

NANOGEN INC  
Form 10-Q  
August 09, 2007

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**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 June 30, 2007

**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)

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

(858) 587-1121

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

92121  
(Zip Code)

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(Registrant's telephone number, including area code)

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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): 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 July 31, 2007, were as follows:

|   | Class | Number of Shares |
|---|-------|------------------|
| Common Stock, \$0.001 per share par value |       | 72,819,006       |

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NANOGEN, INC.

QUARTERLY REPORT ON FORM 10-Q

FOR THE THREE MONTHS ENDED JUNE 30, 2007

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## PART I. FINANCIAL INFORMATION

## ITEM 1. Financial Statements

## NANOGEN, INC.

## CONDENSED CONSOLIDATED BALANCE SHEETS

(in thousands, except par value and share data)

|   | June 30,<br>2007<br>(unaudited) | December 31,<br>2006 |
|---|---------------------------------|----------------------|
| <b>ASSETS</b>   |                                 |                      |
| Current assets:   |                                 |                      |
| Cash and cash equivalents   | \$ 7,285                        | \$ 11,261            |
| Short-term investments  | 6,084                           | 13,923               |
| Receivables, net  | 15,537                          | 11,568               |
| Inventories, net  | 7,470                           | 7,691                |
| Other current assets  | 3,020                           | 2,058                |
| Total current assets  | 39,396                          | 46,501               |
| Property and equipment, net   | 8,522                           | 9,388                |
| Acquired technology rights, net   | 16,091                          | 17,894               |
| Restricted cash   | 2,013                           | 5,131                |
| Other assets  | 967                             | 1,312                |
| Goodwill  | 38,853                          | 39,027               |
| Total assets  | \$ 105,842                      | \$ 119,253           |
| <b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>   |                                 |                      |
| Current liabilities:  |                                 |                      |
| Accounts payable and accrued liabilities  | \$ 15,963                       | \$ 13,395            |
| Acquisition payable, secured by letter of credit  |                                 | 2,061                |
| Deferred revenue  | 2,923                           | 3,376                |
| Assigned royalty interests obligation   | 2,780                           | 3,447                |
| Common stock warrants   | 1                               | 11                   |
| Current portion of debt obligations   | 4,288                           | 3,590                |
| Total current liabilities   | 25,955                          | 25,880               |
| Debt obligations, less current portion  | 405                             | 535                  |
| Debt obligation of variable interest entity   | 11,835                          | 9,941                |
| Sponsored research payable  | 4,851                           | 4,851                |
| Long-term assigned royalty interests obligation   | 16,257                          | 15,529               |
| Other long-term liabilities   | 2,654                           | 2,304                |
| Total long-term liabilities   | 36,002                          | 33,160               |
| Commitments and contingencies   |                                 |                      |
| Stockholders' equity:   |                                 |                      |
| Convertible preferred stock, \$0.001 par value, 5,000,000 shares authorized at June 30, 2007 and December 31, 2006; no shares issued and outstanding at June 30, 2007 and December 31, 2006                         |                                 |                      |
| Common stock, \$0.001 par value, 135,000,000 shares authorized at June 30, 2007 and December 31, 2006; 72,733,697 and 67,468,252 shares issued and outstanding at June 30, 2007 and December 31, 2006, respectively | 73                              | 68                   |

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|  |                   |                   |
|--|-------------------|-------------------|
| Additional paid-in capital   | 439,753           | 429,971           |
| Accumulated other comprehensive loss   | (692)             | (956)             |
| Capital deficit in consolidated variable interest entity, net                  | (7,373)           | (7,373)           |
| Accumulated deficit  | (387,105)         | (360,726)         |
| Treasury stock, at cost, 416,027 shares at June 30, 2007 and December 31, 2006 | (771)             | (771)             |
| <b>Total stockholders' equity</b>  | <b>43,885</b>     | <b>60,213</b>     |
| <b>Total liabilities and stockholders' equity</b>                              | <b>\$ 105,842</b> | <b>\$ 119,253</b> |

See accompanying notes.

## NANOGEN, INC.

## CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

(unaudited)

(in thousands, except per share data)

|   | Three Months<br>Ended June 30, |               | Six Months Ended<br>June 30, |               |
|---|--------------------------------|---------------|------------------------------|---------------|
|   | 2007                           | 2006          | 2007                         | 2006          |
| <b>Revenues:</b>  |                                |               |                              |               |
| Product sales   | \$ 5,294                       | \$ 4,016      | \$ 11,378                    | \$ 6,138      |
| License fees  | 2,058                          | 1,814         | 3,300                        | 3,628         |
| Contracts and grants  | 2,963                          | 481           | 5,291                        | 897           |
| <b>Total revenues</b>   | <b>10,315</b>                  | <b>6,311</b>  | <b>19,969</b>                | <b>10,663</b> |
| <b>Costs and expenses:</b>  |                                |               |                              |               |
| Cost of product sales (excluding amortization of purchased intangibles) | 4,529                          | 4,023         | 9,359                        | 6,262         |
| Research and development  | 7,546                          | 6,552         | 14,007                       | 12,812        |
| Selling, general and administrative                                     | 11,233                         | 8,928         | 20,137                       | 16,297        |
| Amortization of purchased intangible assets                             | 760                            | 730           | 1,527                        | 1,290         |
| <b>Total costs and expenses</b>   | <b>24,068</b>                  | <b>20,233</b> | <b>45,030</b>                | <b>36,661</b> |
| Loss from operations  | (13,753)                       | (13,922)      | (25,061)                     | (25,998)      |
| <b>Other income (expense):</b>  |                                |               |                              |               |
| Interest income   | 31                             | 219           | 136                          | 480           |
| Interest expense  | (768)                          | (121)         | (1,397)                      | (202)         |
| Other expense   | (25)                           | (300)         | (53)                         | (397)         |
| Warrant valuation adjustment  |                                | 88            | 10                           | 63            |
| Loss on foreign currency translation                                    | (16)                           | (15)          | (14)                         | (18)          |
| <b>Total other expense</b>  | <b>(778)</b>                   | <b>(129)</b>  | <b>(1,318)</b>               | <b>(74)</b>   |
| Net loss  | \$ (14,531)                    | \$ (14,051)   | \$ (26,379)                  | \$ (26,072)   |
| Net loss per share basic and diluted                                    | \$ (0.20)                      | \$ (0.23)     | \$ (0.37)                    | \$ (0.50)     |
| Number of shares used in computing net loss per share basic and diluted | 72,616                         | 61,477        | 71,562                       | 51,917        |

See accompanying notes.

## NANOGEN, INC.

## CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

(unaudited)

(in thousands)

|   | Six Months Ended<br>June 30, |             |
|---|------------------------------|-------------|
|   | 2007                         | 2006        |
| <b>Operating activities:</b>  |                              |             |
| Net loss  | \$ (26,379)                  | \$ (26,072) |
| Adjustments to reconcile net loss to net cash used in operating activities:   |                              |             |
| Depreciation and amortization   | 4,161                        | 3,073       |
| Other asset impairment and non-cash charges   | 195                          | 68          |
| Loss on disposal of fixed assets  | 1                            | 340         |
| Accretion related to short-term investments   | 12                           | 76          |
| Foreign currency transactions gain  |                              | (18)        |
| Stock-based compensation expense  | 2,348                        | 3,026       |
| Warrant valuation adjustment  | (10)                         | (63)        |
| Increase (decrease) in cash caused by changes in operating assets and liabilities, excluding the effects of acquisitions: |                              |             |
| Receivables, net  | (3,969)                      | (2,457)     |
| Inventories, net  | 221                          | (629)       |
| Other current and long-term assets  | (962)                        | (55)        |
| Accounts payable and accrued liabilities  | 4,314                        | (289)       |
| Acquisition payable, secured by letter or credit  |                              | 2,570       |
| Deferred revenue and other long-term liabilities  | (453)                        | 141         |
| Net cash used in operating activities   | (20,521)                     | (20,289)    |
| <b>Investing activities:</b>  |                              |             |
| Purchase of short-term investments  | (14,141)                     | (18,197)    |
| Proceeds from sale and maturities of short-term investments   | 21,965                       | 31,339      |
| Acquisition of business, net of cash acquired   | (2,001)                      | (5,812)     |
| Proceeds from the conversion of restricted cash to cash   | 3,118                        |             |
| Purchase of equipment and technology rights   | (1,227)                      | (814)       |
| Net cash provided by investing activities   | 7,714                        | 6,516       |
| <b>Financing activities:</b>  |                              |             |
| Principal payments on capital lease obligations   | (322)                        | (404)       |
| Proceeds from factoring receivables   | 733                          |             |
| Principal payments on assigned royalty interests obligation   | (977)                        |             |
| Proceeds from debt obligations of variable interest entity  | 1,894                        | 1,138       |
| Issuance of common stock  | 7,083                        | 15,052      |
| Proceeds from long-term obligations   | 154                          | 165         |
| Net cash provided by financing activities   | 8,565                        | 15,951      |
| Effect of exchange rate changes   | 266                          | (479)       |
| Net increase (decrease) in cash and cash equivalents  | (3,976)                      | 1,699       |
| Cash and cash equivalents at beginning of period  | 11,261                       | 6,194       |
| Cash and cash equivalents at end of period  | \$ 7,285                     | \$ 7,893    |

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See accompanying notes.



