

NANOGEN INC  
Form 10-Q  
May 12, 2008  
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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 March 31, 2008

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)

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**Delaware**  
(State or other jurisdiction of  
incorporation or organization)

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

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

**92121**  
(Zip Code)

**(858) 410-4600**  
(Registrant's telephone number, including area code)

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

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

Large Accelerated Filer

Accelerated Filer

Non-Accelerated Filer

Smaller Reporting Company

(Do not check if a smaller reporting company)

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 April 26, 2008, were as follows:

| Class                                     | Number of Shares |
|---|------------------|
| Common Stock, \$0.001 per share par value | 74,459,642       |

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**NANOGEN, INC.**

**QUARTERLY REPORT ON FORM 10-Q**

**FOR THE THREE MONTHS ENDED MARCH 31, 2008**

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**Table of Contents****PART I. FINANCIAL INFORMATION****ITEM 1. Financial Statements****NANOGEN, INC.****CONSOLIDATED BALANCE SHEETS****(in thousands, except par value and share data)**

|  | <b>March 31,<br/>2008</b> | <b>December 31,<br/>2007</b> |
|--|---------------------------|------------------------------|
|  | <b>(Unaudited)</b>        |                              |
| <b>ASSETS</b>  |                           |                              |
| Current assets:  |                           |                              |
| Cash and cash equivalents  | \$ 10,528                 | \$ 5,806                     |
| Short-term investments   | 300                       | 1,450                        |
| Receivables, net   | 17,384                    | 14,821                       |
| Inventories, net   | 2,647                     | 2,267                        |
| Other current assets   | 2,288                     | 1,840                        |
| Total current assets   | 33,147                    | 26,184                       |
| Property and equipment, net  | 7,243                     | 6,662                        |
| Acquired technology rights and intangibles, net  | 14,148                    | 14,905                       |
| Restricted cash  | 9,437                     | 9,626                        |
| Other assets, net  | 1,359                     | 2,011                        |
| Goodwill   | 39,019                    | 38,963                       |
| Total assets   | \$ 104,353                | \$ 98,351                    |
| <b>LIABILITIES AND STOCKHOLDERS EQUITY</b>   |                           |                              |
| Current liabilities:   |                           |                              |
| Accounts payable and accrued liabilities   | \$ 19,383                 | \$ 15,600                    |
| Deferred revenues  | 6,586                     | 663                          |
| Conversion feature of convertible debt   | 4,201                     | 664                          |
| Current portion of assigned royalty interests obligation   |                           | 2,868                        |
| Common stock warrants  | 3,194                     | 1,708                        |
| Current portion of debt obligations  | 6,083                     | 4,868                        |
| Total current liabilities  | 39,447                    | 26,371                       |
| Debt obligations, less current portion   | 14,785                    | 8,139                        |
| Long-term deferred revenues  | 22,492                    |                              |
| Sponsored research payable   | 4,848                     | 4,848                        |
| Long-term assigned royalty interests obligation  |                           | 14,711                       |
| Other long-term liabilities  | 2,871                     | 2,778                        |
| Total long-term liabilities  | 44,996                    | 30,476                       |
| Commitments and contingencies  |                           |                              |
| Stockholders' equity:  |                           |                              |
| Convertible preferred stock, \$0.001 par value, 5,000,000 shares authorized at March 31, 2008 and December 31, 2007; no shares issued and outstanding at March 31, 2008 or December 31, 2007 | 73                        | 73                           |

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|   |                |               |
|---|----------------|---------------|
| Common stock, \$0.001 par value, 135,000,000 shares authorized at March 31, 2008 and December 31, 2007; 73,353,962 and 73,218,128 shares issued and outstanding at March 31, 2008 and December 31, 2007, respectively |                |               |
| Additional paid-in capital  | 441,157        | 440,583       |
| Accumulated other comprehensive income  | 3,029          | 2,237         |
| Accumulated deficit   | (423,578)      | (400,618)     |
| Treasury stock, at cost, 416,027 shares at March 31, 2008 and December 31, 2007   | (771)          | (771)         |
| <br>Total stockholders' equity  | <br>19,910     | <br>41,504    |
| <br>Total liabilities and stockholders' equity  | <br>\$ 104,353 | <br>\$ 98,351 |

See accompanying notes.

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

|   | <b>Three Months Ended<br/>March 31,</b> |                    |
|---|---|--------------------|
|   | <b>2008</b>                             | <b>2007</b>        |
| Revenues:   |   |                    |
| Product sales   | \$ 8,070                                | \$ 6,084           |
| License fees and royalty income   | 1,762                                   | 1,241              |
| Contracts and grants  | 852                                     | 2,328              |
| <b>Total revenues</b>   | <b>10,684</b>                           | <b>9,653</b>       |
| Costs and expenses:   |   |                    |
| Cost of product sales (excluding amortization of purchased intangibles) | 4,838                                   | 4,830              |
| Research and development  | 4,186                                   | 6,512              |
| Selling, general and administrative                                     | 8,727                                   | 8,853              |
| Amortization of purchased intangible assets                             | 934                                     | 767                |
| <b>Total costs and expenses</b>   | <b>18,685</b>                           | <b>20,962</b>      |
| Loss from operations  | (8,001)                                 | (11,309)           |
| Other income (expense):   |   |                    |
| Interest income   | 336                                     | 538                |
| Interest expense  | (1,910)                                 | (1,143)            |
| Other expense   | (229)                                   | (28)               |
| Loss on extinguishment of debt  | (10,221)                                |                    |
| Warrant and conversion rights valuation adjustments                     | (2,911)                                 | 10                 |
| Gain (loss) on foreign currency transactions                            | (26)                                    | 2                  |
| <b>Total other income (expense)</b>                                     | <b>(14,961)</b>                         | <b>(621)</b>       |
| <b>Net loss</b>   | <b>\$ (22,962)</b>                      | <b>\$ (11,930)</b> |
| Net loss per share basic and diluted                                    | \$ (0.31)                               | \$ (0.17)          |
| Number of shares used in computing net loss per share basic and diluted | 73,277                                  | 70,496             |

See accompanying notes.

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

|   | <b>Three Months Ended<br/>March 31,</b> |             |
|---|---|-------------|
|   | <b>2008</b>                             | <b>2007</b> |
| <b>Operating activities:</b>  |   |             |
| Net loss  | \$ (22,962)                             | \$ (11,930) |
| Adjustments to reconcile net loss to net cash used in operating activities:   |   |             |
| Depreciation and amortization   | 1,889                                   | 1,803       |
| Other asset impairment and non-cash charges   | 100                                     | 97          |
| Accretion related to short-term investments   |   | 20          |
| Stock-based compensation expense  | 540                                     | 1,132       |
| Warrant valuation and conversion right adjustment   | 2,911                                   | (10)        |
| Loss on extinguishment of debt  | 10,221                                  |             |
| Accretion of long-term debt   | 717                                     | 81          |
| Increase (decrease) in cash caused by changes in operating assets and liabilities, excluding the effects of acquisitions: |   |             |
| Receivables, net  | (1,683)                                 | (3,081)     |
| Inventories, net  | (263)                                   | 229         |
| Other current and long-term assets  | (1,381)                                 | (241)       |
| Accounts payable and accrued liabilities  | 3,887                                   | 253         |
| Deferred revenue and other long-term liabilities  | 11,564                                  | (109)       |
| Net cash provided by (used in) operating activities   | 5,540                                   | (11,756)    |
| <b>Investing activities:</b>  |   |             |
| Purchase of short-term investments  |   | (12,242)    |
| Proceeds from sale and maturities of short-term investments   | 1,078                                   | 13,700      |
| Acquisition of business, net of cash acquired   |   | (2,001)     |
| Proceeds from the conversion of restricted cash to cash   | 271                                     | 3,103       |
| Purchase of equipment and technology rights   | (1,052)                                 | (746)       |
| Net cash provided by investing activities   | 297                                     | 1,814       |
| <b>Financing activities:</b>  |   |             |
| Principal payments on capital lease obligations   | (147)                                   | (179)       |
| Principal payments on debt obligations  | (80)                                    |             |
| Proceeds from capital lease obligations   |   | 62          |
| Payments on receivable financing  | (1,876)                                 |             |
| Proceeds from debt financing secured by receivables   | 1,828                                   | 296         |
| Principal payments on assigned royalty interests obligation   | (738)                                   | (419)       |
| Proceeds from debt obligations of variable interest entity  |   | 712         |
| Issuance of common stock  |   | 7,069       |
| Net cash provided by (used in) financing activities   | (1,013)                                 | 7,541       |
| Effect of exchange rate changes   | (102)                                   | (49)        |
| Net increase (decrease) in cash and cash equivalents  | 4,722                                   | (2,450)     |

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|  |           |          |
|--|-----------|----------|
| Cash and cash equivalents at beginning of period | 5,806     | 11,261   |
| Cash and cash equivalents at end of period       | \$ 10,528 | \$ 8,811 |

See accompanying notes.



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**NANOGEN, INC.**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (UNAUDITED)**

**March 31, 2008**

**1. Summary of Significant Accounting Policies**

***Organization and Business Activity***

Nanogen, Inc. (the Company) was incorporated in California in November 1991 and, in November 1997, was reincorporated in Delaware. We are in the business of developing, manufacturing, and selling diagnostic products for use in the *in vitro* diagnostic (IVD) market.

***Basis of Presentation***

The accompanying unaudited consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America for interim financial information and with the instructions to Form 10-Q and Article 10 of Regulation S-X. Accordingly, they do not include all of the information and disclosures required by accounting principles generally accepted in the United States of America for complete financial statements. The consolidated balance sheet as of March 31, 2008, consolidated statements of operations for the three months ended March 31, 2008 and 2007, and the consolidated statements of cash flows for the three months ended March 31, 2008 and 2007 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 months ended March 31, 2008 shown herein are not necessarily indicative of the results that may be expected for the year ending December 31, 2008.

The Company has incurred net losses of \$23.0 million, for the three months ended March 31, 2008, and has an accumulated deficit of \$423.6 million as of March 31, 2008. Based on the Company's operating plan, its existing working capital is not sufficient to meet the cash requirements to fund the Company's planned operating expenses, capital expenditures, and working capital requirements through December 31, 2008 without additional sources of cash and/or the deferral, reduction or elimination of significant planned expenditures.

These factors raise substantial doubt about the Company's ability to continue as a going concern. 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's plan to address the expected shortfall of working capital is to generate additional financing through a combination of financing sources (in addition to the monetization of intellectual property disclosed in Note 8), equity, or debt, and incremental product sales. If the Company is unsuccessful in raising sufficient additional capital from any of these sources, it will have to defer, reduce, or eliminate certain planned expenditures. The Company will continue to consider other financing alternatives. There can be no assurance that the Company will be able to obtain any sources of financing on acceptable terms, or at all.

If the Company cannot obtain sufficient additional financing in the short-term, it will be forced to restructure or significantly curtail its operations, file for bankruptcy or cease operations. The consolidated financial statements do not include any adjustments relating to the recoverability and classification of recorded asset amounts or amounts and classification of liabilities that might be necessary should the Company be forced to take any such actions.

The accompanying consolidated financial statements include the accounts of the Company and all of the subsidiaries. Intercompany transactions and balances are eliminated in consolidation.

For more complete financial information, these financial statements, and notes thereto, should be read in conjunction with the audited consolidated financial statements included in the Nanogen, Inc. Annual Report on Form 10-K for the year ended December 31, 2007 filed with the Securities and Exchange Commission on March 31, 2008.

***Basis of Consolidation***

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These consolidated financial statements and the accompanying notes relate to Nanogen, Inc. and its consolidated subsidiaries which include the following:

*Nanogen Point-of-Care, Inc.:* includes assets purchased from SynX Pharma ( SynX ) on April 21, 2004, and from Spectral Diagnostics ( Spectral ) on February 6, 2006.

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

*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.

In addition, we have several other legal entities which are included in the consolidation, but collectively they are not material.

### ***Variable Interest Entities***

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 FASB Interpretation No. 46R, *Consolidation of Variable Interest Entities, an Interpretation of ARB No. 51*, ( FIN 46(R) ) we determined we were the primary beneficiary and were 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. In July 2007, a reconsideration event occurred as a result of Jurilab obtaining new equity financing from a third party. We have determined that under FIN 46(R), we no longer qualify as the primary beneficiary as a result of the new equity financing and therefore no longer consolidate Jurilab s assets and liabilities in our financial statements. The results of Jurilab s operations through the date of the reconsideration event are included in our consolidated results of operations.

### ***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 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 EITF Issue No. 00-21, *Accounting for Revenue Arrangements with Multiple Deliverables*, ( EITF 00-21 ) 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 through various distribution channels.

Revenue from product sales 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) 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 payment streams are one of the primary indicators of our customer s perceived useful life of the technology

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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.

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Royalty payments that are based on product sales by the licensees are generally not determinable until the licensee has completed their internal computations of the royalties due and/or remitted their cash payment. Therefore, we will recognize revenue tied to third party sales on an accrual basis if information is available to enable us to accurately estimate the royalty due to us. In certain situations we may not be able to receive information on licensee product sales on a timely basis that will allow us to reasonably estimate the amount of royalty revenue to be recognized in the quarter the third party sales take place. We will not recognize this royalty revenue until we are able to ensure that we have reliable information, which maybe in a subsequent period. Therefore, we could experience fluctuations in revenues from quarter to quarter depending on the timing of the receipt of third party sales reports or cash payments.

