NANOGEN INC
Form 10-Q
November 14, 2008
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UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, DC 20549

FORM 10-Q

(Mark one)

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

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

(858) 410-4600

(Registrant s telephone number, including area code)

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 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 x 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 ¨ (Do not check if a smaller reporting company)	Smaller Reporting Company x

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

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

The number of shares outstanding of each of the issuer s classes of common stock, as of the close of business on October 29, 2008, was as follows:

Class	Number of Shares
Common Stock, $0.001 per share par value	**82,296,609**

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NANOGEN, INC.

QUARTERLY REPORT ON FORM 10-Q

FOR THE THREE MONTHS ENDED SEPTEMBER 30, 2008

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PART I. FINANCIAL INFORMATION

ITEM 1. Financial Statements

NANOGEN, INC.

CONSOLIDATED BALANCE SHEETS

(in thousands, except par value and share data)

	September 30, 2008 (Unaudited)	December 31, 2007
ASSETS		
Current assets:		
Cash and cash equivalents	$ 1,689	$ 5,806
Short-term investments		1,450
Receivables, net	18,130	14,821
Inventories, net	2,587	2,267
Other current assets	2,213	1,840
Total current assets	24,619	26,184
Property and equipment, net	5,562	6,662
Acquired technology rights and intangibles, net	12,029	14,905
Restricted cash	9,340	9,626
Other non-current assets, net	1,679	2,011
Goodwill	38,948	38,963
Total assets	$ 92,177	$ 98,351
LIABILITIES AND STOCKHOLDERS EQUITY		
Current liabilities:		
Accounts payable and accrued liabilities	$ 19,866	$ 15,600
Deferred revenues	5,312	663
Conversion feature of convertible debt	5,227	664
Current portion of assigned royalty interests obligation		2,868
Common stock warrants	3,605	1,708
Current portion of debt obligations	12,089	4,868
Total current liabilities	46,099	26,371
Debt obligations, less current portion	7,780	8,139
Long-term deferred revenues	20,140	
Sponsored research payable	4,839	4,848
Long-term assigned royalty interests obligation		14,711
Other long-term liabilities	2,887	2,778
Total long-term liabilities	35,646	30,476
Commitments and contingencies		
Stockholders equity:		
Convertible preferred stock, $0.001 par value, 5,000,000 shares authorized at September 30, 2008 and December 31, 2007; no shares issued and outstanding at September 30, 2008 or December 31, 2007		
Common stock, $0.001 par value, 245,000,000 and 135,000,000 shares authorized at September 30, 2008 and December 31, 2007, respectively; 81,200,909 and 73,218,128 shares issued and outstanding	81	73

at September 30, 2008 and December 31, 2007, respectively		
Additional paid-in capital	445,209	440,583
Accumulated other comprehensive income	1,863	2,237
Accumulated deficit	(436,721)	(400,618)
Treasury stock, at cost, 0 and 416,027 shares at September 30, 2008 and December 31, 2007, respectively		(771)
Total stockholders equity	10,432	41,504
Total liabilities and stockholders equity	$ 92,177	$ 98,351

See accompanying notes.

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NANOGEN, INC.

CONSOLIDATED STATEMENTS OF OPERATIONS

(unaudited)

(in thousands, except per share data)

	Three months ended September 30,		Nine months ended September 30,	
	2008	2007	2008	2007
Revenues:				
Product sales	$ 7,819	$ 5,549	$ 23,861	$ 16,927
License fees	1,514	1,833	4,772	5,132
Contracts and grants	4,428	986	8,744	6,277
Total revenues	13,761	8,368	37,377	28,336
Costs and expenses:				
Cost of product sales (excluding amortization of purchased intangibles)	4,466	8,705	14,783	18,064
Research and development	4,768	7,540	13,710	21,598
Selling, general and administrative	8,036	9,167	25,093	29,253
Amortization of purchased intangible assets	707	733	2,350	2,260
Total costs and expenses	17,977	26,145	55,936	71,175
Loss from operations	(4,216)	(17,777)	(18,559)	(42,839)
Other income (expense):				
Interest income	154	188	631	757
Interest expense	(3,135)	(1,439)	(6,341)	(3,438)
Other income (expense)	37	27	325	(26)
Loss on extinguishment of debt	(3,050)		(15,295)	
Change in fair value of warrants and conversion rights	4,185	5,426	3,126	5,436
Gain (loss) on foreign currency transactions	33	(12)	10	(26)
Gain on deconsolidation of VIE		12,686		12,686
Total other income (expense)	(1,776)	16,876	(17,544)	15,389
Net loss	$ (5,992)	$ (901)	$ (36,103)	$ (27,450)
Net loss per share basic and diluted	$ (0.08)	$ (0.01)	$ (0.48)	$ (0.38)
Number of shares used in computing net loss per share basic and diluted	78,468	72,966	75,624	72,035