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NANOGEN, INC.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (UNAUDITED)

June 30, 2007

**1. Summary of Significant Accounting Policies**

***Organization and Business Activity***

Nanogen, Inc. was incorporated in California in November 1991 and, in November 1997, was reincorporated in Delaware, as were our consolidated subsidiaries. We are in the business of developing, manufacturing, and selling advanced diagnostic products.

***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 June 30, 2007, condensed consolidated statements of operations for the three and six months ended June 30, 2007 and 2006, and the condensed consolidated statements of cash flows for the six months ended June 30, 2007 and 2006 are unaudited, but include all adjustments (consisting of normal recurring adjustments) which in the opinion of management are considered necessary for a fair presentation of the financial position, results of operations and cash flows for the periods presented. The results of operations for the three and six months ended June 30, 2007 shown herein are not necessarily indicative of the results that may be expected for the year ending December 31, 2007.

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern. This basis of accounting contemplates the recovery of the Company's assets and the satisfaction of liabilities in the normal course of business. The Company actively seeks additional financing to fund its development efforts and to commercialize its technologies. There is no assurance such financing will be available to the Company when needed or that such financing would be available under favorable terms.

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, 2006 included in the Nanogen, Inc. Annual Report on Form 10-K for the year ended December 31, 2006 filed with the Securities and Exchange Commission on March 16, 2007.

***Basis of Consolidation***

These consolidated financial statements and the accompanying notes relate to Nanogen, Inc. and its consolidated subsidiaries and entities.

***Consolidated Entities:***

*SynX Pharma* ( *SynX* ): all of the outstanding stock was acquired on April 21, 2004.

*Epoch Biosciences, Inc.* ( *Epoch* ): all of the outstanding stock was acquired on December 16, 2004.

*Spectral Diagnostics* ( *Spectral* ): acquired assets related to the rapid cardiac immunoassay test business of an unaffiliated company on February 6, 2005.

*Nanogen Advanced Diagnostics, S.r.L.* ( *Amplimedical* ): formed in 2006 and acquired the assets related to rapid cardiac immunoassay test business of an unaffiliated company on May 1, 2006.

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*Nanogen Europe B.V.* ( BV ): formed as a limited liability company in August 2000 in the Netherlands.

*Recognomics GmbH*: formed as a majority-owned joint venture in July 2001 with Aventis, Inc.

*Nanogen Advanced Diagnostics GmbH*: formed in 2007.

### ***Variable Interest Entity***

In a series of investments from July 2005 to June 2006, we purchased \$3.0 million in equity of Jurilab LTD ( Jurilab ). Using the methodology prescribed in Financial Accounting Standards Board Interpretation ( FIN ) No. 46R, *Consolidation*

of *Variable Interest Entities, an Interpretation of ARB No. 51*, we determined we were the primary beneficiary and are required to include Jurilab's assets and liabilities in our consolidated financial statements.

We included Jurilab's assets and liabilities as of the date of our initial investment on July 20, 2005 and its operating results after this date. However, because our maximum loss is limited to our \$3.0 million investment, the liabilities we have consolidated in our financial statements do not represent additional claims on our general assets; rather, they represent claims only on the specific assets of Jurilab. Conversely, assets recognized as a result of consolidating Jurilab do not represent additional assets that may be used to satisfy claims against our general assets.

#### ***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, liabilities and revenues 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 royalty revenue, 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.

#### ***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 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 costs of product sales related to a sold instrument are recorded in the period in which the corresponding revenue is recognized. Through June 30, 2007, we have not entered into any sales transactions where rights-of-return exist.

##### **(ii) Reagent rental 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 a reagent rental 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.

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We provide product warranty coverage for our molecular testing platforms except those sold to distributors. The warranty periods are generally for one year for direct sales. 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.

#### *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 payments 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 finalized until the licensee has completed their internal computations of the royalties due and/or remitted their cash payment. However, we will recognize revenue tied to third party sales on an accrual basis if information is available to enable us to reasonably 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 or have adequate history with the licensed product line 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 reasonably ensure that we have reliable information, which may be in a subsequent period. Therefore, we could experience fluctuations in revenues from quarter to quarter depending on the timing of the receipt of third party sales reports or cash payments, or from the true-up of the prior quarterly revenue estimate.

#### *Sponsored research, contract and grants revenue*

We earn revenue for performing tasks under research agreements with both private enterprises and governmental agencies. Sponsored research, contract and grants 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 had no impairment losses in the three and six months ended June 30, 2007 and 2006.

#### *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 and warrants is computed using the treasury stock method.



The weighted average common shares outstanding during the period do 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.

**Adoption of FIN No. 48, Accounting for Uncertainty in Income Taxes An Interpretation of FASB Statement No. 109**

On July 13, 2006, the FASB issued Interpretation No. 48, Accounting for Uncertainty in Income Taxes An Interpretation of FASB Statement No. 109 ( FIN 48 ). FIN 48 clarifies the accounting for uncertainty in income taxes recognized in an entity's financial statements in accordance with FASB Statement No. 109, Accounting for Income Taxes and prescribes a recognition threshold and measurement attributes for financial statement disclosure of tax positions taken or expected to be taken on a tax return. Under FIN 48, the impact of an uncertain income tax position on the income tax return must be recognized at the largest amount that is more-likely-than-not to be sustained upon audit by the relevant taxing authority. An uncertain income tax position will not be recognized if it has less than a 50% likelihood of being sustained. Additionally, FIN 48 provides guidance on derecognition, classification, interest and penalties, accounting in interim periods, disclosure and transition. FIN 48 is effective for fiscal years beginning after December 15, 2006.

The Company adopted the provisions of FIN 48 on January 1, 2007. There are no unrecognized tax benefits as of the date of adoption. As a result of the implementation of FIN 48, the Company recognized no decrease in deferred tax assets or in the valuation allowance. There are no unrecognized tax benefits included in the balance sheet that would, if recognized, affect the effective tax rate.

The Company's practice is to recognize interest and/or penalties related to income tax matters in income tax expense. During the years ended December 31, 2006 and 2005, the Company has not recognized any significant interest or penalties. Upon adoption of FIN 48 on January 1, 2007, the Company did not record any interest or penalties.

The Company is subject to taxation in the U.S. and various state and foreign jurisdictions. The Company's tax years for 1993 and forward are subject to examination by the U.S., foreign, and California tax authorities due to the carryforward of unutilized net operating losses and research and development credits.

The adoption of FIN 48 did not impact our consolidated financial condition, results of operations or cash flows. At January 1, 2007, we had net deferred tax assets of \$148.6 million. The deferred tax assets are primarily composed of federal and state tax net operating loss ( NOL ) carryforwards and federal and state research and development ( R&D ) credit carryforwards. Due to uncertainties surrounding our ability to generate future taxable income to realize these assets, a full valuation has been established to offset our net deferred tax asset. Additionally, the future utilization of our NOL and R&D credit carryforwards to offset future taxable income may be subject to a substantial annual limitation as a result of ownership changes resulting from past financings or that could occur in the future. We have not yet determined whether such an ownership change has occurred; however, the Company plans to complete a Section 382 analysis regarding the limitation of the net operating losses and research and development credits. When this project is completed, the Company plans to update their unrecognized tax benefits under FIN 48. Therefore, the Company expects that the unrecognized tax benefits may change within 9 months of this reporting date. At this time, the Company cannot estimate how much the unrecognized tax benefits may change. Any carryforwards that will expire prior to utilization as a result of such limitations will be removed from deferred tax assets with a corresponding reduction of the valuation allowance. Due to the existence of the valuation allowance, future changes in our unrecognized tax benefits will not impact our effective tax rate.

**2. 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 |             | Six months ended |             |
|---|--------------------|-------------|------------------|-------------|
|   | June 30,           |             | June 30,         |             |
|   | 2007               | 2006        | 2007             | 2006        |
|   | (Unaudited)        | (Unaudited) | (Unaudited)      | (Unaudited) |
| Comprehensive loss:   |                    |             |                  |             |
| Net unrealized gain on short-term investments and other investments | \$ 3               | \$ 52       | \$ 1             | \$ 84       |
| Foreign currency translation adjustment                             | (315)              | (322)       | (266)            | (479)       |
| Net loss  | (14,531)           | (14,051)    | (26,379)         | (26,072)    |
| Comprehensive loss  | \$ (14,843)        | \$ (14,321) | \$ (26,644)      | \$ (26,467) |





### 3. Commitments and Contingencies

#### *Hitachi, Ltd. Purchase Commitment*

We have a manufacturing agreement with Hitachi, Ltd. ( Hitachi ) that requires certain minimum purchase commitments for the second generation multiplexed instrument platforms from Hitachi. As of June 30, 2007, we have commitments to purchase approximately \$0.7 million in second generation microarray instrument platforms through December 2007. At June 30, 2007, based upon current and estimated forecasted demand, our purchase commitment with Hitachi is within our projected usage levels.