### *Contract and grant revenue*

We earn revenue for performing tasks under research agreements with both private enterprises and governmental agencies. Contract and grant revenue is recorded as the costs and expenses to perform the research are incurred. Continuation of certain 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*

Quarterly we assess our long-lived assets (excluding goodwill) for indicators of impairment using the methodology prescribed in SFAS No. 144, *Accounting for the Impairment or Disposal of Long-Lived Assets*. During our assessments, if there are indicators of impairment related to our long-lived assets, we are required to determine that the carrying value of the assets can be recovered through undiscounted future cash flows. If the carrying value of the asset can not be recovered, we are required to write down the value of the long-lived asset to its fair value. We had no impairment losses in the three months ended March 31, 2008 and 2007.

### *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.

### *Recent Accounting Pronouncements*

In September 2006, the Financial Accounting Standards Board ( FASB ) issued Statement of Financial Accounting Standards No. 157, Fair Value Measurements ( SFAS No. 157 ). SFAS No. 157 provides guidance for using fair value to measure assets and liabilities. It also responds to investors' request for expanded information about the extent to which companies measure assets and liabilities at fair value, the information used to measure fair value, and the effect of fair valued measurements on earnings. SFAS No. 157 applies whenever standards require (or permit) assets or liabilities to be measured at fair value, and does not expand the use of fair value in any new circumstances. SFAS No. 157 is effective for financial assets and liabilities in financial statements issued for fiscal years beginning after November 15, 2007.

The Company adopted this statement for financial assets and liabilities measured at fair value effective January 1, 2008. There was no financial statement impact as a result of adoption. In accordance with the guidance of FASB Staff Position No. 157-2, the Company has postponed adoption of the standard for non-financial assets and liabilities that are measured at fair value on a non-recurring basis, until the fiscal year beginning after November 15, 2008. The Company does not anticipate adoption will have a material impact on its consolidated financial position, results of operations or liquidity. See Note 9 for more information.

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In February 2007, the FASB issued SFAS No. 159, *The Fair Value Option for Financial Assets and Financial Liabilities* including an amendment of FASB Statement No. 115 (SFAS No. 159). SFAS No. 159 expands the use of fair value accounting but does not affect existing standards that require assets or liabilities to be carried at fair value. Under SFAS No. 159, a company may elect to use fair value to measure accounts and loans receivable, equity method investments, accounts payable, guarantees and issued debt. Other eligible items include firm commitments for financial instruments that otherwise would not be recognized at inception and non-cash warranty obligations where a warrantor is permitted to pay a third party to provide the warranty goods or services. If the use of fair value is elected, any upfront costs and fees related to the item must be recognized in earnings and cannot be deferred (e.g., debt issue costs). The fair value election is irrevocable and generally made on an instrument-by-instrument basis, even if a company has similar instruments that it elects not to measure based on fair value. At the adoption date, unrealized gains and losses on existing items for which fair value has been elected are reported as a cumulative adjustment to beginning retained earnings. Subsequent to the adoption of SFAS No. 159, changes in fair value are recognized in earnings. SFAS No. 159 is effective for fiscal years beginning after November 15, 2007.

The Company adopted this statement effective January 1, 2008. During the first quarter of 2008, the Company did not elect fair value as an alternative measurement for any financial instruments not previously carried at fair value.

In December 2007, the FASB issued SFAS No. 141 (Revised 2007), *Business Combinations* (SFAS No. 141 (Revised 2007)). SFAS No. 141 (Revised 2007) changes how a reporting enterprise accounts for the acquisition of a business. SFAS No. 141 (Revised 2007) requires an acquiring entity to recognize all the assets acquired and liabilities assumed in a transaction at the acquisition-date fair value, with limited exceptions, and applies to a wider range of transactions or events. SFAS No. 141 (Revised 2007) is effective for fiscal years beginning on or after December 15, 2008 and early adoption and retrospective application is prohibited. The Company does not expect the adoption of this statement will have a material impact on its financial statements.

In December 2007, the FASB issued SFAS No. 160, *Noncontrolling Interests in Consolidated Financial Statements: an Amendment to ARB No. 51* (SFAS No. 160). SFAS No. 160 establishes new accounting and reporting standards for the noncontrolling interest in a subsidiary and for the deconsolidation of a subsidiary. Specifically, it requires the recognition of a noncontrolling interest as equity in the consolidated financial statements which will be separate from the parent's equity. SFAS No. 160 is effective for fiscal years and interim periods in those fiscal years beginning on or after December 15, 2008 and early adoption is prohibited. The Company does not expect the adoption of this statement will have a material impact on its financial statements.

In March 2008, the FASB issued SFAS No. 161, *Disclosures about Derivative Instruments and Hedging Activities* an amendment of FASB Statement No. 133 (SFAS 161). This Standard requires enhanced disclosures regarding derivatives and hedging activities, including: (a) the manner in which an entity uses derivative instruments; (b) the manner in which derivative instruments and related hedged items are accounted for under SFAS No. 133, *Accounting for Derivative Instruments and Hedging Activities*; and (c) the effect of derivative instruments and related hedged items on an entity's financial position, financial performance, and cash flows. The Standard is effective for financial statements issued for fiscal years and interim periods beginning after November 15, 2008. As SFAS 161 relates specifically to disclosures, the Standard will have no impact on the Company's results of operations or financial position.

**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<br>March 31, |             |
|--|---------------------------------|-------------|
|  | 2008                            | 2007        |
|  | (Unaudited)                     | (Unaudited) |
| Comprehensive loss:  |                                 |             |
| Net unrealized gain / (loss) on short-term investments and other investments | \$ 29                           | \$ (4)      |
| Foreign currency translation adjustment                                      | 764                             | (49)        |
| Net loss   | (22,962)                        | (11,930)    |
| Comprehensive loss   | \$ (22,169)                     | \$ (11,983) |



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**3. Commitments and Contingencies**

*Restricted Cash*

We have restricted cash representing cash, cash equivalents and short term investments. \$7.3 million of restricted cash is security for our convertible debt obligation and the balance is pledged in lieu of cash deposits primarily for facility lease deposits. Restricted cash balances were approximately \$9.4 million and \$9.6 million at March 31, 2008 and December 31, 2007, 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 the disposition of product lines such as the micro array. These matters 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 March 31, 2008. We have no significant accrual for any pending claims.

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

*Debt Obligations*

In August 2007, we entered into a definitive agreement for the sale and issuance of \$20 million in aggregate principal amount of unsecured senior convertible notes ( Notes ) which were convertible initially into an aggregate of up to 15,748,030 shares of our common stock. In addition, upon conversion we are required to issue an additional number of shares representing present value of future interest. The Notes bear interest at 6.25% per annum and interest is accrued and payable on a quarterly basis. Any portion of the Notes and all accrued but unpaid interest which is not converted are repayable in cash in August 2010. The Notes were issued in our debt financing transaction (the August 2007 Debt Financing ) pursuant to the Indenture, dated August 27, 2007, between us and The Bank of New York Trust Company, N.A. as trustee (the Trustee ), as modified by the First Supplemental Indenture, dated August 27, 2007 between us and the Trustee (the Indenture ).

On March 13, 2008, we entered into an Amendment and Exchange Agreement (the Exchange Agreement ) with holders (the Holders ) of the Notes. Pursuant to the Exchange Agreement, the Holders exchanged an aggregate \$12,917,000 in principal amount of the Notes (the Exchange Offer ) with our 9.75% Senior Secured Convertible Notes due 2010 (the New Notes ) with an aggregate principal amount of \$15,500,400. The New Notes are convertible initially into an aggregate of 22,784,653 shares of common stock of our common stock at an initial conversion price of \$0.6803 per share. The Exchange Offer is made pursuant to an exemption from registration requirement under Section 3(a)(9) of the Securities Act of 1933, as amended (the Act ). Neither the New Notes nor shares of Common Stock eligible for issue upon conversion of the New Notes are registered under the Act.

Upon consummation of the Exchange Offer, Notes in an aggregate principal amount of \$7,000,000 remained outstanding under the Indenture. Upon closing of the Exchange Offer, the conversion price of remaining Notes and the exercise prices of certain warrants issued to the Holders in the August 2007 Debt Financing were adjusted, in accordance with the terms of the documents governing the securities, to an amount equal to \$0.6803. In addition, we agreed to pay Holders certain tax gross up payments and legal fees incurred as a result of the Exchange Offer in the amount of \$448,000.

In December 2006, we obtained a revolving working capital debt facility for up to approximately \$5.2 million secured by our Italian accounts receivable. As of March 31, 2008, our outstanding liability is \$4.7 million under this agreement.

We have entered into various debt obligations to provide financing for equipment purchases. There was no additional borrowing available under these agreements as of March 31, 2008. The interest rates on the outstanding notes range from 10.0% to 11.5% per annum with principal and interest due in monthly aggregated payments of approximately \$56,000 maturing in 1 to 3 years and are secured by the specific equipment being financed.



**Table of Contents****4. Financial Statement Details*****Receivables***

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

|                                 | <b>March 31,<br/>2008<br/>(Unaudited)</b> | <b>December 31,<br/>2007</b> |
|---------------------------------|---|------------------------------|
| Product                         | \$ 15,788                                 | \$ 11,996                    |
| License fees                    |   | 1,100                        |
| Contract and grant              | 1,910                                     | 1,993                        |
|                                 | 17,698                                    | 15,089                       |
| Allowance for doubtful accounts | (314)                                     | (268)                        |
|                                 | \$ 17,384                                 | \$ 14,821                    |

***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:

|                                     | <b>March 31,<br/>2008<br/>(Unaudited)</b> | <b>December 31,<br/>2007</b> |
|-------------------------------------|---|------------------------------|
| Raw materials                       | \$ 5,914                                  | \$ 6,084                     |
| Work in process                     | 789                                       | 529                          |
| Finished goods                      | 4,689                                     | 4,813                        |
|                                     | 11,392                                    | 11,426                       |
| Reserve for excess and obsolescence | (8,745)                                   | (9,159)                      |
|                                     | \$ 2,647                                  | \$ 2,267                     |

***Other long-term liabilities***

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

|               | <b>March 31,<br/>2008<br/>(Unaudited)</b> | <b>December 31,<br/>2007</b> |
|---------------|---|------------------------------|
| Deferred rent | \$ 1,823                                  | \$ 1,906                     |
| Other         | 1,048                                     | 872                          |

|  |          |          |
|--|----------|----------|
|  | \$ 2,871 | \$ 2,778 |
|--|----------|----------|

**Long-term debt***Convertible notes payable*

The convertible debt, detachable warrant and conversion rights liabilities (in thousands) are disclosed below:

|   | <b>March 31,<br/>2008<br/>(Unaudited)</b> | <b>December 31,<br/>2007</b> |
|---|---|------------------------------|
| <b>Current Liabilities:</b>   |   |                              |
| Detachable warrants   | \$ 2,990                                  | \$ 1,708                     |
| Conversion feature related to convertible debt  | 4,201                                     | 664                          |
| Convertible senior secured 9.75% note payable in August 2010  | 1,014                                     |                              |
| <b>Long Term Liabilities:</b>   |   |                              |
| Convertible senior subordinated notes payable in August 2010 at interest rate of 6.25%, net of discount | \$ 3,001                                  | \$ 7,824                     |
| Convertible senior secured notes payable in August 2010 at interest rate of 9.75%, net of discount      | \$ 11,549                                 | \$                           |

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*9.75% Senior Secured Convertible Notes*

On March 13, 2008, we entered into an Exchange Agreement with the Holders of our 6.25% Senior Convertible Notes due 2010 issued on August 27, 2007. Pursuant to the Exchange Agreement, the Holders exchanged an aggregate \$12,917,000 in principal amount of the Notes with our New Notes with an aggregate principal amount of \$15,500,400. The New Notes are convertible initially into an aggregate of 22,784,653 shares of common stock of our common stock at an initial conversion price of \$0.6803 per share. The Exchange Offer was made pursuant to an exemption from registration requirement under Section 3(a)(9) of the Securities Act of 1933, as amended (the Act). Neither the New Notes nor shares of Common Stock eligible for issue upon conversion of the New Notes are registered under the Act.

Upon consummation of the Exchange Offer, Notes in an aggregate principal amount of \$7,000,000 remained outstanding under the Indenture. Upon closing of the Exchange Offer, the conversion price of remaining Notes and the exercise prices of certain warrants issued to the Holders in the August 2007 Debt Financing were adjusted, in accordance with the terms of the documents governing the securities, to an amount equal to \$0.6803. In addition, we agreed to pay Holders certain tax gross up payments and legal fees incurred as a result of the Exchange Offer.

In connection with the Exchange Offer, on March 13, 2008, we and each Holder entered into a consent and agreement, pursuant to which each Holder consented to a potential sale of certain royalties, effective upon the closing of the Exchange Offer (Consent and Agreement). The Consent and Agreement also approves a second supplemental indenture entered into by us and the Trustee on or prior to closing of the Exchange Offer, for the purpose of making certain technical amendments to the Indenture in order permit us to consummate the potential sale of certain royalties, and to revise the terms in the Indenture, including certain covenants, in order to conform to the terms of the New Notes.

To secure our obligations under the New Notes, we entered into a security agreement pursuant to which we granted a security interest in substantially all of our assets and stock. Certain assets are excluded from such security interest, including (i) more than 65% of capital stock of foreign subsidiaries of the Company; (ii) Amplimedical receivables subject to a factoring agreement; (iii) intellectual property assets securing our obligations and obligations of our subsidiaries under certain royalty assignment transactions; (iv) cash collateral securing the letter of credit for the benefit of Holders, and (v) assets covering certain permitted liens set forth in the terms of the New Notes. The Security Agreement contains customary representations, warranties and covenants.

As of March 31, 2008, we recorded \$126,000 in interest expense relating to the 9.75% coupon rate and the amortization of the financing costs. The financing costs of \$398,000 are being amortized into interest expense over the term of the New Notes.

Under EITF 96-19, we have determined that the modification of the original definitive agreement was substantial since the discounted cash flows that would have occurred under the modified portion of the Notes differed by greater than 10% from the discounted cash flows associated with the New Notes. Thus the modification of debt under the Exchange Agreement should be accounted for as an extinguishment of debt.