See accompanying notes.

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NANOGEN, INC.

CONSOLIDATED STATEMENTS OF CASH FLOWS

(unaudited)

(in thousands)

	Nine Months Ended September 30,	
	2008	**2007**
Operating activities:		
Net loss	$ (36,103)	$ (27,450)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	4,490	5,818
Gain on deconsolidation of VIE		(12,686)
Other asset impairment and non-cash charges	1,342	2,134
Inventory provision	141	4,574
Accretion related to short-term investments		104
Stock-based compensation expense	1,462	3,180
Warrant valuation and conversion right adjustment	(3,126)	(5,426)
Loss on extinguishment of debt	15,295	
Accretion of long-term debt	2,927	169
Non-controlling interests share in loss of VIE		302
Increase (decrease) in cash caused by changes in operating assets and liabilities:		
Receivables, net	(3,604)	(3,485)
Inventories, net	(451)	(370)
Other current and long-term assets	(1,166)	(2,770)
Accounts payable and accrued liabilities	4,781	5,234
Deferred revenue and other long-term liabilities	7,926	95
Net cash used in continuing operating activities	(6,086)	(30,577)
Investing activities:		
Purchase of short-term investments		(19,374)
Proceeds from sale and maturities of short-term investments	1,450	26,225
Acquisition of business, net of cash acquired		(2,030)
Proceeds from the conversion of restricted cash to cash	269	(3,904)
Purchase of equipment and technology rights	(1,937)	(1,798)
Net cash used in investing activities	(218)	(881)
Financing activities:		
Principal payments on capital lease obligations	(385)	(530)
Principal payments on debt obligations	(374)	
Payments on receivable financing	(6,699)	(3,299)
Proceeds from debt financing secured by receivables	5,918	4,208
Principal payments on assigned royalty interests obligation	(738)	(1,528)
Proceeds from debt obligations of variable interest entity		1,894
Issuance of common stock		7,587
Proceeds from short-term obligations	4,617	19,051
Net cash provided by financing activities	2,339	27,383
Effect of exchange rate changes	(152)	1,050

Net decrease in cash and cash equivalents	(4,117)	(3,025)
Cash and cash equivalents at beginning of period	5,806	11,261
Cash and cash equivalents at end of period	$ 1,689	$ 8,236

See accompanying notes.

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NANOGEN, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (UNAUDITED)

September 30, 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. The Company is 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 September 30, 2008, consolidated statements of operations for the three and nine months ended September 30, 2008 and 2007, and the consolidated statements of cash flows for the nine months ended September 30, 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 and nine months ended September 30, 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 $6.0 million and $36.1 million, for the three and nine months ended September 30, 2008, respectively, and has an accumulated deficit of $436.7 million as of September 30, 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 raise cash through a combination of debt and equity, including $3.0 million from issuance of the Second Bridge Note described in note 5. If the Company is unsuccessful in raising sufficient additional capital, it will have to defer, reduce, or eliminate certain planned expenditures and may be unable to complete the proposed business combination with Financiére Elitech S.A.S. (Elitech). 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 its 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

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.

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, the Company has several other legal entities which are included in the consolidation, but collectively they are not material.