#### *Restricted Cash*

We have restricted cash representing cash, cash equivalents and short term investments pledged in lieu of cash deposits primarily for facility lease deposits and, in 2006, for acquisition related payables. The restricted cash balance was approximately \$2.0 million and \$5.1 million at June 30, 2007 and December 31, 2006, respectively.

#### *Litigation*

We may be subject to potential liabilities under various claims and legal actions that may be asserted. These matters may arise 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 June 30, 2007 we have no significant accrual for any pending claims.

### 4. Variable Interest Entity

In a series of investments from July 2005 through June 30, 2006, we invested approximately \$3.0 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 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 \$3.0 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.

Included in our consolidated balance sheet at June 30, 2007 and December 31, 2006 were the net liabilities (in thousands) of Jurilab:

|                             | June 30,<br>2007<br>(Unaudited) | December 31,<br>2006<br>(Unaudited) |
|-----------------------------|---------------------------------|-------------------------------------|
| Cash                        | \$ 29                           | \$ 743                              |
| Restricted cash             | 675                             | 660                                 |
| Other assets                | 496                             | 589                                 |
| Deferred revenues           | (2,126)                         | (2,639)                             |
| Debt obligations            | (11,835)                        | (9,941)                             |
| Other long-term liabilities | (1,465)                         | (922)                               |
| <b>Net liabilities</b>      | <b>\$ (14,226)</b>              | <b>\$ (11,510)</b>                  |

Consolidation of Jurilab's results of operations (in thousands) included the following:

|                                  | Three months ended,<br>June 30,<br>2007<br>(Unaudited) |                                 | Six months ended,<br>June 30,<br>2007<br>(Unaudited) |                                 |
|----------------------------------|--|---------------------------------|--|---------------------------------|
|                                  | June 30,<br>2006<br>(Unaudited)                        | June 30,<br>2006<br>(Unaudited) | June 30,<br>2006<br>(Unaudited)                      | June 30,<br>2006<br>(Unaudited) |
| Net sales                        | \$ 297   | \$ 12                           | \$ 578   | \$ 16                           |
| Cost of product sales            |  | (7)                             |  | (66)                            |
| Research and development expense | (1,971)  | (1,592)                         | (2,908)  | (2,560)                         |
| Other expenses                   | (74)   | (94)                            | (139)  | (144)                           |
| Net loss                         | \$ (1,748)   | \$ (1,681)                      | \$ (2,469)   | \$ (2,754)                      |

## 5. Financial Statement Details

### Receivables

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

|                                 | June 30,<br>2007<br>(Unaudited) | December 31,<br>2006 |
|---------------------------------|---------------------------------|----------------------|
| Product                         | \$ 12,774                       | \$ 10,240            |
| License fees                    | 1,556                           | 1,369                |
| Contract and grant              | 1,604                           | 142                  |
|                                 | 15,934                          | 11,751               |
| Allowance for doubtful accounts | (397)                           | (183)                |
|                                 | \$ 15,537                       | \$ 11,568            |

### Inventories

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

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

|                                     | June 30,<br>2007<br>(Unaudited) | December 31,<br>2006 |
|-------------------------------------|---------------------------------|----------------------|
| Raw materials                       | \$ 4,759                        | \$ 5,190             |
| Work in process                     | 1,677                           | 2,308                |
| Finished goods                      | 5,254                           | 5,061                |
|                                     | 11,690                          | 12,559               |
| Reserve for excess and obsolescence | (4,220)                         | (4,868)              |
|                                     | \$ 7,470                        | \$ 7,691             |

### Other long-term liabilities

Other long-term liabilities are comprised of the following (in thousands) as of:

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|                                 | June 30,    | December 31, |
|---------------------------------|-------------|--------------|
|                                 | 2007        | 2006         |
|                                 | (Unaudited) |              |
| Jurilab's long-term liabilities | \$ 1,465    | \$ 922       |
| Deferred rent                   | 458         | 777          |
| Other                           | 731         | 605          |
|                                 | \$ 2,654    | \$ 2,304     |

## 6. Stock Award Activity

### *Stock Option Grants*

Approximately 415,570 stock options subject to time based vesting were granted during the six months ended June 30, 2007, and the weighted average estimated fair value of stock options granted during the same period was \$1.23 per share. In the six month period ended June 30, 2007, \$61,000 in share-based compensation expense was capitalized as inventory overhead. At June 30, 2007, total unrecognized estimated compensation cost related to non-vested stock options granted prior to that date was \$3.8 million, excluding options with performance-based vesting which is expected to be recognized over a weighted-average period of 1.3 years as of the beginning of the fiscal period.

### *Performance options*

In December 2006, we issued 990,000 performance options to our executives and key members of management. In June 2007, we issued 1,950,000 performance options. These options vest when these individuals meet specific performance targets and align the interest of our employees with specific internal goals over a wide-range of the company's operations. As of June 30, 2007, we have evaluated the probability and timing of vesting of these options, and determined that expensing the fair value of these awards was not required at this time. We will continue to evaluate the probability of each performance option vesting and, if required, begin expensing the fair value of the award. The grant date fair value of each December 2006 option was valued at \$1.70, and each June 2007 option was valued at \$0.98. As of June 30, 2007, there is an aggregate unrecognized compensation expense of \$3.6 million related to performance options.

### *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 six months ended June 30, 2007 this resulted in \$450,000 in amortization of stock based compensation which is included in loss from operations.

On December 12, 2006, we granted 300,000 restricted stock units to certain employees under the 1997 plan at a fair value of \$2.09 per restricted stock unit. The restricted stock units vest monthly through December 2008. In the six months ended June 30, 2007, this resulted in \$154,000 in amortization of stock based compensation which is included in loss from operations.

As of June 30, 2007, we had 647,875 non-vested restricted stock units outstanding with a weighted-average grant date fair value of \$3.33 and an aggregated unrecognized compensation expense of \$539,000. In the six months ended June 30, 2007, 38,875 restricted stock units were cancelled, resulting in a adjustment of \$79,000 of amortization expense.

### *Employee Stock Purchase Plan*

In 1997, the Board of Directors approved the 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. During the six months ended June 30, 2007, 85,309 shares were issued under the ESPP plan. As of June 30, 2007, approximately 257,332 shares were reserved for future issuance.

### *Share-Based Payments*

Total share-based compensation expense was as follows (in thousands):

|                                     | Three Months Ended |       | Six Months     |        |
|-------------------------------------|--------------------|-------|----------------|--------|
|                                     | June 30,           |       | Ended June 30, |        |
|                                     | 2007               | 2006  | 2007           | 2006   |
| Cost of product sales               | \$ 82              | \$ 73 | \$ 169         | \$ 135 |
| Research and development            | 283                | 478   | 555            | 878    |
| Selling, general and administrative | 851                | 1,029 | 1,624          | 2,013  |

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|  |          |          |          |          |
|--|----------|----------|----------|----------|
| Total stock-based compensation expense | \$ 1,216 | \$ 1,580 | \$ 2,348 | \$ 3,026 |
|--|----------|----------|----------|----------|

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### **Earnings Per Share**

Employee stock options to purchase approximately 7,554,635 and 7,712,230 shares of common stock during the six months ended June 30, 2007 and December 31, 2006, respectively, were outstanding but not included in the computation of diluted earnings per common share because the effect on diluted earning per share would be anti-dilutive.

### **7. Related Party Transaction**

#### ***Consulting Agreement with Board Member***

In October 2006, we signed a consulting agreement with Mr. Dreismann, one of our Board members, and the agreement was amended in November 2006. Mr. Dreismann received \$30,000 in compensation under this agreement in the six months ended June 30, 2007. Total compensation under the agreement is capped at a maximum of \$60,000 over the life of the agreement.

### **8. Stock Transaction**

In May 2006, we entered into an equity financing agreement with Azimuth Opportunity Ltd. ( Azimuth ), pursuant to which Azimuth agreed to purchase, subject to certain limitations and closing conditions, up to \$25 million of our common stock over the subsequent eighteen months. These purchases were made pursuant to the June 2005 shelf registration statement. 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 \$1.58 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.

On February 1, 2007, we agreed with Azimuth to terminate our equity financing agreement.