Per APB 26, the difference between the modified debt principal amount, \$15.5 million, and the net carrying amount of the extinguished debt, \$5.5 million, was recorded as a loss on extinguishment of debt in the first quarter of 2008. In addition, a pro-rata share of unamortized debt issuance costs, \$964,000, associated with the Notes was recognized in the same manner. These losses were offset by the write-off of a pro-rata share of the conversion rights, \$703,000, associated with the extinguished debt.

We evaluated the New Notes to determine if the embedded components of those contracts qualify as derivatives to be separately accounted for under SFAS 133, and related interpretations including EITF 00-19. As a result of this evaluation, we have identified the conversion rights as a derivative financial instrument that is required to be recorded as a liability.

Upon closing the Exchange Offer, the fair value of the conversion rights of the New Notes of \$2.8 million were separated from the host debt contract and recorded as a derivative liability which resulted in a reduction of the initial notional carrying amount of the New Note as unamortized discount which will be accreted over the term of the New Notes using the effective interest method.

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The fair value of the embedded derivative will be accounted for in a similar manner to the embedded derivatives that are associated with the original unsecured senior 6.25% convertible notes.

The holders of the New Notes have full-ratchet anti-dilution protection initially for a certain period from the date of funding and weighted average anti-dilution thereafter. Upon conversion of the New Notes whether at our election or the debt holders' election, we are also required to pay the present value of the future interest payments that would have been made if the conversion had not occurred ( "Make Whole Payments" ).

*6.25% Unsecured Senior Convertible Notes*

In August 2007, we entered into a definitive agreement for the sale and issuance of \$20 million in aggregate principal amount of Notes which were convertible initially into an aggregate of up to 15,748,030 shares of our common stock. The Notes bear interest at 6.25% per annum and interest is accrued and payable on a quarterly basis. Upon conversion whether at our election or the debt holders' election, we are also required to pay the present value of the future interest payments that would have been made if the conversion had not occurred ( "Make Whole Payments" ). We received net proceeds of approximately \$18.5 million from the sale of the Notes and warrants after deducting the placement agent fees and estimated offering expenses of \$1.5 million. \$7.3 million of the proceeds of the Notes has been restricted until our stock price reaches \$1.52.

The holders of the Notes have full-ratchet anti-dilution protection for the eighteen months from the date of funding and weighted average anti-dilution thereafter. In March 2008, the conversion price of the Notes and exercise prices of related warrants were adjusted to \$0.6803 per share pursuant to the terms of the Exchange Offer.

If, at any time after the twenty-four-month anniversary of the issuance date of the Notes, the last closing sale price of our common stock exceeds \$2.22 for any twenty out of thirty consecutive trading days, we have the right, subject to compliance with certain conditions, to require the holders of the Notes to convert all or any portion of the conversion amount of the Notes into shares of our common stock at the then applicable conversion price, subject to certain limitations on beneficial ownership.

The maturity date of the Notes is August 27, 2010, subject to extension for an additional two-year period with respect to any amounts not converted as of the initial maturity date due to limitations on beneficial ownership. The Notes are not secured by any of our assets or assets of our subsidiaries, except that we have agreed to obtain a \$7.3 million letter of credit. We have deposited \$7.3 million in a trust as collateral on this letter of credit.

The Notes contain customary events of default provisions, including without limitation related to failure to pay principal or interest when due, suspension from trading, failure to cure conversion failures or maintain sufficient shares of common stock available for conversion, breaches of covenants, breaches of material representations, failure to repay certain indebtedness exceeding \$250,000, the occurrence of bankruptcy or similar events, defaults under our agreements, and the rendering of a final judgment in excess of \$500,000 not covered by insurance. From and during the occurrence of an event of default (as defined in the Notes), the interest rate under the Notes will increase to 12.0% per annum.

The notes contain provisions, that in connection with a change of control transaction, the holders of the Notes will have the right to require us to redeem all of their Notes at a redemption price in cash.

We have agreed, for so long as any Notes or related warrants remain outstanding, that we will not issue or sell, subject to certain exceptions, securities with a conversion or exercise price that varies from the market price of our common stock. In addition, we have agreed that we will not incur additional indebtedness other than in connection with existing indebtedness or other permitted indebtedness, grant liens on our assets other than certain ordinary permitted liens, or make distributions on or repurchase shares of our common stock.

We evaluated the Notes and detachable warrants to determine if these contracts or embedded components of those contracts qualify as derivatives to be separately accounted for under SFAS 133, and related interpretations including EITF 00-19. As a result of this evaluation, we identified the detachable warrants and the conversion rights as derivative financial instruments and are required to be recorded as liabilities.

In August 2007, we allocated the proceeds received from the Notes between the underlying debt instruments, conversion rights, and the detachable warrants. At inception, the fair value of the detachable warrants of \$6.4 million and the conversion rights of \$6.6 million were separated from the host debt contract and recorded as a derivative liability which resulted in a reduction of the initial notional carrying amount of the Notes as unamortized discount which will be accreted over the term of the Notes using the effective interest method. In the first quarter of 2008, we have recorded \$717,000 non-cash interest expense relating to the accretion of this discount.



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The result of this accounting treatment is that the fair value of the embedded derivative is marked-to-market each balance sheet date and recorded as a liability. The change in fair value is recorded in the statement of operations as Change in fair value of the detachable warrants and conversion right. Upon conversion or exercise of a derivative instrument, the instrument is marked to fair value at the conversion date and then that fair value is reclassified to equity.

The fair value of these warrants on the Notes, and the conversion rights on the Notes and the New Notes are primarily affected by our stock price, but are also affected by our stock price volatility, expected life and interest rates. We recorded approximately \$2.9 million of other expense in the first quarter of 2008 related to the change in the fair value of the warrants and the conversion feature on the Notes. This change in fair value was driven by the adjustment of the conversion price of the Notes and the exercise price of the warrants in connection with the consummation with the Exchange Offer as well as by the effect of the increase in our stock price from the end of 2007 to the end of the quarter. Assuming our stock volatility, expected life and the interest rates remain constant, the fair value of the warrants would and we would recognize a charge to earnings if the price of our stock increases. If the price of our stock decreases and our stock price volatility expected life and the risk-free interest rates remain constant, the fair value of the warrants will decrease and we will recognize income.

As of March 31, 2008, we recorded \$283,000 in interest expense on the Notes relating to the 6.25% coupon rate and the amortization of the financing costs. As a result of the Exchange agreement, we charged \$913,000 of financing costs relating to the Notes to loss on extinguishment of debt. The remaining financing costs of \$495,000 are being amortized into interest expense over the term of the remaining Notes. Amortization of financing costs recorded in the first quarter of 2008 totaled \$90,000.

## **5. Stock Award Activity**

### ***Stock Option Grants***

Approximately 1,361,392 stock options subject to time based vesting were granted during the three months ended March 31, 2008, and the weighted average estimated fair value of stock options granted during the same period was \$0.30 per share. At March 31, 2008, total unrecognized estimated compensation cost related to non-vested stock options was \$2.9 million, excluding options with performance-based vesting, and is expected to be recognized over a weighted-average period of 3.36 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, and in March 2008 we issued 1,860,000 performance options. These options vest if 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 March 31, 2008, we have evaluated the probability and timing of vesting of these options, and recorded \$12,000 in expense during the first quarter of 2008 as a result. We will continue to evaluate the probability of each performance option vesting and, if required, continue expensing the fair value of the awards. The compensation expense for the performance options is recorded based on the probability that the performance criteria will be met. The recognition of compensation expense associated with performance-based grants requires judgment in assessing the probability of meeting the performance goals, as well as defined criteria for assessing achievement of the performance related goals. The continued assessment of probability may result in additional expense recognition or expense reversal, dependent upon the level of achievement of a performance goal. The grant date fair value of each December 2006 option was \$1.77, each June 2007 option was valued at \$1.02, and each March 2008 option was \$0.30. As of March 31, 2008, there is an aggregate unrecognized compensation expense of \$4.1 million related to performance options.

### ***Restricted Stock Units***

As of March 31, 2008, we had 205,000 non-vested restricted stock units that were granted to employees in previous years outstanding with a weighted-average grant date fair value of \$3.16 and an aggregated unrecognized compensation expense of \$486,000.

### ***Employee Stock Purchase Plan***

In 1997, the Board of Directors approved the Employee Stock Purchase Plan ( ESPP ), as amended, under which 1.6 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 three months ended March 31, 2008, no shares were issued under the ESPP plan.



**Table of Contents****Share-Based Payments**

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

|  | <b>Three Months<br/>Ended March 31,</b> |             |
|--|---|-------------|
|  | <b>2008</b>                             | <b>2007</b> |
| Cost of product sales                  | \$ 26                                   | \$ 87       |
| Research and development               | 127                                     | 272         |
| Selling, general and administrative    | 387                                     | 773         |
| Total stock-based compensation expense | \$ 540                                  | \$ 1,132    |

**6. Related Party Transaction****Consulting Agreement with Board Member**

In October 2006, we signed a consulting agreement with Mr. Dreismann, one of our Board members. Mr. Dreismann received \$15,000 in compensation under this agreement in the three months ended March 31, 2008. Total compensation under the agreement is capped at a maximum of \$60,000 per year.

**Fisher Development Agreement**

In February 2008, we entered into a distribution and license agreement with Fisher under which we will provide certain distribution and technology access rights to Fisher. As part of the agreement, Fisher has agreed to fund a development program related to the development, manufacture and marketing of new molecular testing products on a cost incurred based. Upon commercial launch of the new products, Fisher has agreed to certain minimum purchases over a six-year period.

**7. Stock Transaction**

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, on a best efforts basis, to certain institutional investors. We agreed to pay a placement agent fee in an amount equal to 5% of the gross cash proceeds of the offering. Under this agreement and related purchase agreements with the investors, in February 2007 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 \$7.2 million.

**8. Assignment of Royalties**

In September 2006, the Company entered into an agreement with Drug Royalty LP2 ( DRT ) under which we assigned rights to a royalty stream due to us from Applied Biosystems, Inc (ABI) under a license agreement. through December 31, 2011 in exchange for an up-front cash payment from DRT of \$20,000,000 (Royalty Agreement). In connection with the Royalty Agreement, we were required to make payments to DRT if the royalties assigned to DRT did not exceed certain minimum annual amounts. In 2006 we recorded the \$20 million payment as a liability. We continued to record revenue for amounts received from ABI under the license agreement. We recorded interest expense and a reduction of the liability to DRT as the payments we received from ABI under the license agreement were remitted to DRT under the Royalty Agreement. As of March 28, 2008, the carrying value of our liability to DRT under the Royalty Agreement was approximately \$17,600,000.

On March 28, 2008, we entered into a Supplemental Royalty Interest Assignment Agreement with DRT ( Supplemental DRT Agreement ). This agreement revised certain terms in the Royalty Agreement. Under the Supplemental DRT Agreement we are no longer required to make minimum payments to DRT.

On March 28, 2008, we entered into a new royalty interest assignment agreement (2008 Royalty Interest Assignment Agreement) with DRT in which we received an up-front payment of \$9.9 million, net of transaction costs, in exchange for assigning the royalty rights under the same



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license agreement with ABI to DRT for the period of January 1, 2012 through the end of our license agreement with ABI.

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Under the Supplemental Royalty Agreement and the 2008 Royalty Interest Assignment Agreement we have certain ongoing obligations to DRT through the end of the term of these agreements. Accordingly, we have deferred the recognition of revenue under these agreements and will recognize revenue under these agreements ratably through the end of the term of these agreements.

Under the Supplemental Royalty Agreement and 2008 Royalty Interest Assignment Agreement, we have agreed to certain covenants including but not limited to prosecution and maintenance of the patent, and using our best efforts to find a replacement agreement should this become necessary.

### **9. Fair Value Measurement**

We adopted SFAS No. 157 effective January 1, 2008 for financial assets and liabilities measured at fair value. SFAS No. 157 defines fair value, expands disclosure requirements around fair value and specifies a hierarchy of valuation techniques based on whether the inputs to those valuation techniques are observable or unobservable. Observable inputs reflect market data obtained from independent sources, while unobservable inputs reflect our market assumptions. These two types of inputs create the following fair value hierarchy:

Level 1 Quoted prices for identical instruments in active markets.

Level 2 Quoted prices for similar instruments in active markets; quoted prices for identical or similar instruments in markets that are not active; and model-derived valuations in which all significant inputs and significant value drivers are observable in active markets.

Level 3 Valuations derived from valuation techniques in which one or more significant inputs or significant value drivers are unobservable.

This hierarchy requires us to use observable market data, when available, and to minimize the use of unobservable inputs when determining fair value. A financial instrument's categorization within the valuation hierarchy is based upon the lowest level of input that is significant to the fair value measurement.

#### ***Determination of fair value***

We measure fair value using the procedures set out below for all assets and liabilities measured at fair value. When available, we generally use quoted market prices to determine fair value, and classifies such items in Level 1. If quoted market prices are not available, fair value is based upon internally developed valuation techniques that use, where possible, current market-based or independently sourced market parameters. Items valued using such internally generated valuation techniques are classified according to the lowest level input or value driver that is significant to the valuation. Thus, an item may be classified in Level 3 even though there may be some significant inputs that are readily observable.

Following is a description of our valuation methodologies used for instruments measured at fair value, as well as the general classification of such instruments pursuant to the valuation hierarchy. Where appropriate, the description includes details of the valuation models, the key inputs to those models, as well as any significant assumptions.