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Variable Interest Entities

In a series of investments from July 2005 to June 2006, the Company 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)) the Company determined it was the primary beneficiary and was required to include Jurilab s assets and liabilities in the Company s consolidated financial statements. The Company included Jurilab s assets and liabilities as of the date of the 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. The Company determined that under FIN 46(R), the Company no longer qualified as the primary beneficiary as a result of the new equity financing and therefore was no longer required to consolidate Jurilab s assets and liabilities in the Company s financial statements. The results of Jurilab s operations through July 2007, the date of the reconsideration event, are included in the Company s 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. The Company regularly evaluates estimates and assumptions related to royalty revenue, allowances for doubtful accounts, sales returns and allowances, warranty reserves, inventory reserves, the fair value of warrants and conversion rights, stock-based compensation expense, goodwill and purchased intangible asset valuations, strategic investments and other loss contingencies. The Company bases its estimates and assumptions on current facts, historical experience and various other factors that the Company believes 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 the Company may differ materially and adversely from the Company s estimates. To the extent there are material differences between the estimates and the actual results, future results of operations will be affected.

Revenue Recognition

The Company generates revenue through product sales, license and royalty fees, and contracts and grants from third parties. The Company recognizes 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) collectability is reasonably assured, and v) both the title and the risks and rewards of ownership are transferred to an unrelated third party. In addition, the Company applies the prescribed methodology in EITF Issue No. 00-21, *Accounting for Revenue Arrangements with Multiple Deliverables*, (EITF 00-21) to evaluate 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

The Company sells its commercial products under various sales programs directly to end users through various distribution channels.

Revenue from product sales is recognized when the Company receives a purchase order, has 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, the Company defers revenue recognition until the customer has accepted the product and the right-of-return period has lapsed.

License and royalty fees

The Company applies the prescribed methodology in EITF 00-21 to evaluate license and royalty fee contracts to determine if these contracts involve more than one identifiable deliverable. The Company then determines 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, the Company recognizes 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 the Company is required to estimate the useful life of the technology transferred to ratably recognize revenue over this period. The Company believes that cash payment streams are one of the primary indicators of the customer s perceived useful life of the technology transferred; therefore, the Company recognizes revenue during this period of time unless there are other contrary indicators in the license and royalty contract. In addition, as indicators are determinable under contract the Company recognizes 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 to the Company. Therefore, the Company will recognize revenue tied to third party sales on an accrual basis if information is available to enable the Company to accurately estimate the royalty due. In certain situations the Company may not be able to receive information on licensee product sales on a timely basis that will allow the Company to reasonably estimate the amount of royalty revenue to be recognized in the quarter during which the third party sales take place. The Company will not recognize this royalty revenue until the Company is able to ensure that there is reliable information to make a decision whether to recognize this revenue, which may be in a subsequent reporting period. Therefore, the Company 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

The Company earns 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 the Company s achievement of specific contractual milestones. Milestone payments are recognized as revenue upon meeting the following criteria: i) the Company has achieved a specified milestone and has 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 the Company s revenue recognition criteria are recorded as deferred revenue in the balance sheet.

Long-Lived Assets

Quarterly the Company assesses 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 the assessments, if there are indicators of impairment related to long-lived assets, the Company is required to determine that the carrying value of the assets can be recovered through undiscounted future cash flows. If the carrying value of the assets can not be recovered, the Company is required to write down the value of the long-lived asset to its fair value. As a result of the consolidation of the Company s operations in Toronto, Canada, the Company recorded asset impairment charges of $278,000 and $973,000 for the three and nine months ended September 30, 2008, respectively.

Net Loss per Share

The Company computed net loss per share in accordance with SFAS No. 128, *Earnings per Share*. The Company computed basic net loss per share from operations 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.

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

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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 three quarters 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 has entered into a share exchange agreement with Elitech to purchase all of the outstanding stock of Elitech in exchange for an aggregate number of shares of the Company s common stock. The Company expects this transaction will be completed in the first quarter of 2009. The company is currently evaluating the impact of the adoption of SFAS No. 141 (Revised 2007) on its financial position. See Note 2 for additional information related to this business combination.

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.