On February 5, 2007, we entered into a placement agency agreement with Ascendant Securities, LLC (Ascendant) relating to the offering of stock pursuant to an effective shelf registration statement. Under the placement agency agreement, Ascendant agreed to act as our placement agent in connection with the issuance and sale of our common stock and warrants to purchase shares of common stock to certain institutional investors. We paid a placement agent fee of 5% of the gross cash proceeds of the offering. Under this agreement and related purchase agreements with the investors, we sold 4,916,667 shares of our common stock and 983,333 warrants to purchase a share of our common stock for net proceeds of approximately \$7.1 million.

### **9. Lease Termination**

In November 2001, SynX Pharma, Inc. entered into a lease of a 50,000 square foot building at 15 Marmac Drive in Toronto, Canada. In April 2004 we acquired Synx Pharma. As a result of the acquisition of the assets of Spectral Diagnostics in February of 2006 (also located in Toronto), we have been operating two Toronto locations. As part of our plan to consolidate operations to improve efficiencies and reduce cost, a lease termination notice was given to the landlord of 15 Marmac Drive, triggering lease termination related expenses which are expected to total \$2.3 million. As of June 30, 2007, we have recognized \$1.9 million in expenses related to the termination, and the majority of the remaining expenses are expected to be incurred by September 30, 2007. The most significant item included in the total termination expenses recognized as of June 30, 2007 is a lease termination penalty of \$1.7 million, which is expected to be paid in November 2007. The lease termination related expenses are reflected in the financial statements in general and administrative expenses.

## **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 Part II, 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*

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*thereto in our Annual Report on Form 10-K for the year ended December 31, 2006.*

## 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. MD&A is provided as 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:

*Summary* an executive summary of the significant business events that have occurred after January 1, 2007.

*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, 2007.

*Results of Operations* an analysis of our consolidated results of operations for the three and six months ended June 30, 2007 and 2006, 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:

Subsequent to December 31, 2006, the following significant business developments occurred:

On July 17, 2007 we announced that we began shipments of our congestive heart failure (CHF) product, the *StatusFirst* CHF NT-proBNP rapid test. The product is CE-marked and has been cleared by the FDA for diagnostic use with EDTA plasma samples. It has been developed by Nanogen under license from Roche and is being manufactured for Nanogen by Princeton BioMeditech Corporation (PBM). Distribution in the United States is handled by PBM's affiliate LifeSign. A version of this product that will use whole blood for the sample is currently under development.

On April 17, 2007 we announced submission of a 510(K) application to the Food and Drug Administration related to our Cystic Fibrosis Kit and NanoChip 400 microarray system. The Cystic Fibrosis Kit is intended to be used for carrier testing in adults of reproductive age, as an aid in newborn screening, and in confirmatory diagnostic testing in newborns and children.

We have substantially completed work on the \$4.5 million contract awarded in December 2006 by the Centers for Disease Control and Prevention (CDC) to develop a diagnostic assay for the flu. The goal is a low cost, high sensitivity point-of-care immunoassay that detects both seasonal flu and avian flu. HX Diagnostics will commercialize the product upon FDA clearance. The current award of \$4.5 million funds the first two phases of a five-phase development project. If all five phases are funded by the CDC, the award can total about \$12.5 million. Additional future awards are based on the achievement of milestones and approval by the CDC.



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In the six months ended June 30, 2007, we used \$20.5 million in cash in operating activities, which was primarily a result of the costs associated with the development of unique solutions for the clinical, research and point-of-care markets and the execution of our multi-product commercialization strategy. We believe we will continue to use cash and have quarterly net losses for at least the next year until our product offerings gain traction in the market place and begin to generate a return on investment. To continue to fund our commercialization strategy, on February 5, 2007, we entered into a placement agency agreement with Ascendant Securities, LLC (Ascendant) relating to the offering of stock pursuant to an effective shelf registration statement. Under the placement agency agreement, Ascendant agreed to act as our placement agent in connection with the issuance and sale of our common stock and warrants to purchase shares of common stock to certain institutional investors. We paid a placement agent fee of 5% of the gross cash proceeds of the offering. Under this agreement and related purchase agreements with the investors, we sold 4,916,667 shares of our common stock and 983,333 warrants to purchase a share of our common stock for net proceeds of approximately \$7.1 million. In July 2007, we filed a \$50 million shelf registration statement (which replaced an existing shelf registration statement filed in May 2007) in anticipation of future financing requirements.

**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.

The table below illustrates how our platform technologies address our customers' requirements for advanced molecular diagnostic tools:

|  |  |   |
|--|--|---|
| <b>Potential customers addressed by our technologies:</b>                  |  |   |
| Advanced Research<br><i>(Universities, research facilities, etc.)</i>      | Clinical Laboratory (CLIA<br><i>certified central laboratories and clinical research laboratories)</i> | Point-of-care ( <i>Emergency room or urgent care settings</i> ) |
| Molecular testing platforms ( <i>Instrumentation</i> )                     |  |   |
| Molecular Reagents<br><i>(Reagents, ASRs, Custom Assays and Test Kits)</i> |  |   |
| Advanced genetic markers   |  |   |
| Point-of-Care Tests<br><i>(Test Kits and Instruments)</i>                  |  |   |

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<sup>®</sup>400 system and the Molecular Biology Workstation. These systems are based on our proprietary lab on a chip detection technology that allows testing for multiple gene markers or mutations on one test site. Using our open system architecture, researchers and research 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

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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 cystic fibrosis genes (CTFR) and blood clotting (Factor VII).

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. These diagnostic test kits include multiplexed reagent 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 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, and in July 2007 we announced that we begun shipment of the product. The test has been developed by Nanogen under license from Roche and is being manufactured for Nanogen by Princeton BioMeditech Corporation (PBM). Distribution in the United States is handled by LifeSign, an affiliate of Princeton BioMeditech Corporation (PBM). 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.

#### *License fee and royalty income: Developments*

In January 2006, we renegotiated our contract with Applied Biosystems, Inc. ( Applied Biosystems ), with the underlining patents expiring at various dates between 2010 and 2015. The revised contract maintained minimum quarterly payments through December 31, 2006 and royalties are based on actual sales thereafter. As a result, beginning January 1, 2007, royalties are based on actual sales. These sales are typically not reported to us from Applied Biosystems until subsequent to the reporting for the related quarter. If the royalty report has not been received prior to reporting earnings, we will accrue royalty revenue based on our knowledge of the underlying product and the history we have developed related to such product royalties. Actual amounts may vary from these estimates and will be trued up in the following quarter. Although we expect this relationship to continue into the foreseeable future this contract can be terminated with a 180 day notice by Applied Biosystems.

In September 2006, we entered into an agreement to assign certain rights associated with our 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 the minimum undiscounted payment to DRT guaranteed by us for each remaining fiscal year:



| Calendar year ending | Minimum payment<br>(in thousands) |
|----------------------|-----------------------------------|
| 2007 (remainder)     | \$ 2,003                          |
| 2008                 | 4,820                             |
| 2009                 | 5,200                             |
| 2010                 | 5,410                             |
| 2011                 | 5,374                             |
| Total                | \$ 22,807                         |

**Acquisitions, investments and goodwill: Developments**

We actively and 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 or approximately U.S. \$4.8 million in cash 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.

*Amplimedical*

On May 1, 2006, we completed the acquisition of the diagnostic division of Amplimedical which is a manufacturer and distributor of molecular diagnostic products, based in Italy, for approximately \$9.9 million.

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.

*Jurilab, LTD investment*

In a series of investments from July 2005 through June 2006, we invested approximately \$3.0 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 entire entity.

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 approximately \$1.2 million. Through June 30, 2007, we paid Jurilab approximately \$715,000 for the completion of certain milestones.

*Pharmacogenetics Diagnostic Laboratory, LLC*

Beginning in July 2005, we made a series of investments in Pharmacogenetics Diagnostic Laboratory, LLC ( PGx ), a development stage research and development company, to provide us access to certain technologies related to pharmacogenetics.

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

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.

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 a reasonably priced instrument that uses our reagents 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***

On July 17, 2007, our Point-of-Care Division received a warning letter from the FDA following an inspection of the division s facility in Toronto, Canada in February 2007. The letter cited violations of the FDA s Current Good Manufacturing Practice requirements of the Quality System Regulations with respect to the manufacture, packing and installation of products in our cardiac business: Cardiac STATus, Decision Point and i-Lynx. Since the inspection in February 2007, we have undertaken steps to address these concerns, and will continue to take appropriate corrective and preventive actions in response to the warning letter. Failure to obtain and maintain full compliance with FDA regulations could lead to further regulatory actions that could have an adverse effect on our business, financial position and results of operations.

In April 2007 we submitted a 510(K) application to the Food and Drug Administration (FDA) related to our Cystic Fibrosis Kit and NanoChip 400 microarray system. The Cystic Fibrosis Kit is intended to be used for carrier testing in adults of reproductive age, as an aid in newborn screening, and in confirmatory diagnostic testing in newborns and children.