#### ***Assets and liabilities measured at fair value on a recurring basis:***

##### ***Short-term investments***

The short-term investments category on our consolidated balance sheets includes available-for-sale debt securities. Our entire balance in short-term investments at March 31, 2008 consists of auction rate securities which were valued using significant unobservable inputs, and therefore are listed below under the Level 3 valuation category. Our common stock warrants liabilities, as well as the conversion feature of convertible debt also uses significant unobservable inputs and thus shown as a Level 3 hierarchy items.



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The following table presents the financial instruments carried at fair value, by caption on the consolidated balance sheet and by SFAS No. 157 valuation hierarchy (as described above) as of March 31, 2008 (in thousands):

|  | Quoted prices in<br>active markets for<br>identical<br>assets<br>(Level 1) | Significant other<br>observable inputs<br>(Level 2) | Significant<br>unobservable<br>inputs<br>(Level 3) | Total value in<br>consolidated<br>balance |
|--|--|---|--|---|
| Short-term investments                 | \$   | \$  | \$ 300   | \$ 300                                    |
| Total assets at fair value             | \$   | \$  | \$ 300   | \$ 300                                    |
| Common stock warrants                  | \$   | \$  | \$ 3,194   | \$ 3,194                                  |
| Conversion feature of convertible debt |  |   | 4,201  | 4,201                                     |
| Total liabilities at fair value        | \$   | \$  | \$ 7,395   | \$ 7,395                                  |

**Assets and liabilities measured at fair value on a non-recurring basis:**

Certain assets and liabilities are measured at fair value on a non-recurring basis and therefore are not included in the table above. Such instruments are not measured at fair value on an ongoing basis but are subject to fair value adjustments in certain circumstances (for example, when there is evidence of impairment).

**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 thereto in our Annual Report on Form 10-K for the year ended December 31, 2007.*

**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 supplement to and should be read in conjunction with our annual report on Form 10-K, and our quarterly 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, 2008.

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*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, 2008.

*Results of Operations* an analysis of our consolidated results of operations for the three months ended March 31, 2008 and March 31, 2007, as presented in our 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 consolidated financial statements, to provide the reader an understanding of how these decisions materially effected the results of operations.

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**Summary:**

Subsequent to December 31, 2007, the following significant business developments occurred:

On March 28, 2008 we entered into an agreement with DRT for DRT to purchase for \$10 million all future royalties generated by Applied Biosystems (ABI) under a license ABI has taken from us for use of the MGB technology (minor groove binder technology). This agreement revised certain terms in the original assignment of royalty interests to DRT which was entered into in September 2006 related to the same license agreement with Applied Biosystems, Inc. whereby we received \$20 million for the assignment of royalty rights through December 31, 2011.

On March 14, 2008 we announced that we entered into agreements with the holders of our 6.25% Convertible Notes due 2010 (the Notes) issued on August 27, 2007 to restructure the indebtedness. In the restructuring, the Holders exchanged an aggregate of \$12.9 million in principal amount of the Notes with the Company's 9.75% Senior Secured Convertible Notes due 2010 with an aggregate principal amount of \$15.5 million. The 9.75% Senior Secured Convertible Notes are convertible initially into an aggregate of approximately 22,784,000 shares of common stock of the Company at an initial conversion price of \$0.6803 per share. The terms of the 9.75% Senior Secured Convertible Notes provide for the mandatory payment of the principal in specified periodic installments as well upon certain asset disposition and financing transactions. An aggregate of \$7.0 million will remain outstanding under the Notes, secured by a \$7.0 million letter of credit. In connection with the restructuring, we granted a collateral agent on behalf of the holders of the 9.75% Senior Secured Convertible Notes a security interest in substantially all of the assets of the Company. Upon closing of the restructuring, the conversion price of the remaining Notes and the exercise prices of related warrants issued in the August 2007 debt financing were adjusted to \$0.6803.

On February 19, 2008 we entered into an employment agreement with Nicholas Venuto regarding the terms of Mr. Venuto's employment with us. Mr. Venuto was appointed the Vice President and Chief Financial Officer of the Company on December 14, 2007 with an effective date of February 29, 2008.

In February 2008, we entered into a distribution and license agreement with Thermo Fisher, Inc. (Fisher) under which we will provide certain distribution and technology access rights to Fisher. As part of the agreement, Fisher has agreed to fund a development program related to the development, manufacture and marketing of new molecular testing products on a cost incurred basis. Upon commercial launch of the new products, Fisher has agreed to certain minimum purchases over a six-year period.

**Our business:**

We are a diagnostics company with the mission to make the diagnosis, and treatment and monitoring of an individual's health easier and faster. We were founded on innovative research and technology development and have been in business since 1993. We have been publicly traded on NASDAQ (symbol: NGEN) since 1998.

During 2007, we significantly restructured our operations. In the fourth quarter of 2007, we decided to eliminate one of our three product lines, the micro array platform, and focus on products and technologies we acquired in the past four years. Although the micro array platform was technologically a success, the market for highly complex molecular testing has remained small and we can no longer support this product line as we wait for the market to grow.

While our consolidated revenue has been growing, we recognize the need to reduce our expenses in order to dramatically accelerate our path to profitability. By making the difficult decision to discontinue the micro array platform, we will be able to enhance financial performance and predictability. We expect that this restructuring will improve operational performance by at least \$15 million in annual cash. Despite the loss of micro array revenue, we expect our 2008 revenues to significantly exceed our 2007 revenues.

In 2008 and beyond, we will continue to participate in two large and growing markets. The first is the molecular diagnostics market where we offer assays for real-time polymerase chain reaction (PCR) applications. The second is the point-of-care (POC) market where we offer rapid immunoassay tests for cardiac emergency care. Both are ready markets that our customers understand and participate in today, as opposed to the micro array market which was a new market that required significant education and training of potential customers. Products in the molecular

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diagnostics and POC markets were developed by us and incorporate proprietary technologies that improve product performance and competitiveness, and are supported by a strong patent portfolio.

We operate in the United States, Canada and Europe and have grown rapidly in the past four years through both internal development and acquisition.

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### **Markets**

We participate in two major *in vitro* diagnostic markets: the molecular diagnostic market and the point-of-care market. Molecular diagnostics is the analysis of DNA, RNA and proteins at the molecular level and is typically performed in clinical laboratories. This differs from the point-of-care market, where the diagnostic may be performed in near patient settings such as an emergency room or doctor's office. Within these two markets, we focus on infectious disease and cardiac testing.

### **Products**

Our products, broken out by market, are summarized as follows:

#### *Molecular Diagnostic Market*

We sell real-time PCR molecular products in the molecular diagnostic market. These products accounted for approximately 75% of our total 2007 product revenues. We offer two real-time PCR molecular product lines:

*Q-PCR Alert* we offer a comprehensive menu of real-time diagnostic kits that are in the TaqMan format, coupled with our proprietary MGB technology. MGB is an abbreviation for minor groove binder which is a small crescent-shaped molecule that fits into the minor groove of duplex DNA. These products are CE marked for *In-Vitro* Diagnostic (IVD) use and are sold in Italy via a contract sales force and in other European countries through a network of distributors. In Italy, sales are mostly made through government tenders, which are contracts that last for two to five years and cover multiple products.

*MGB Alert*® the real-time molecular products we sell in the US and Canada are sold as Analyte Specific Reagents (ASRs) or Research Use Only (RUO) products. Today, the products are sold either direct to an end user or through a distribution relationship with ThermoFisher. The MGB Probe Technology used in these reagents is proprietary and provides significant performance and economic advantages. These products are platform independent and are currently used by customers on multiple instrument platforms for lab developed tests.

The majority of our molecular diagnostic products target the detection of DNA or RNA associated with infectious diseases, with the largest medical application being for use in identifying viral infection in transplant and immunocompromised patients. There are additional tests for genetic conditions and oncology. Examples of the diseases tested for include: Cytomegalovirus, Epstein-Barr Virus, BK Virus, Herpes Simplex Virus, and Human Herpes Virus

Our proprietary real-time technology provides chemistry elements that offer distinct competitive advantages as well as reduced cost. These elements include the MGB molecule that increases binding and specificity of designs, modified bases that provide design alternatives for improved sequence detection and discrimination, and proprietary dyes and quenchers that improve overall system performance and reduce costs and royalty burdens. In total, the system permits the development of assays that can reduce the royalties normally paid by customers to other technology providers.

Our PCR product line is described as real time to distinguish it from traditional end point technology. Real time PCR is an advance over traditional end point technology as data provided with traditional PCR is available only at the end of the chain reaction. The key feature of real-time PCR is that DNA is quantified in real time as it accumulates after each amplification cycle in the chain reaction. As a result, real-time PCR provides fast, precise, and accurate results as the chain reaction is proceeding.

#### *Point of Care Diagnostics*

POC products account for approximately 15% of Nanogen's product revenues in 2007. This ratio is expected to increase in future years. Our point-of-care products currently include tests for two critical cardiac conditions, and we plan to add infectious disease assays in the future.



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*Qualitative cardiac tests* these products are rapid test (less than 15 minutes) assays that are used in emergency care settings for the diagnosis of myocardial infarction. The products measure the presence of Troponin I, Myoglobin and CKMB versus predetermined cutoff levels and are visually read by the attending physician or nurse. There is also a handheld instrument that can be used to read and record the test results. The market for qualitative (yes/no) tests is flat or declining.

*Quantitative cardiac tests* our newest product is a rapid, quantitative measure of NT-proBNP for the diagnosis of congestive heart failure (CHF). The product is offered for use in plasma samples and the whole blood version is expected to come on to the market in 2008. This product addresses a large opportunity. The product target is licensed from Roche, produced by Princeton Biomeditech (PBM), and is FDA cleared. In the future, the cardiac menu will be extended to include quantitative tests for Troponin I and other cardiac markers. These quantitative tests are performed on a small, desktop reader that measures and reports the quantitative amounts of target proteins present in the patient sample.

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*Infectious Disease* as part of a competitive contract awarded by the Center for Disease Control (the CDC); we are developing a pandemic influenza test that detects and differentiates the various strains of influenza including potential pandemic strains. This product will operate using our proprietary technology that we believe will provide significant improvements in sensitivity as well as the capability of detecting multiple protein markers in a single test system. The system will provide a rapid quantitative test using a small, desktop reader.

The Point of Care cardiac products are sold through distribution channels in the US, Canada and Europe using a small sales force to sell to and manage the distributors. The US distribution rights to the CHF product are exclusive to LifeSign, a PBM company. The influenza test will be marketed through HX Diagnostics.

We believe that the CDC point of care platform offers an opportunity to develop point of care assays not possible using existing technologies. The POC area is dominated by lateral flow solutions that lack sensitivity and are generally unable to produce tests that correlate results with those performed in the hospital laboratory. The CDC platform utilizes a synthetic DNA and a rare earth metal (europium) to produce a diagnostic platform that can be used at the point of patient care with results that show increased sensitivity and an ability to meet the correlation requirements of the central laboratory. This increased sensitivity, the ability to detect multiple simultaneous protein markers on the same test strip and the potential to meet CLIA wavier requirements presents an opportunity to develop new and far reaching point of care diagnostics. We expect to continue development of tests for this proprietary platform that will include additional infectious disease diagnostics as well as future cardiac tests. This technology platform is compatible with low cost manufacturing approaches and has the further economic advantage of a non-lateral flow design that reduces licensing and royalty costs.

*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 quarters ended March 31, 2008 and 2007**Revenues*

The following table summarizes our revenues for the quarter ended March 31, 2008 and 2007 (in thousands):

|                                | For the three months ended |          |            |
|--------------------------------|----------------------------|----------|------------|
|                                | March 31,                  |          | Difference |
|                                | 2008                       | 2007     |            |
| Product sales                  | \$ 8,070                   | \$ 6,084 | \$ 1,986   |
| License fee and royalty income | 1,762                      | 1,241    | 521        |
| Contracts and grants           | 852                        | 2,328    | (1,476)    |
| Total                          | \$ 10,684                  | \$ 9,653 | \$ 1,031   |

Our real-time molecular products account for approximately 80% of our product sales. Point-of-care products account for approximately 15% of product sales, and the remaining 5% is related to the micro array business which is being discontinued. The increase in product sales revenue in the first quarter of 2008 as compared to the same period in 2007 is due primarily to overall increased revenues in the real time product line as well as in the point of care business.

*The future:* We expect revenue to continue to increase significantly in 2008 as compared to 2007 despite the discontinuation of our micro array product line. The projected increases are primarily based on existing products, but also include the anticipated introduction of additional new products we intend to introduce in 2008.

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The whole blood congestive heart failure 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 majority of our license fee and royalty revenue was related to our royalty minimums under a licensing agreement with Applied Biosystems Inc. (Applied Biosystems) for the use of our MGB technology with their TaqMan<sup>®</sup> 5'-nuclease real-time PCR. The increase in license fees and royalty revenues in the quarter ended March 2008 as compared to the same period in 2007 is primarily due to higher royalty revenues recognized related to ABI royalty interests, as well as higher royalty revenues recognized through real-time PCR licensing agreements.

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*The future:* In March 2008, we entered into an agreement for DRT under which we sold to DRT, for \$10 million, all future royalties generated under a license agreement with ABI. DRT also released Nanogen of its obligation to guarantee minimum royalty payments in exchange for the termination of sharing arrangements included in a previous agreement between Nanogen and DRT, which was reflected as a liability of \$17.6 million in our December 31, 2007 balance sheet. We expect revenues to continue at approximately \$1 million per quarter, slightly less than the recent run rate experienced under the contract. We anticipate the remainder of our license and royalty income to remain at levels similar to 2007.

In addition, with our growing intellectual property profile of 191 U.S. patents, 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 represent funding by various federal, state and private agencies earned through 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 decrease in contract and grant revenues in 2008 as compared to 2007 is primarily due to deferral of funding received for an influenza project that we anticipate recognizing in the second quarter of 2008.

