issued Staff Position No. SFAS No. 123R-3, *Transition Election Related to Accounting for Tax Effects of Share-Based Payment Awards* (SFAS No. 123R-3). We elected to adopt the alternative transition method provided in SFAS No. 123R-3 for calculating the tax effects of stock-based compensation pursuant to SFAS No. 123R. The alternative transition method includes simplified methods to establish the beginning balance of the additional paid-in capital pool (APIC Pool) related to the tax effects of employee stock-based compensation expense, and to determine the subsequent impact on the APIC Pool and unaudited condensed consolidated statements of cash flows of the tax effects of employee stock-based compensation awards that were outstanding at our adoption of SFAS No. 123R. In addition, in accordance with SFAS No. 123R, SFAS No. 109, *Accounting for Income Taxes*, and EITF Topic D- 32, *Intraperiod Tax Allocation of the Tax Effect of Pretax Income from Continuing Operations*, due to the uncertainty related to our realization of any tax assets net of liabilities we generate from our operations we have a full valuation allowance against all of our net tax assets and we have not recognized excess income tax benefits from stock option exercises in additional paid-in capital during the three and nine months ended September 30, 2006.

On March 29, 2005, the SEC published Staff Accounting Bulletin (SAB) No. 107, which provided the Staff's views on a variety of matters relating to stock-based payments. SAB 107 requires stock-based compensation expense to be classified in the same expense line items as the employee's cash compensation.

Valuation Assumptions for share based payments

Approximately 422,000 and 846,000 stock options were granted during the three and nine months ended September 30, 2006, respectively. The fair value for each stock option granted was estimated at the date of grant using a Black-Scholes option-pricing model, using the following assumptions which are based on type of option award and stratified by employee classification:

Vesting period	Expected	Risk Free	Volatility	Dividend	Pre-vesting
	life in	Interest			
	years	Rate			rate
Four year vesting period with a one year cliff, thereafter monthly vesting	4.9 -5.4	4.6%	94.5%	0%	14.8%
	4.7 -5.4	4.6%	94.5%	0%	7.4%

Edgar Filing: NANOGEN INC - Form 10-Q

Two year vesting period with a six month cliff, thereafter
monthly vesting

Four year vesting period with monthly vesting	5.4	6.2	4.6%	94.5%-103.45%	0%
---	-----	-----	------	---------------	----

Table of Contents

Expected volatilities are based on the historical volatility of our common stock over the expected life of the grant. The expected life represents the weighted average period of time that grants are expected to be outstanding given the vesting schedules and historical exercise patterns. The risk-free rate is based on the U.S. Treasury yield curve in effect at the time of grant for periods corresponding with the expected life of the option. We do not anticipate paying any dividends in the foreseeable future therefore our dividend yield is zero. The pre-vesting cancellation rates are the percentage of forfeitures expected to occur before the awards vest.

The weighted average estimated fair value of stock options granted during the three and nine months ended September 30, 2006 was \$1.95 and \$2.31, respectively.

Pro Forma Information under SFAS No. 123 before January 1, 2006

In the three and nine months ended September 30, 2005, as permitted by SFAS No. 123R, we elected to apply the intrinsic value-based methodology, under Opinion No. 25, *Accounting for Stock Issued to Employees*, to account for the stock options and ESPP compensation granted to our employees. We issued stock options to our employees at an exercise price equal to the fair market value of our stock; therefore, the stock options had no intrinsic value upon grant and no compensation expense was recorded. In addition, we were not required to record compensation expense related to our ESPP plan. If we had elected to adopt the fair value methodology in SFAS No. 123, the pro forma net loss and net loss per common share would have been (in thousands):

	Three months ended September 30, 2005 (unaudited)	Nine months ended September 30, 2005 (unaudited)
Net loss:		
As reported	\$ (8,838)	\$ (26,816)
Add: Stock based employee compensation expense included in reported net loss, net of related tax effects	194	806
Deduct: Total stock based employee compensation expense determined under Black-Scholes method for all awards, net of related tax effects	(1,288)	(4,111)
Pro forma	\$ (9,932)	\$ (30,121)
Basic and diluted loss per share:		
Basic and diluted loss per common share:		
As reported	\$ (0.18)	\$ (0.56)
Pro forma	\$ (0.21)	\$ (0.63)

The pro forma effects of estimated share-based compensation on net loss and loss per common share for the three and nine months ended September 30, 2005 were estimated at the date of grant using the Black-Scholes option-pricing model based on the following assumptions:

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

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.

Recent accounting pronouncements

In September 2006, the Securities and Exchange Commission issued Staff Accounting Bulletin No. 108, *Considering the Effects of Prior Year Misstatements when Quantifying Misstatements in Current Year Financial Statements* (SAB 108). SAB 108 provides guidance on how prior year misstatements should be taken into consideration when quantifying misstatements in current year financial statements for purposes of determining whether the current year's financial statements are materially misstated. SAB 108 becomes effective during our 2007 fiscal year. We do not expect the adoption of SAB 108 to have a material impact on our financial statements.

Table of Contents

In September 2006, the FASB issued SFAS No. 157, *Fair Value Measurements*. This statement clarifies the definition of fair value, establishes a framework for measuring fair value, and expands the disclosures on fair value measurements. SFAS No. 157 is effective for fiscal years beginning after November 15, 2007. We have not determined the effect, if any, the adoption of this statement will have on our results of operations or financial position.

In July 2006, the Financial Accounting Standards Board (FASB) adopted FASB Interpretation No. 48 *Accounting for Uncertainty in Income Taxes* (FIN 48). FIN 48 prescribes a recognition threshold and measurement attribute for financial statement recognition of positions taken or expected to be taken in income tax returns. Only tax positions meeting a more-likely-than-not threshold of being sustained are recognized under FIN 48. FIN 48 also provides guidance on derecognition, classification of interest and penalties and accounting and disclosures for annual and interim financial statements. FIN 48 is effective for fiscal years beginning after December 15, 2006. The cumulative effect of the changes arising from the initial application of FIN 48 is required to be reported as an adjustment to the opening balance of retained earnings in the period of adoption. We do not believe that the adoption of this statement will have a material impact on its financial condition, consolidated results of operations or cash flows.

In May 2005, the FASB issued SFAS No. 154, *Accounting Changes and Error Corrections* . This new standard replaces APB Opinion No. 20, *Accounting Changes* , and SFAS No. 3, *Reporting Accounting Changes in Interim Financial Statements*. Among other changes, SFAS No. 154 requires that a voluntary change in accounting principle be applied retrospectively with all prior period financial statements presented on the new accounting principle, unless it is impracticable to do so. SFAS No. 154 also provides that (1) a change in method of depreciating or amortizing a long-lived non-financial asset be accounted for as a change in estimate (prospectively) that was effected by a change in accounting principle, and (2) correction of errors in previously issued financial statements should be termed a restatement. The new standard is effective for accounting changes and correction of errors made in fiscal years beginning after December 15, 2005. We do not believe that the adoption of SFAS No. 154 will have a significant effect on our financial statements.

2. Purchase of Assets*Spectral Diagnostics Inc.*

On February 6, 2006, we completed the acquisition of the rapid cardiac immunoassay test business from Spectral Diagnostics Inc. (Spectral) for CDN \$5.6 million in cash or approximately \$4.8 million and 975,193 shares of our common stock with a fair value of approximately \$2.9 million. Based in Toronto, Canada, the rapid cardiac immunoassay test business includes a portfolio of point-of-care tests such as the Cardiac STATus® and Decision Point product lines, the i-Lynx reader, related intellectual property and manufacturing capabilities. This acquisition provided us a fully integrated point-of-care group with resources and capabilities in manufacturing, and sales and marketing with a worldwide distribution network to compete in the point-of-care market. These factors were among those that contributed to a purchase price resulting in the preliminary allocation of \$1.6 million in goodwill. 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.

To determine the value of the 975,193 shares of common stock provided to Spectral we used the prescribed methodology in EITF 99-12 *Determination of the Measurement Date for the Market Price of Acquirer Securities Issued in a Purchase Business Combination*. This accounting standard requires that we use the quoted market price a few days before and after the number of shares to be exchanged in the acquisition is agreed to and announced. We agreed to and announced this acquisition on February 6, 2006. Therefore, we used the average quoted closing price of our common stock from January 31, 2006 through February 6, 2006 to value these shares at \$2.98 per common share. In addition, because we were unable to register these issued shares with the Securities and Exchange Commission within fifteen days of the closing of the acquisition, we triggered a cash settlement provision in the purchase agreement. Therefore, we were required to provide Spectral a cash settlement for the difference between their realized sales price of the common stock above \$2.26 and below \$3.01 per share. On April 3, 2006, Spectral sold our common stock at an average price of \$2.80 and under the cash settlement provision we were required to pay them \$210,000 in cash which was offset by certain agreed upon closing settlements. The results of operations of Spectral have been included in the accompanying consolidated financial statements from the date of acquisition on February 6, 2006. The preliminary purchase price of the acquisition has been recorded as follows (in thousands):

Nanogen common stock exchanged	\$ 2,906
Cash payment	4,755
Direct transaction costs	1,200
Total purchase price	\$ 8,861

Table of Contents

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

Accounts Receivable	\$ 230
Inventory	1,194
Fixed assets	596
Tangible assets acquired	2,020
Intangible assets	
Completed technology	4,143
Distributor relationships	810
Trade name	270
Backlog	24
Goodwill	1,594
Total assets acquired	8,861
Liabilities assumed	
Net assets acquired	\$ 8,861

We used a third party valuation specialist to assist us in performing a preliminary purchase price allocation analysis of our purchased intangibles and potential IPR&D and we reviewed their assumptions and calculations for reasonableness. We used valuation techniques comparable with others in the high technology industry. We evaluated the technology acquired from Spectral in accordance with FASB Interpretation No. 4, *Applicability of FASB Statement No. 2 to Business Combinations Accounted for by the Purchase Method*, and determined there was no IPR&D.

In addition, as part of the acquisition, we acquired a commitment to lease Spectral's manufacturing and administrative facilities through February 2007 for approximately \$308,000 with an option to extend the lease until July 2007. We believe this approximates current market lease rates for comparable properties.

Amplimedical, S.p.A.

Effective May 1, 2006, we completed the acquisition of the diagnostics division of Amplimedical S.p.A. (Amplimedical), which is a manufacturer of molecular diagnostic products based in Italy, for \$8.1 million, consisting of \$2.0 million or approximately \$2.5 million for the issuance of a letter of credit, securitized by restricted cash and \$6.1 million or approximately \$7.5 million in a promissory note issued by us. The promissory note was convertible into shares of our common stock. On June 30, 2006, we paid the promissory note in full by issuing Amplimedical 2,886,935 shares of our common stock at a conversion price of \$2.63 per share and incurred no interest charges. Under our asset purchase agreement we had the option to pay the promissory note with cash at a 10% discount through June 30, 2006. Due to this provision in the purchase agreement, we reduced the fair value of the promissory note by 10% when calculating the purchase price. Based in Italy, Amplimedical has been active in the European and other markets since the early 1990s with its molecular diagnostic reagents. Nanogen and Amplimedical have shared a business relationship for approximately five years, during which time Amplimedical has been a distributor of Nanogen's NanoChip[®] Molecular Biology Workstation and NanoChip[®] 400 instrument systems in Italy. We believe this acquisition will allow our molecular diagnostics business to further expand in Europe by providing additional resources and scale. These factors were among those that contributed to a purchase price resulting in the preliminary allocation of \$1.2 million in goodwill. 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.

The results of operations of Amplimedical have been included in the accompanying consolidated financial statements from the date of acquisition on May 1, 2006. The preliminary purchase price of the acquisition has been recorded as follows (in thousands):

Promissory note (converted to Nanogen common stock effective June 30, 2006)	\$ 6,939
Issuance of a letter of credit	2,570
Direct transaction costs	1,450

Total purchase price

\$ 10,959

Table of Contents

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

Cash	\$ 63
Inventory	1,441
Fixed assets	2,718
Other assets	509
Tangible assets acquired	4,731
Intangible assets	
Completed technology	3,374
Distributor and customer relationships	2,161
Trade name	354
Goodwill	1,227
Total assets acquired	11,847
Liabilities assumed	(888)
Net assets acquired	\$ 10,959

We used a third party valuation specialist to assist us in performing a preliminary purchase price allocation analysis of our purchased intangibles and potential IPR&D and we reviewed their initial assumptions and calculations for reasonableness. We used valuation techniques comparable with others in the high technology industry. We evaluated the technology acquired from Amplimedical in accordance with FASB Interpretation No. 4, *Applicability of FASB Statement No. 2 to Business Combinations Accounted for by the Purchase Method*, and determined there was no IPR&D.

In addition, as part of the acquisition, we acquired a commitment to lease Amplimedical's manufacturing and administrative facilities through December 2006 for approximately \$42,000. We believe this approximates current market lease rates for comparable properties.

Pro forma information

The following unaudited pro forma information assumes the acquisition of Spectral and Amplimedical occurred on January 1, 2006. These 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 occurred on January 1, 2006, or of future results of operations. The unaudited pro forma results for the three and nine months ended September 30, 2006 are as follows (in thousands):

	Three months ended	Nine months ended
	September 30,	September 30, 2006
	2006	
Revenues	\$ 7,505	\$ 21,632
Net loss	\$ (11,781)	\$ (38,235)
Net loss per share basic and diluted	\$ (0.19)	\$ (0.72)

3. 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	Nine months ended
---------------------------	--------------------------

Edgar Filing: NANOGEN INC - Form 10-Q

	September 30,		September 30,	
	2006	2005	2006	2005
	(Unaudited)	(Unaudited)	(Unaudited)	(Unaudited)
Comprehensive loss:				
Net unrealized gain / (loss) on short-term investments and other investments	\$ (6)	\$ 29	\$ 78	\$ 64
Foreign currency translation adjustment	37	3	(442)	27
Net loss	(11,782)	(8,838)	(37,854)	(26,816)
Comprehensive loss	\$ (11,751)	\$ (8,806)	\$ (38,218)	\$ (26,725)

4. Common Stock Warrant Liability

As a result of our December 2004 acquisition of Epoch Biosciences Inc. (Epoch), we assumed warrants for 381,317 shares of our common stock. The warrants have an exercise price of \$8.32 per share and expire in early 2009. The warrants have a provision that allows them to be redeemed for cash based on the Black-Scholes pricing model under certain circumstances if there is a change of control of Nanogen. However, the volatility variable in the Black-Scholes pricing model is limited to the lesser of 50% or our actual historical volatility and we used U.S. Treasury Bond rates with terms similar to the expected term to determine the interest rate. Using the methodology prescribed in EITF 00-19, *Accounting for*

Table of Contents

Derivative Financial Instruments Indexed To, and Potentially Settled In a Company's Own Stock, we recorded a current liability for the fair value of the cash redemption feature of the warrants. The valuation of the warrants and the corresponding liability is re-measured quarterly, in accordance with the terms of the warrant, until the warrants are exercised or expire.

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

	September 30,	December 31,
	2006	2005
Common stock price	\$ 1.78	\$ 2.61
Expected term	2.4 years	3.2 years
Interest rate	4.7%	4.5%
Volatility	50%	50%
Dividends		
Calculated cash redemption value of the warrants	\$ 13,000	\$ 86,000

The non-cash gains and losses in the three and nine months ended September 30, 2006 and 2005 were a result of changes in the fair value of the warrants as calculated by the Black-Scholes pricing model.

5. Commitments and Contingencies*Assigned royalty interests*

In September 2006, we entered into an agreement to assign the rights associated with our Applied Biosystems, Inc. (Applied Biosystems) royalty agreement from the period of July 2006 through December 2011 to Drug Royalty Trust (DRT) for an upfront payment of \$20.0 million. Under the agreement, we have guaranteed minimum royalty payments from Applied Biosystems to DRT. If the royalty payments fall below certain minimums in a given fiscal year, we are required to pay cash to DRT for the difference between the actual royalty payments from Applied Biosystems and the minimums. In addition, if royalty payments from Applied Biosystems are above certain thresholds for a given calendar year we will receive, in cash, a certain percentage of the amount above the threshold. The table below illustrates each fiscal year's minimum payment to DRT:

Calendar year ending	Minimum payment (in thousands)
2006 (remainder)	\$ 1,820
2007	4,300
2008	4,820
2009	5,200
2010	5,410
2011	5,410
Total	\$ 26,960

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 March 2006 (first equipment funding agreement). In June 2006, we entered into another equipment funding agreement for up to approximately \$2.3 million through December 31, 2007 (second equipment funding agreement).