Our micro-array instrumentation is to be used only for research purpose, whereas our ASR and real-time PCR products are to be used 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 plasma based NT-proBNP congestive heart failure product for use on human plasma. For the larger point-of-care market, our NT-proBNP congestive heart failure product for use on human whole blood remains under development. Shipments of this product began in 2007.

In August 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 construed as a closed system and therefore a medical device that requires a pre-market 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 pre-market review. In November 2006, we met with the FDA to discuss the second letter. Subsequently, we have revised our labeling for the microarray NanoChip®400 system to reflect it is for Research Use Only . We believe that our microarray NanoChip® systems and ASR products are not subject to FDA pre-market review. If there is an unfavorable decision by the FDA in these matters, it could adversely impact sales of our ASRs to clinical laboratories in the United States.

***Other***

***Manufacturing:***

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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 facility in San Diego, California.

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 an advanced diagnostic product line from Amplimedical and acquired the ability to manufacture the associated products in our facilities in Buttigliera, Italy.

*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 Part II, 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 six months ended June 30, 2007 and 2006*

#### *Revenues*

The following table summarizes our revenues for the three and six months ended June 30, 2007 and 2006 (in thousands):

|                                | For the three months<br>ended June 30, |          |            | For the six months<br>ended June 30, |           |            |
|--------------------------------|--|----------|------------|--------------------------------------|-----------|------------|
|                                | 2007                                   | 2006     | Difference | 2007                                 | 2006      | Difference |
| Product sales                  | \$ 5,294                               | \$ 4,016 | \$ 1,278   | \$ 11,378                            | \$ 6,138  | \$ 5,240   |
| License fee and royalty income | 2,058                                  | 1,814    | 244        | 3,300                                | 3,628     | (328)      |
| Contracts and grant            | 2,963                                  | 481      | 2,482      | 5,291                                | 897       | 4,394      |
| Total                          | \$ 10,315                              | \$ 6,311 | \$ 4,004   | \$ 19,969                            | \$ 10,663 | \$ 9,306   |

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 for the three and six months ended June 2007 as compared to the same periods of 2006 occurred in multiple product lines with a significant increase due to the acquisition of Amplimedical in May 2006. Amplimedical's revenues were not consolidated in the first four months of 2006, but their revenues totaled \$2.0 million for May and June 2006 and totaled \$7.2 million for the six months ended June 2007.

*The future:* We expect revenue to continue to increase in the remainder of 2007 as compared to 2006 when we record a full year of sales revenue from Amplimedical. In addition to this acquired revenue, we expect increases in revenue from our advanced diagnostic instruments and our internally developed diagnostic products. However, this may be impacted by the U.S. FDA requiring regulatory clearance for certain of our reagents.

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

License fee and royalty revenue is generated by licensing our intellectual property rights to third parties. The decrease in license fees and royalty income in the first and second quarter of 2007 as compared to the same periods of 2006 was primarily due to lower license payments from two expired agreements and a third agreement with Applied Biosystems, Inc. (Applied Biosystems) for their

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right to manufacture and sell our TaqMan<sup>®</sup> 5'-nuclease real-time PCR. An additional licensing agreement with ABI for patents, expiring at various dates between 2010 and 2015, remains in place.

*The future:* Royalties from Applied Biosystems are based on actual sales. From our review of the sales trends of products under this license agreement, we expect that future royalty revenue will remain at similar levels as seen in recent quarters. 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 million upfront payment in cash. Going forward we will not receive any cash from this license agreement until 2012 unless actual sales exceed certain annually agreed upon thresholds. We recognized this payment as assigned royalty interest obligations and will continue to recognize revenue quarterly based on actual royalties 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 into the foreseeable future this contract may be terminated by Applied Biosystems with a 180 day notice.

In addition, with our growing intellectual property profile of 171 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.

Contracts and grants revenue represents nonrefundable payments by various federal, state and private agencies for our research and development efforts awarded through contracts and grants. Contracts and grants revenue is recorded as the costs and expenses to perform the research are incurred, if the amount is reasonably commensurate with the effort expended and collection of the payment is reasonably assured. Under certain arrangements where funding is provided contractually on a scheduled basis, revenue is recorded ratably over the term of the arrangement. Payments received in advance under these arrangements are recorded as deferred revenue until the expenses are incurred. The increase in contract and grant revenue in the three and six months ended June 30, 2007 as compared to the same period of 2006 was primarily related to additional revenue generated from the U.S. Centers for Disease Control and Prevention ( CDC ) grant with no comparable award in the first or second quarter of 2006.

*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. On December 4, 2006 we announced we were awarded a \$4.5 million contract from the CDC. The current award is for the first two phases of a five-phase development project. If we are awarded all five phases, the award may total approximately \$12.5 million over life of the award, including amounts received to date. As of June 30, 2007, we had substantially completed work required by the first two phases. The third phase, if awarded, may not occur during the third quarter. As a result, we anticipate a short term reduction in contract and grant revenue, if the award is not granted during the third quarter.

#### **Cost and expenses**

*Cost of product sales (in thousands):*

|                       | For the three months ended June 30, |          |            | For the six months ended June 30, |          |            |
|-----------------------|-------------------------------------|----------|------------|-----------------------------------|----------|------------|
|                       | 2007                                | 2006     | Difference | 2007                              | 2006     | Difference |
| Cost of product sales | \$ 4,529                            | \$ 4,023 | \$ 506     | \$ 9,359                          | \$ 6,262 | \$ 3,097   |

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 first half of 2007 as compared to the same period in 2006 primarily related to increased product sales arising from the acquisition of the Amplimedical product line related manufacturing costs on May 1, 2006. Following the commercial launch of the second generation molecular testing platform, we converted a significant portion of our San Diego, California, product development facilities to a manufacturing and assembly facility, in late 2005. This was reflected in changes to our inventory overhead model, and as a result, beginning January 1, 2006 we have been incurring additional excess capacity charges that were previously expensed into research and development. In the six months ended June 30, 2007, we incurred additional \$1,136,000 in excess capacity charges as compared to \$897,000 incurred in the same period of 2006.

*The future.* For the remainder of 2007 we expect our cost of product sales to increase as compared to 2006 as a result of both organic sales growth as well as including a full year of Amplimedical s product sales and manufacturing costs. 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 to absorb our fixed overhead costs.

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### Research and development expenses (in thousands):

|                          | For the three months ended June 30, |          |            | For the six months ended June 30, |           |            |
|--------------------------|-------------------------------------|----------|------------|-----------------------------------|-----------|------------|
|                          | 2007                                | 2006     | Difference | 2007                              | 2006      | Difference |
| Research and development | \$ 7,546                            | \$ 6,552 | \$ 994     | \$ 14,007                         | \$ 12,812 | \$ 1,195   |

Research and development relates to the expenses associated with our efforts to develop advanced 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. Research and development costs increased in the three and six months ended June 2007, as we began substantial work on the CDC contract in the first half of 2007 and redirected resources to support this contract. In addition, Jurilab's research and development costs have increased for the three and six months ended June 2007, compared to the same periods last year.

*The future.* As a part of our continual focus on narrowing our losses and working towards positive cash flows from operations, we plan to reduce costs in research and development expenditures that are not funded by contracts or grants.

### Selling, general and administrative expenses (in thousands):

|  | For the three months ended June 30, |          |            | For the six months ended June 30, |           |            |
|--|-------------------------------------|----------|------------|-----------------------------------|-----------|------------|
|  | 2007                                | 2006     | Difference | 2007                              | 2006      | Difference |
| Selling, general and administrative expenses | \$ 11,233                           | \$ 8,928 | \$ 2,305   | \$ 20,137                         | \$ 16,298 | \$ 3,839   |

Selling, general and administrative expenses relate to the costs associated with promoting and selling our products and the administrative costs required to support our company's operations. The increase in selling, general and administrative expenses in the three and six months ended June, 2007 as compared to the same period of 2006 is related to the acquisition of the Spectral and Amplimedical on February 6, 2006 and May 1, 2006, respectively, as well as \$1.9 million of costs related to the termination of the Marmac facility lease in Toronto Canada, to be paid in November, 2007.

*The future.* We expect that our selling, general and administrative expenses, on a percentage basis, will trend lower than increases in revenue. We will achieve this by creating efficiencies in our general and administrative functions by eliminating redundant functional areas in the entities we acquire. In addition, we anticipate another \$400,000 in lease termination related costs related to vacating the Marmac facility. Expenses may also be further impacted by potential future business combinations or corporate development transactions.