In May 2008, FASB issued FASB Staff Position No. APB 14-1, *Accounting for Convertible Debt Instruments that May be Settled in Cash upon Conversion (Including Partial Cash Settlement)* (FSP APB 14-1) that significantly impacts the accounting for convertible debt. The FSP APB 14-1 requires cash settled convertible debt to be separated into debt and equity components at issuance and a value to be assigned to each. The value assigned to the debt component would be the estimated fair value, as of the issuance date, of a similar bond without the conversion feature. The difference between the bond cash proceeds and this estimated fair value would be recorded as a debt discount and amortized to interest expense over the expected life of the bond. Although FSP APB 14-1 has no impact on a company s actual past or future cash flows, it requires a Company to record a significant amount of non-cash interest expense as the debt discount is amortized. As a result, there would be a material adverse impact on the results of operations and earnings (loss) per share. In addition, if a company s convertible debt is redeemed or converted prior to maturity, any unamortized debt discount would result in a loss on extinguishment. FSP APB 14-1 will become effective for fiscal years beginning after December 15, 2008, and early adoption is not permitted. The adoption will require retrospective application. The company is currently evaluating the impact of this standard on the results of operations, but the Company expects Adoption of FSP APB 14-1 may result in recording a material amount of additional non-cash interest expense related to the amortization of debt discount. In addition, in the event of conversion or redemption prior to maturity the Company may need to record a loss on extinguishment.

In May 2008, the FASB issued SFAS No. 162 *The Hierarchy of Generally Accepted Accounting Principles*. SFAS No. 162 identifies the sources of accounting principles and the framework for selecting the principles to be used in the preparation of financial statements of nongovernmental entities that are presented in conformity with generally accepted accounting principles (GAAP) in the United States (the GAAP hierarchy). This Statement is effective 60 days following the Security and Exchange Commission (SEC s) approval of the Public Company Accounting Oversight Board amendments to AU Section 411, The Meaning of Present Fairly in Conformity With Generally Accepted Accounting Principles. The Company is currently evaluating the impact of SFAS No. 162.

2. Business Combination

In August 2008, the Company entered into a share exchange agreement with the stockholders of Elitech to sell all of the outstanding stock of Elitech to the Company in exchange for an aggregate number of shares of the Company s common stock. Elitech

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is an independent distributor of in vitro diagnostic products based in France. The share exchange agreement is subject to the approval of the Company s stockholders. A special stockholder meeting to vote on the proposed business combination will take place in early 2009. Assuming stockholder approval, the Company will exchange an aggregate number of shares of its common stock equal to the greater of (i) 58.7% of the fully diluted outstanding shares of the combined entity or (ii) the number of shares of common stock equivalent to 66.5 million. The 66.5 million will be calculated by taking the closing price of the Company s common stock on the fifth trading day prior to closing of the transaction. The closing amount will be adjusted by the euro-dollar currency exchange rate on the date of the closing. However, the number of shares of common stock issued shall not exceed 68.7% of the fully diluted outstanding shares of the combined company (the Business Combination). Upon the closing, Elitech will become a wholly-owned subsidiary of the Company, and the combined company will be controlled by the current stockholders of Elitech. The Company s Board of Directors has approved the Business Combination. The Board of Directors of the combined company will consist of seven members, four of whom will be designated by Elitech and three of whom will be designated by the Company. The share exchange agreement states that if either Elitech or the Company elects to terminate the share exchange agreement under certain conditions, the Company would have to pay Elitech between $2.3 million and $2.5 million under certain circumstances.

The consummation of the share exchange agreement is subject to regulatory review, Nanogen stockholder approval and other customary closing conditions. In addition, the share exchange agreement includes the following closing conditions:

(i) the Company s modified earnings before interest, taxes, depreciation, and amortization, calculated consistent with past practice (Modified EBITDA), for the most recently completed fiscal quarter immediately preceding the closing date of the Business Combination shall exceed Modified EBITDA as reported for the first quarter of 2008 by 50% or more,

(ii) the parties shall have secured or entered into an agreement to secure financing for the working capital of the combined company in connection with or as soon as practicable after the closing in an amount not less than $10.0 million,

(iii) Elitech shall have delivered to the Company audited consolidated financial statements that do not vary in any material respect from the Elitech financial statements delivered to the Company in connection with the Share Exchange Agreement,

(iv) Elitech shall have restructured its business and entered into certain distributions agreements, each in a manner satisfactory to the Company, and

(v) Elitech shall have caused certain of its shareholders to enter into a purchase option agreement with the Company granting the Company an option to purchase certain assets in the future.