*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 U.S. Centers for Disease Control and Prevention (CDC). This award was 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 the next two to three years. As a result, our future contract and grant revenue will be significantly impacted by whether or not we are awarded the remaining phase of the CDC contract.

**Cost and expenses**

*Cost of product sales (in thousands):*

|                       | For the three months ended |          |            |
|-----------------------|----------------------------|----------|------------|
|                       | March 31,                  |          |            |
|                       | 2008                       | 2007     | Difference |
| Cost of product sales | \$ 4,838                   | \$ 4,830 | \$ 8       |

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 as well as inventory impairment charges. Cost of product sales in 2008 as compared to the same period in 2007 is essentially consistent despite the growth in revenues. This is partially due to product mix, *i.e.* a higher proportion of real-time PCR revenues with higher margins and cost savings realized in the first quarter of 2008 resulting from the exit from the micro array business as compared to the same period in 2007.

*The future.* In 2008 we expect our cost of product sales to increase relative to the increase in product sales.

*Research and development expenses (in thousands):*

|                          | For the three months ended March 31, |          |            |
|--------------------------|--------------------------------------|----------|------------|
|                          | 2008                                 | 2007     | Difference |
| Research and development | \$ 4,186                             | \$ 6,512 | \$ (2,326) |

Research and development relates to the expenses associated with our efforts to develop molecular diagnostics products for commercialization and the expenses incurred while conducting reimbursable research and development under contractual agreements with various federal, state and private entities. The significant decrease in research and development costs in the first quarter of 2008

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as compared to first quarter of 2007 is primarily due to deconsolidation of Jurilab in the second half of 2007, as well as our discontinuation of research and development costs related to the micro array business.

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*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 |          |            |
|-------------------------------------|----------------------------|----------|------------|
|                                     | March 31,                  |          |            |
|                                     | 2008                       | 2007     | Difference |
| Selling, general and administrative | \$ 8,727                   | \$ 8,853 | \$ (126)   |

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. SG&A costs remained consistent with prior year levels despite growth in revenues. This was partially due to the savings resulting from exiting the micro array business.

*The future.* We expect that our selling, general and administrative expenditures on a percentage basis will trend lower than the increases in our revenue. We also anticipate our costs will further decline as we work to reduce expenses and further focus our business as a result of our exit of the micro array business.

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

|   | For the three months ended |        |            |
|---|----------------------------|--------|------------|
|   | March 31,                  |        |            |
|   | 2008                       | 2007   | Difference |
| Amortization of purchased intangible assets | \$ 934                     | \$ 767 | \$ 167     |

Amortization of purchased intangibles is our effort to match the benefits of the intellectual property we have acquired with current period expenses.

*The future.* We expect this amortization expense to remain consistent at the level without the impairment charges. However, amortization expense may also be impacted by potential future business combinations.

**Other income**

The following table summarizes our other income for the three months ended March 31, 2008, and 2007 (in thousands):

|  | For the three months ended |          |             |
|--|----------------------------|----------|-------------|
|  | March 31,                  |          |             |
|  | 2008                       | 2007     | Difference  |
| Interest income                                    | \$ 336                     | \$ 538   | \$ (202)    |
| Interest expense                                   | (1,910)                    | (1,143)  | (767)       |
| Other expense                                      | (229)                      | (28)     | (201)       |
| Loss on extinguishment of debt                     | (10,221)                   |          | (10,221)    |
| Warrant and conversion rights valuation adjustment | (2,911)                    | 10       | (2,921)     |
| Gain (loss) on foreign currency translation        | (26)                       | 2        | (28)        |
| Total other income                                 | \$ (14,961)                | \$ (621) | \$ (14,340) |

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The increase in interest expense in 2008 as compared to 2007 is primarily related to our convertible debt offering signed in August 2007, and the loss on extinguishment of debt and change in the warrant valuation adjustment amount related to the restructuring of our convertible debt during the first quarter of 2008.

### **Liquidity and capital resources**

#### *Short-term and long-term liquidity*

At March 31, 2008 we have cash and cash equivalents and short-term investments, available for sale of approximately \$10.8 million. We will need to raise additional funds through financing transactions in order to continue to support our planned operations until we achieve cash flow break even. Without access to this financing, on terms acceptable to us, we may have to curtail or cease operations and product development that will materially alter our current business strategy.

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The following is a summary of our key liquidity measures as of March 31, 2008 and December 31, 2007 (in thousands):

|   | March 31,<br>2008 | December 31,<br>2007 | Difference      |
|---|-------------------|----------------------|-----------------|
| Cash and cash equivalents   | \$ 10,528         | \$ 5,806             | \$ 4,722        |
| Short-term investments, available for sale  | 300               | 1,450                | (1,150)         |
| <b>Total cash and cash equivalents and short-term investments, available for sale</b> | <b>\$ 10,828</b>  | <b>\$ 7,256</b>      | <b>\$ 3,572</b> |
| Current assets  | \$ 33,147         | \$ 26,184            | \$ 6,963        |
| Current liabilities   | (39,447)          | (26,371)             | (13,076)        |
| <b>Working capital</b>  | <b>\$ (6,300)</b> | <b>\$ (187)</b>      | <b>\$ 6,113</b> |

Our cash and cash equivalents and short-term investments, available for sale increased by \$3.6 million, while our working capital decreased by \$6.1 million, at March 31, 2008 as compared to December 31, 2007. The decrease in working capital was primarily due to an increase in current liabilities. Current liability balances include \$6.6 million of deferred revenue balance, as well as \$7.4 million in convertible debt warrant and conversion feature liability, all of which represent non-cash liabilities. The increase in cash and cash equivalents and short term investments, available for sale, was primarily due to cash receipts from the sale of royalty stream to DRT for \$10 million in March 2008, partially offset by the cash used in our on-going research and business development efforts. Going forward, with our exit from the micro array business, we believe we can use less cash as we focus on further cutting costs and work to increase sales to achieve cash flow break even.

From inception to March 31, 2008, we have financed our operations primarily by:

Issuing our stock and warrants

Issuing convertible debt

Generating revenues

Assignment and sale of certain royalty interests to DRT

Financing our trade receivables

Obtained cash through our acquisition of Epoch

Using proceeds from our litigation settlement with CombiMatrix

Obtaining a modest amount of capital equipment long-term financing



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

Cash used in operating, investing and financing activities for the three months ended March 31, 2008 and 2007 is as follows (in thousands):

|   | March 31,<br>2008 | March 31,<br>2007 |
|---|-------------------|-------------------|
| Net cash provided by (used in) operating activities | \$ 5,540          | \$ (11,756)       |
| Net cash provided by investing activities           | 297               | 1,814             |
| Net cash provided by (used in) financing activities | \$ (1,013)        | \$ 7,541          |

### *Operating activities*

Net cash used in operating activities for the three months ended March 31, 2008 and 2007 primarily related to our net losses and changes in working capital. The decrease in cash used in operating activities in first quarter of 2008 as compared to the same period of 2007 primarily related to a \$10 million sale of certain royalty rights, as well as cost savings due to our exit from the micro array business and deconsolidation of Jurilab.

### *Investing activities*

Net cash provided by investing activities in the three months ended March 31, 2008 and 2007 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 decreased in the three months ended March 31, 2008 as compared to the same period of 2007 primarily due to drawing down our invested balances with no significant other balances to use for operational needs.

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Capital spending is essential to our product innovation initiatives and maintaining our operational capabilities. Therefore in the first quarter of 2008 and 2007 we used cash to purchase \$1,052,000 and \$746,000, respectively, in property and equipment to support the development of our product lines.

*Financing activities*

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

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.

We have no significant contractual obligations not fully recorded on our Consolidated Balance Sheets or fully disclosed in the Notes to our Consolidated Financial Statements. We have no off-balance sheet arrangements as defined in S-K 303(a)(4)(ii).

*Additional Financing Required in 2008*

We will require additional financing in order to complete our stated plan of operations through December 31, 2008. There can be no assurance, however, that such financing will be available or, if it is available, that we will be able to structure such financing on terms acceptable to us and that it will be sufficient to fund our cash requirements until we can reach a level of profitable operations and positive cash flows. If we are unable to obtain the financing necessary to support our operations, we will be unable to continue as a going concern.

Our independent registered public accounting firm has included an explanatory paragraph in its report on our 2007 financial statements related to the uncertainty in our ability to continue as a going concern. We anticipate that our cash at December 31, 2007, together with the net proceeds from our sale of certain patent rights in March 2008, are not sufficient to meet the cash requirements to fund our operating expenses, capital expenditures, and working capital through December 2008 without additional sources of cash.

While we believe that we will be successful in generating additional cash through a combination of corporate equity, debt, partnerships, collaborations, federal and state grant funding, sale or licensing of intellectual property and incremental product sales, if we are unsuccessful in obtaining additional cash flows from any of these sources, we need to defer, reduce or eliminate certain planned expenditures. There can be no assurance that we will be able to obtain any sources of financing on acceptable terms, or at all. If we are not able to defer, reduce or eliminate our expenditures, secure additional sources of revenue or otherwise secure additional funding, we will need to restructure or significantly curtail our operations, file for bankruptcy or cease operations.

The trading price of our shares of common stock, a downturn in the United States stock and debt markets, and the existence of, and covenants in our indebtedness could make it more difficult to obtain financing through the issuance of equity or debt securities. We will also seek to raise capital from other sources, such as sale of assets, licensing of technology or intellectual property. Any delay in reaching cash flow break even will require us to raise additional capital. Under the terms of our 9.75% Notes, we are required to use a portion of the proceeds of certain financings to redeem the 9.75% Notes. Any additional equity financing will be dilutive to our stockholders, and debt financing, if available, may include additional restrictive covenants and require significant additional collateral. Further, if we issue additional equity or debt securities, stockholders may experience additional dilution or the new equity securities may have rights, preferences or privileges senior to those of existing holders of our shares of common stock. If additional financing is not available or is not available on acceptable terms, we will have to curtail our operations.

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**Table of Contents****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, and litigation. We base our estimates on historical and anticipated results and trends and on various other assumptions that we believe are reasonable under the circumstances, including assumptions as to future events. These estimates form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. By their nature, estimates are subject to an inherent degree of uncertainty. Actual results that differ from our estimates could have a significant adverse effect on our operating results and financial position. We consider an accounting estimate and policy to be critical if: 1) the accounting estimate requires us to make assumptions about matters that were highly uncertain at the time the accounting estimate was made, and 2) changes in the estimate that are reasonably likely to occur from period to period, or the use of different estimates that we reasonably could have used in the current period, would have a material impact on our financial condition or results of operations. We believe that the following critical accounting policies and assumptions may involve a higher degree of judgment and complexity than others. There were no material changes in the critical accounting policies or estimates from those at December 31, 2007.

*Going Concern*

We have incurred net losses of \$23.0 million in the three months ending March 31, 2008, \$33.9 million, \$46.7 million, and \$104.8 million for the years ended December 31, 2007, 2006 and 2005, and have an accumulated deficit of \$423.6 million as of March 31, 2008. Based on our operating plan, our existing working capital is not sufficient to meet the cash requirements to fund our planned operating expenses, capital expenditures, and working capital requirements through December 31, 2008 without additional sources of cash and/or the deferral, reduction or elimination of significant planned expenditures.

These factors raise substantial doubt about our ability to continue as a going concern. The accompanying consolidated financial statements have been prepared assuming that we 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.

*Valuation of Goodwill*

We have \$39.0 million of goodwill on our March 31, 2008 consolidated balance sheet related to our acquisitions of Amplimedical and Spectral in 2006, and our acquisitions of SynX and Epoch 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 impairment on an annual basis in the fourth quarter or more frequently if we believe indicators of impairment exist. The performance of the test involves a two-step process. The first step of the impairment test involves comparing the fair values of the applicable reporting units with their aggregate carrying values, including goodwill. The Company generally determines the fair value of its reporting units using a combination of the income approach methodology of valuation that includes the discounted cash flow method and a market based methodology. If the carrying amount of a reporting unit exceeds the reporting unit's fair value, the Company performs the second step of the goodwill impairment test to determine the amount of impairment loss. The second step of the goodwill impairment test involves comparing the implied fair value of the affected reporting unit's goodwill with the carrying value of that goodwill.

During our annual review for impairment in 2007 and 2006 we determined that no impairment of goodwill existed. In the fourth quarter of 2005, under the first step of the SFAS 142 analysis we determined that the carrying value of the reporting unit that included Epoch was in excess of its fair value. Therefore, we were required to proceed to the second step of the SFAS 142 analysis for the Epoch reporting unit and use the methodology described in SFAS No. 141, *Business Combinations*, to determine the fair value of the reporting unit as if we purchased the reporting unit on October 1, 2005. The fair value was based on a combination of the income approach, which estimates the fair value based on the future discounted cash flows, and the market approach, which estimates the fair value based on comparable market prices. Under the income approach, we assumed a cash flow period through 2010 with terminal values thereafter, long-term annual revenue growth rates of 5% to 43%, a discount rate of 20% and terminal value growth rates of 5%. We determined the fair value by weighting 67% to the income approach and 33% to the market approach. The resulting fair value of the Epoch reporting unit was approximately \$26.6 million. Therefore, we incurred a non-cash impairment charge to our goodwill of \$59.0 million during the fourth quarter of 2005.

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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.

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### *Valuation of embedded derivatives.*

We value certain embedded features issued in connection with our February and August 2007 financing activities and in connection with our restructuring of debt in March 2008. Our February 2007 financing included issuance of warrants, while our August 2007 convertible debt financing included warrants and conversion features that we are required to fair value at each balance sheet date. The warrants, along with the conversion feature of the notes, have been recorded at their relative fair value at the inception date of the agreement and will continue to be recorded at fair value at each subsequent balance sheet date. Any change in value between reporting periods will be recorded as other income (expense) at each reporting date. The fair value of these warrants and rights are primarily affected by our stock price and its volatility, expected life and interest rates. We recorded approximately \$2.9 million of other expense in 2008 related to the change in the fair value of the warrants and the conversion feature. As of March 31, 2008, the fair value of the warrants and conversion feature was determined to be \$7.4 million. This amount is reflected in our financial statements as a current liability.