### Amortization of purchased intangible assets (in thousands):

|   | For the three months ended June 30, |        |            | For the six months ended June 30, |          |            |
|---|-------------------------------------|--------|------------|-----------------------------------|----------|------------|
|   | 2007                                | 2006   | Difference | 2007                              | 2006     | Difference |
| Amortization of purchased intangible assets | \$ 760                              | \$ 730 | \$ 30      | \$ 1,527                          | \$ 1,290 | \$ 237     |

Amortization of purchased intangibles is our effort to match the benefits of the intellectual property we have acquired with current period expenses. The amortization expense for the three months ended June 30, 2007 and same period in 2006 remained consistent while the increase in the amortization of purchased intangible assets in the six months ended June 30, 2007 as compared to the same period of 2006 related to additional amortization of acquired identifiable intangible assets when we purchased Spectral's and Amplimedical's assets on February 6, 2006 and May 1, 2006, respectively.

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

### Other income

The following table summarizes our other income for the three and six months ended June 30, 2007, and 2006 (in thousands):



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|   | For the three months ended June 30, |          |            | For the six months ended June 30, |         |            |
|---|-------------------------------------|----------|------------|-----------------------------------|---------|------------|
|   | 2007                                | 2006     | Difference | 2007                              | 2006    | Difference |
| Interest income                             | \$ 31                               | \$ 219   | \$ (188)   | \$ 136                            | \$ 480  | \$ (344)   |
| Interest expense                            | (768)                               | (121)    | (647)      | (1,397)                           | (202)   | (1,195)    |
| Other expense                               | (25)                                | (300)    | 275        | (53)                              | (397)   | 344        |
| Warrant valuation adjustment                |                                     | 88       | (88)       | 10                                | 63      | (53)       |
| Gain (loss) on foreign currency translation | (16)                                | (15)     | (1)        | (14)                              | (18)    | 4          |
| Total                                       | \$ (778)                            | \$ (129) | \$ (649)   | \$ (1,318)                        | \$ (74) | \$ (1,244) |

The increase in interest expense from 2006 to 2007 is the result of the \$20 million assignment of royalty obligations made to DRT.

**Liquidity and capital resources**

*Short-term and long-term liquidity*

At June 30, 2007 we have cash and cash equivalents and short-term investments, available for sale of approximately \$13.4 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 or raise money through issuing debt 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, or 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.

The following is a summary of our key liquidity measures as of June 30, 2007 and December 31, 2006 (in thousands):

|  | June 30,<br>2007 | December 31,<br>2006 | Difference  |
|--|------------------|----------------------|-------------|
| Cash and cash equivalents  | \$ 7,285         | \$ 11,261            | \$ (3,976)  |
| Short-term investments, available for sale                                     | 6,084            | 13,923               | (7,839)     |
| Total cash and cash equivalents and short-term investments, available for sale | \$ 13,369        | \$ 25,184            | \$ (11,815) |
| Current assets   | \$ 39,396        | \$ 46,501            | \$ (7,105)  |
| Current liabilities  | (25,955)         | (25,880)             | (75)        |
| Working capital  | \$ 13,441        | \$ 20,621            | \$ (7,180)  |

Our cash and cash equivalents and short-term investments, available for sale decreased by \$11.8 million, and our working capital decreased by \$7.2 million, at June 30, 2007 as compared to December 31, 2006. Decrease in working capital was primarily due to a decrease in cash and cash equivalents and short term investments, available for sale, for cash used in our on-going research and business development efforts, partially offset by an increase in accounts receivables from the CDC and accounts receivable recorded by Amplimedical. In December 2006, we obtained a revolving working capital debt facility for up to \$5.2 million secured by the Amplimedical accounts receivables. As of June 30, 2007, we had borrowed \$3.7 million under the agreement. Decrease in cash and cash equivalents and short term investments, available for sale, was primarily due cash receipts from revenues and capital financing of \$7.5 million in February 2007, offset by the cash used in our on-going research and business development efforts. In addition, we have been using cash to support the businesses we acquired in 2006 and 2004. We believe we will continue to consume cash and have quarterly net losses at least through the next twelve months. We have had negative cash flows from operations since inception and do not expect to generate positive cash flows to fund our operations until we generate significant revenues from our product offerings and/or begin generating a return on our intellectual property. Going forward, we believe we can use less cash as sales revenues increase as we aggressively manage expense levels and because our European operations which have long accounts receivable collection cycles, will require less capital to support their growth as collections on their accounts receivable have begun.

From inception to June 30, 2007, we have financed our operations primarily by:

Issuing our stock and warrants

Generating revenues

Assignment of certain royalty interests to DRT

Financing our trade receivables

Obtained cash through our acquisitions

Using proceeds from litigation settlements

Obtaining a modest amount of capital equipment long-term financing

Reimbursement from federal, state and private agencies for certain research and development projects.

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.

Cash used in operating, investing and financing activities for the six months ended June 30, 2007 and 2006 is as follows (in thousands):

|   | June 30,<br>2007 | June 30,<br>2006 |
|---|------------------|------------------|
| Net cash used in operating activities     | \$ (20,521)      | \$ (20,289)      |
| Net cash provided by investing activities | 7,714            | 6,516            |
| Net cash provided by financing activities | \$ 8,565         | \$ 15,951        |

*Operating activities*

Net cash used in operating activities for the six months ended June 30, 2007 and 2006 primarily related to our net losses and changes in working capital. The increase in cash used in operating activities in six months ended June 30, 2007 as compared to the same period of 2006 primarily related to additional on-going operational costs after our acquisitions of Spectral and Amplimedical, as well as the additional impact on working capital for the increase in accounts receivable at Amplimedical due to the long collection cycle. The collection cycle at Amplimedical is considered normal in the Italian healthcare market where the majority of the sales have taken place.

*Investing activities*

Net cash provided by investing activities in the six months ended June 30, 2007 and 2006 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). Net cash provided by investing activities increased in the six months ended June 30, 2007 as compared to the same period of 2006 primarily due to lower acquisition costs, offset by more purchases of short term investments in the first quarter of 2007. In the first half of 2007 we paid \$2.0 million as part of the final payment for the acquisition of Amplimedical's assets as compared to \$5.6 million paid in the first half of 2006 for the acquisition of Spectral's assets.

Capital spending is essential to our product innovation initiatives and maintaining our operational capabilities. Therefore, in the first half of 2007 and 2006 we used cash to purchase \$1,227,000 and \$814,000, respectively, in property and equipment to support the development of our product lines.

*Financing activities*



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Due to our negative cash flows from operations, we remained dependent on equity financing or other sources of non-dilutive financing to fund our operations.

To continue to fund our commercialization strategy, on February 5, 2007, we entered into a placement agency agreement with Ascendant Securities, LLC (Ascendant) relating to the offering of stock pursuant to an effective shelf registration statement. Under the placement agency agreement, Ascendant agreed to act as our placement agent in connection with the issuance and sale of our common stock and warrants to purchase shares of common stock to certain institutional investors. We paid a placement agent fee of 5% of the gross cash proceeds of the offering. Under this agreement and related purchase agreements with the investors, we sold 4,916,667 shares of our common stock and 983,333 warrants to purchase a share of our common stock for net proceeds of approximately \$7.1 million.

*Significant equity financing activities*

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 under this shelf registration statement as of May 9, 2006 by approximately \$4.0 million. In July 2007, we filed a shelf registration statement (which replaced an existing shelf registration statement filed in May 2007) with the Securities and Exchange Commission that would allow us to raise up to \$50.0 million in equity or debt transactions. As of the date of this filing, no financings under this shelf filing have taken place.

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

| Date of Financing | Number of Shares     | Issuance Share Price | Proceeds, Net<br>(in million) |
|-------------------|----------------------|----------------------|-------------------------------|
| 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   | \$1.58               | 3.9                           |
| September 2006    | 0.8 million shares   | \$1.80               | 1.5                           |
| February 2007     | 4.9 million shares   | \$1.54               | 7.2                           |
| February 2007     | 1.0 million warrants | \$1.85               |                               |

|                                      |              |                    |      |
|--------------------------------------|--------------|--------------------|------|
| Total shares<br>and warrants issued: | 22.7 million | Total proceeds: \$ | 46.4 |
|--------------------------------------|--------------|--------------------|------|

In the six months ended June 30, 2006, we issued approximately 39,000 shares of common stock to our employees under stock options plans and received in net proceeds of approximately \$52,000. There were no shares of common stock issued to our employees in the first half of 2007.

*Significant non-dilutive financing activities*

In September 2006, we entered into an agreement where we assigned certain rights associated with a royalty agreement from July 2006 through December 2011 for a \$20.0 million upfront payment in cash.

In December 2006, we obtained a revolving working capital debt facility for up to approximately \$5.2 million secured by our Italian accounts receivables.

In 2006 we entered into an equipment funding agreement for up to approximately \$2.3 million through December 31, 2007. 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

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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, 2006.

*Valuation of Goodwill*

We have recorded as assets \$38.9 million of goodwill in our June 30, 2007 consolidated financial statements related to our acquisitions of Amplimedical and Spectral in 2006 and our acquisitions of SynX Pharma and Epoch Biosciences in 2004. 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.