In March 2006, we issued a promissory note under the first equipment funding agreement in an aggregate principal amount of approximately \$70,000. This note is secured by equipment with a cost of \$70,000. This note bears interest at 11.48% per annum with principal and interest due in monthly payments of approximately \$2,300 for 36 months.

Edgar Filing: NANOGEN INC - Form 10-Q

In June 2006, we issued a promissory note under the second equipment funding agreement in an aggregate principal amount of approximately \$96,000. This note is secured by equipment with a cost of \$96,000. This note bears interest at 11.20% per annum with principal and interest due in monthly payments of approximately \$3,100 for 36 months.

Table of Contents

In September 2006, we issued a promissory note under the second equipment funding agreement in an aggregate principal amount of approximately \$372,000. This note is secured by equipment with a cost of \$372,000. This note bears interest at 10.78% per annum with principal and interest due in monthly payments of approximately \$12,000 for 36 months.

As of September 30, 2006, the future contractual principal payments on all of our promissory notes are as follows (in thousands):

For the years ended December 31,	
2006 (remainder)	\$ 190
2007	638
2008	362
2009	116
Total	\$ 1,306

The interest expense for the three and nine months ended September 30, 2006 was \$28,000 and \$88,000, 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, 2006, we had commitments to purchase \$672,000 of the NanoChip® 400 instruments from Hitachi through December 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 and certain commitments under our purchase agreement with Amplimedical that are reflected as restricted cash in the accompanying condensed consolidated balance sheet. We had approximately \$4.3 million and \$1.8 million in long-term certificates of deposit and letters of credit at September 30, 2006 and December 31, 2005, respectively.

Jurilab

In May 2006, we entered into a collaboration agreement with Jurilab LTD (Jurilab), where Jurilab would identify and validate new prognostic markers for Type II diabetes with certain milestone payments of up to 950,000 or approximately \$1.2 million. In May 2006, we paid Jurilab 200,000 or \$386,000 for the completion of the first milestone.

General 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 partially, by insurance. Claim estimates that are probable and can be reasonably estimated are reflected as liabilities and as of September 30, 2006 we have no significant accrual for any pending claims. 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, 2006, with respect to these matters cannot be ascertained, we believe that any resulting liability should not materially affect our consolidated financial position, results of operations or cash flows.

6. Variable Interest Entity

In a series of investments from July 2005 through June 30, 2006, we invested approximately \$3.3 million to purchase 29.7% of the outstanding stock of Jurilab. In addition, we have the option to purchase the entire company at not-to-exceed prices through December 31, 2007. By investing in Jurilab, a development stage research and development company, we gained access to technologies related to certain gene markers. 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

Edgar Filing: NANOGEN INC - Form 10-Q

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 \$3.3 million investment in the entity. Conversely, assets recognized as a result of consolidating Jurilab do not represent additional assets that could be used to satisfy claims against our general assets.

Table of Contents

Included in our condensed consolidated balance sheet at September 30, 2006 and December 31, 2005 were the net liabilities (in thousands) of Jurilab:

	September 30,	December 31,
	2006 (Unaudited)	2005 (Unaudited)
Cash	\$ 19	\$ 77
Restricted cash		355
Other assets	714	719
Debt obligations	(7,417)	(7,245)
Other long-term liabilities	(1,053)	(1,018)
Net liabilities	\$ (7,737)	\$ (7,112)

Included in our condensed consolidated statement of operations were the following results of Jurilab's operations (in thousands):

	Three months ended,		Nine months ended,	
	September 30,	September 30,	September 30,	September 30,
	2006 (Unaudited)	2005 (Unaudited)	2006 (Unaudited)	2005 (Unaudited)
Net sales	\$ 20	\$ 58	\$ 36	\$ 58
Cost of product sales	(31)	(28)	(97)	(28)
Research and development expense	(1,204)	(689)	(3,764)	(689)
Other expenses	(94)	(42)	(238)	(42)
Net loss	\$ (1,309)	\$ (701)	\$ (4,063)	\$ (701)

7. Financial Statement Details**Receivables**

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

	September 30,	December 31,
	2006 (Unaudited)	2005
Product	\$ 6,376	\$ 1,119
License fees	975	1,034
Contract and grant	582	58
	7,933	2,211
Allowance for doubtful accounts	(154)	(70)
	\$ 7,779	\$ 2,141

Inventories

Edgar Filing: NANOGEN INC - Form 10-Q

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,	December 31,
	2006	2005
	(Unaudited)	
Raw materials	\$ 4,466	\$ 3,168
Work in process (materials, labor and overhead)	1,735	2,233
Finished goods (materials, labor and overhead)	6,206	3,704
	12,407	9,105
Reserve for excess and obsolescence	(5,041)	(5,381)
	\$ 7,366	\$ 3,724

Table of Contents**Property and Equipment**

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

	Estimated Useful Life (years)	September 30,	December 31,
		2006 (Unaudited)	2005
Scientific equipment	5	\$ 10,999	\$ 10,998
Office furniture and equipment	3 5	4,605	4,530
Manufacturing equipment	5	4,368	1,240
Leasehold improvements	(lesser of lease term or life of improvements)	7,361	7,336
		27,333	24,104
Less accumulated depreciation and amortization		(17,909)	(16,514)
		\$ 9,424	\$ 7,590

For the three and nine months ended September 30, 2006, depreciation and amortization expense related to property and equipment totaled \$665,000 and \$2.3 million, respectively. 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 intangibles

Acquired intangibles consist of the following (in thousands) as of:

	Life	September 30, 2006		December 31, 2005	
		Gross		Gross	
		Carrying Amount (Unaudited)	Accumulated amortization (Unaudited)	Carrying Amount	Accumulated amortization
Trade names and other intangible assets	Less than 1 8 years	\$ 521	\$ (55)	\$	\$
In-licensed technology rights	3 10 years	6,249	(5,801)	6,033	(5,463)
Customer contracts acquired	7 years	4,181	(641)	1,210	(173)
Completed technology acquired	3 10 years	17,039	(3,037)	9,395	(1,398)
Total acquired technology rights		\$ 27,990	\$ (9,534)	\$ 16,638	\$ (7,034)
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, 2006 was \$872,000 and \$2.3 million, respectively. In the three and nine months ended September 30, 2006 we incurred \$29,000 in impairments of acquired technology. The amortization expense of intangibles for the three and nine months ended September 30, 2005 was \$433,000 and \$1.7 million, respectively. In the three and nine months ended September 30, 2005 we incurred \$167,000 in impairments of acquired technology.

Edgar Filing: NANOGEN INC - Form 10-Q

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

2006 (three months)	\$ 873
2007	3,394
2008	3,227
2009	3,118
2010	2,639
2011	2,483
Thereafter	2,722
	\$ 18,456

Table of Contents**Accounts Payable and Accrued Liabilities**

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

	September 30,	December 31,
	2006 (Unaudited)	2005
Trade accounts payable	\$ 3,746	\$ 1,262
Accrued compensation and benefits	2,249	1,418
Other	5,391	5,048
	\$ 11,386	\$ 7,728

8. Stock Award Activity*Equity Incentive Plans*

Stock option and restricted stock unit awards are designed to reward employees for their long-term contributions to the Company and to provide incentive for them to remain an employee. We believe that such awards better align the interests of our employees with those of our shareholders. We have multiple stock option plans, including several option plans that were assumed through acquisitions. The stock option plans include: Nanogen's 1993 Stock Option Plan, 1995 Stock Option/Stock Issuance Plan, and 1997 Stock Incentive Plan; SynX's 2001 Stock Option Plan; and Epoch's 1991 Incentive Stock Option, Nonqualified Stock Option And Restricted Stock Purchase Plan, 1993 Incentive Stock Option, Nonqualified Stock Option And Restricted Stock Purchase Plan, and 2003 Stock Incentive Plan. Of these option plans, only two plans have shares available for future grants: Nanogen's 1997 Stock Incentive Plan (1997 plan), and Epoch's 2003 Stock Incentive Plan (2003 plan).

As of September 30, 2006, the cumulative amount of shares initially reserved, or subsequently approved by stockholders, for all option plans totaled approximately 16.1 million. Of this amount, outstanding stock options and restricted stock totaled approximately 7.7 million, and approximately 2.4 million were available for future grants.

Active Equity Incentive Plans (Containing Shares Available for Grant)

In August 1997, the Board of Directors adopted the 1997 Plan, under which, as amended, 12.0 million shares were reserved for issuance. Of this amount, outstanding stock options and restricted stock totaled approximately 6.6 million, and approximately 1.5 million were available for future grants. As part of the acquisition of Epoch on December 16, 2004, we assumed the 2003 Plan. The 2003 Plan had approximately 1.7 million shares reserved for issuance. Of this amount, outstanding stock options totaled approximately 967,000 and approximately 728,000 were available for future grants. In addition, the 2003 Plan has an evergreen provision that provides for annual increases in the number of shares available for issuance annually on January 1. This increase is based on a percentage of fully diluted outstanding shares; however, it is limited to a maximum annual increase of approximately 350,500 shares. On January 1, 2006, based on Epoch's 2003 Plan's evergreen provision an additional 350,500 options for our common stock became available for grant.

Stock Option Grants

Employees vest in stock option awards ratably over the service term, generally between two and four years. Outstanding stock options generally have a term of 10 years from the date of grant. The exercise price of the stock options granted under the plans, have historically been issued at an exercise price equal to the fair market value of our stock on the date of grant. However, our 1997 Plan provides us the ability to issue certain stock options with an exercise price of greater or equal to 85% of the fair market value of our common stock on the date of grant. Stock options expire after a period not to exceed ten years, except in the event of termination, whereupon vested shares must be exercised generally within 90 days under the 1997 Plan and within a time frame specified by the plan administrator (the plan administrator's policy is 90 days) under the Epoch plans, or upon death or disability, where an extended twelve-month exercise period is specified in the 1997 Plan. All of our issued stock options are exercisable only after they vest. The vesting period varies with the type of award.

Table of Contents

The following table summarizes all stock option activity in all plans through September 30, 2006:

	Number of Shares	Weighted Average Exercise Price	Weighted Remaining Contractual Term (years)	Aggregate Intrinsic Value
Outstanding at December 31, 2005	7,229,344	\$ 5.34		
Granted	846,175	2.31		
Exercised	(41,527)	1.35		
Cancelled	(226,704)	5.42		
Outstanding at September 30, 2006	7,807,288	\$ 5.03	7.13	\$ 29,000

In the nine months ended September 30, 2006 the total intrinsic value of the stock options exercised was \$110,000. In addition, we received \$56,000 in cash from our employees for the exercise of these stock options and we recorded no related tax benefits.

The following table summarizes information about our stock options outstanding at September 30, 2006:

Range of Exercise Prices	Options Outstanding			Options Exercisable	
	Options	Weighted Average Remaining Life in Years	Weighted Average Exercise Price	Options Exercisable	Weighted Average Exercise Price of Options Exercisable
\$1.00 - \$2.50	1,160,773	7.52	\$ 1.89	694,104	\$ 1.84
\$2.54 - \$3.57	1,698,994	7.49	\$ 3.25	1,123,502	\$ 3.38
\$3.58 - \$4.39	871,381	6.61	\$ 4.01	638,556	\$ 4.03
\$4.40 - \$5.04	1,913,156	8.02	\$ 4.60	1,516,709	\$ 4.62
\$5.07 - \$6.00	683,537	6.40	\$ 5.61	546,155	\$ 5.56
\$6.02 - \$7.34	838,046	7.15	\$ 6.64	534,958	\$ 6.67
\$7.47 - \$9.52	144,454	5.90	\$ 8.16	111,496	\$ 8.22
\$9.63 - \$15.51	310,428	4.45	\$ 11.72	304,718	\$ 11.72
\$15.52 - \$31.30	114,773	3.28	\$ 18.80	114,773	\$ 18.80
\$32.00 - \$41.86	71,746	1.34	\$ 39.89	71,999	\$ 39.89
	7,807,288	7.13	\$ 5.03	5,656,970	\$ 5.44

The following table provides the number of stock options outstanding with exercise prices less than or greater than our September 30, 2006 quoted stock price of \$1.78 per share (number of shares in thousands):

Edgar Filing: NANOGEN INC - Form 10-Q

Exercise Price	Exercisable		Unexercisable Weighted		Total Weighted	
	Number of Shares	Weighted Average Exercise Price	Number of Shares	Average Exercise Price	Number of Shares	Average Exercise Price
Less than \$1.78	173	\$ 1.63	16	\$ 1.59	189	\$ 1.63
Greater than \$1.78	5,484	\$ 5.56	2,135	\$ 3.95	7,619	\$ 5.11
Total Outstanding	5,657	\$ 5.44	2,151	\$ 4.00	7,808	\$ 5.03

Net stock options, after forfeitures and cancellations, granted during the nine months ended September 30, 2006 represented 0.9% of outstanding shares as of September 30, 2006. Total stock options granted during the nine months ended September 30, 2006 represented 1.2% of outstanding shares at September 30, 2006.

On the date we grant a stock option to an employee we use the Black-Scholes option-pricing model to determine its fair value. This option-pricing model is affected by a number of highly complex and subjective variables. Using the Black-Scholes option pricing model we estimate the fair value of our employee's vested stock options is approximately \$15.2 million as of September 30, 2006. At September 30, 2006, total unrecognized estimated compensation cost related to non-vested stock options granted prior to that date was \$5.8 million, which is expected to be recognized over a weighted average period of 1.2 years. In the nine months ended September 30, 2006, \$83,000 in share-based compensation expense was capitalized as inventory overhead.

Table of Contents

Restricted Stock Units

On July 29, 2005, we granted 402,250 restricted stock units to certain employees under the 1997 plan at a fair value of \$4.40 per restricted stock unit. The restricted stock unit grants have a two year cliff vesting period and on July 29, 2007 these restricted stock units will become convertible into our common shares. In the nine months ended September 30, 2006 this resulted in \$655,000 in amortization of stock based compensation which is included in loss from operations. As of September 30, 2006, we had 399,750 non-vested restricted stock units outstanding with a weighted-average grant date fair value of \$4.40 and an aggregated unrecognized compensation expense of \$728,000. These restricted stock units will vest in July 2007. In the nine months ended September 30, 2006, 2,500 restricted stock units were cancelled.

Employee Stock Purchase Plan

In 1997, the Board of Directors approved the Employee Stock Purchase Plan (ESPP), as amended, under which 1.1 million shares of common stock were authorized for issuance. The ESPP permits eligible employees to purchase shares of common stock, at semi-annual intervals, through periodic payroll deductions. Payroll deductions may not exceed 15% of the employee's base salary subject to certain limitations, and the purchase price will not be less than 85% of the lower of the fair value of the stock at either the beginning of the applicable offering period or the last day of the accumulation period. Each offering period is 24 months, with new offering periods commencing every six months, and an accumulation period is six months in duration. On June 30, 2006 we issued 90,462 shares under the ESPP plan and recognized approximately \$87,000 in stock based compensation expense. At September 30, 2006, approximately 423,270 shares were reserved for future issuance.

401(k) Plan

We have a 401(k) defined contribution savings and retirement plan (the Plan). The Plan is for the benefit of all qualifying employees and permits employees to make voluntary contributions up to a maximum of 20% of their base salary, subject to certain limitations. The Compensation Committee of the Board of Directors (Compensation Committee) may, at its sole discretion, approve matching contributions. In February 2006, the Compensation Committee approved a match in the form of our common stock equal to 25% of employee contributions subject to a four year vesting period from the employee's date of hire. On September 8, 2006 we issued 89,803 shares from our treasury stock and 3,124 shares from our 1997 Stock Incentive Plan as a result of this matching contribution.

9. Related Party Transaction

FasTraQ, Inc.