### *Valuation of intangible and other long-lived assets.*

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

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

loss of legal ownership or title to the asset;

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

the impact of significant negative industry or economic trends.

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

### *Revenue Recognition*

We recognize revenue principally from various real-time PCR products (both custom and proprietary tests), molecular testing platforms (the NanoChip<sup>®</sup> systems), various ASRs, cardiac tests, sponsored research, contract and grant agreements and from license and royalty fees for intellectual property. Each element of revenue recognition requires a certain amount of judgment to determine if the following criteria have been met: i) persuasive evidence of an arrangement exists; ii) delivery has occurred or services have been rendered; iii) the seller's price to the buyer is fixed or determinable; iv) collectibility is reasonably assured, and v) both title and the risks and rewards of ownership are transferred to the buyer. We are required to make more significant estimates involving our recognition of revenue from license and royalty fees, than from revenue generated from our products sales and contracts and grant agreements. Our license and royalty fees revenue estimates depend upon on 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.

### *Inventory valuation and related reserves*

We have a history of writing down the value of our inventory due to lack of market demand. We have approximately \$8.7 million of inventory reserves as of March 31, 2008, with a net ending inventory balance of approximately \$2.6 million. Given the inherent unpredictability of

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demand for new products, we are 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.

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*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, 2007, our valuation allowance was \$44.6 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 change in recognition, classification, or 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. We believe it is important for investors to be aware of the high degree of subjectivity involved when using option pricing models to estimate share-based compensation under SFAS No. 123R. The determination of the fair value of share-based payment awards on the date of grant using an option-pricing model is affected by our stock price as well as assumptions regarding a number of complex and subjective variables. These variables include, but are not limited to, our valuation methodology, the expected term, expected stock price volatility over the term of the awards, the risk-free interest rate, expected dividends and pre-vesting forfeitures. If any one of these factors changes and we employ different assumptions in the application of SFAS No. 123R in future periods, the compensation expense that we record under SFAS No. 123R will differ significantly from what we have recorded in the current period.

For share-based awards issued during the year ended December 31, 2007, we estimated the expected term by considering various factors including the vesting period of options granted employees historical exercise and post-employment termination behavior and aggregation by homogeneous employee groups. Our estimated volatility was derived using our historical stock price volatility. We have never declared or paid any cash dividends on our common stock and currently do not anticipate paying such cash dividends. The risk-free interest rate is based upon U.S. Treasury securities with remaining terms similar to the expected term of the share-based awards.

*Related Party Transactions*

In October 2006, we signed a consulting agreement with Mr. Dreismann, one of our Board members. Mr. Dreismann received \$60,000 and \$20,000 in compensation under this agreement during 2007 and 2006, respectively. Total compensation under the agreement is capped at a maximum of \$5,000 per month.

On August 3, 2006, we entered into research and development collaboration arrangements with Thermo Fisher Scientific Inc., ( Fisher ) a related party, that owns approximately 5.7 million shares of our common stock, and Athena Diagnostic, a wholly-owned subsidiary of Fisher. We agreed to share certain technology and patent rights related to the development, manufacture and marketing of new molecular diagnostic products. On August 9, 2006, we entered into an exclusive distribution agreement with Fisher. There was approximately \$128,000 of sales under this agreement in the three months ended March 31, 2008.

In February 2008, we entered into a distribution and license agreement with Fisher under which we will provide certain distribution and technology access rights to Fisher. As part of the agreement, Fisher has agreed to fund a development program

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related to the development, manufacture and marketing of new molecular diagnostic products on a cost incurred based. Upon commercial launch of the new products, Fisher has agreed to certain minimum purchases over a six-year period. There was approximately \$98,000 of sales under this agreement in the three months ended March 31, 2008.

**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 \$0.3 million as of March 31, 2008, 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 March 31, 2008, 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. We 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 subsidiary is the U.S. dollar and the functional currency of our subsidiary in Italy is the euro. The Italian subsidiaries' accounts are translated from the euro to the U.S. dollar using the current exchange rate in effect at the balance sheet date for balance sheet accounts, and using the average exchange rate during the period for revenues and expense accounts. The effects of translation are recorded in accumulated other comprehensive income in the consolidated financial statements included herein. In certain instances, our subsidiaries conduct business with customers and vendors in euros or in other local European currencies. Exchange gains and losses arising from these transactions are recorded using the actual exchange rate differences on the dates of the transactions. 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 \$9.2 million at March 31, 2008.

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 maintain disclosure controls and procedures that are designed to ensure that (a) the information required to be disclosed by us in the reports we file or submit under the Exchange Act is recorded, processed, summarized and reported within the periods specified in the SEC's rules and forms, and (b) that 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. In designing and evaluating the disclosure controls and procedures, management recognized that any controls and procedures, no matter how well designed and operated, can only provide reasonable assurance of achieving the desired control objectives, and in reaching a reasonable level of assurance, management necessarily was required to apply its judgment in evaluating the cost-benefit relationship of possible controls and procedures.

Under the supervision and with the participation of our management, including our Chief Executive Officer and our Chief Financial Officer, we carried out an evaluation of the effectiveness of our disclosure controls and procedures (as such term is defined in SEC Rules 13a-15(e) and 15d-15(e)) as of December 31, 2007. Based on such evaluation, such officers have concluded that, as of March 31, 2008, our disclosure controls



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and procedures were not effective because of the identification of material weaknesses in our internal control over the financial close and inventory valuation processes.

Notwithstanding the material weakness, we believe our unaudited quarterly consolidated financial statements included in this Quarterly Report on Form 10-Q fairly present in all material respects our financial position, results of operations and cash flows for the periods presented in accordance with generally accepted accounting principles. In preparing our Exchange Act filings, including this Quarterly Report on Form 10-Q, we implemented processes and procedures to provide reasonable assurance that the identified material weaknesses in our internal control over financial reporting were mitigated with respect to the information that we are required to disclose. As a result, we believe, and our CEO and CFO have certified that, to their knowledge, this Quarterly Report on Form 10-Q does not contain any untrue statements of material fact or omit to state any material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered in this Quarterly Report.

We have taken corrective action to address the material weakness in our internal controls as disclosed under the section entitled Change in Internal Control over Financial Reporting.

There can be no assurance, however, that our disclosure controls and procedures will detect or uncover all failures of persons within the Company and its consolidated subsidiaries to disclose material information otherwise required to be set forth in our periodic reports. There are inherent limitations to the effectiveness of any system of disclosure controls and procedures, including the possibility of human error and the circumvention or overriding of the controls and procedures. Accordingly, even effective disclosure controls and procedures can only provide reasonable, not absolute, assurance of achieving their control objectives.

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(b) Change in Internal Control over Financial Reporting.

In order to remediate the weaknesses identified in our internal controls as of December 31, 2007, we began implementation of additional controls and procedures in the first quarter of 2008, including:

recruitment of additional staff (subsequent to December 31, 2007, we have hired an accounting manager and a senior accountant to help remediate the insufficient number of qualified staff accountants); and

adding detailed review procedures over accounting close activities, including inventory valuation analysis.

We anticipate these measures to be fully implemented on or before December 31, 2008.

**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 may have arisen in the ordinary course and conduct of our business, as well as through acquisitions or divestitures. These matters 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 March 31, 2008 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 March 31, 2008, 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 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 (in addition to the \$10 million raised in March 2008 through the sale of a royalty stream as more fully described in this report) to continue our planned operations. Our independent registered public accounting firm has included a going concern assumption in its audit report included in the Form 10-K for the fiscal year ended December 31, 2007. We may seek additional funds through public and private securities offerings, arrangements with corporate partners, borrowings under lease lines of credit or other sources, sale of assets or licensing of technology or intellectual property. 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. In addition, the terms of our 9.75% senior secured convertible notes issued in March 2008 (the 9.75% Notes ) and 6.25% senior convertible notes issued in August 2007 (the 6.25% Notes , together with the 9.75% Notes, the Notes ) contain restrictive covenants that limit our ability to raise capital through additional financing unless we obtain consent from holders of the Notes, and there is no guarantee that we will be able to obtain such consents on terms acceptable to us, or at all. Under the terms of the 9.75% Notes, we are required to use a portion of the proceeds of certain financings to redeem the 9.75% Notes. Any additional equity financing will be dilutive to stockholders, and debt financing, if available, may include restrictive covenants and require significant collateral.

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

Since our inception, we have incurred cumulative net losses which, as of March 31, 2008, total approximately \$423.6 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. 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, whether and when new products are successfully developed and introduced by us or our competitors, and the achievement of milestones under our collaborative agreements with 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 expenses before knowing whether our products can be sold successfully.

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

We are at an early stage of development. As of March 31, 2008, we had only a limited product offering that includes real-time PCR products and point-of-care diagnostic tests for cardiac disease. Our congestive whole-blood heart failure point-of-care test remains in development. 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.

*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.



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*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.

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 test system 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. Further, PBM has the rights to distribute the products in certain markets including the US. 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.

*Our indebtedness obligations may adversely affect our cash flow.*

In March 2008, we completed a restructuring transaction for our 6.25% Notes, or the unsecured Notes, in which we exchanged an aggregate \$12.9 million in principal amount of unsecured Notes with our secured 9.75% Notes, with an aggregate principal amount of \$15.5 million. As a result of this transaction, we increased the total amount of convertible debt outstanding, as well as the amount of interest payments under the Notes. Furthermore, we have agreed to make the following redemption payments on the 9.75% Notes:

beginning on April 1, 2008, we will pay monthly installment payment of \$80,000 per month, which will increase to \$160,000 per month after January 1, 2009;

following quarterly announcement of our earnings, we will redeem an amount of the 9.75% Notes equal to the greater of (i) \$10,000 for each quarter prior to January 1, 2009 or \$20,000 for each fiscal quarter after January 1, 2009 and (ii) the product of 5% (for each quarter prior to January 1, 2009) or 10% (for each quarter after January 1, 2009) multiplied by the consolidated product revenue of the Company for such prior fiscal quarter minus the aggregate monthly installment payment made for such quarter;

if we sell, transfers or dispose all or any part of its business, property or assets, we may be required to use 50% of the net cash proceeds over \$3.5 million from such asset disposition to redeem the 9.75% Notes; and

if we offer or sell any of debt, equity, or equity equivalent securities, we may be required to use 20% of the aggregate net cash proceeds in excess of \$10 million to redeem the 9.75% Notes.

The increased amount of indebtedness and additional payments required to service our indebtedness impose a significant burden on our liquidity and cash flow. Should we be unable to satisfy our payment obligations under the 9.75% Notes, we may have to restructure or limit our operations. Our indebtedness could have significant additional negative consequences, including, but not limited to:

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increasing our vulnerability to general adverse economic and industry conditions;

limiting our ability to obtain additional financing;

placing us at a possible competitive disadvantage to competitors with less debt obligations and competitors that have better access to capital; and

restricting the availability of strategic alternative.

*We may not have sufficient funds to make required payments on the Notes.*

Our liquidity position is constrained by the operating losses from our business. In addition, we are not be able to pay interest on the Notes with shares of our common stock if the valuation of our stock is below \$1.14 per share or if we do not satisfy certain

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equity conditions set forth in the Notes, including maintaining a minimum bid price of our common stock as required by applicable NASDAQ listing standard, in which case we will be required to pay interest in cash. Under the terms of the 9.75% Notes, we are also required to make certain monthly installment payments and quarterly catch-up payments to redeem the Notes. We are also required to apply a portion of net proceeds received from certain sales of assets and equity or debt financing to redeem the 9.75% Notes. As a result, we may not have sufficient funds to make the required interest, redemption and principal payments on the Notes when due, either at maturity, applicable installment payment dates, or upon the occurrence of various events of default or specified change of control transactions. If we do not have sufficient funds to make these payments, we will have to obtain an alternative source of funds, including sales of our assets or assets of our subsidiaries or sales of our equity securities or capital. We cannot assure you that we will be able to obtain sufficient funds to meet our payment obligations under the Notes through any of these alternatives or that we will be permitted by our senior lenders to obtain funds through any of these alternatives. In the event that we are not able to make the required payments at maturity or otherwise, we will be forced to seek alternatives, including seeking additional debt financing or equity financing or a potential reorganization under Chapter 11 of the United States Bankruptcy Code.

*We have granted a first priority security interest in substantially all of our assets, including certain intellectual property.*

To secure our obligations under the Notes, we have granted holders of the Notes a first priority security interest in substantially all of our assets and stock, including certain intellectual property assets. Upon an event of default under the Notes, the holders could elect to declare all amounts outstanding, together with accrued and unpaid interest and penalty, to be immediately due and payable. If we are unable to repay those amounts, the holders will have a first claim on our assets, including such intellectual property. If holders should attempt to foreclose on the collateral, it is unlikely that there would be any assets remaining after repayment in full of such secured indebtedness. Any such default and resulting foreclosure would have a material adverse effect on our financial condition and our ability to continue our operations.

*The Notes provide that upon the occurrence of various events of default and change of control transactions, the holders would be entitled to require us to repay the Notes for cash, which could leave us with little or no working capital for operations or capital expenditures, or force us to sell the collateral subject to the security interest granted under the Notes.*

The Notes allow the holders to require us to repay the Notes upon the occurrence of various events of default, such as the termination of trading of our common stock on a qualified stock market or quotation system or a breach by us of the covenants set forth in the Note, as well as specified change of control transactions. In such a situation, we may be required to repay all or part of the Notes, including any accrued interest, applicable premiums and penalties. Some of the events of default include matters over which we may have little or no control. If an event of default or a change of control occurs, we may be unable to repay the full price in cash. Even if we were able to prepay the full amount in cash, any such repayment could leave us with little or no working capital for our business. We have not established a sinking fund for payment of our obligations under our Notes, nor do we anticipate doing so.