We test goodwill for possible impairment on an annual basis. This testing requires that we make judgments to identify our reporting units and that significantly affects 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;

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

the impact of significant negative industry or economic trends.

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 real-time PCR products (both custom and proprietary tests), molecular testing platforms (the NanoChip® systems), 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. In addition, if we believe sufficient current facts are known and we have historical experience, we may estimate royalty revenue on an accrual basis.

#### *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 \$4.2 million of inventory reserves as of June 30, 2007, with a net ending inventory balance of approximately \$7.5 million. 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 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 changes 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, future taxable income, the expected timing of the reversals of existing temporary differences and the implementation of tax-planning strategies. As of December 31, 2006, our valuation allowance was \$148.6 million.

In July 2006, the Financial Accounting Standards Board ( FASB ) issued FASB Interpretation No. 48 ( FIN No. 48 ) Accounting for Uncertainty in Income Taxes an interpretation of Statement of Financial Accounting Standards ( SFAS ) No. 109, which prescribes a recognition threshold and measurement process for recording in the financial statements uncertain tax positions taken or expected to be taken in a tax return. Additionally, FIN No. 48 provides guidance on the derecognition, classification, accounting in interim periods and disclosure requirements for uncertain tax positions. The Company adopted this statement effective January 1, 2007, which did not result in an adjustment for the net impact of the change in guidance. The Company does not anticipate that the adoption of FIN No. 48 will have a material effect on its statements of income and effective tax rate in future periods.

#### *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. There is a 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.

#### *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 and our newest director, Dr. Heiner Dreismann, became CEO of FasTraQ in 2006. 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 up to an additional \$500,000 in funding based on certain milestones, of which \$200,000 was paid in 2006 and expensed into research and development. In February 2007, the companies terminated these agreements by mutual agreement.

On August 3, 2006, we entered into research and development collaboration arrangements with Fisher Scientific International Inc., ( Fisher Scientific ) a related party, that owned 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.

### **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 \$6.1 million as of June 30, 2007, 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 June 30, 2007, 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 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 subsidiary in Italy is the euro. The Italian subsidiary's accounts are translated from the euro to the U.S. dollar using the current exchange rate in effect at the balance sheet date for balance sheet accounts, and using the average exchange rate during the period for revenues and expense accounts. The effects of translation are recorded in accumulated other comprehensive income in the consolidated financial statements included herein. In certain instances, our subsidiaries conduct business with customers and vendors in euros or in other local European currencies. Exchange gains and losses arising from these transactions are recorded using the actual exchange rate differences on the date of the transaction. We have not taken any action to reduce our exposure to changes in foreign currency exchange rates, such as options or futures contracts, with respect to transactions with our European customers and vendors. The net tangible assets of our foreign subsidiaries, excluding intercompany balances, were approximately \$10.7 million at June 30, 2007.

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.

### **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.

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 June 30, 2007 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 June 30, 2007, 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 June 30, 2007, total approximately \$387.1 million. Moreover, our negative cash flow and losses from operations will continue for the foreseeable future. We may never generate sufficient product revenue to become profitable. We also expect to have quarter-to-quarter fluctuations in revenues, expenses and losses, which 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, acquisition, goodwill or other impairment charges, non-cash stock option expenses, market acceptance of our existing product offerings, and potential other products under development, including the whole-blood 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.

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

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

We will need to raise more money to continue the research and development necessary to further develop our current products to bring our products to market and to further our manufacturing and marketing capabilities. We may seek additional funds through public and private securities 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, significantly 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.

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

We are at an early stage of development. As of June 30, 2007, we had only a limited product offering that includes real-time PCR products (both custom and proprietary tests), molecular testing platforms (NanoChip<sup>®</sup> system), ASRs, and point-of-care diagnostic tests for myocardial infarction and drugs of abuse. Our congestive whole-blood heart failure point of care test remains in development. Most of our ASRs are under development. Our molecular testing platforms and 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.

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. 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. A new CFTR ASR was introduced in March 2006. We may encounter similar product performance issues, we may not be able to address such issues to the satisfaction of our customers, and they may decide to adopt alternative products.

*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<sup>®</sup> 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.

*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<sup>®</sup> 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;

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uncertainties in product pricing and market acceptance; and

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

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

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*The Fisher Scientific and CDC collaborations and awards may not continue beyond the currently funded projects.*

We have entered into two non-binding agreements to provide research services to various units of Fisher Scientific under a collaboration announcement of August 2006 that anticipated up to \$5.0 million of funding in each of 2007 and 2008. No projects have been identified for either 2007 or 2008 at this time under this collaboration announcement. There is no guarantee that our collaboration with Fisher Scientific will result in the anticipated funding. Fisher Scientific was acquired by Thermo Electron in November 2006.

We have received a \$4.5 million contract from the CDC to cover the first two phases of a possible five phase development program totaling up to \$12.5 million. Future awards will be given at the discretion of the CDC. In making further contract awards, the CDC may consider the achievement of certain milestones in the current contract but there can be no assurance that we will successfully attain them. The exact reimbursement rates provided by the CDC are also subject to our performance of the contract under allowed rates of reimbursement and the ratio of internal versus outside supplier expenses. The CDC could modify our rates of reimbursement based on our actual performance.

*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.

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

On May 1, 2006, we completed the acquisition of the molecular testing division of Amplimedical S.r.L. On February 6, 2006, we completed the acquisition of the rapid cardiac immunoassay test business of Spectral Diagnostics ( Spectral ). In 2004, we completed the acquisition of SynX Pharma, Inc. ( SynX ) in April 2004 and Epoch Biosciences, Inc. ( Epoch ) in December 2004. In 2007, we expect that the Spectral and SynX product lines will accelerate our entry into the point-of-care market and that the Amplimedical and Epoch acquisitions will broaden our reach in the molecular diagnostic 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 products. Additionally, Amplimedical is located in Italy, Spectral and SynX are located in Canada, Epoch is located in the state of Washington, 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



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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.

*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 clearance/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.

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*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.

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*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. After our opposition to this patent, Oxford Gene Technology narrowed its claims. However, we are still opposing such narrower claims before the European Patent Office's Opposition Division. Even if Oxford Gene Technology successfully defends its current, narrower claims, and even if a patent is subsequently granted for such claims, we do not believe that our product will infringe upon such claims. Nonetheless, Oxford Gene Technology may still later assert that some of our products infringe upon its patents that Oxford Gene Technology may obtain from time to time. If the decision of the Opposition Division is successfully appealed by Oxford Gene Technology 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 and we may incur unanticipated costs in defending such accusations.

*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 Technology 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 Technology pursuant to which the lawsuit was dismissed by Oxford Gene Technology without prejudice. Under the tolling agreement, we are obligated to give Oxford Gene Technology 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 Technology are obliged to discuss in good faith for 30 days whether we wish to acquire, and whether Oxford Gene Technology is willing to grant a license under the patent involved in the litigation. If we and Oxford Gene Technology 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 Technology notice that we desired to commercialize DNA arrays for use in such assay formats. Oxford Gene Technology 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 Technology'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 or 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 in development and assets we acquired in our Spectral acquisition, are not subject to 510(k) clearance or premarket approval requirements. 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 current products are subject to 510(k) clearance and premarket approval requirements or other similar procedures, our business may experience incremental costs, increased regulatory risks and production delays. In addition, we could be subject to:

the recall or seizure of our products;

total or partial suspension of the production of our products;

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

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

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

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

In August 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 concern that the microarray NanoChip systems and certain related products sold as ASRs might be a closed system and therefore a medical device that requires a pre-market 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 pre-market review. In November 2006, we met with the FDA to discuss the second letter. Subsequently, we have revised our labeling for the microarray NanoChip<sup>®</sup> 400 system to reflect its status as For Research Use Only. We believe that our microarray NanoChip systems and ASR products are not subject to FDA pre-market review. If there is an unfavorable decision by the FDA in these matters, it could adversely impact sales of our ASRs and NanoChip systems to clinical laboratories in the United States. In 2007, we submitted a premarket notification to the FDA for a cystic fibrosis test. We will continue our development of additional IVD products on the NC400 system platform, and have plans for filing additional 510(k)s later this year and in early 2008.

Thus far the FDA has not agreed with our position that the NanoChip<sup>®</sup>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 or clearances. 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 seek to preclude us from shipping the NanoChip<sup>®</sup> 400 or other products in the United States until we

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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 submission of 510(k) applications for the NanoChip<sup>®</sup> 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 document is finalized in its current form, we may have to incur substantial cost to repackage our products to meet the guideline. 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, and compliance with regulations applicable to, 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 asks other questions. The premarket approval process generally takes between one and two years from the time of submission but can take longer. Prior to submitting to the FDA a 510(k) clearance or pre-market application, we must spend time and money preparing the submission, including generating the necessary data. 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 or clearances from regulatory authorities could have a material adverse effect on our business, results of operations and financial condition. In other countries, the manufacture or sale of our products may require approval by local government agencies with missions comparable to the FDA's. The process of obtaining any such approval may also be lengthy, expensive and uncertain.