In June 2005, we signed a letter of agreement with FasTraQ, Inc. (FasTraQ) for the development of a certain future product. Our Chief Executive Officer and Chairman of the Board, Mr. Birndorf, is a director and an investor in FasTraQ. In October and December 2005, we amended this letter of agreement. As a result of this agreement and related amendments we made an initial non-refundable payment of \$500,000 in 2005 to begin the initial development of this product. As of December 31, 2005, we expensed the initial \$500,000. In February 2006, we converted this letter of agreement into two executed contracts, a Development and License Agreement and a Collaboration Agreement. In February 2006, we committed to provide FasTraQ an additional \$500,000 in funding based on certain milestones. We paid FasTraQ \$15,000 and \$302,000, during the three and nine months ending September 30, 2006, respectively, for reaching certain milestones and expensed this amount into research and development.

Fisher development agreement

On August 3, 2006, we entered into research and development collaboration arrangements with Fisher Scientific International Inc., (Fisher Scientific) a related party, that owns approximately 5.7 million shares of our common stock, and Athena Diagnostic, a wholly-owned subsidiary of Fisher Scientific. We agreed to share certain technology and patent rights related to the development, manufacture and marketing of new molecular diagnostic products. Under these arrangements, Fisher Scientific has the option to provide up to \$10 million in 2007 and 2008 for the research and development of infectious disease and molecular diagnostic tests that will be mutually agreed upon. These arrangements are included in non-binding general agreements, thus the obligation of the parties are subject to further negotiation and final terms of definitive collaboration agreements. On August 9, 2006, we entered into an exclusive distribution agreement with Fisher Scientific. There were no sales under this agreement in the third quarter of 2006.

10. Stock Transactions

Edgar Filing: NANOGEN INC - Form 10-Q

In March 2006, we sold approximately 5.7 million shares of our common stock to Fisher Scientific at a price of \$2.65 per share, for net proceeds of approximately \$15.0 million.

In May 2006, we filed a 462(b) registration statement with the Securities and Exchange Commission to increase our available funding under the June 2005 shelf registration statement by approximately \$4.0 million and as a result of this filing we had \$25.0 million in equity financing available as of May 2006.

Table of Contents

In May 2006, we entered into an equity financing agreement (agreement) with Azimuth Opportunity Ltd. (Azimuth), pursuant to which the private investor agrees to purchase, subject to certain limitations and closing conditions, up to \$25 million of our common stock over the next eighteen months. These purchases will be made pursuant to the June 2005 shelf registration statement. During the eighteen month period, we may, from time to time and at our sole discretion, present the private investor with draw down notices to purchase our common stock at a price that is calculated pursuant to a pricing matrix over 10 consecutive trading days, or such other period mutually agreed upon by us and the private investor. We are able to present the investor with up to 24 draw down notices during the term of the agreement, with a minimum of five trading days required between each draw down period. Only one draw down is allowed in each draw down pricing period, unless otherwise mutually agreed upon by us and the private investor. Once presented with a draw down notice, the private investor is required to purchase a pro-rata portion of the shares on each trading day during the 10-day trading period on which the daily volume weighted average price for our common stock exceeds a threshold price for such draw down determined by us. The per share purchase price for these shares equals the daily volume weighted average price of our common stock on each date during the draw down period on which shares are purchased, less a discount ranging from 3.8% to 5.8%, based on our market capitalization. Each draw down will be settled on the second trading day following the last trading day of each pricing period. If the daily volume weighted average price of our common stock falls below the threshold price on any trading day during a draw down period, the agreement provides that the private investor will not be required to purchase the pro-rata portion of shares of common stock allocated to that day. However, at the private investor's election, the private investor could buy the pro-rata portion of shares allocated to that day at the threshold price less the discount described above.

The agreement also provides that from time to time and at our sole discretion we may grant the private investor the right to exercise one or more call options to purchase additional shares of our common stock during each draw down pricing period for the amount that we specify. Upon the private investor's exercise of the call option, we would sell to the private investor the shares of our common stock subject to the call option at a price equal to the greater of the daily volume weighted average price of our common stock on the day the private investor notifies us of its election to exercise its call option or the threshold price for the call option determined by us, less a discount ranging from approximately 3.8% to 5.8%, based on our market capitalization.

On July 11, 2006, under our equity financing agreement with Azimuth we issued 2,524,130 shares at an aggregate purchase price of \$4.0 million or approximately \$1.59 per share. We received net proceeds of approximately \$3.9 million after deducting our offering expenses. On September 20, 2006, under this agreement we issued 833,333 shares at an aggregate purchase price of \$1.5 million or approximately \$1.80 per share. We received net proceeds of approximately \$1.47 million after deducting our offering expenses.

11. Subsequent Event

On October 5, 2006, we announced a plan to consolidate certain of our North American operations. As a part of this consolidation process we expect to reduce our headcount by approximately 15% across all of our operations by December 31, 2006. As of September 30, 2006, we have not accrued any liabilities associated with this event.

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 discussed herein under item 1a. Risk Factors below. We assume no obligation to update any forward-looking statements. The Management's Discussion and Analysis of Financial Condition and 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, 2005 in our Annual Report on Form 10-K.

Overview

The following Management's Discussion and Analysis of Financial Condition and Results of Operations (MD&A) is intended to help provide the reader a clear and straightforward understanding through the eyes of management of our operations and present business conditions. When used in this management discussion, the terms Nanogen, Company, we, us, or our mean Nanogen, Inc. and its subsidiaries. The MD&A is provided

Edgar Filing: NANOGEN INC - Form 10-Q

a supplement to and should be read in conjunction with our annual report on Form 10-K, and our quarterly condensed consolidated financial statements and the accompanying notes. This overview summarizes information within the MD&A, which includes the following sections:

Table of Contents

Summary an executive summary of the significant business events that have occurred after January 1, 2006.

Our Business a general description of our business, our technologies and the actions we have taken to develop our business to help the reader better understand our objectives, areas of focus, various strategic investments, relationships and agreements we have entered into after January 1, 2006.

Results of Operations an analysis of our consolidated results of operations for the three months and nine months ended September 30, 2006 and 2005, as presented in our condensed consolidated financial statements, to provide the reader information about trends and material changes in revenues and expenditures.

Liquidity and Capital Resources an analysis of our cash flow statement and financial position to help the reader understand our current and anticipated capital resource requirements and our ability generate the liquidity required to support our current and planned operations.

Critical Accounting Policies and Estimates an analysis of the judgmental accounting policies, estimates and assumptions we made while completing our condensed consolidated financial statements, to provide the reader an understanding of how these decisions materially effected the results of operations.

Summary:

The following significant business developments occurred after January 1, 2006:

In February, we completed the acquisition of the rapid cardiac immunoassay test business from Spectral Diagnostics (TSX: SDI) for CDN \$5.6 million or U.S. \$4.9 million in cash and 975,193 shares of our common stock with a fair value of approximately \$2.9 million. The transaction expanded our portfolio of point-of-care diagnostics to include Spectral's Cardiac STATu[®] and Decision Point product lines, the i-Lynx reader, related intellectual property and manufacturing capabilities. The i-Lynx reader is a unique hand-held reader designed to capture and analyze the results of the Cardiac STATu[®] products. This acquisition provided us a fully integrated point-of-care group with resources and capabilities in manufacturing and sales and marketing with a worldwide distribution network to compete in the point-of-care market.

In March 2006, we received 510(k) clearance from the FDA to market our *StatusFirst*[™] CHF NT-proBNP EDTA plasma test to aid in the diagnosis of individuals suspected of having congestive heart failure (CHF). This was our first 510(k) clearance and is considered a significant milestone toward the commercial launch of our CHF point-of-care test. We are currently considering various product launch alternatives for this product. In addition, we are continuing our development work on the *StatusFirst* CHF whole blood test, which would significantly expand the potential market and revenue generating capability of our CHF product.

In March 2006, we sold approximately 5.7 million shares of our common stock to Fisher Scientific International, Inc. at a price of \$2.65 per share, for net proceeds of approximately \$15.0 million.

On May 1, 2006 we completed the acquisition of the diagnostics division of Amplimedical S.P.A. (Amplimedical), which is a manufacturer and distributor of molecular diagnostic products, based in Italy, for \$8.1 million consisting of \$2.0 million in cash or approximately \$2.5 million and \$6.1 million or approximately \$7.5 million in a promissory note that is convertible into our common stock. On June 30, 2006 we paid the promissory note in full by issuing Amplimedical 2,886,935 shares of our common stock at a \$2.63 per share conversion price and incurred no interest charges. Based in Italy, Amplimedical has been active in the European and other markets since the early 1990s with its molecular diagnostic reagents. Nanogen and Amplimedical have shared a business relationship for approximately five years, during which time Amplimedical has been a distributor of Nanogen's NanoChip[®] Molecular

Edgar Filing: NANOGEN INC - Form 10-Q

Biology Workstation and NanoChip® 400 instrument systems in Italy. We believe this acquisition will allow our molecular diagnostics business to further expand in Europe by providing additional resources and scale. Amplimedical's portfolio of real-time molecular diagnostic test kits are all CE marked for in vitro diagnostics. Amplimedical's diagnostic test kits also include multiplexed reagent kits, sold in Europe, such as the CE/IVD-marked set of reagents used to detect mutations in the GJB2 gene for the diagnosis of hereditary deafness and a research-use-only set of reagents to test for genetic causes of beta thalassemia, a type of inherited blood disorder that can cause anemia.

On August 3, 2006, we entered into several non-binding research and development collaboration arrangements with Fisher Scientific International Inc., (Fisher Scientific) a related party, that owns approximately 5.7 million shares of our common stock, and Athena Diagnostic, a wholly-owned subsidiary of Fisher Scientific. We agreed to share certain technology and patent rights related to the development, manufacture and marketing of new molecular diagnostic products. Under these agreements, Fisher Scientific has the option to provide up to \$10 million in 2007 and 2008 for the research and development of infectious disease and molecular diagnostic tests that will be mutually agreed upon. These arrangements are subject to further negotiation and the terms of definitive collaboration agreements are required to be finalized.

Table of Contents

On September 30, 2006, we had approximately \$32.7 million in cash and short-term investments. This compares to our use of approximately \$34.0 million in cash in our operating activities in the nine months ended September 30, 2006. Included in cash and short-term investments are the proceeds of approximately \$5.5 million from our equity financing agreement and \$20.0 million upfront payment for an agreement with Drug Royalty Trust (DRT), where we assigned the rights associated with our Applied Biosystems, Inc. (Applied Biosystems) royalty agreement from July 2006 through December 2011. Under the agreement with DRT, we have guaranteed certain annual minimum royalty payments to DRT through December 2011 for an aggregate amount of approximately \$26.9 million. Due to our negative cash flows from operations we remain dependent on capital financing or other non dilutive sources, such as the potential Fisher Scientific research and development agreements, of funding to support on going operations through September 30, 2007. Therefore, we remain dependent on our ability to draw down on our equity financing agreement that may provide us capital (see note 10) and our ability to narrow our losses. However, we can not provide you assurance that we will be able to utilize existing or obtain new sources of financings when and as needed in the future.

On October 5, 2006, as a part of our continual focus on narrowing our losses and working towards positive cash flows from operations, we announced a plan to consolidate certain of our North American operations. As a part of this consolidation process we expect to reduce our headcount by approximately 15% across all of our operations by December 31, 2006.

Our business:

Our company is based on the vision of providing a higher quality of healthcare through advanced diagnostic products. Our business strategy is to assemble the companies, products and knowledge base to become a leading supplier of the technologies and products that will help drive a new era of personalized medicine. We were early to recognize that the adoption of personalized medicine is dependent on the advancement of diagnostic technologies. The commercialization of our products and technologies will help bridge the gap between early-stage scientific research and actual clinical practice. We are developing several product lines that are directly targeting specific markets within the advanced diagnostics field that have significant potential for revenue growth. We see recent successes and a growing capability in the clinical laboratories ability to perform accurate advanced diagnostic testing as a strong validation of our strategy. In addition, the FDA has recently released guidance encouraging the generation of more pharmacogenomics data and molecular diagnostic testing during drug development and clinical trials, and before the use of medications. We believe these applications of advanced diagnostics will help build demand for our products and technologies.

Technology

Our diagnostic technologies focus on the identification of the nucleic acid sequences, gene variations and gene expressions associated with both genetic conditions and infectious diseases. We believe that our research will contribute to a new healthcare paradigm where disease is diagnosed and understood at the molecular level. We believe that this will lead to the introduction of new therapies, targeted therapeutics and an abundance of new screening tests that will, in turn, shift the focus of medicine to be increasingly proactive as well as being increasingly specific to the individual patient. Our tests will provide doctors with the information they require to tailor specific therapies to the individual patient. Therefore, we have developed a variety of diagnostic tools for both the relatively simple and complex testing required to render disease-specific molecular information accessible to researchers and clinicians.

Below illustrates how our platform technologies address our customer s requirements for advanced molecular diagnostic tools:

Potential customers addressed by our technologies:

<p>Advanced Research <i>(Universities, research facilities, etc.)</i></p>	<p>Clinical Laboratory (<i>CLIA</i> <i>certified central laboratories and clinical research laboratories)</i></p>	<p>Point-of-care (<i>Emergency room or urgent care settings)</i></p>
---	---	--

Molecular testing platforms (*Instrumentation*)
Molecular Reagents

(Reagents, ASRs, Custom Assays)

Point-of-Care Tests

(Test Kits and Instruments)

Advanced genetic markers

Table of Contents

As illustrated above we have four categories of advanced diagnostic technologies: 1) molecular testing platforms 2), molecular reagents 3) point-of-care tests and 4) advanced genetic markers.

1) Molecular Testing Platforms (Instrumentation)

For our customers that need to develop or perform more complex testing than is available with real-time instruments, we have developed the second generation NanoChip[®]400 system and the Molecular Biology Workstation. These systems are based on our proprietary molecular detection technology that allows testing for multiple gene markers or mutations on one test site. Using our open system architecture, researchers and clinical laboratories can readily develop assays to test multiple genetic mutations for multiple patient samples and to perform them on an automated system.

2) Molecular Reagents (RUO Reagents, ASRs, Custom Assays)

Molecular reagents encompass real-time PCR products and molecular reagents. The real-time products include both custom designed products for the research market and ASRs which are sold to laboratories certified under the Clinical Laboratory Improvement Amendments of 1998 (CLIA) to develop, optimize and validate tests for clinical uses. These products are advanced molecular probes that amplify disease specific genetic sequences for analysis or identification in a simple test with rapid turn around. 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 complement our current sales and marketing efforts with a wider array of solutions for our customers. The customers for this product line are primarily advanced research and clinical laboratories that test for single markers or mutations in genes. We also offer reagents for more complex testing. These reagents provide the capability of laboratories to test a patient sample against multiple targets. We currently offer reagents for the testing of respiratory viruses (RVA) and blood clotting (Factor V/II).

In addition, in May 2006 we acquired Amplimedical's portfolio of real-time molecular diagnostic test kits which are all CE marked for *in vitro* diagnostics use. We also acquired multiplexed reagent diagnostic test kits that are sold in Europe, including a CE/IVD-marked set of reagents to detect mutations in the GJB2 gene for the diagnosis of hereditary deafness and a research-use-only set of reagents to test for genetic causes of beta thalassemia, a type of inherited blood disorder that can cause anemia.

3) Point-of-Care (Test Kits)

Our point-of-care tests consist of highly specific tests for identifying proteins that play a role in specific diseases. By identifying the level of specific proteins present in a patient sample, doctors can more accurately diagnose and monitor the progress of specific diseases. Our researchers are developing diagnostic products that focus on congestive heart failure, stroke and traumatic brain injury. We believe our technologies will help to move many of these tests from the clinical reference lab to the point-of-care settings such as the emergency room. On February 6, 2006, with our acquisition of Spectral's point-of-care assets, we acquired several revenue generating rapid cardiac immunoassay tests that broadened our menu of products available for point-of-care customers. The acquired products include rapid tests for levels of CKMB, Myoglobin and Troponin, all of which are frequently used in cardiac care. In addition, we acquired the ability to manufacture these and other point-of-care products.