The Company has expensed approximately $1.1 million in business combination costs in the three and nine months ended September 30, 2008.

3. Comprehensive Loss

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

	Three months ended September 30,		Nine months ended September 30,	
	2008 (Unaudited)	2007 (Unaudited)	2008 (Unaudited)	2007 (Unaudited)
Comprehensive loss:				
Net unrealized gain on short-term investments and other investments	$ 69	$ 95	$ 101	$ 94
Foreign currency translation adjustment	(1,225)	1,806	(475)	2,072
Net loss	(5,992)	(901)	(36,103)	(27,450)

Comprehensive gain (loss)	$ (7,148)	$ 1,000	$ (36,477)	$ (25,284)

4. Commitments and Contingencies

Restricted Cash

The Company has restricted cash representing cash, cash equivalents and short term investments consisting of $7.3 million as security for the convertible debt obligation (see note 5) and $2.0 million is pledged in lieu of cash deposits primarily for facility lease deposits. Restricted cash balances were approximately $9.3 million and $9.6 million at September 30, 2008 and December 31, 2007, respectively.

Litigation

The Company 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 business, as well as through the disposition of product lines such as the micro array platform. 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 September 30, 2008, the Company has no significant accrual for any claims or pending claims.

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In the normal course of business the Company has been and may continue to be subject to litigation incidental to the Company s 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 of whether it has merit can be expensive and disruptive to normal business operations. As litigation is inherently uncertain, the Company cannot predict the outcome of such matters. The Company can provide no assurance that the ultimate outcome either individually or in the aggregate will not have an adverse effect on the Company s business or financial results.

Debt Obligations

The following table is a summary of the aggregate principle balance and shares convertible on the Company s convertible debt obligations (in thousands, except for conversion price):

	September 30, 2008 (Unaudited)			December 31, 2007		
	Principal outstanding	Share convertible	Conversion Price	Principal outstanding	Share convertible	Conversion Price
Convertible senior subordinated note payable in August 2010 at interest rate of 6.25% (*Debentures*)	$ 7,000	17,632	$ 0.397	$ 19,918	15,683	$ 1.27
Convertible senior secured bridge notes payable (*First Bridge Notes*)	5,000	12,595	0.397			
Amended and restated 9.75% senior secured convertible notes (*Amended Note*)	12,146	30,595	0.397			
9.75% Senior Secured Convertible Notes (*Additional Notes*)	2,708	5,683	0.476			
Warrants associated with issuance of convertible note		29,041	0.397		17,322	1.14 1.13
Totals	$ 26,854	95,546		$ 19,918	33,005	

See footnote 5 for the details of convertible debt obligations.

5. Financial Statement Details

Receivables

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

	September 30, 2008 (Unaudited)	December 31, 2007
Product	$ 14,178	$ 11,996
License fees		1,100
Contract and grant	4,184	1,993
	18,362	15,089
Allowance for doubtful accounts	(232)	(268)
	$ 18,130	$ 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. The Company periodically evaluates on-hand inventories and makes appropriate provisions for any inventories deemed excess or obsolete.

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

	September 30, 2008 (Unaudited)	December 31, 2007
Raw materials	$ 5,215	$ 6,084
Work in process	603	529
Finished goods	2,630	4,813
	8,448	11,426
Reserve for excess and obsolescence	(5,861)	(9,159)
	$ 2,587	$ 2,267

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Other long-term liabilities

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

	September 30, 2008 (Unaudited)	December 31, 2007
Deferred rent	$ 1,731	$ 1,906
Other	1,156	872
	$ 2,887	$ 2,778

Notes payable, Detachable Warrants and Conversion Features Related to Issuance of Convertible Debt