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

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, promotion 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 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. 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 or all facilities registered with the FDA under our name.

On July 17, 2007, our Point-of-Care Division received a warning letter from the FDA following an earlier inspection of the division's facility in Toronto, Canada in February 2007. The letter cited violation of the FDA's Current Good Manufacturing Practice requirements of the Quality System Regulations with respect to the manufacture, packing and installation of products in our cardiac business: Cardiac STATUS, Decision Point and i-Lynx. Since the inspection in February 2007, we have undertaken steps to address these concerns, and will continue to take appropriate corrective and preventive actions in response to the warning letter. There is no guarantee that we will correct all of the violations cited in the letter to the satisfaction of the FDA. Failure to do so may result in further regulatory actions, including suspension of sales of our Point-of-Care products in the United States and delay in the granting of pre-market approval applications, which could have a material adverse effect on our business, financial position and results of operations. In addition, we may need to expend substantial funds and efforts implementing corrective measures and maintaining our Toronto facility in full compliance with the FDA's regulatory requirement.

*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.

*We currently rely on one manufacturer of our NanoChip® 400 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 companies for the manufacture of these products, any disruption in either of these companies' businesses or in our relationship with such companies may have a material adverse effect on our business. To the extent we have adverse developments in our relationship with Hitachi or PBM, or to the extent we develop contractual disputes, it may have an adverse impact on our business, our ability to implement existing products or launch new products. In particular, to the extent we seek to amend, modify or extend or otherwise change aspects of our contractual relationship with either of these parties, we may experience manufacturing delays associated with negotiating the terms of those arrangements and other related complications. If we determine to curtail or terminate our manufacturing relationship with either of these parties, a lengthy process would be required to negotiate and begin work under a manufacturing agreement with a new manufacturer which could disrupt our manufacturing process and harm our business. Furthermore, the manufacturing of 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 June 30, 2007, we had 49 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<sup>®</sup> System, including the second-generation NanoChip<sup>®</sup> 400, ASRs, point-of-care diagnostics, and other products in foreign countries due to:

licenses, tariffs and other trade barriers;

costs and difficulties in establishing and maintaining foreign distribution partnerships;

potentially adverse tax consequences; and

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

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

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

*We may have significant product liability exposure.*

We face an inherent business risk of exposure to product liability and other claims in the event that our technologies or products are alleged to have caused harm. These risks are inherent in the testing, manufacturing and marketing of our products. In addition, we began a targeted acquisition strategy during 2004, and our due diligence of acquired companies may fail to reveal material risks relating to product liabilities of such companies. Any product liability claim brought against us could be expensive to defend and could result in a diversion of management's attention from our core business. We may be required to pay substantial damages in connection with any product liability claims. A successful product liability claim or series of claims could have an adverse effect on our business, financial condition and results of operations. Further, we

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

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

We are highly dependent on the principal members of our scientific, manufacturing, marketing, administrative, management and executive personnel, the loss of whose services might significantly delay or prevent the achievement of our objectives. We face competition from other companies, academic institutions, government entities and other organizations in attracting and retaining personnel. For the six months ended June 30, 2007 and twelve months ended December 31, 2006, 2005 and 2004, we experienced turnover rates of 10%, 13%, 17% and 27%, 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 October 2006, we announced a reduction of approximately 15% of our workforce and incurred severance related expenses of approximately \$500,000 in the fourth quarter of 2006. This reduction in force was a combination of selective rehiring of voluntary terminations and planned

separations as we integrated the activities of our various acquisitions. Several of the planned separations did not occur until the first quarter of 2007. 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.*

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;

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;

our 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;

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. *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, may be subject to uncertainty. We expect that our internal controls will continue to evolve as our business activities change. In addition, the acquisitions of SynX and Epoch made during 2004, our minority interest investment in Jurilab in 2005, and the acquisitions of Spectral and Amplimedical in 2006, and any future acquisitions 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, Epoch, Jurilab, Spectral or Amplimedical 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 Global Market, have continued to develop additional regulations and requirements in response to 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.*

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 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 would have a material adverse effect on us.

*We will be dependent upon our agreement with Applied Biosystems for a significant portion of our revenues for 2007 and future periods, and a reduction of sales under or early termination of this agreement would seriously harm our revenues and operating results and would likely cause our stock price to decline.*

In January 1999, Epoch and Applied Biosystems entered into a License and Supply Agreement pursuant to which we licensed some of our technology to Applied Biosystems for use in its TaqMan<sup>®</sup> 5 - nuclease real-time PCR assays, (TaqMan<sup>®</sup> is a registered trademark of Roche Molecular Systems, Inc.). In July 1999, Epoch licensed its proprietary software, which speeds the design of oligonucleotide probes used in the study of genes, to Applied Biosystems. In August 2000, the agreement was amended to, among other things, to provide for Epoch manufacturing the product for Applied Biosystems. In July 2002 this agreement was further amended to remove the manufacturing rights from the contract effective October 2002, redefine product categories, increase the minimum royalties and royalty rates, and establish that minimum royalties are measured and paid quarterly. In January 2006, we renegotiated the contract with Applied Biosystems to maintain minimum quarterly payments through December 31, 2006 and convert to actual royalties thereafter. We will depend upon product sales from Applied Biosystems sales of its TaqMan<sup>®</sup> assays under this agreement for a significant portion of our royalty revenues in 2007 and future periods.

Although we expect this relationship to continue into the foreseeable future this contract can be terminated by Applied Biosystems with a 180 day notice. In the event that this agreement is terminated, our revenues, financial condition and operating results would be adversely affected and our stock price would likely decline.





Our royalty revenues for Applied Biosystems are recorded on an accrual basis based on estimates. These estimates may be materially different than actual results and when tried up in the subsequent quarter could negatively impact our statement of operations.

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

In a series of investments from July 2005 through June 2006, we acquired a minority equity interest in Jurilab of approximately 29% and we hold two of Jurilab's four board of director seats. Our relationship with Jurilab subjects us to numerous risk and uncertainties, including:

we have invested approximately \$3.0 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 operating 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;

subsequent to the quarter end Jurilab received a 2.0 million euro investment from a third party that will reduce our ownership percentage of Jurilab, and remove our ability to acquire them at a fixed price. Additionally, we surrendered one of two board seats held.

*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**

(a) On June 13, 2007, we held our Annual Meeting of Stockholders.

(1) As listed below, management's director nominee was elected at the meeting:

| <b>Name of Nominee</b> | <b>No. of Votes For</b> | <b>No. of Votes Withheld</b> |
|------------------------|-------------------------|------------------------------|
| Heiner Dreismann       | 55,640,715              | 2,567,119                    |

In addition, directors whose terms of office continue after the Annual Meeting are: Howard C. Birndorf, Robert Whalen, Stelios B. Papadopoulos, and David R. Schreiber.

- (2) The proposal to amend the Company's 1997 Stock Incentive Plan to increase the number of shares reserved for issuance by 4,000,000 was approved with 15,941,553 shares voting in favor, 3,443,610 shares voting against, and 161,099 shares abstaining. There were 38,661,572 shares classified as broker non-votes.
- (3) The appointment of Ernst & Young LLP as independent auditors of the Company for the fiscal year ending December 31, 2007 was ratified with 57,299,114 shares voting in favor, 738,654 shares voting against, and 170,066 shares abstaining.

**ITEM 5. OTHER INFORMATION**

Not applicable

**ITEM 6. EXHIBITS**

| <b>Exhibit No.</b> | <b>Description</b>   |
|--------------------|--|
| 10.1               | Amended and Restated 1997 Stock Incentive Plan of Nanogen, Inc. (1)  |
| 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.                     |

- (1) Incorporated by reference to Appendix A of the Company's definitive proxy statement filed on April 30, 2007.

**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.

Date: August 9, 2007

NANOGEN, INC.

/s/ HOWARD C. BIRNDORF

Howard C. Birndorf

*Chairman of the Board and Chief Executive Officer*

Date: August 9, 2007

/s/ ROBERT SALTMARSH

Robert Saltmarsh

*Chief Financial Officer*

**NANOGEN, INC.**

**EXHIBIT INDEX**

## Edgar Filing: NANOGEN INC - Form 10-Q

| <b>Exhibit No.</b> | <b>Description</b>   |
|--------------------|--|
| 10.1               | Amended and Restated 1997 Stock Incentive Plan of Nanogen, Inc. (1)  |
| 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.                     |

(1) Incorporated by reference to Appendix A of the Company's definitive proxy statement filed on April 30, 2007.