In March 2006, we received FDA clearance to begin marketing our plasma based NT-proBNP congestive heart failure product for use on human plasma. We are currently considering various product launch alternatives for this product. For the larger point-of care market, our NT-proBNP congestive heart failure product for use on human whole blood remains under development.

4) Advanced Genetic Markers

With our investment in Jurilab in 2005, 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 prognostic indicators of disease. We expect this collaboration to enhance the development and commercialization of our technology 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.

Table of Contents*License fee and royalty income: Developments*

In January 2006, we renegotiated our royalty agreement with Applied Biosystems, Inc. (Applied Biosystems), with the underlining patents expiring at various dates between 2010 and 2015, to maintain minimum quarterly payments through December 31, 2006 and royalties based on actual sales, thereafter. Although we expect this relationship to continue for the foreseeable future, this agreement can be terminated with a 180 day notice.

On September 29, 2006, to provide us with a non-dilutive means of raising capital, we entered into an agreement with Drug Royalty Trust (DRT) where we assigned the rights associated with the Applied Biosystems royalty agreement from July 2006 through December 2011 for a \$20.0 million upfront payment in cash. Under the agreement with DRT, we have guaranteed certain annual minimum royalty payments to DRT through December 2011 in an aggregate amount of approximately \$26.9 million.

The table below illustrates each fiscal years minimum royalty payments to DRT:

	Minimum payment
Calendar year ending:	(in thousands)
2006 (remainder)	\$ 1,820
2007	4,300
2008	4,820
2009	5,200
2010	5,410
2011	5,410
Total	\$ 26,960

In addition, if royalty payments from Applied Biosystems are above certain thresholds for each fiscal year of the agreement we will receive, in cash, a certain percentage of the amount above the threshold.

Acquisitions, investments and goodwill: Developments

We will selectively seek to acquire or invest in companies with complementary products and strong intellectual property positions to allow us to penetrate emerging markets. We anticipate using a combination of cash and common stock to purchase future companies or assets.

Spectral Diagnostics Inc. asset purchase

On February 6, 2006, we completed the acquisition of the rapid cardiac immunoassay test business from Spectral Diagnostics Inc. (Spectral) for CDN \$5.6 million in cash or approximately \$4.8 million and 975,193 shares of our common stock with a fair value of approximately \$2.9 million.

Based in Toronto, Canada, the rapid cardiac immunoassay test business includes a portfolio of point-of-care tests such as the Cardiac STATus® and Decision Point product lines, the i-Lynx reader, related intellectual property and manufacturing capabilities. This acquisition provided us a fully integrated point-of-care group with resources and capabilities in manufacturing, and sales and marketing with a worldwide distribution network to compete in the point-of-care market. These factors were among those that contributed to a purchase price resulting in the preliminary allocation of \$1.6 million in goodwill.

We used a third party to assist us in performing a preliminary valuation analysis of our purchased intangibles and potential IPR&D and we reviewed their assumptions, calculations and conclusions for reasonableness. We used valuation techniques comparable with others in the high technology industry and determined that we had no IPR&D and we acquired the following purchased intangible assets (in thousands):

Edgar Filing: NANOGEN INC - Form 10-Q

Intangible assets	
Completed technology	\$ 4,143
Distributor relationships	810
Trade name	270
Backlog	24
Total purchased intangibles	\$ 5,247

Table of Contents

In addition, as part of the acquisition, we acquired a commitment to lease Spectral's manufacturing and administrative facilities through February 2007 for approximately \$308,000 with an option to extend the lease until July 2007. We believe this approximates current market lease rates for comparable properties.

Amplimedical

On May 1, 2006, or the effective date, we completed the acquisition of the diagnostics division of Amplimedical S.p.A. (Amplimedical), which is a manufacturer and distributor of molecular diagnostic products based in Italy, for \$8.1 million, consisting of \$2.0 million or approximately \$2.5 million for the issuance of a letter of credit, securitized by restricted cash and \$6.1 million or approximately \$7.5 million in a promissory note issued by us. The promissory note was convertible into shares of our common stock. On June 30, 2006 we paid the promissory note in full by issuing Amplimedical 2,886,935 shares of our common stock at a conversion price of \$2.63 per share and incurred no interest charges. Under our asset purchase agreement we had the option to pay the promissory note with cash at a 10% discount through June 30, 2006. As such, we reduced the fair value of the promissory note by 10% when we calculated the purchase price. These factors were among those that contributed to a purchase price resulting in the preliminary allocation of \$1.2 million in goodwill.

Based in Italy, Amplimedical has been active in the European and other markets since the early 1990s with its molecular diagnostic reagents. Nanogen and Amplimedical have shared a strong business relationship for approximately five years, during which time Amplimedical has been a distributor of Nanogen's NanoChip[®] Molecular Biology Workstation and NanoChip[®] 400 instrument systems in Italy. We believe this acquisition will allow our molecular diagnostics business to further expand in Europe by providing additional resources and scale. Amplimedical's portfolio of real-time molecular diagnostic test kits are all CE marked for in vitro diagnostics. Amplimedical's diagnostic test kits also include multiplexed reagent kits, sold in Europe, such as the CE/IVD-marked set of reagents used to detect mutations in the GJB2 gene for the diagnosis of hereditary deafness and a research-use-only set of reagents to test for genetic causes of beta thalassemia, a type of inherited blood disorder that can cause anemia.

We used a third party to assist us in performing a preliminary valuation analysis of our purchased intangibles and potential IPR&D and we reviewed their assumptions, calculations and conclusions for reasonableness. We used valuation techniques comparable with others in the high technology industry and determined that we had no IPR&D and we acquired the following purchased intangible assets (in thousands):

Intangible assets	
Completed technology	\$ 3,374
Distributor and customer relationships	2,161
Trade name	354
Total purchased intangibles	\$ 5,889

Once we receive a final third party purchase price allocation the preliminary allocation may need to be adjusted. The related impact to amortization expense, if any, will be adjusted prospective basis.

In addition, as part of the acquisition, we acquired a commitment to lease Amplimedical's manufacturing and administrative facilities through December 2006 for approximately \$42,000. We believe this approximates current market lease rates for comparable properties.

Jurilab, LTD investment

In a series of investments from July 2005 through June 2006, we invested approximately \$3.3 million to purchase 29.7% of the outstanding stock of Jurilab LTD (Jurilab). In addition, we have the option to purchase the entire company at not-to-exceed prices through December 31, 2007. By investing in Jurilab, a development stage research and development company, we gained access to technologies related to certain gene markers. 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 Jurilab's 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 Jurilab's activities are conducted on our behalf despite our disproportionate ownership percentage. Therefore, we have consolidated Jurilab's operations

into our financial

Table of Contents

results; however, their creditors have no recourse against us and our maximum exposure to loss is the \$3.3 million we have invested 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, 2006 were the net liabilities (in thousands) of Jurilab:

Included in our condensed consolidated balance sheet at September 30, 2006 and December 31, 2005 were the net liabilities (in thousands) of Jurilab:

	September 30, 2006 (Unaudited)	December 31, 2005 (Unaudited)
Cash	\$ 19	\$ 77
Restricted cash		355
Other assets	714	719
Debt obligations	(7,417)	(7,245)
Other long-term liabilities	(1,053)	(1,018)
Net liabilities	\$ (7,737)	\$ (7,112)

Included in our condensed consolidated statement of operations were the following results of Jurilab's operations (in thousands):

	Three months ended, September 30,		Nine months ended, September 30,	
	2006 (Unaudited)	2005 (Unaudited)	2006 (Unaudited)	2005 (Unaudited)
Net sales	\$ 20	\$ 58	\$ 36	\$ 58
Cost of product sales	(31)	(28)	(97)	(28)
Research and development expense	(1,204)	(689)	(3,764)	(689)
Other expenses	(94)	(42)	(238)	(42)
Net loss	\$ (1,309)	(701)	\$ (4,063)	(701)

In May 2006, we entered into a collaboration agreement with Jurilab, where Jurilab would identify and validate new prognostic markers for Type II diabetes with certain milestone payments of up to \$950,000 or approximately \$1.2 million. In May 2006, we paid Jurilab \$200,000 or \$386,000 for the completion of the first milestone.

Pharmacogenetics Diagnostic Laboratory, LLC

In July 2005, we invested \$400,000 in Pharmacogenetics Diagnostic Laboratory, LLC (PGx), a development stage research and development company, to provide us access to certain technologies related to pharmacogenetics. We may increase our investment to an aggregate amount of 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 PGx has and will continue to obtain additional and operating funding from other third parties. Moreover, even if PGx were a VIE, its creditors have no recourse against us and our maximum exposure to PGx's losses is the extent of our investment. Therefore, we will continue to 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. For the three months and nine months ended September 30, 2006 we have expensed \$8,000 and \$76,000 of PGx's net losses into research and development.

FasTraQ, Inc.

In June 2005, we signed a letter of agreement with FasTraQ, Inc. (FasTraQ) for the development of a certain future product. Our Chief Executive Officer and Chairman of the Board, Mr. Birndorf, is a director and an investor in FasTraQ. In October and December 2005 we amended this letter of agreement. As a result of this agreement and related amendments we made an initial non-refundable payment of \$500,000 in 2005 to begin the initial development of this product. As of December 31, 2005 we expensed the initial \$500,000. In February 2006, we converted this letter of agreement into two executed contracts, a Development and License Agreement and a Collaboration Agreement. In February 2006, we committed to provide FasTraQ an additional \$500,000 in funding based on certain milestones. As of September 30, 2006, we paid FasTraQ \$302,000 and expensed this amount into research and development.

Table of Contents*Acquisition of SynX Pharma Inc. and Epoch Biosciences, Inc.*

As a part of our long-term strategy to build a stronger company with products to serve the advanced diagnostic marketplace, in 2004, we identified SynX Pharma Inc. (SynX) and Epoch Biosciences, Inc. (Epoch) as businesses operating in market niches that were complementary to our existing business. In addition, they provided us the opportunity to broaden our product lines in the proteomics technology pipeline (e.g. point-of-care) and real-time PCR diagnostic markets. Therefore, we acquired SynX and Epoch in all stock transactions on April 21, 2004 and December 14, 2004, respectively.

Employee Share Based Payments: Developments

As required by SFAS No. 123R *Share-Based Payment* and a ruling by the U.S. Securities and Exchange Commission, on January 1, 2006, we changed the accounting treatment of stock options, restricted stock units and the employee stock purchase plan (ESPP) shares issued to our employees.

Stock options. We periodically issue stock options to our employees that are designed to reward employees for their long-term contributions to us and to provide incentive for them to remain an employee. We believe that such awards better align the interests of our employees with those of our shareholders. Prior to our adoption of SFAS No. 123R, we elected to account for the issuance of stock options to employees using the intrinsic value-based methodology as prescribed by Accounting Principles Board (APB) Opinion No. 25, *Accounting for Stock Issued to Employees*, and its related interpretations, as permitted by SFAS No. 123 *Accounting for Stock-Based Compensation* and its related interpretations. Under this methodology, if the stock option we issued to an employee was equal to the quoted market price of our common stock, on the date of grant, we did not record any compensation expense. If the exercise price of the stock option we issued to an employee was below the quoted market price of our common stock, the difference between the market price and exercise price was recorded as deferred compensation in the balance sheet. The compensation expense was then recorded on a straight-line basis over the stock option's vesting period. To the extent stock awards were subject to an exchange offer, other modifications, or performance criteria, such awards were subject to variable accounting treatment. To the extent stock awards were forfeited prior to vesting, the corresponding previously recognized expense was reversed as an offset to operating expenses. After the adoption of SFAS No. 123R, we are required to calculate, as of the date of grant, the fair value of the stock options issued to our employees. We are then required to expense the fair value of the stock option over the employee's required service period (the vesting period). SFAS No. 123R requires that share-based payment forfeitures to be estimated at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates. As of September 30, 2006, all of the stock options we have issued are conditioned on the employee's continued employment and we have not issued any stock options conditioned on the results of any measure of market or financial performance.

Restricted stock units. We periodically issue restricted stock units (RSUs) with two year cliff vesting periods to key employees to provide incentive for them to remain as an employee over the service period. Prior to our adoption of SFAS No. 123R, we recorded the value of the RSUs we issued to our employees at their fair value, defined as the quoted market price of the underlying shares on the grant date, in equity as deferred compensation. We amortized the associated deferred compensation as an expense over the vesting period. After the adoption of SFAS No. 123R, we reversed the remaining balance of deferred compensation and additional paid-in capital in equity associated with our RSUs awards issued before January 1, 2006. To record the compensation expense associated with the RSUs we are required to determine the fair value on the grant date, defined as the closing market price on the date of grant, and expense this amount over the vesting period. In addition, we are required to reduce the associated compensation expense by the estimated number of employees not expected to complete the requisite service period. In the nine months ended September 30, 2006 our estimated pre-vesting forfeitures rate was determined to be 0%, due to the lack of pre-vesting forfeitures during our testing period.

Employee Stock Purchase Plan. To encourage our employees to own stock in our company we have an Employee Stock Purchase Plan (ESPP) that permits eligible employees to purchase shares of common stock, at semi-annual intervals, through periodic payroll deductions. Payroll deductions may not exceed 15% of the employee's base salary subject to certain limitations, and the purchase price will not be less than 85% of the lower of the fair value of the stock at either the beginning of the applicable offering period or the last day of the accumulation period. Each offering period is 24 months, with new offering periods commencing every six months, and an accumulation period is six months in duration. Prior to our adoption of SFAS No. 123R we did not record any compensation expense associated with our ESPP. After the adoption of SFAS No. 123R, we are required to calculate, as of the date of grant, the fair value of the ESPP shares issued to our employees and record this cost as compensation expense over the vesting period. At September 30, 2006, approximately 423,270 shares were reserved for future issuance.

Table of Contents

Tax Effects. Due to the uncertainty related to our realization of any tax assets or liabilities we generate from our operations, we record a full valuation allowance against all of our tax assets or liabilities. Therefore, we have not recorded any tax benefits resulting from stock-based compensation deductions in excess of amounts reported for financial reporting purposes in the nine months ended September 30, 2006.

Application methodology. We elected to implement SFAS No. 123R using the prescribed modified prospective application methodology. The modified prospective application methodology requires us to apply the standards under SFAS No. 123R to all new awards, outstanding awards and to any modification or cancelled awards after January 1, 2006. For awards issued before January 1, 2006, we will use the derived fair value and vesting period of the share-based compensation costs as calculated in our prior period pro forma disclosures under SFAS No. 123 and recognize this derived fair value as an expense over the employee's remaining required service period. When presenting prior period financial statements, under the modified prospective application, prior periods are not revised for comparative purposes and the fair value of the options is disclosed in a pro-forma footnote (see note 1).

Valuation methodology. We believe it is important for investors to be aware of the high degree of subjectivity involved when using option pricing models to estimate share-based compensation under SFAS No. 123R. The determination of the fair value of share-based payment awards on the date of grant using an option-pricing model is affected by our stock price as well as assumptions regarding a number of complex and subjective variables. Because there is no observable market for share based payments similar to the ones we provide to our employees, consistent with the guidance in SFAS No. 123R and the Securities and Exchange Commission's Staff Accounting Bulletin (SAB) No. 107, we elected to continue to use the Black-Scholes option-pricing model to determine the fair value of our share based payments. The Black-Scholes option-pricing model has significant deficiencies as a valuation model because it 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. Despite these deficiencies, we have a history of using the Black-Scholes option pricing model and we can more accurately develop the highly subjective assumptions required as inputs into the model. Further, our investors are more familiar with the Black-Scholes option valuation model and can better analyze the potential impact these assumptions will have on our current and future results of operations. In the future, as our industry develops a consensus and best practices are developed for share based payment valuation models, we may adopt a different method of valuation that better reflects the fair value of our share based payments. However, because any valuation methodology uses assumptions that are based on historical trends to model future events, no matter which valuation methodology we use, the fair value of our share based payments is our best estimate and may potentially differ materially from the ultimate value realized by the recipient employee.