	September 30, 2008 (Unaudited)	December 31, 2007
Current Liabilities:		
Equipment financing	$ 310	$ 474
Revolving working capital debt financing	3,569	4,394
Current portion of the Convertible 9.75% bridge notes payable, net of discount (*First Bridge Notes*)	3,402	
Current portion of the Convertible senior secured 9.75% notes payable, net of discount (*New Exchange Notes*)	4,808	
	$ 12,089	$ 4,868
Long Term Liabilities:		
Equipment financing	$ 95	$ 315
Convertible senior subordinated notes payable in August 2010 at interest rate of 6.25%, net of discount (*Debentures*)	3,577	7,824
Convertible senior secured notes payable in August 2010 at interest rate of 9.75%, net of discount (*New Exchange Notes*)	4,108	
	$ 7,780	$ 8,139
Conversion Features Related to Issuance of Convertible Debt:		
Convertible senior secured bridge notes payable (*First Bridge Notes*)	$ 484	$
Convertible senior subordinated notes payable in August 2010 at interest rate of 6.25% (*Debentures*)	1,802	664
Convertible senior secured 9.75% notes payable (*New Exchange Notes*)	2,941	
	$ 5,227	$ 664
Common Stock Warrants:		
Warrants related to February 2007 placement agreement	$ 122	$ 161
Warrants related to issuance of convertible senior subordinated notes payable in August 2010 at interest rate of 6.25% (*Debentures*)	3,483	1,547
	$ 3,605	$ 1,708

Equipment financing

The Company has entered into various debt obligations to provide financing for equipment purchases. There was no additional borrowing available under these agreements as of September 30, 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 $36,000, maturing over the next 2 years and are secured by the specific equipment being financed.

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Revolving working capital debt facility

In December 2006, the Company obtained a revolving working capital debt facility for up to approximately $5.2 million secured by the Company s Italian accounts receivable. At September 30, 2008 the Company s Italian accounts receivable balance was $11.9 million. The interest rate is based on the Euro Interbank Offered Rate index averaged over three months based on 365 days per year plus 1.2% as of September 30, 2008, the outstanding liability is $3.6 million under this agreement with an interest rate of 6.2%.

Convertible debt financing agreements

The Company entered into a series of convertible debt and bridge financing agreements from August 2007 through August of 2008. The following is timeline of these financing agreements:

The First Bridge Notes

In August 2008, the Company entered into securities purchase agreements with each of the holders of the Company s outstanding 9.75% Senior Secured Convertible Notes (New Notes), where the Company agreed to issue and sell an aggregate of $5.0 million of Bridge Notes (First Bridge Notes). The First Bridge Notes were initially convertible into an aggregate of 12,594,458 shares of common stock at an initial conversion price of $0.397 per share. The First Bridge Notes were issued and sold pursuant to an exemption from the registration requirements of the Securities Act of 1933 (the Act), as amended provided under Section 4(2) of the Act, and Rule 506 promulgated thereunder. The securities purchase agreements require us to hold a special meeting of stockholders to approve the issuance of First Bridge Notes prior to March 31, 2009.

The First Bridge Notes will mature upon the earlier of (i) May 15, 2009 or (ii) the fifth business day following the consummation of the Business Combination, subject to extension under certain circumstances. The First Bridge Notes bear interest at 20.0% per annum, payable quarterly in arrears commencing on September 30, 2008. At the option of the Company, interest is to be paid in cash or by adding the remaining amount of interest due to the outstanding principal amount of the First Bridge Notes (the Capitalized Interest). Upon and during the occurrence of an Event of Default, the interest rate under the First Bridge Notes will increase to 25.0% per annum. In addition, in the event that any payment of principal or other amounts payable under the First Bridge Notes or other transaction documents in the First Bridge Financing are not paid when due, such past due amounts are subject to a late charge of 15% per annum from the date due until paid. At September 30, 2008 the Company is not in default on any of its debt.

So long as the Company satisfies certain milestones relating to the Business Combination by certain dates, including filing of the proxy statement and stockholder approval of the Business Combination, then the Company s obligations to make interest and principal payments are deferred. While such payments are deferred, interest is accrued at the Event of Default interest rate (25% per annum) and late charges are accrued on all amounts so deferred. On September 30, 2008 the Company has elected to defer the interest and principal payments and thus is subject to the Event of Default interest rate and the applicable penalty rate of 15% per annum.