In addition, we have granted holders of the Notes a first priority security interest in substantially all of our assets and stock of our subsidiaries to secure our obligations under the Notes. Upon the occurrence of an event of default, the holders would have the right to foreclose upon and sell, or otherwise transfer, the collateral subject to their security interest. Accordingly, our secured creditors would be entitled to have the debt owed to them satisfied from our assets before we could make any distribution to other stockholders.

*If we are not able to access the funds in the cash collateral account, it will adversely affect our cash flow, financial results and our ability to meet payment obligations.*

We have deposited \$7.3 million of the total \$20 million purchase price of the Notes in a cash collateral account for the purpose of securing the letter of credit issued in favor of the holders of the Notes. The funds in the cash collateral account, including interests earned, will be released to us only if we meet certain conditions to terminate the letter of credit. These conditions include, but are not limited to, all of the following: (i) the closing sales price of our common stock on the NASDAQ Global Market equal to or exceeds \$1.524 per share for 20 out of 30 consecutive trading days; (ii) there is no event of default under the Indenture; and (iii) our common stock has not been suspended from trading on NASDAQ Global Market. There is no guarantee that we will meet all of the conditions for the termination of the letter of credit. In addition, there is no guarantee that the price of our common stock will reach the target level described above, and even if it does, there is no assurance that the price will maintain at such level for the required period of time. The price of our stock as of May 7, 2008 was \$0.39 per share. If the price of our common stock does not meet this requirement or if we cannot meet any of the conditions, we will not have access to the funds in the cash collateral account, which will adversely affect our cash flow, financial results and our ability to meet payment obligations under the Notes.



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*If our convertible notes do not convert to equity within its three year term, we will be forced to replace them with additional financing that may not be available on favorable terms.*

Our Notes have a three year term expiring in August 2010 and will need to be refinanced if not converted to stock before that time. There can be no assurance that financing will be available at that time, which would force the company to curtail or cease operations. The Notes contain features giving the company access to additional capital over the next several years dependent on the achievement of pre-determined stock prices. There is no assurance that those conditions will be met. The Notes further restrict us from additional borrowing without permission of the note holders whose consent cannot be assured.

*We may continue to incur significant non-operating, non-cash charges resulting from changes in the fair value of our warrants and derivatives.*

In August 2007, we entered into a definitive agreement for the sale and issuance of \$20 million in aggregate principal amount of the unsecured Notes which included warrants to purchase up to 17,322,833 shares of our common stock. On March 13, 2008, we entered into an Exchange Agreement with the Holders of our Notes issued in August 2007 and pursuant to the Exchange Agreement, the Holders exchanged an aggregate \$12,917,000 in principal amount of the Notes with our New Notes with an aggregate principal amount of \$15,500,400. Both the Notes and the New Notes contain a conversion features. The conversion features of the Notes and New Notes, and the warrants have been recorded at their relative fair value at the inception date of the agreement and will continue to be recorded at fair value at each subsequent balance sheet date. Any change in value between reporting periods will be recorded as other income (expense) at each reporting date. The impact of these non-operating, non-cash charges could have an adverse effect on our stock price in the future. The fair value of the warrant and derivatives is tied in large part to our stock price. If our stock price increases between reporting periods, the warrant and derivatives become more valuable. As such, there is no way to forecast what the impact on other income (expense) will be in the future or what the future impact will be on our financial statements.

*We have agreed to certain limitations on our ability to sell our securities in future financings, which may restrict our ability to raise capital, and any future financing may require the consent of our note holders, who may be unwilling to provide such consent.*

We have agreed, for so long as any Notes or related warrants remain outstanding, that we will not issue or sell, subject to certain exceptions, shares of our common stock for a consideration per share less than the conversion price of the Notes or the exercise price of the such warrants immediately prior to such sale, if the effect of the issuance or sale is to cause the conversion price or exercise price to be adjusted below certain fixed floor prices, unless we first obtain stockholder approval. In addition, we have agreed, for so long as any Notes or related warrants remain outstanding, that we will not sell, subject to certain exceptions, securities with a conversion or exercise price that varies from the market price of our common stock. These limitations will restrict our ability to raise capital through equity or debt financing in the future, unless we obtain prior written consent from the holders of the Notes. There is no assurance that the holders will provide us with such consent. If we cannot raise more capital or obtain additional financings on terms satisfactory to us, 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, which will have an adverse effect on our business operations and financial results.

*Restrictive covenants in the Indenture and the secured Notes may limit our ability to expand our operations and capitalize on our business opportunities.*

The terms of the Notes include restrictive covenants which limit our ability to borrow money, create liens, dispose assets, transact businesses with affiliates, effect equity and debt financing and engage in certain other activities. These restrictive covenants may limit our ability to expand our operations and capitalize on business opportunities. If we are unable to expand our operation or otherwise capitalize on our business opportunities, our business, financial condition and results of operations could be materially adversely affected and we may not be able to meet our debt service obligations. In addition, as described above, we are required to apply a portion of net proceeds received from certain disposition of assets and financing transactions to redeem the secured 9.75% Notes, which may limit our ability to capitalize on these opportunities.

*Conversion of the Notes and exercise of related warrants and issuance of shares of common stock in payment of interests on the Notes will dilute the ownership interest of existing stockholders, including holders who had previously converted their Notes.*

The conversion or exercise of some or all of the Notes and related warrants, respectively, and the issuance of shares of common stock in payment of interests on the Notes, could significantly dilute the ownership interests of existing stockholders. The restructuring transaction completed in March 2008 also increased substantially the number of shares that may be issued upon

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conversion of the Notes by lowering the initial conversion price of the Notes from \$1.27 per share to \$0.68 per share, which will result in increased dilution. Any sales in the public market of the common stock issuable upon such conversion or exercise could adversely affect prevailing market prices of our common stock. In addition, the existence of the Notes may encourage short selling by market participants because the conversion of the Notes could be used to satisfy short positions, or anticipated conversion of the Notes into shares of our common stock could depress the price of our common stock.

*The CDC project may not continue beyond the previously funded phases.*

We 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. We currently estimate that completion of the contract will require more than \$12.5 million in funding. 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 we fail to regain compliance with the minimum bid price requirement under NASDAQ rules, we could lose our listing on the NASDAQ Global Market, and the loss of listing will result in an event of default under our Notes.*

Our common stock is listed on the NASDAQ Global Market and NASDAQ's marketplace rules for continued listing on the NASDAQ Global Market require, among other things, that the bid price for our common stock not fall below \$1.00 per share for a period of 30 consecutive trading days. If our minimum bid price is below \$1.00 for 30 consecutive trading days, under the current NASDAQ Global Market rules we will have a period of 180 days to attain compliance by meeting the minimum bid price requirement for 10 consecutive days during such compliance period.

On November 27, 2007, we received a letter from NASDAQ Stock Market informing us that the closing bid price of our common stock was under \$1.00 per share for 30 consecutive business days, and that we have 180 calendar days, or until May 27, 2008, to regain compliance with the minimum bid requirement under NASDAQ rules. If the Company does not regain compliance by May 27, 2008, the NASDAQ staff will send us a written notification that our common stock will be delisted from NASDAQ Global Market. At that time, we may appeal the delisting determination to a NASDAQ Listings Qualifications Panel, or we may transfer our common stock to the NASDAQ Capital Market if the common stock satisfies all criteria, other than compliance with the minimum bid price requirement, for initial inclusion on such market. In the event of such a transfer, we will be afforded an additional 180 calendar days to comply with the minimum bid price requirement while listed on the NASDAQ Capital Market.

There is no guarantee that we will be able to regain compliance of the minimum bid price requirement under NASDAQ rules prior to May 27, 2008, nor can we be sure that we will satisfy the initial listing requirement of NASDAQ Capital Market in order to take advantage of the additional 180-day grace period to regain compliance. In addition, while stockholders have approved a measure to give our board of directors the authority to effectuate a reverse stock split of our common stock in order to raise the stock price, there is no guarantee that such reverse stock split will result in a higher stock price. Our stock price as of May 7, 2008 was \$0.39 per share. Our failure to meet NASDAQ's minimum bid price requirement may result in the delisting of our common stock, which will make our stock significantly less liquid and negatively affect its value. Delisting may also result in an event of default under our Notes and a breach of certain covenants with our warrant holders, which will have a material adverse effect on us.

*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. 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;

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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.

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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 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 April 2004, we completed the acquisition of SynX Pharma, Inc. ( SynX ), and in December 2004, we completed the acquisition of Epoch Biosciences, Inc. ( Epoch ). We expected that the Spectral and SynX product lines would accelerate our entry into the point-of-care market and that the Amplimedical and Epoch acquisitions would broaden our reach in the molecular diagnostic market. However, we cannot be certain that we will achieve these and other benefits which we expected 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 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 identify and 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, or 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:

companies developing molecular diagnostic tests;

companies developing point-of-care diagnostic tests;

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

diagnostic and pharmaceutical companies; and

companies developing drug discovery technologies.

If we are successful in developing new 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.

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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.

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

Our success will depend in part on obtaining, maintaining and enforcing meaningful patent protection on our inventions, technologies and discoveries. Our ability to compete effectively will depend on our ability to develop and maintain proprietary aspects of our technology, and to operate without infringing the proprietary rights of others, or to obtain rights to third-party proprietary rights, if necessary. Our pending patent applications may not result in the issuance of patents. Our patent applications may not have priority over others' applications, and even if issued, our patents may not offer protection against competitors with similar technologies. Any patents issued to us may be challenged, invalidated or circumvented, and the rights created thereunder may not afford us a competitive advantage. Budgetary concerns may cause us to not file, or continue, litigation against known infringers of our patent rights, or may cause us not to file for, or pursue, patent protection for all of our inventive technologies in jurisdictions where they may have value.

We also rely upon trade secrets, technical know-how and continuing inventions to develop and maintain our competitive position. Others may independently develop substantially equivalent proprietary information and techniques or otherwise gain access to our trade secrets or disclose our technology and we may not be able to meaningfully protect our trade secrets, or be capable of protecting our rights to our trade secrets. We seek to protect our technology and patents, in part, by confidentiality agreements with our employees and contractors. Our employees may breach their existing confidentiality agreements and these agreements may not protect our intellectual property. This could have a material adverse effect on us.

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

Our commercial success also depends in part on us neither infringing valid, enforceable patents or proprietary rights of third parties, nor breaching any licenses that may relate to our technologies and products. We are aware of other third-party patents that may relate to our technology. It is possible that we may unintentionally infringe these patents or other patents or proprietary rights of third parties. In the past, we and the companies we have acquired have received, and may in the future receive, notices claiming infringement from third parties as well as invitations to take licenses under third-party patents which have, in some instances, resulted in litigation, settlement of litigation and our licensing of third party intellectual property rights. In particular, the receipt of infringement notices by us may subject us to costly litigation, divert management resources and result in the invalidation of our intellectual property rights. These claims may require us to pay significant damages, cease production of infringing products, terminate our use of infringing technologies or develop non-infringing technologies. Further, any legal action against us or our collaborative partners claiming damages and seeking to enjoin commercial activities relating to our products and processes affected by third-party rights may require us or our collaborative partners to obtain licenses in order to continue to manufacture or market the affected products and processes. These actions may also subject us to liability for damages. Although in the past we and the companies we have acquired have succeeded in settling some third party claims concerning alleged infringement of intellectual property rights, which settlements have involved the payment of royalties by us or such companies we have acquired, there can be no assurance that in the future we would be successful in settling such claims. In addition, there can be no assurance that, even if such settlements are achieved, that they would be on commercially reasonable terms or would not otherwise have a material adverse impact on the company's business. We or our collaborative partners may not prevail in an action and any license required under a patent may not be made available on commercially acceptable terms, or at all.

There are many U.S. and foreign patents and patent applications held by third parties in our areas of interest, and we believe that there may be significant other litigation in the industry regarding patent and other intellectual property rights. Additional litigation could result in substantial costs and the diversion of management's efforts regardless of the result of the litigation. Additionally, the defense and prosecution of interference proceedings before the U.S. Patent and Trademark Office, or USPTO, and related administrative proceedings would result in substantial expense to us and significant diversion of effort by our technical and management personnel. We may in the future become subject to other USPTO interference proceedings to determine the priority of inventions. In addition, laws of some foreign countries do not protect intellectual property to the same extent as do laws in the U.S., which may subject us to additional difficulties in protecting our intellectual property in those countries.



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*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, in vitro diagnostic devices require FDA approval or clearance prior to marketing in the United States. 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 micro array 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 micro array and multiplexed reagents require FDA pre-market review. In November 2006, we met with the FDA to discuss the second letter. In the fourth quarter 2007, we made the decision to exit the micro array business. Our remaining molecular ASRs are subject to the FDA's new final ASR guidance document. We believe that our ASR products must be repackaged to meet the guidance and we may incur substantial costs in this repackaging effort. This will also divert resources from other efforts. Further, there can be no assurance that the repackaged 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, fraught with uncertainty. An inability to obtain or maintain the required approvals for the commercialization of our products 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. 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.



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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

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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 compliance with the FDA's regulatory requirements.

*If we are unable to manufacture products on a commercial scale, our business may suffer.*

We manufactured the majority of our products sold in 2007. In the future, we anticipate significant new sales in point-of-care quantitative tests that will be manufactured by PBM. We and PBM rely on subcontractors to manufacture the limited quantities of 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 or PBM either alone, together or with subcontractors, attempt to further scale up manufacturing procedures or to manufacture new products. We 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 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 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, PBM or other third-party manufacturers we utilize, 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 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 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 or PBM or incompatible with our or PBM's manufacturing processes, could harm our or PBM's ability to manufacture our products. We 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 or PBM fail to obtain a supplier for the manufacture of components of our products, we may be forced to curtail or cease operations.