Approximately 846,000 stock options were granted during the nine months ended September 30, 2006. The weighted-average estimated fair value of employee stock options granted during the nine months ended September 30, 2006 was \$2.32 per share using the Black-Scholes model with the following assumptions:

	Expected		Risk Free	Volatility	Dividend	Pre-vesting
	life in	Interest	Rate			
Vesting period	years	Rate	Rate	Yield	Yield	rate
Four year vesting period with a one year cliff, thereafter monthly vesting	4.9 5.4	4.4%	4.4%	94.5%	0%	14.8%
Two year vest period with a six month cliff, thereafter monthly vesting	4.7 5.4	4.4%	4.4%	94.5%	0%	7.4%
Four year vest period with monthly vesting	5.4 6.2	4.4%	4.4%	94.5%-103.45%	0%	0%

Volatility. Volatility is a measure of the amount the share price has or will fluctuate during the expected term. Because an options value is unaffected by negative swings in stock price, other things being equal, an option with higher volatility is worth more than an option with lower volatility. We used the daily quoted market prices of our common stock to derive our volatility by using a look back period equal to our expected term. We did not exclude any daily closing prices during this period of time. Prior to our adoption of SFAS No. 123R, for the nine months ended September 30, 2005, we used our historical stock prices in accordance with SFAS No. 123 for purposes of our pro forma information.

Risk free interest rate. The risk-free interest rate assumption is based upon U.S. constant rate Treasury Security's market interest rates with a contractual life approximately equal to the expected term of our employee stock options or ESPP awards.

Dividend yield. We have not paid any cash dividends to date and do not anticipate any being paid in the foreseeable future therefore our dividend yield is zero.

Table of Contents

Expected term. The expected term of employee stock options is impacted by all of the underlying assumptions used in our model. The expected term of share-based payments granted is estimated based on a number of factors, including but not limited to the vesting term of the award, historical employee exercise behavior (for both share-based payments that have run their course and outstanding share-based payments), the expected volatility of our common stock and an employee's average length of service. In addition, we stratify our employees into groups that have historically similar exercise behavior patterns. Our model assumes that employees' exercise behavior is a function of the extent to which the option is in-the-money (i.e., the average stock price during the period is above the strike price of the stock option).

Pre-vesting forfeitures. SFAS No. 123R requires that share-based payment forfeitures to be estimated at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates. Pre-vesting forfeitures were estimated to be approximately 14.8% for grants with a one year cliff and 7.4% for grants with a six month cliff in the nine months ended September 30, 2006 based on historical experience. In our pro forma information required under FAS 123 for the periods before January 1, 2006, we were required to account for forfeitures as they occurred.

The effect of adopting SFAS No. 123R in the three and nine months ended September 30, 2006 was (in thousands, except per share data):

	Three months ended September 30, 2006			Nine months ended September 30, 2006		
	Using Previous	123R	As Reported	Using Previous	123R	As Reported
	Accounting	Adjustments	As Reported	Accounting	Adjustments	As Reported
Cost of product sales	\$ 3,479	\$ 30	\$ 3,509	\$ 9,606	\$ 165	\$ 9,771
Research and development	5,992	250	6,242	18,167	887	19,054
Selling general and administrative	7,815	626	8,441	22,683	2,055	24,738
Amortization of purchased intangible assets	869		869	2,159		2,159
Total cost and expenses	\$ 18,155	\$ 906	\$ 19,061	\$ 52,615	\$ 3,107	\$ 55,722
Net loss	\$ (10,876)	\$ (906)	\$ (11,782)	\$ (34,747)	\$ (3,107)	\$ (37,854)
Basic and diluted earning per share:	\$ (0.16)	\$ (0.02)	\$ (0.18)	\$ (0.64)	\$ (0.05)	\$ (0.69)

Goodwill impairment analysis: Developments

In accordance with SFAS No. 142, *Goodwill and Other Intangible Assets*, we do not amortize goodwill and intangible assets with indefinite useful lives. Using the purchase method of accounting we recorded goodwill with our acquisitions of Amplimedical, Spectral, SynX and Epoch that represented the difference between the purchase price and the fair value of the identifiable tangible and intangible net assets. This goodwill was subject to our quarterly reviews for indicators of impairment.

The following table summarizes the changes in the carrying amounts of goodwill for the nine months ended September 30, 2006 (in thousands):

Balance as of December 31, 2005	\$ 37,178
Acquisition of Spectral	1,593
Acquisition of Amplimedical	1,227
Adjustment to purchase price of Epoch	(271)
Balance as of September 30, 2006	\$ 39,727

In the third quarter of 2006, we determined there were no material events or changes in circumstances to indicate that the carrying amount of goodwill might not be recoverable. Therefore, we will perform the required annual goodwill impairment testing during the fourth quarter of our fiscal year.

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

Edgar Filing: NANOGEN INC - Form 10-Q

Through SynX we were a party to a 2001 development and manufacturing agreement between SynX and Princeton BioMeditech Corporation (PBM) to jointly develop and market various point-of-care tests for certain biomarkers and protein targets. As of January 2006, we terminated all of our previous agreements with PBM and superseded them with renegotiated contracts. These agreements include a manufacturing and distribution agreement and a development agreement. There were no payments between us and PBM associated with entering into these revised agreements and there were no minimum purchase requirements between the parties.

Table of Contents

We agreed to continue the joint development of a point-of-care test that incorporates PBM's proprietary technology, our proprietary reagents and an exclusive license between us and Roche Diagnostics GmbH. PBM is responsible for the development of a reasonably priced instrument for this test to determine the amount of target NT-proBNP present in a patient. We will fund a portion of the development cost of the instrument, up to an agreed upon maximum amount. In addition, we are required to develop and manufacture the reagents used in the instrument and supply them to PBM. We also have to conduct the testing of our reagents required to obtain regulatory approval to market and sell them. Further, we will share revenues associated with this point-of-care instrument with the majority of revenues being allocated to the party responsible for selling, marketing and distributing the instrument within a specific geographic territory. Each party will be responsible for its own manufacturing, sales and marketing expenses and both parties are required to provide each other a forecast of expected demand for each others product (reagents or instruments).

We provided PBM with an option to purchase or to receive a nonexclusive license for certain biological markers for the incorporation into a future point-of-care instrument related to congestive heart failure, stroke or traumatic brain injury. We have agreed to negotiate in good faith commercially reasonable terms for such a license or supply arrangement. However, if we are unable to agree upon such terms PBM will pay Nanogen a certain royalty for use of these markers.

FDA regulations: Developments

Our micro-array instrumentation and ASR products are to be used only for research purposes or by CLIA-certified laboratories when developing and validating their own diagnostic tests. When we begin to distribute and manufacture products for non-CLIA laboratories and point-of-care customers, we are subject to additional FDA requirements such as pre-market applications.

In March 2006, we received FDA clearance to begin marketing our NT-proBNP congestive heart failure product for use with human plasma. For the larger point-of-care market, our NT-proBNP congestive heart failure product for use with human whole blood remains under development.

In the third quarter of 2005, we received an untitled letter from the Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD), a division of the FDA. The letter described the OIVD's concerns that our microarray NanoChip® systems and certain related ASRs might be construed as a medical device that requires a premarket notification/application. During the first quarter of 2006 we met with the FDA and made certain changes in our marketing materials and sales approach. In September 2006, the FDA published Draft Guidance for Industry and FDA Staff: Commercially Distributed Analyte Specific Reagents (ASRs): Frequently Asked Questions setting forth the FDA's interpretation of the regulations governing the sale of ASR products. Subsequently, we received a second letter from the OIVD in which the FDA asserted that our microarray and multiplexed reagents require FDA market review. In November 2006, we met with the FDA to discuss the second letter. We believe that our microarray NanoChip® systems and ASR products are not subject to FDA premarket review. If there is an unfavorable decision by the FDA in these matters, it could delay or prevent sales of our NanoChip®400 to clinical laboratories in the United States and could adversely impact sales of our ASRs to clinical laboratories in the United States. During 2007, we plan to submit the NanoChip®400 with one or more assays to the FDA for clearance.

Manufacturing:

Except for our custom real time PCR products 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.

In February 2006, we purchased a point-of-care product line from Spectral Diagnostics, Inc. and acquired the ability to manufacture the associated future point-of-care products in our facilities in Toronto, Canada.

In May 2006, we purchased a real-time product line from Amplimedical and acquired the ability to manufacture certain real-time products in our facilities in Italy.

Table of Contents*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 fluctuations will depend upon several factors, including those discussed under item 1a Risk Factors. In addition, the timing of orders from distributors and the mix of sales between our product lines could affect our results of operations. We cannot assure you that we will be able to achieve revenue growth on a quarterly or annual basis.

Results of Operations*For the three and nine months ended September 30, 2006 and 2005*Revenues

The following table summarizes our revenues for the three and nine months ended September 30, 2006 and 2005 (in thousands):

	For the three months			For the nine months		
	ended September 30,			ended September 30,		
	2006	2005	Difference	2006	2005	Difference
Product sales	\$ 4,727	\$ 1,060	\$ 3,667	\$ 10,865	\$ 3,348	\$ 7,517
License fee and royalty income	1,866	1,748	118	5,494	5,071	423
Contracts and grant	912	363	549	1,809	1,063	746
Total	\$ 7,505	\$ 3,171	\$ 4,334	\$ 18,168	\$ 9,482	\$ 8,686

Product sales revenue is primarily generated from real-time PCR products (both custom and proprietary tests), a portfolio of rapid cardiac immunoassay point-of-care tests (cardiac tests), molecular testing instruments (NanoChip[®] systems) and various ASRs. The increase in product sales revenue in the three and nine months ended September 30, 2006 as compared to the same period in 2005 was primarily due to our acquisitions of Spectral's and Amplimedical's product lines on February 6, 2006 and May 1, 2006, respectively. In the three and nine months ended September 30, 2006 these products accounted for \$3.6 million and \$7.5 million, respectively, of the increase in product revenue as compared to the same periods in 2005.

The future: Due to the acquisition of Spectral's and Amplimedical's acquired product lines we expect revenue to continue to increase in the remainder of 2006 as compared to 2005. In addition to this acquired revenue, we expect increases in revenue from our molecular testing instruments and our internally developed ASRs products. However, before we gain commercial acceptance of our ASRs from clinical diagnostic customers the FDA may require regulatory clearance for our reagents.

We do not expect any significant revenue from our initial NT-proBNP, congestive heart failure test, that received a 510(k) clearance from the FDA, until we decide how we will commercialize this product. The whole blood test, which remains in development, if cleared with the FDA, will significantly expand the potential market and revenue generating capability of the product.

License fee and royalty revenue is generated by licensing our intellectual property rights to third parties. The increase in license fees and royalty revenue in the three and nine months ended September 30, 2006 as compared to the same period in 2005 was due to renegotiating our contract with Applied Biosystems Inc. (Applied Biosystems), in January 2006, to increase our minimum royalties this year.

The future: There is one remaining quarterly minimum royalty due to Nanogen of approximately \$950,000 with Applied Biosystems through December 31, 2006. After January 1, 2007 royalties will be based on actual sales. Therefore, throughout the remainder of 2006, we expect that our license fee revenue will remain constant. On September 29, 2006, we entered into an agreement with Drug Royalty Trust (DRT) where we assigned the rights associated with this royalty agreement from July 2006 through December 2011 to DRT for a \$20.0 million upfront payment in cash. We recognized this payment as assigned royalty interests and will continue to recognize revenue quarterly based on actual royalties

Edgar Filing: NANOGEN INC - Form 10-Q

under the Applied Biosystems agreement. We will amortize the assigned royalty interests under the DRT agreement quarterly through December 2011.

Although we expect our relationship with Applied Biosystems to continue for the foreseeable future, this contract may be terminated with a 180 day notice.

In addition, with our growing intellectual property profile of 167 U.S. patents and with our relationship with Jurilab, LTD, we are continuing to evaluate royalty and licensing opportunities and we may choose to license other intellectual property in the future, if we believe the terms and conditions are acceptable.

Table of Contents

Contracts and grants revenue is generated by reimbursement for research and development efforts directed by various federal, state and private agencies. The increase in contract and grant revenue in the three and nine months ended September 30, 2006 as compared to the same period in 2005, was primarily related to additional revenue generated from a research and development agreements we entered into with a private entity in July 2006, The Bill and Melinda Gates Foundation and various National Institute of Health grants with no comparable awards in the first quarter of 2005.

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 agreements and contracts. In the future, we expect contract and grant revenue to become a 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			For the nine months		
	ended September 30,			ended September 30,		
	2006	2005	Difference	2006	2005	Difference
Cost of product sales	\$ 3,509	\$ 799	\$ 2,710	\$ 9,771	\$ 3,073	\$ 6,698

Cost of product sales relates to the expenses associated with manufacturing our products. These expenses include the materials, labor, and various overhead costs required to build our products. Included in our overhead expenses are charges for excess capacity. The increase in the cost of product sales in the three and nine months ended September 30, 2006 as compared to the same periods in 2005, related to additional costs associated with the product lines we acquired with our acquisitions of Spectral and Amplimedical with no comparable expenses in 2005. In the three and nine months ended September 30, 2006 these products accounted for \$1.7 million and \$3.8 million, respectively, of the increase in the cost of product sales as compared to the same periods in 2005. In addition, we incurred additional cost of product sales charges that related to the conversion of a significant portion of our San Diego, California, product development facilities to a manufacturing and assembly facility, in late 2005, following the commercial launch of the second generation molecular testing platform. This was reflected in changes to our inventory overhead model, and beginning January 1, 2006 we incurred additional excess capacity charges in the three and nine months ended September 30, 2006 as compared to the same periods in 2005 when these overhead charges were expensed into research and development.

The future. For the remainder of 2006 we expect our cost of product sales as compared to 2005 to increase due to our acquisitions of Spectral's and Amplimedical's product lines. We also expect to continue to incur excess production capacity within our manufacturing facilities while we work to build demand for our second generation molecular testing system and ASRs. In addition, our second generation molecular testing system has a lower selling price per unit; therefore, our gross margins depend on the number of units sold or rented and the number of higher margin test kits we are able to sell to absorb our fixed overhead costs.

Research and development expenses (in thousands):

	For the three months			For the nine months		
	ended September 30,			ended September 30,		
	2006	2005	Difference	2006	2005	Difference
Research and development	\$ 6,242	\$ 5,701	\$ 541	\$ 19,054	\$ 15,773	\$ 3,281

Research and development relates to expenses associated with our efforts to develop advance molecular diagnostics products for commercialization and the expenses incurred while conducting reimbursable research and development under contractual agreements with various federal, state and private entities. The increase in research and development costs in the three months ended September 30, 2006 as compared to the same period in 2005 primarily related to \$188,000 in additional research and development activities acquired after our acquisition of Spectral and Amplimedical and \$250,000 in non-cash stock base compensation expenses

Edgar Filing: NANOGEN INC - Form 10-Q

with no comparable expenses in 2005. In the nine months ended September 30, 2006 compared to the same period in 2005, we incurred an additional \$2.6 million in research and development expenses related to the consolidation of Jurilab s (a variable interest entity) research and development expenses. This was a result of incurring a full nine months of research and development expenses in 2006 as compared to the same period in 2005 where we only incurred three months of Jurilab s operating expense after our initial equity investment in July, 2005. In addition, as we were required to begin to incur expenses related to the issuance of stock options to our employees, we recorded an additional \$887,000 in non-cash stock based expense in the nine months ended September 30, 2006 with no comparable expenses during the same period in 2005.

Table of Contents

The future. As a part of our continual focus on narrowing our losses and working towards positive cash flows from operations, in October 2006, we announced a plan to consolidate certain of our North American operations. As a part of this consolidation process we expect to reduce our headcount by approximately 15% across all of our operations, including research and development by December 31, 2006. We expect this plan to reduce costs in research and development expenditures in the future. However, until this consolidation process is completed our research and development expenditures are likely to continue at similar levels through at least the remainder of the year. In addition, if our revenue from contracts and grants revenue increases we will incur additional research and development expenses.

Selling, general and administrative expenses (in thousands):

	For the three months			For the nine months		
	ended September 30,			ended September 30,		
	2006	2005	Difference	2006	2005	Difference
Selling, general and administrative expenses	\$ 8,441	\$ 5,326	\$ 3,115	\$ 24,738	\$ 17,703	\$ 7,035

Selling, general and administrative expenses relates to the costs associated with promoting and selling our products and the administrative costs required to support our operations. The increase in expenses in the three months ended September 30, 2006 as compared to the same period in 2005 included an additional \$1.3 million for the on-going operational costs associated with Spectral and Amplimedical and \$626,000 in non-cash stock based compensation with no comparable charges in 2005. The remainder of the increase in expenses during the three month period primarily related to our efforts to market our second generation molecular testing instrument and ASRs developed during 2006. The increase in expenses in the nine months ended September 30, 2006 as compared to the same period in 2005 included an additional \$2.9 million for the on-going operational costs associated with Spectral and Amplimedical and \$2.1 million in non-cash stock based compensation with no comparable charges in 2005. The remainder of the increase in the nine month period expenses primarily related to our efforts to market our second generation molecular testing instrument and ASRs developed during 2006.

The future. As a part of our continual focus on narrowing our losses and working towards positive cash flows from operations, in October 2006 we announced a plan to consolidate certain of our North American operations. As a part of this consolidation process we expect to reduce our headcount by approximately 15% across all of our operations, including selling, general and administrative expenses by December 31, 2006. As we review our operations for efficiencies and cost savings during the forth quarter we expect a reduction in expenditures after January 1, 2007. Until this consolidation process is completed our selling, general and administrative expenditures are likely to continue at similar levels through at least the remainder of the year.

Amortization of purchased intangible assets (in thousands):

	For the three months			For the nine months		
	ended September 30,			ended September 30,		
	2006	2005	Difference	2006	2005	Difference
Amortization of purchased intangible assets	\$ 869	\$ 393	\$ 476	\$ 2,159	\$ 1,178	\$ 981

Amortization of purchased intangibles is our effort to match the benefits of the intellectual property we have acquired with current period expenses. In the nine months ended September 30, 2006 we acquired approximately \$11.1 million in acquired technology intangible assets with our acquisition of Spectral and Amplimedical. The increase in the amortization of purchased intangible assets in the three and nine months ended September 30, 2006 as compared to the same periods in 2005 related to the increase in amortization of the acquired technology assets of Spectral and Amplimedical.

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

Table of ContentsOther income

The following table summarizes our other income (loss) for the three and nine months ended September 30, 2006 and 2005 (in thousands):

	For the three months			For the nine months		
	ended September 30,			ended September 30,		
	2006	2005	Difference	2006	2005	Difference
Interest income, net	\$ 32	\$ 110	\$ (78)	\$ 310	\$ 598	\$ (288)
Other expense	(93)	(8)	(85)	(490)	(118)	(372)
Warrant valuation adjustment	10	109	(99)	73	946	(873)
Provision for income tax	(150)		(150)	(150)		(150)
Gain (loss) on foreign currency translation	(25)	(1)	(24)	(43)	3	(46)
Total	\$ (226)	\$ 210	\$ (436)	\$ (300)	\$ 1,429	\$ (1,729)

Interest income, net

Interest income primarily relates to the interest we received on our cash, cash equivalents and short-term investments netted against the interest expense we incurred from our debt obligations. The decrease in interest income in the three and nine months ended September 30, 2006 was primarily due to having less cash, cash equivalents and short-term investments than in the comparable periods; therefore, we received less interest income as compared to the same periods in 2005.

Other expense

The increase losses from other expense in the three and nine month periods ended September 30, 2006 as compared to the same periods in 2005 primarily related to losses from the disposal of fixed assets in 2006.

Warrant valuation adjustment

As a result of our December 2004 acquisition of Epoch, we assumed warrants for 381,317 shares of our common stock. The warrants have an exercise price of \$8.32 per share and expire in early 2009. If there is a change of control of Nanogen, under certain circumstances the warrants have a provision that allows them to be redeemed for cash based on the Black-Scholes formula. However, the volatility variable in the Black-Scholes formula is limited to the lesser of 50% or our actual historical volatility. Using the methodology prescribed in EITF 00-19, *Accounting for Derivative Financial Instruments Indexed To, and Potentially Settled In a Company's Own Stock*, we recorded a current liability for the fair value of the cash redemption portion of the warrants. The liability was measured and recorded in accordance with the terms of the warrant agreements. The valuation of the warrants and the corresponding liability are re-measured quarterly until the warrants are exercised or expire.

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

	September 30,	September 30,
	2006	2005
Common stock price	\$ 1.78	\$ 3.21

Edgar Filing: NANOGEN INC - Form 10-Q

Expected term	2.4 years	3.4 years
Interest rate	4.7%	4.2%
Volatility	50%	50%
Dividends		
Calculated cash redemption value of the warrants	\$ 13,000	\$ 166,000

The non-cash gains in the three and nine months ended September 30, 2006 and 2005 were a result of changes in the fair value of the warrants as calculated by the Black-Scholes option pricing model. Any changes to the fair value of our common stock have a large impact on the fair value of the warrants when using the Black-Scholes valuation model. Therefore, in the three and nine months ended September 30, 2006 and 2005, as a result of our common stock price declining each quarter from its December 31, 2005 and 2004 fair value, we recorded non-cash income each quarter as the fair value of the warrants decreased.

Provision for income tax

The provision for income tax in the three and nine months ended September 30, 2006 is a result of our estimated income tax liability associated with the sales revenue from our Italian operations that we acquired during our acquisition of Amplimedical.

Table of Contents**Liquidity and capital resources***Short-term and long-term liquidity*

The following is a summary of our key liquidity measures as of September 30, 2006 and December 31, 2005 (in thousands):

	September 30,	December 31,	
	2006	2005	Difference
Cash and cash equivalents	\$ 26,761	\$ 6,194	\$ (20,567)
Short-term investments, available for sale	6,025	26,185	20,160
Total cash and cash equivalents and short-term investment, available for sale	\$ 32,786	\$ 32,379	\$ (407)
Current assets	\$ 50,053	\$ 39,701	\$ 10,352
Current liabilities	(18,363)	(9,050)	(9,313)
Working capital	\$ 31,690	\$ 30,651	\$ 1,039

Our cash and cash equivalents and short-term investments, available for sale decreased by \$407,000 and working capital increased by \$1.0 million, respectively, at September 30, 2006 as compared to December 31, 2005. Our liquidity measures remained relatively flat primarily due to drawing down of approximately \$5.5 million of our equity financing agreement (see note 10) and a contract with Drug Royalty Trust (DRT) where we assigned the rights associated with our Applied Biosystems royalty agreement from July 2006 through December 2011 for a \$20.0 million upfront payment. Under this agreement with DRT, we have guaranteed certain annual minimum royalty in an aggregate amount of approximately \$26.9 million in payments to DRT through December 2011.

Due to our negative cash flows from operations we remain dependent on capital financing or other non dilutive sources, such as the potential Fisher Scientific research and development agreements, of funding to support on going operations through September 30, 2007. Therefore, we remain dependent on our ability to draw down on our equity financing agreement that may, subject to certain limitations, provide us access of up to \$19.5 million in capital (see note 10) and on our ability to narrow our losses. The equity financing agreement contains certain provisions (related to our stock price and potential material adverse events) that will relieve the financing party of any obligations to purchase our stock. Without access to this financing, on terms acceptable to us, we will have to cease or curtail significant operations and product development that will materially alter our current business strategy.

From inception to September 30, 2006, we have financed our operations primarily by:

Issuing our stock

Generating revenues

An upfront payment to assign the rights associated with a royalty agreement

Obtained cash through our acquisition of Epoch

Using proceeds from our litigation settlement with CombiMatrix

Obtaining a modest amount of capital equipment long-term financing

Reimbursements for research and development expenses

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.

Financing under our June 2005 shelf registration statement

In June 2005, we filed a shelf registration statement with the Securities and Exchange Commission that allowed us to raise up to \$60.0 million in equity transactions. On May 9, 2006, we filed a 462(b) registration statement with the Securities and Exchange Commission to increase our available funding by \$4.0 million under the June 2005 shelf registration statement, which increased the amount available under this shelf registration to \$25.0 million as of May 2006. On May 10, 2006, we entered into an equity financing arrangement with Azimuth Opportunity Ltd. (Azimuth), pursuant to which Azimuth agrees to purchase, subject to certain limitations and closing conditions, up to \$25 million of our common stock over eighteen-month period from May 10, 2006.

Table of Contents

The following table illustrates our financing under the June 2005 shelf registration statement:

Date of financing	Number of shares	Issuance share	
		price	Proceeds, net (millions)
September, 2005	6.8 million shares	\$2.94	\$ 18.8
September, 2005	1.0 million warrants	\$4.00	
March, 2006	5.7 million shares	\$2.65	15.0
July, 2006	2.5 million shares	\$1.59	3.9
September, 2006	833,333 shares	\$1.80	1.5
Total shares and warrants issued:	16.8 million	Total proceeds, net:	\$ 39.2

Statement of cash flows

Cash provided by (used in) operating, investing and financing activities for the nine months ended September 30, 2006 and 2005 is as follows (in thousands):

	September 30,	September 30,
	2006	2005
Net cash used in operating activities	\$ (34,043)	\$ (26,527)
Net cash provided by investing activities	12,176	19,241
Net cash provided by financing activities	\$ 42,875	\$ 19,557

Operating activities

Net cash used in operating activities for the nine months ended September 30, 2006 and 2005 primarily related to our net losses and changes in working capital. The net losses and changes in working capital included; the costs associated with commercializing our products including the expansion, development and support of our sales and marketing organization; regulatory compliance; the procurement of inventory pursuant to our manufacturing arrangement with Hitachi, Ltd; support of our continuing research and development efforts; and legal fees relating to establishing, maintaining and defending our intellectual property portfolio.

In addition to the uses of cash noted above, we expect the Amplimedical acquisition to continue to consume cash through at least the end of 2006 due to the lengthy accounts receivable collection period common to the Italian market.

Investing activities

Net cash provided by investing activities in the nine months ended September 30, 2006 and 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 and financing activities). In addition, we converted a portion of our short-term investments into cash to allow us to acquire companies. In the nine months ended September 30, 2006 we acquired Spectral's assets for stock and approximately \$7.0 million in cash (approximately \$4.8 million in cash and approximately \$1.2 million in related acquisition expenses). In the second quarter we acquired the certain of Amplimedical's assets of with debt and had approximately \$1.4 million in transaction expenses. In addition, we were required to use cash to purchase \$2.6 million in restricted Euro denominated short-term investments to securitize a letter of credit to settle certain closing costs and this use of cash was reflected in the cash flow statements in the purchase of short-term investments. In the nine months ended September 30, 2005 we had payments of approximately \$1.7 million in expenses related to our December 2004 acquisition of Epoch.

Capital spending is essential to our product innovation initiatives and maintaining our operational capabilities. Therefore in the nine months ended September 30, 2006 and 2005 we used cash to purchase \$1.5 million and \$927,000, respectively, in property and equipment to support the development of our product lines.

Edgar Filing: NANOGEN INC - Form 10-Q

Financing activities

In March 2006, we received approximately \$15 million in cash by issuing to Fisher Scientific 5,660,377 shares of common stock at \$2.65 per share. On July 11, 2006, under our equity financing agreement with a private investor we issued 2,524,130 shares at an aggregate purchase price of \$4.0 million or approximately \$1.59 per share. We received net proceeds of approximately \$3.9 million after deducting our offering expenses. On September 20, 2006, under this agreement we issued

Table of Contents

833,333 shares at an aggregate purchase price of \$1.5 million or approximately \$1.80 per share. We received net proceeds of approximately \$1.47 million after deducting our offering expenses. Jurilab, a consolidated variable interest entity, received approximately \$2.2 million in net transactions related to financing activities.

On September 29, 2006, to provide us with a non-dilutive means of raising capital, we entered into an agreement with DRT where we assigned the rights associated with the Applied Biosystems royalty agreement from July 2006 through December 2011 for a \$20.0 million upfront payment in cash. Under the agreement with DRT, we have guaranteed certain minimum royalty payments to DRT through December 2011 in an aggregate amount of approximately \$26.9 million.

In the first quarter of 2006 our equipment funding agreement expired; however, in June 2006, we entered into another equipment funding agreement for up to approximately \$2.3 million through December 31, 2007. In the nine months ended September 30, 2006 and 2005 we received \$538,000 and \$480,000, respectively, under these agreements. In the nine months ended September 30, 2006 and 2005 financing activities were offset by payments related to our debt obligations of \$577,000 and \$546,000, 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 as defined in S-K 303(a)(4)(ii).

Critical Accounting Policies and Estimates

Our discussion and analysis of our results of operations and liquidity and capital resources are based on our consolidated financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States. The preparation of these financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, revenues and expenses, and disclosure of contingent assets and liabilities. On an ongoing basis, we evaluate our estimates and judgments, including those related to revenue recognition, valuation of inventory, intangible assets and investments, income taxes, and litigation. We base our estimates on historical and anticipated results and trends and on various other assumptions that we believe are reasonable under the circumstances, including assumptions as to future events. These estimates form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. By their nature, estimates are subject to an inherent degree of uncertainty. Actual results that differ from our estimates could have a significant adverse effect on our operating results and financial position. 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 the 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. We believe that the following critical accounting policies and assumptions may involve a higher degree of judgment and complexity than others. There were no material changes in the critical accounting policies or estimates from those at December 31, 2005 other than the required changes associate with the implementation of SFAS No. 123R.

Liquidity

At September 30, 2006 we have cash and cash equivalents and short-term investments, available for sale of approximately \$32.8 million. We expect that our access to financing combined with our existing capital resources, anticipated product revenues, license fees and contract and grant funding will be sufficient to support our planned operations, at least through the next twelve months. As we continue to consume cash and have quarterly net losses we are required to make significant assumptions about our operating cash requirements and our ability to continue to raise capital to finance our on-going operations. We assume that we will have the ability to sell a sufficient amount of securities to investors to continue our strategy of expanding our product pipeline by acquiring companies or assets and supporting our on-going internal product development. Without access to this financing, on terms acceptable to us, we will have to cease or curtail operations and product development that may materially alter our current business strategy.

Valuation of Goodwill

We have recorded as assets \$39.7 million of goodwill in our September 30, 2006 consolidated financial statements related to our 2006 acquisition of Amplimedical's and Spectral's assets and our 2004 acquisitions of SynX Pharma and Epoch Bioscience, Inc. We used significant estimates and assumptions to determine the value of these assets. In many cases we use a third party to perform a valuation analysis on these assets, while we review their assumptions, calculations and conclusions for reasonableness and accuracy.

Table of Contents

We test goodwill for possible impairment on an annual basis. This testing requires that we make judgments to identify our reporting units and requires significant judgments and directly effects our valuation analysis. In addition, we test goodwill for possible impairment if events occur or circumstances indicate that the carrying amount of goodwill may not be recoverable. We assess potential impairments to goodwill assets when there is evidence that events or circumstances indicate that the recorded value of an asset (the carrying amount) may not be recovered. These assessments are based on judgments and estimates of the materiality of various on-going events and circumstances related to the asset. Indicators of impairment may include, but are not limited to:

a significant adverse change in legal factors or in the business climate;

a significant decline in our stock price or the stock price of comparable companies;

a significant decline in our projected revenue or earnings growth or cash flows;

an adverse action or assessment by a regulator;

unanticipated competition;

a loss of key personnel; and

a more-likely-than-not expectation that a reporting unit or a significant portion of a reporting unit will be sold or otherwise disposed of;

The estimates and assumptions we use are consistent with our internal planning and there are inherent uncertainties in this assessment process as it is difficult to model all possible future events. If these estimates or their related assumptions change in the future, we may be required to record an impairment charge on all or a portion of our goodwill or intangible assets. Any resulting impairment loss could have an adverse impact on our results of operations.

Valuation of intangible and other long-lived assets.

We assess the carrying value of intangible and other long-lived assets each quarter, which requires us to make assumptions and judgments regarding the future cash flows of these assets. The assets are considered to be impaired if we determine that the carrying value may not be recoverable based upon our assessment of the following events or changes in circumstances such as:

the asset's ability to continue to generate income from operations and positive cash flow in future periods;

loss of legal ownership or title to the asset;

significant changes in our strategic business objectives and utilization of the asset(s); and

the impact of significant negative industry or economic trends.