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*Lead times for obtaining materials and components for our products and the manufacturing and introduction of our products may vary significantly which could lead to excess inventory levels as well as shortages of critical components and products if our supply and demand forecasts are inaccurate.*

We anticipate that our products, including our ASRs and most of our other products will be manufactured and introduced by us and third parties, if any, based on forecasted demand and that we will seek to purchase components and materials in anticipation of the actual receipt of purchase orders from our customers. Lead times for materials and components to be included in our products vary significantly and may depend on factors such as the business practices of each specific supplier and the terms of the particular

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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 for some of our point-of-care products, and such reliance may delay the manufacture and shipment of our products to customers.*

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 one company for the manufacture of these products, any disruption in the company's business or in our relationship with 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 PBM, 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 PBM, 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.

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

We expect that a significant 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 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 significant 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, and may cause fluctuations in our operating results. 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.

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*We may have significant product liability exposure.*

We face an inherent business risk of exposure to product liability and other claims in the event that our technologies or products are alleged to have caused harm. These risks are inherent in the testing, manufacturing and marketing of our products. In addition, we began a targeted acquisition strategy during 2004, and our due diligence of acquired companies may fail to reveal material risks relating to product liabilities of such companies. Any product liability claim brought against us could be expensive to defend and could result in a diversion of management's attention from our core business. We may be required to pay substantial damages in connection with any product liability claims. A successful product liability claim or series of claims could have an adverse effect on our business, financial condition and results of operations. Further, we may not be able to maintain adequate levels of product liability insurance at reasonable cost or reasonable terms. Excessive insurance costs or uninsured claims would add to our future operating expenses and adversely affect our financial condition.

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

We are highly dependent on the principal members of our scientific, manufacturing, marketing, administrative, management and executive personnel, the loss of whose services might significantly delay or prevent the achievement of our objectives. We face competition from other companies, academic institutions, government entities and other organizations in attracting and retaining personnel. For the twelve months ended December 31, 2007, 2006, and 2005, we experienced turnover rates of 14%, 13%, and 17%, 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 November 2007, we announced a phased reduction in force of approximately 18%, and incurred severance related expenses of \$800,000. In September 2007, we announced a reduction of approximately 4% of our workforce and incurred severance related expenses of approximately \$305,000 in the third quarter of 2007. 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.

Future layoffs could have an adverse effect on us and on our ability to retain critical staff.

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

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

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

*If ethical and other concerns surrounding the use of genetic information become widespread, we may have less demand for our products.*

Genetic testing has raised ethical issues regarding confidentiality and the appropriate uses of the resulting information. For these reasons, governmental authorities may call for limits on or regulation of the use of genetic testing or prohibit testing for genetic predisposition to certain conditions, particularly for those that have no known cure. Any of these scenarios could reduce the potential markets for our products, which could seriously harm our business, financial condition and results of operations.



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*We use hazardous materials in our business. Any claims relating to improper handling, storage or disposal of these materials could be time consuming and costly.*

Our research and development processes involve the controlled storage, use and disposal of hazardous materials including, but not limited to, biological hazardous materials and radioactive compounds. We are subject to federal, state and local regulations governing the use, manufacture, storage, handling and disposal of materials and waste products. Although we believe that our safety procedures for handling and disposing of these hazardous materials comply with the standards prescribed by law and regulation, the risk of accidental contamination or injury from hazardous materials cannot be completely eliminated. In the event of an accident, we could be held liable for any damages that result, and any liability could exceed the limits or fall outside the coverage of our insurance. We may not be able to maintain insurance on acceptable terms, or at all. We could be required to incur significant costs to comply with current or future environmental laws and regulations.

*Our stock price could continue to be highly volatile and our stockholders may not be able to resell their shares at or above the price they paid for them.*

The market price of our common stock, like that of many other life sciences companies, has been highly volatile and is likely to continue to be highly volatile. The following factors, among others, could have a significant impact on the market price of our common stock:

delisting, or risk of delisting, from the NASDAQ Global Market;

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;

conversion, restructuring, repricing or exercise of a significant amount of our Notes or related warrants;

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;



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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

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changes in the United States war on terrorism and other geopolitical and military situations in which the country is involved. *As of December 31, 2007, we identified material weaknesses in internal control over financial reporting. If we fail to maintain an effective system of internal controls, we may not be able to accurately report our financial results or prevent fraud and as a result, investors may be misled and lose confidence in our financial reporting and disclosures, and the price of our common stock may be negatively affected.*

The Sarbanes-Oxley Act of 2002 requires that we report annually on the effectiveness of our internal control over financial reporting. A significant deficiency means a deficiency or a combination of deficiencies, in internal control over financial reporting that is less severe than a material weakness yet important enough to merit attention by those responsible for oversight of the Company's financial reporting. A material weakness is a deficiency or a combination of deficiencies in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of the annual or interim financial statements will not be prevented or detected on a timely basis.

In connection with the assessment of our internal control over financial reporting for the Annual Report on Form 10-K, as further described in Item 4 of this report on Form 10-Q, we and our independent registered public accounting firm determined that as of December 31, 2007 our internal controls over financial reporting were ineffective due to material weaknesses in the financial statement close process and inventory valuation process. These material weaknesses were caused primarily by the following:

inadequate management oversight of the financial statement close process; and

an insufficient number of staff accountants with a sufficient level of knowledge;

insufficient controls over assessing inventory values including reserve requirements.

In addition, continuing assessment or subsequent assessment by us and our independent registered public accounting firm, may reveal additional deficiencies in our internal controls, some of which may require disclosure in future reports.

Although we have made and are continuing to make improvements in our internal controls, if we are unsuccessful in remediating the material weaknesses in our internal controls over financial reporting, or if we discover other deficiencies or material weaknesses, it may adversely impact our ability to report accurately and in a timely manner our financial condition and results of operations in the future, which may cause investors to lose confidence in our financial reporting and may negatively affect the price of our common stock. Moreover, effective internal controls are necessary to produce accurate, reliable financial reports and to prevent fraud. If we continue to have deficiencies in our internal controls over financial reporting, these deficiencies may negatively impact our business and operations.

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

The approval of two-thirds of our voting stock is required to take some stockholder actions, including the amendment of any of the anti-takeover provisions contained in our certificate of incorporation or amendment of our bylaws.

Further, pursuant to the terms of our stockholder rights plan adopted in November 1998, as amended, we have distributed a dividend of one right for each outstanding share of common stock. These rights will cause substantial dilution to the ownership of a person or group that attempts to acquire us on terms not approved in advance by our board of directors and may have the effect of deterring unsolicited takeover attempts.

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

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

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

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In addition, as a result of the deficiencies in our internal control over financial reporting, we will incur significant professional fees and other expenses to implement remedies and prepare our consolidated financial statements in compliance with the requirements of Section 404 of the Sarbanes-Oxley Act. Until our remediation is completed, we will continue to incur these additional costs and management burdens, which may divert valuable resources from our business operations.

*The closure of our micro array business may result in loss of revenue due to returns by existing customers and subject us to potential claims by such customers*

During the fourth quarter of 2007, we made a decision to close our micro array business, which will result in the cessation of the manufacturing and distribution of our molecular array-based testing products, including the NanoChip instrument system and related multiplexed reagents and other supporting hardware. The termination of these production activities may prompt our existing molecular array-based diagnostic customers to return their products and demand refunds, which will negatively impact our revenue and cash flow. The closure may also disrupt the business operation of our existing customers and cause them to suffer financial loss. These customers may decide to file claims against us to recover such losses, and we may be required to divert valuable resources to defend such claims and incur significant cost, which will have an adverse effect on our business operations.

*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**

The following matters were submitted to a vote of security holders and were approved at a special meeting of stockholders held in February 2008:

|  | <b>For</b> | <b>Against</b> | <b>Abstain</b> |
|--|------------|----------------|----------------|
| To approve and ratify the Company's debt financing in August 2007 in which the Company issued and sold an aggregate of \$20 million of senior convertible notes, convertible initially into an aggregate of up to 15,748,030 shares of the Company's common stock, and related warrants to purchase shares of our common stock, exercisable initially into an aggregate of 11,023,621 shares of our common stock, and may become exercisable for an additional 6,299,212 shares of our common stock; | 22,252,101 | 2,746,392      | 980,963        |



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To approve an amendment to the Company's Certificate of Incorporation to effect a reverse stock split 42,873,489 5,677,612 1,337,677 of our common stock, \$0.001 par value per share, at a specific ratio within a range of 1:5 to 1:15, to be determined by our Board of Directors, in its sole discretion, within a twelve month period following stockholder approval;

To approve an amendment to the Company's Certificate of Incorporation to increase the number of 41,923,783 7,145,025 819,971 authorized shares of common stock from one hundred thirty-five million (135,000,000) to two hundred and fifty million (250,000,000).

**ITEM 5. OTHER INFORMATION**

As previously disclosed in our December 31, 2007 10-K, the Staff of the Securities and Exchange Commission (the SEC) has reviewed and issued comments pertaining to our Form 10-K for the fiscal year ended December 31, 2006 and our Form 10-Q for the three and nine-month periods ended September 30, 2007. As of the date of this filing, there were unresolved comments related to our accounting for a variable interest entity originally consolidated in the quarter ending September 30, 2005.

After thorough consideration of the questions and comments raised in the SEC review process relating to accounting treatment for the variable interest entity, on March 28, 2008, our Audit Committee of the Board of Directors, in consultation with management and our independent registered public accounting firm, concluded that certain adjustments are required to properly apply the consolidation methodology under FIN46(R), *Consolidation of Variable Interest Entities*. The adjustments required to correct the previously issued financial statements primarily related to complying with a requirement to: record the fair value of assets, liabilities and noncontrolling interests of the variable interest entity at the time of initial consolidation rather than recording the book value on the date of initial consolidation; and, to allocate operating losses in future periods to noncontrolling interests.

We have restated our consolidated financial statements for the impacted periods herein and have provided expanded quarterly financial information in footnote 2 to the financial statements in our Form 10-K for the year ended December 31, 2007 reconciling the restated quarterly consolidated Balance Sheets and Statements of Operations to previously filed quarterly financial information.

Although we believe the restatement made to our historical financial statements will address the comments raised by the SEC, as of the date of this filing the comments are still unresolved.

**ITEM 6. EXHIBITS**

| <b>Exhibit No.</b> | <b>Description</b>   |
|--------------------|--|
| 3.1(1)             | Certificate of Amendment of the Restated Certificate of Incorporation of the Company. (3.1)  |
| 4.1(4)             | Form of 9.75% Senior Secured Convertible Notes due 2010. (4.2)   |
| 4.2(4)             | Second Supplemental Indenture dated as of March 27, 2008, between the Company and The Bank of New York Trust Company, N.A. (4.1)       |
| 10.1(2)            | Employment Agreement by and between the Company and Nicholas Venuto, dated February 19, 2008. (10.1)                                   |
| 10.2(3)            | Amendment and Exchange Agreement, dated March 13, 2008, between the Company and each Purchaser, together with all schedules. (10.1)    |
| 10.3(3)            | Consent and Agreement, dated March 13, 2008, between the Company and each Holder thereto. (10.3)                                       |
| 10.4(4)            | Security Agreement dated as of March 27, 2008, between the Company and Portside Growth & Opportunity Fund, as collateral agent. (10.1) |
| 10.5(4)            | Amendment and Consent Agreement dated as of March 27, 2008, between the Company and the Holder. (10.2)                                 |

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| <b>Exhibit No.</b> | <b>Description</b>  |
|--------------------|---|
| 10.6               | Royalty Interest Assignment Agreement dated as of March 28, 2008, between Epoch Biosciences, Inc., a wholly-owned subsidiary of the Company, and Drug Royalty LP2.              |
| 10.7               | Security Agreement dated as of March 28, 2008, between Epoch Biosciences, Inc., a wholly-owned subsidiary of the Company, and Drug Royalty LP2.                                 |
| 10.8               | Supplemental Royalty Interest Assignment Agreement dated as of March 28, 2008, between Epoch Biosciences, Inc., a wholly-owned subsidiary of the Company, and Drug Royalty LP2. |
| 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 the Company's Form 8-K filed on February 4, 2008. Parenthetical references following the description of each document relate to the exhibit number under which such exhibit was initially filed.
  - (2) Incorporated by reference to the Company's Form 8-K filed on February 22, 2008. Parenthetical references following the description of each document relate to the exhibit number under which such exhibit was initially filed.
  - (3) Incorporated by reference to Company's Form 8-K filed on March 14, 2008. Parenthetical references following the description of each document relate to the exhibit number under which such exhibit was initially filed.
  - (4) Incorporated by reference to Company's Form 8-K filed on March 28, 2008. Parenthetical references following the description of each document relate to the exhibit number under which such exhibit was initially filed.
- Confidential treatment has been requested for certain information contained in this document. Such information has been omitted and filed separately with the Securities and Exchange Commission.

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**SIGNATURES**

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

NANOGEN, INC.

Date: May 12, 2008

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

Date: May 12, 2008

/s/ NICHOLAS J. VENUTO  
Nicholas J. Venuto  
*Chief Financial Officer*



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**NANOGEN, INC.**

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| (4)                | Incorporated by reference to Company's Form 8-K filed on March 28, 2008. Parenthetical references following the description of each document relate to the exhibit number under which such exhibit was initially filed.   |
| (5)                | Supersedes Exhibit 10.1 attached to the Company's Form 8-K filed on March 14, 2008<br>Confidential treatment has been requested for certain information contained in this document. Such information has been omitted and filed separately with the Securities and Exchange Commission. |