Edgar Filing: NANOGEN INC - Form 10-Q

If the assets are considered to be impaired, the impairment we recognize is the amount by which the carrying value of the assets exceeds the fair value of the assets. In addition, we base the useful lives and related amortization or depreciation expense on our estimate of the period that the assets will generate revenues or otherwise be used by us. We also periodically review the lives assigned to our intangible assets to ensure that our initial estimates do not exceed any revised estimated periods from which we expect to realize cash flows from the technologies. If a change were to occur in any of the above-mentioned factors or estimates, the likelihood of a material change in our reported results would increase.

Revenue Recognition

We recognize revenue principally from various real-time PCR products (both custom and proprietary tests), molecular testing platforms (the NanoChip® systems), various ASRs, cardiac tests, sponsored research, contract and grant agreements and from license and royalty fees for intellectual property. Each element of revenue recognition requires a certain amount of judgment to determine if the following criteria have been met: i) persuasive evidence of an arrangement exists; ii) delivery has occurred or services have been rendered; iii) the seller's price to the buyer is fixed or determinable; iv) collectibility is reasonably assured, and v) both title and the risks and rewards of ownership are transferred to the buyer. We are required to make more significant estimates involving our recognition of revenue from license and royalty fees, than from revenue generated from our products sales and contracts and grant agreements. Our license and royalty fees revenue estimates depend upon our interpretation of the specific terms of each individual arrangement and our judgment to determine if the arrangement has more than one deliverable and how each of these deliverables should be measured and allocated to revenue. In addition, we have to make significant estimates about the useful life of the technology transferred to determine when the risk and rewards of ownership have transferred to the buyer to decide the period of time to recognize revenue. In certain circumstances we are required to make judgments about the reliability of third party sales information and recognition of royalty revenue before actual cash payments for these royalties have been received.

Table of Contents

Inventory and related reserves

We have a history of writing down the value of our inventory due to lack of market demand. We have approximately \$7.4 million of inventory reserved as of September 30, 2006. In addition, we have approximately \$4.5 million in finished goods inventory. Given the inherent unpredictability of demand for new product lines, we were required to make significant estimates about the future demand for this inventory. Our estimates of realizable value are based upon our analysis and assumptions including, but not limited to, forecasted sales levels by product, expected product lifecycle, product development plans and future demand requirements. If actual market conditions are less favorable than our forecasts or actual demand from our customers is lower than our estimates, we may be required to record additional inventory write downs. If actual market conditions are more favorable than anticipated, inventory previously written down may be sold, resulting in lower cost of sales and higher income from operations than expected in that period.

Variable Interest Entities

We provide various forms of funding into other entities for business purposes. Examples of these include our investments into Jurilab, FasTraq and PGx. FIN46R *Consolidation of Variable Interest Entities* requires that we make significant assumptions about these entities ability to generate unrelated additional capital funding and/or revenues. In addition, we are required to make assumptions about the intentions of unrelated parties initial and potential future investments to determine if we are required to consolidate or de-consolidate these entities. If any of these facts, circumstances or assumptions change in the future we maybe required to consolidate or de-consolidate these entities operations.

Income Taxes

We regularly review our established valuation allowance against our potential tax assets that is based on historical taxable income, projected future taxable income, the expected timing of the reversals of existing temporary differences and the implementation of tax-planning strategies. As of December 31, 2005, our valuation allowance was \$135.6 million.

Share-Based Compensation

Share-based compensation expense is significant to our financial position and results of operations, even though no cash is used for such expense. In determining the period expense associated with unvested options, we estimate the fair value of each option at the date of grant. We believe it is important for investors to be aware of the high degree of subjectivity involved when using option pricing models to estimate share-based compensation under SFAS No. 123R. The determination of the fair value of share-based payment awards on the date of grant using an option-pricing model is affected by our stock price as well as assumptions regarding a number of complex and subjective variables. These variables include, but are not limited to, our valuation methodology, the expected term, expected stock price volatility over the term of the awards, the risk-free interest rate, expected dividends and pre-vesting forfeitures. If any one of these factors changes and we employ different assumptions in the application of SFAS No.123R in future periods, the compensation expense that we record under SFAS No. 123R will differ significantly from what we have recorded in the current period.

To estimate the fair value of each stock option to our employees we are required to make the following assumptions:

Valuation methodology. Because there is no observable market for share based payments similar to the ones we provide to our employees to determine the fair value of share based compensation we were required to select an option pricing model. Option-pricing models were generally developed for use in estimating the value of traded options that have no vesting or hedging restrictions, are fully transferable and do not cause dilution. Because our share-based payments have characteristics significantly different from those of freely traded options, and because changes in the subjective input assumptions can materially affect our estimates of fair values, in our opinion, existing valuation models, including the Black-Scholes, which we currently use, and lattice binomial models, may not provide reliable measures of the fair values of our share-based compensation. Consequently, it is highly probable that our estimates of the fair values of our share-based compensation awards on the grant dates that were recorded in our statement of operations will not bear any resemblance to the actual values realized upon the exercise, expiration, early termination or forfeiture of those share-based payments in the future. Certain share-based payments, such as employee stock options, may expire worthless or otherwise result in zero intrinsic value as compared to the fair values originally estimated on the grant date and reported in our financial statements. Alternatively, value may be realized from these instruments that is significantly in excess of the fair values originally estimated on the grant date and reported in our financial statements. There is currently no market-based mechanism or other practical application to verify the reliability and accuracy of the estimates stemming from these valuation models, nor is there a means to compare and adjust the estimates to actual values. Although the fair value of employee share-based awards is determined in accordance with SFAS

Edgar Filing: NANOGEN INC - Form 10-Q

No. 123R and the SAB 107 using an option-pricing model, that value may not be indicative of the fair value observed in a willing buyer/willing seller market transaction. Despite these deficiencies, we elected to continue to use the Black-Scholes option-pricing model to determine the fair value of our share based payments. Because we have a history of using the

Table of Contents

Black-Scholes option pricing model and we can more accurately develop the highly subjective assumptions required as inputs in to the model. Further, we believe our investors are more familiar with the Black-Scholes option valuation model and can better analyze the potential impact these assumptions will have on our current and future results of operations. In the future, as our industry develops a consensus and best practices are developed for share based payment valuation models, we may adopt a different method of valuation that better reflects the fair value of our share based payments. Sophisticated mathematical models may require voluminous historical information, modeling expertise, financial analyses, correlation analyses, integrated software and databases, consulting fees, customization and testing for adequacy of internal controls. Market-based methods are emerging that, if employed by us, may dilute our earnings per share and involve significant transaction fees and ongoing administrative expenses. The uncertainties and costs of these extensive valuation efforts may outweigh the benefits to investors. However, because any valuation methodology uses assumptions that are based on historical trends to model future events, no matter which valuation methodology we use, the fair value of our share based payments is our best estimate and will potentially differ materially from the ultimate value realized by the recipient employee.

Expected term. We estimate expected term of employee stock options to determine the length of time before our employees will exercise their option grants. This estimate is impacted by all of the underlying assumptions used in our model and is estimated based on a number of factors, including but not limited to the vesting term of the award, historical employee exercise behavior (for both share-based payments that have run their course and outstanding share-based payments), the expected volatility of our common stock and an employee's average length of service. In addition, we stratify our employees in to groups that have historically similar exercise behavior patterns. We also assume that employees' exercise behavior is a function of the extent to which the option is in-the-money (i.e., the average stock price during the period is above the strike price of the stock option).

Volatility. We estimate volatility to measure the amount the share price has or will fluctuate during our estimated expected term of our option and ESSP grants because it is assumed that an option with more volatility is of greater value than one with less volatility. We assumed that historical volatility is a better measure of future volatility than implied volatility, as we believe implied volatility is a more subjective measure. In addition, we were not aware of any traded options in the market that achieve the so called synchronization of variables with our stock or stock options that would allow us to use implied volatility. We assumed that the daily quoted market prices of our common stock for a look back period equal to the expected term of the award will equal the future volatility over the expected term of the options grants. We assumed all historical stock prices were relevant to our calculations and did not exclude any daily closing prices during the look back period.

Risk free interest rate. We assumed the risk-free interest rate is the same as the U.S. constant rate Treasury Security's market interest rates with a contractual life approximately equal to the expected term of our employee stock options or ESPP awards.

Dividend yield. We assumed we will not paid any cash dividends in the foreseeable future therefore our dividend yield is zero.

Pre-vesting forfeitures. SFAS No. 123R requires that we estimate share-based payment forfeitures at the time of grant and be revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates. Pre-vesting forfeitures were estimated on historical experience based on the assumption that our historical experience will model future pre-vesting forfeitures.

Had any of these estimates changed, our results of operations would differ significantly.

Related Party Transactions:

In June 2005, we signed a letter of agreement with FasTraQ, Inc. (FasTraQ) for the development of a certain future product. Our Chief Executive Officer and Chairman of the Board, Mr. Birndorf, is a director and an investor in FasTraQ. In October and December 2005 we amended this letter of agreement. As a result of this agreement and related amendments we made an initial non-refundable payment of \$500,000 in 2005 to begin the initial development of this product. As of December 31, 2005 we expensed the initial \$500,000. In February 2006, we converted this letter of agreement into two executed contracts, a Development and License Agreement and a Collaboration Agreement. In February 2006, we committed to provide FasTraQ an additional \$500,000 in funding based on certain milestones. As of September 30, 2006, we paid FasTraQ \$301,000 and expensed this amount into research and development.

Edgar Filing: NANOGEN INC - Form 10-Q

On October 27, 2006, the Chief Executive Officer of FasTraQ, Inc., Mr. Heiner Dreismann, Ph.D., was elected to our Board of Directors. Dr. Dreismann was elected to Class III of our Board of Directors and will serve a term expiring at our 2007 Annual Meeting of Stockholders. In June, 2005, we signed a letter of agreement with FasTraQ, Inc. for the development of a certain future product. In February 2006, we converted this letter of agreement into two executed contracts, a Development and License Agreement and a Collaboration Agreement. Prior to his election, on October 1, 2006, we entered

Table of Contents

into an Independent Contractor Agreement for Consulting Services, as amended in November 2006, with Dr. Dreismann, where he agreed to provide certain technical consulting services on molecular diagnostic products and markets. In consideration for such services, we agreed to pay Dr. Dreismann a fee of \$10,000 for the month of October, 2006 and \$5,000 each month thereafter, provided that the total amount of payment to Dr. Dreismann under the Consulting Agreement shall not exceed \$60,000. The Board of Directors has determined that Dr. Dreismann is not independent under the rules of NASDAQ, and therefore does not expect to appoint him to any of the committees of the Board of Directors.

On August 3, 2006, we entered in to research and development collaboration arrangements with Fisher Scientific International Inc., (Fisher Scientific) a related party, that owns approximately 5.7 million shares of our common stock, and Athena Diagnostic, a wholly-owned subsidiary of Fisher Scientific. We agreed to share certain technology and patent rights related to the development, manufacture and marketing of new molecular diagnostic products. Under these arrangements, Fisher Scientific has the option to provide up to \$10 million in 2007 and 2008 for the research and development of infectious disease and molecular diagnostic tests that will be mutually agreed upon. These arrangements are included in non-binding general agreements, thus the obligation of the parties are subject to further negotiation and final terms of definitive collaboration agreements. On August 9, 2006, we entered into an exclusive distribution agreement with Fisher Scientific. There were no sales under this agreement in the third quarter of 2006.

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 \$32.8 million as of September 30, 2006, 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, 2006, 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.

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 subsidiaries in Italy is the euro. The Italian subsidiaries' 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 \$11.5 million at September 30, 2006.

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.

Table of Contents**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 2006, we continued to make minor improvements to our internal control structure and financial reporting processes. Due to the acquisition of Spectral and Amplimedical we were required to implement new processes and controls over net product sales, cost of sales and other commercial transactions related to its commercial operations. As required by the implementation of SFAS No. 123R, we changed our internal controls and processes related to the calculation and recording of share based compensation in our statement of operations. We implemented various key controls to mitigate the risks associated with these transitions. However, as of September 30, 2006 we have not tested the operating effectiveness of the new internal controls related to share-based payments or the integration of Spectral or Amplimedical. Other than these changes, there were no significant changes in our internal control over financial reporting identified in connection with the evaluation of such controls that occurred during our most recent fiscal quarter that has materially affected, or is reasonably likely to materially affect our internal control over financial reporting.

PART II. OTHER INFORMATION**ITEM 1. LEGAL PROCEEDINGS**

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 and as of September 30, 2006 we have no significant accrual for any pending claims. 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, 2006, 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.

ITEM 1a. RISK FACTORS

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, 2006, total approximately \$349.5 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 could be significant. The amount and timing of product revenue recognition and cash flow may depend on whether potential customers for the molecular testing platform 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, goodwill or other impairment charges, non-cash stock option expenses, 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 various government and private 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.

Edgar Filing: NANOGEN INC - Form 10-Q

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.

Table of Contents

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 our equity line of credit with Azimuth Opportunity Ltd., 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, significant 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 amount of revenue we are able to generate;

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 will be dilutive to stockholders, and debt financing, if available, may include restrictive covenants and require significant collateral. In addition, our ability to raise capital through our line of credit with Azimuth is subject to the satisfaction of certain terms and conditions set forth in our agreement with Azimuth, and there is no assurance that we will meet these conditions at the time we intend to raise capital through the equity line.

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, 2006, we had only a limited product offering that includes real-time PCR products (both custom and proprietary tests), molecular testing platforms (NanoChip® system), ASRs, cardiac tests and the point-of-care diagnostic tests for myocardial infarction and drugs of abuse. Our congestive heart failure point of care test remains in development. Our second generation molecular testing platform, the NanoChip® 400, began shipping in October 2005. Most of our ASRs are under development. Our molecular testing platforms, ASRs 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.

Edgar Filing: NANOGEN INC - Form 10-Q

We are also party to transactions known as reagent rentals and cost-per-test agreements. Under these types of transactions, we place molecular testing systems 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 result in us investing current capital in the cost of an instrument, while revenues recognized and cash received under these agreements are over the life of the contract, as reagents are shipped to the customer.

Lack of market acceptance of our products and technology would harm us.

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.

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, 2006 and in twelve month ended December 31, 2005, we did not incur any charge to reduce our inventory to

Table of Contents

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. In the first quarter of 2006, we began offering new reagents for CFTR ASRs and 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 ASRs.

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, licensors, licensees and others. Our success depends in part upon the performance by these collaboration partners and potential collaboration partners of their responsibilities under these arrangements. Some collaborators may not perform their obligations as we expect, and we may not derive any revenue or other benefits from these arrangements. We do not know whether our collaborations will successfully develop and market any products under our respective agreements. Moreover, some of our collaborators are also researching competing technologies targeted by our collaborative programs.

Our molecular testing systems platforms, including Molecular Biology Workstation and the second-generation NanoChip[®] 400, are manufactured by Hitachi. As such our success in the molecular testing based diagnostics market is largely dependent upon Hitachi's ability to perform under our manufacturing agreement.

Through SynX we were a party to a 2001 development and manufacturing agreement between SynX and Princeton BioMeditech Corporation (PBM) to jointly develop and market various point-of-care tests for certain biomarkers and protein targets. As of January 2006, we terminated all of our previous agreements with PBM and superseded them with renegotiated contracts. These contracts include a manufacturing and distribution agreement and a development agreement. We agreed to continue the joint development of a point-of-care instrument that incorporates PBM's proprietary technology, our proprietary reagents and an exclusive license between us and Roche Diagnostics GmbH. PBM is responsible for the development of an instrument that uses our reagents to determine the amount of target NT-proBNP present in a patient. We are required to develop and manufacture the reagents used in the instrument and supply them to PBM who manufacture the test device. We also have to conduct the testing of our reagents required to obtain regulatory approval to market and sell them. As a result, our success in the point-of-care market is dependent in part upon PBM's ability to perform under these agreements. 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.

On August 3, 2006, we entered into research and development collaboration arrangements with Fisher Scientific and Athena Diagnostics, a wholly-owned subsidiary of Fisher Scientifics. We agreed to share certain technology and patent rights related to the development, manufacture and marketing of new molecular diagnostic products. Under these arrangements, Fisher Scientific has the option to provide us with up to \$10 million in 2007 and 2008 for the research and development of infectious disease and molecular diagnostics tests that will be mutually agreed upon. These arrangements are included in non-binding general agreements, thus the obligations of the parties are subject to further negotiation and the final terms of definitive collaboration agreements. There is no assurance that we will be able to complete the negotiations and enter into final definitive agreements with Fisher Scientific of Athena Diagnostics regarding these collaboration arrangements.

Table of Contents

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;

a decline in sales of our molecular testing instrumentation and as a result a build-up of an excessive, obsolete supply of inventory;

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

uncertainties in product pricing and market acceptance; and

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

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

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

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

The possibility that we will pay more than the value we derive from the acquisition, which could result in future non-cash impairment charges such as the \$59 million non-cash goodwill impairment charge recorded in the fourth quarter of 2005;

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.

Edgar Filing: NANOGEN INC - Form 10-Q

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 the rapid cardiac immunoassay test business of Spectral Diagnostics, of Epoch Biosciences, Inc., SynX Pharma Inc. or the diagnostic business of Amplimedical or other acquisitions due to integration and other challenges.

On February 6, 2006, we completed the acquisition of the rapid cardiac immunoassay test business of Spectral Diagnostics (Spectral). On May 1, 2006, we completed the acquisition of the diagnostic business of Amplimedical. In 2004, we completed two significant acquisitions: the acquisition of SynX Pharma, Inc. (SynX) in April 2004 and Epoch Biosciences, Inc. (Epoch) in December 2004. We expect that the Spectral and SynX product lines will accelerate our entry into the point-of-care market. 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, 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

Table of Contents

products. Additionally, Spectral and SynX are located in Canada, Epoch is located in the state of Washington and Amplimedical is located in Italy, and because our facilities in San Diego, California are or may be physically separated from facilities of other companies we acquire, it may be difficult for us to communicate effectively with, manage and integrate these employees and operations with the rest of the Company. If we are not able to integrate the operations of these acquired companies and businesses successfully, we may not be able to meet our expectations of future results of operations.

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

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

our ability to retain key employees of acquired companies;

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, Epoch, Spectral, Amplimedical 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.

Changes in financial accounting standards related to share-based payments are expected to continue to have a significant effect on our reported results.

On January 1, 2006, we adopted the revised statement of Financial Accounting Standards (SFAS) No. 123R, Share-Based Payment, which requires that we record compensation expense in the statement of operations for share-based payments, such as employee stock options, using the fair value method. The adoption of this new standard is expected to continue to have a significant effect on our reported earnings, 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 estimate the values of share-based payments. If factors change and we employ different assumptions in the application of SFAS No. 123R in future periods, the compensation expense that we record under SFAS No. 123R may differ significantly from what we have recorded in the current period, which could negatively affect our stock price and our stock price volatility.

Competing technologies may adversely affect us.

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

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

diagnostic and pharmaceutical companies;

companies developing drug discovery technologies;

companies developing molecular diagnostic tests; and

companies developing point-of-care diagnostic tests.

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

In addition, several development-stage companies are currently making or developing products that compete with or will compete with our potential products. Our competitors may succeed in developing, obtaining approval from the FDA 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.

Table of Contents

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 confidentiality agreements and these agreements may not protect our intellectual property. This could have a material adverse effect on us.

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

Our commercial success also depends in part on us neither infringing valid, enforceable patents or proprietary rights of third parties, nor breaching any licenses that may relate to our technologies and products. We are aware of other third-party patents that may relate to our technology. It is possible that we may unintentionally infringe these patents or other patents or proprietary rights of third parties. In the past, we and the companies we have acquired have received, and may in the future receive, notices claiming infringement from third parties as well as invitations to take licenses under third-party patents which have, in some instances, resulted in litigation, settlement of litigation and our licensing of third party intellectual property rights. In particular, the receipt of infringement notices by us may subject us to costly litigation, divert management resources and result in the invalidation of our intellectual property rights. These claims may require us to pay significant damages, cease production of infringing products, terminate our use of infringing technologies or develop non-infringing technologies. Further, any legal action against us or our collaborative partners claiming damages and seeking to enjoin commercial activities relating to our products and processes affected by third-party rights may require us or our collaborative partners to obtain licenses in order to continue to manufacture or market the affected products and processes. These actions may also subject us to liability for damages. Although in the past we and the companies we have acquired have succeeded in settling some third party claims concerning alleged infringement of intellectual property rights, which settlements have involved the payment of royalties by us or such companies we have acquired, there can be no assurance that in the future we would be successful in settling such claims. In addition, there can be no assurance that, even if such settlements are achieved, that they would be on commercially reasonable 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

Table of Contents

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 of our anticipated diagnostic products.

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

In December 2002, Oxford Gene filed a complaint against us in the United States District Court for the District of Delaware claiming that we infringe U.S. Patent No. 6,054,270 entitled Analytical Polynucleotide Sequences. In April 2003, we filed an answer to the complaint that denied that we infringe this patent. In October 2003, we entered into a tolling agreement with Oxford Gene pursuant to which the lawsuit was dismissed by Oxford Gene without prejudice. Under the tolling agreement, we are obligated to give Oxford Gene notice if we determine that we desire to commercialize DNA arrays for use in certain assay formats. If that notice is given, we and Oxford Gene are obliged to discuss in good faith for 30 days whether we wish to acquire, and whether Oxford Gene is willing to grant a license under the patent involved in the litigation. If we and Oxford Gene are unable to enter into such a license or other agreement within such 30 days, Oxford is free to re-initiate the litigation.

On June 30, 2005, we gave Oxford Gene notice that we desired to commercialize DNA arrays for use in such assay formats. Oxford Gene is now free to re-initiate the litigation against us under the tolling agreement. If the litigation were to be reinitiated, significant attorneys' costs and fees could result. Although it is our position that Oxford Gene's assertions of infringement have no merit, neither the outcome of any further litigation nor the amount and range of potential fees can be assessed. No assurances can be given that we would prevail in any future lawsuits or that we could successfully defend ourselves against any future claims.

The regulatory clearances and approvals required to manufacture, market and sell our products are uncertain, and our failure to comply with such clearances and approvals could have a material adverse effect on our company.

Unless otherwise exempt, medical devices require FDA approval or clearance prior to marketing in the United States. We believe our currently marketed products, including general laboratory instruments and analyte specific reagents as well as certain of those products we intend to market in the future, other than our CHF test and assets we acquired in our Spectral acquisition, 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 and delays in entering the market. 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 FDA 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.

In the third quarter of 2005, we received an untitled letter from the Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD), a division of the FDA. The letter described the OIVD's concerns that the microarray NanoChip® systems and certain related ASRs might be

Edgar Filing: NANOGEN INC - Form 10-Q

construed as a medical device that requires a premarket notification/application. During the first quarter of 2006 we met with the FDA and made certain changes in our marketing materials and sales approach in response to their input. In September 2006, the FDA, published Draft Guidance for Industry and FDA Staff: Commercially Distributed Analyte Specific Reagents (ASRs): Frequently Asked Questions setting forth the FDA's interpretation of the regulations governing the sale of ASR products. Subsequently, we received a second letter from the OIVD in which the FDA asserted that our microarray and multiplexed reagents require premarket review. In November 2006, we met with the FDA to discuss the second letter.

Table of Contents

We believe that our microarray NanoChip® systems and ASR products are not subject to FDA premarket review. If there is an unfavorable decision by the FDA in these matters, it could delay or prevent sales of our NanoChip®400 to clinical laboratories in the United States and could adversely impact sales of our ASRs to clinical laboratories in the United States. During 2007, we plan to submit the NanoChip®400 with one or more assays to the FDA for clearance.

Thus far FDA has not agreed with our position that the NanoChip®400 and all of our ASR products are not subject to 510(k) clearance or the premarket approval process. The FDA may ultimately require that we submit our existing and/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. If the FDA makes any such determination or otherwise disagrees with our position, the FDA could preclude us from shipping the NanoChip® 400 in the United States until we have received FDA clearance. 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.

Based on the new draft guidance documents and our ongoing interactions with the FDA, we will undertake to accelerate the development and filing of 510(k) applications for the NanoChip® 400 and test kits for use on the system. This will increase our costs of product development and divert resources from other product development efforts. We believe that our real-time ASR products comply with regulations. However, if FDA's guidance documents are finalized in their current form, we will incur substantial cost to repackage our products to meet the draft guidelines. This will also increase cost and divert resources from other efforts. Further, there can be no assurance that the reconfigured ASR products would be acceptable to all of our customers.

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 the NanoChip®400 and all of our multiplexed reagent products and some of our other 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.

In addition, whether or not our products are subject to 510(k) clearance or premarket approval, we are subject to certain FDA regulations covering, among other things, manufacturing, promotions, advertising 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.

Table of Contents

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 will manufacture certain of our point-of-care products; and we manufacture our NanoChip® Cartridges, our ASRs, the cardiac product line acquired from Spectral, and most of our other products. We, Hitachi and PBM rely on subcontractors to manufacture the limited quantities of microchips and other components we require for use by and sale to our customers, as well as for internal and collaborative purposes. Manufacturing, supply and quality control problems may arise as we, Hitachi or PBM either alone, together or with subcontractors, attempt to further scale up manufacturing procedures or to manufacture new products. We, Hitachi or PBM may not be able to scale-up in a timely manner or at a commercially reasonable cost. Problems could lead to delays or pose a threat to the ultimate commercialization of our products and cause us to fail. We, Hitachi or PBM or any of our contract manufacturers could encounter manufacturing difficulties, including those relating to:

the ability to scale up manufacturing capacity;

production yields;

quality control and assurance; or

shortages of components or qualified personnel.

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

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

Outside vendors provide key components and raw materials used by us, Hitachi and PBM in the manufacture of our products. Although we believe that alternative sources for these components and raw materials are available, any supply interruption in a limited or sole source component or raw material would harm our and Hitachi's or PBM's ability to manufacture our products until a new source of supply is identified and qualified, including qualification under applicable FDA regulations. In addition, an uncorrected defect or supplier's variation in a component or raw material, either unknown to us, Hitachi or PBM or incompatible with our, Hitachi or PBM's manufacturing processes, could harm our, Hitachi or PBM's ability to manufacture our products. We, Hitachi or PBM may not be able to find a sufficient alternative supplier in a reasonable time period, or on commercially reasonable terms, if at all. If we, Hitachi or PBM fail to obtain a supplier for the manufacture of components of our products, we may be forced to curtail or cease operations.

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.

Edgar Filing: NANOGEN INC - Form 10-Q

We currently rely on one manufacturer of our NanoChip® 400 as well as our Workstation and other hardware products, and we will rely on another manufacturer for our some of 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, we have an exclusive manufacturing agreement with PBM for the manufacture of certain future point-of-care products, including CHF tests.

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

Table of Contents

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 certain point-of-care products, including CHF tests, depends on certain intellectual property owned by PBM and licensed by PBM from third parties, and we may not be able to manufacture or find an alternative manufacturer of the design of these products without this intellectual property, which would severely impact our point-of-care products.

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

As of September 30, 2006, we had 29 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.

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.

Table of Contents

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, 2006 and twelve months ended December 31, 2005, 2004 and 2003, we experienced turnover rates of 14%, 17%, 27% and 25%, respectively. Turnover at these rates may continue and, if they continue, may 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. Future layoffs could have an adverse effect on us.

Health care reform and restrictions on reimbursement may adversely affect our business.

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

In addition, sales of our future products may depend, in large part, on the availability of adequate reimbursement to users of those products from government insurance plans, managed care organizations and private insurance plans. Physicians' recommendations to use our products may be influenced by the availability of reimbursement by insurance companies and other third-party payors. There can be no assurance that insurance companies or third-party payors will provide coverage for our products or that reimbursement levels will be adequate for the reimbursement of the providers of our products. In addition, outside the United States, reimbursement systems vary from country to country and there can be no assurance 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.

Table of Contents

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:

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

asset impairment charges, including goodwill and other intangible assets;

adoption of new stock option expensing rules;

the announcement of issues involving our liquidity;

that announcement of product development failures;

the announcement of financing or acquisitions that dilutes our equity;

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

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

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

the announcement by us of acquisitions by customers of our molecular testing platforms, ASRs or our other products;

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

announcements by us of involvement in litigation;

Edgar Filing: NANOGEN INC - Form 10-Q

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;

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;
and

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

Table of Contents

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 reports on Form 10-Q 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, our investment in Jurilab in 2005, the acquisitions of cardiac immunoassay test business of Spectral and the diagnostic business of Amplimedical in 2006, and any future acquisitions, if any, we make may impact our ability to maintain effective internal controls over financial reporting. 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 the Nasdaq Stock Market LLC, 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.

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 have agreed to guarantee certain annual minimum payments and perform other obligations under our agreement with DRT for the assignment of our rights associated with our Applied Biosystems royalty agreement, or the ABI agreement. A reduction of royalty payments under or early termination of the ABI agreement would seriously impair our ability to make these minimum payments or perform our obligations under the DRT agreement, which would have a material adverse effect on us.

As disclosed above, in September 2006 we assigned to DRT our rights to receive royalty payments and related reports under the ABI agreement for an upfront payment approximately \$20 million. Under our agreement with DRT, if annual royalties generated under the ABI agreement is less than a specified minimum amount, we are required to make payments to DRT to achieve such minimum amount. To secure our obligations under the DRT agreement, including the obligation to make such minimum royalty payments, we granted DRT a first priority security interest in our patents licensed under the ABI agreement. If the ABI agreement does not generate sufficient sales volume, or if the ABI agreement is terminated by ABI

Table of Contents

prior to the expiration of the DRT agreement, we will be required to make minimum royalty payments to DRT. There is no assurance that we will have sufficient funds or assets to cover such payments. If the ABI agreement is terminated, we may not be able to obtain replacement royalty arrangement on a timely basis or at all to cover our payment obligations under the DRT agreement. Furthermore, failure to make minimum payment or perform other obligations under the DRT agreement may result in a default under our security agreement with DRT, which, if not cured, would impair our ownership and practice of the patents licensed under the ABI agreement. This will have a material adverse effect on us.

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. In May and June of 2006, we increased our minority equity interest in Jurilab to approximately 29.7%. Our relationship with Jurilab subjects us to numerous risk and uncertainties, including:

we have invested approximately \$3.3 million in Jurilab and we may lose all of our investment;

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

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

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

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 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

Table of Contents

ITEM 6. EXHIBITS

Exhibit No.	Description
10.1(+)	Royalty Interest Assignment Agreement dated September 29, 2006 between Epoch BioSciences Inc. Drug Royalty Trust 9, and Nanogen Inc.
10.2	Security Agreement date September 29, 2006 between Drug Royalty Trust 9 and Epoch BioSciences, Inc.
10.3	Amended and Restated Independent Contractor Agreement for Consulting Service dated November 8, 2006 between Nanogen, Inc. and Heiner Dreismann.
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.

(+) Confidential treatment has been requested for certain information contained in this document. Such information has been omitted and filed separately with the Securities and Exchange Commission.

Table of Contents

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, 2006

/s/ HOWARD C. BIRNDORF
Howard C. Birndorf

Chairman of the Board and Chief Executive Officer

Date: November 9, 2006

/s/ ROBERT SALTMARSH
Robert Saltmarsh

Chief Financial Officer

Table of Contents

NANOGEN, INC.

EXHIBIT INDEX

Exhibit No.	Description
10.1(+)	Royalty Interest Assignment Agreement dated September 29, 2006 between Epoch BioSciences Inc. Drug Royalty Trust 9, and Nanogen Inc.
10.2	Security Agreement date September 29, 2006 between Drug Royalty Trust 9 and Epoch BioSciences, Inc.
10.3	Amended and Restated Independent Contractor Agreement for Consulting Service dated November 8, 2006 between Nanogen, Inc. and Heiner Dreismann.
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.

(+) Confidential treatment has been requested for certain information contained in this document. Such information has been omitted and filed separately with the Securities and Exchange Commission.