The principal amount of the First Bridge Notes together with any accrued, unpaid interest and any late charges will be convertible at the option of the First Bridge Note Holders, at any time following their issuance, into shares of Common Stock at the initial conversion price of $0.397 per share, subject to certain limitations on beneficial ownership. The conversion amount will include the present value of interest through maturity of the Bridge Notes calculated at a 6.25% discount rate upon any optional conversion by the holders or change of control redemption event, subject to certain limitations. The conversion prices are subject to certain adjustments including full ratchet anti-dilution protection for the First Bridge Notes in respect of any equity or convertible securities issuances below $0.397 without subsequent stockholder approval.

The Company evaluated the First Bridge Notes to determine if the embedded components of those contracts qualify as derivatives to be separately accounted for under SFAS 133 *Accounting for Derivative Instruments and Hedging. Activities* (SFAS 133) and related interpretations including EITF 00-19 *Accounting for Derivative Financial Instruments Indexed to, and Potentially Settled in, a Company s Own Stock* (EITF 00-19). As a result of this evaluation, the Company has identified the conversion rights as a derivative financial instrument that is required to be recorded as a liability.

The Company determined the fair value of the conversion rights from the host debt contract and recorded it as a derivative liability which resulted in a reduction of the initial notional carrying amount of the First Bridge Notes as an unamortized discount which will be accreted over the term of the First Bridge Notes using the effective interest method. The Company determined that the initial fair value of the conversion rights of the First Bridge Notes was $1.9 million at August 14, 2008. The Company recorded

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$483,000 in interest expense related to the accretion of the unamortized discount and the 25% Event of Default interest rate through September 30, 2008. The Company is paying the 25% Event of Default interest rate due to its election to defer interest and principle payments. At September 30, 2008 the Company determined the fair value of the conversion rights was $484,000 and recognized approximately $1.4 million as other income in the consolidated statement of operations. The initial financing costs of $232,000 are amortized into interest expense over the term of the First Bridge Notes. As of September 30, 2008 the Company has amortized approximately $41,000 of the financing costs.

The Second Bridge Notes

In August 2008, the Company entered into a securities purchase agreement with Elitech where the Company agreed to issue and sell to Elitech the Second Bridge Notes in an aggregate principle amount of $3.0 million. The Company is expected to issue the Second Bridge Notes in three stages during the fourth quarter of 2008. The first issuance of $1.0 million was received in October 2008, the second issuance of $1.0 million is scheduled on or prior to November 15, 2008 and the final issuance of $1.0 million is scheduled on or prior to December 31, 2008 (Elitech Funding). The Second Bridge Notes were issued and sold pursuant to an exemption from the Act. The securities purchase agreement requires us to hold a special meeting of stockholders to approve the issuance of the Second Bridge Note prior to March 31, 2009.

The Second Bridge Notes will mature upon the earlier of (i) May 15, 2009 or (ii) the fifth business day following the consummation of the Business Combination, subject to extension under certain circumstances. The Second Bridge Notes bear interest at 20.0% per annum, payable quarterly in arrears commencing on September 30, 2008. The interest is to be paid in cash or by adding the remaining amount of interest due at the end of each quarter to the outstanding principal amount of the Second Bridge Notes (the Capitalized Interest). Upon and during the occurrence of an event of default, the interest rate under the Second Bridge Notes will increase to 25.0% per annum. In addition, in the event that any payment of principal or other amounts payable under the Second Bridge Notes or First Bridge Notes are not paid when due, such past due amounts are subject to a late charge of 15% per annum from the date due until paid.

The principal amount of the Second Bridge Notes together with any accrued, unpaid interest and any late charges will be convertible at the option of the Second Bridge Note Holders, at any time following their issuance, into shares of Common Stock at the initial conversion price of $0.397 per share, subject to certain limitations on beneficial ownership. The conversion amount will include the present value of interest on the Bridge Notes calculated at a 6.25% discount rate upon any optional conversion by the holders or change of control redemption event, subject to certain limitations. The conversion prices are subject to certain adjustments including full ratchet anti-dilution protection for the Second Bridge Notes in respect of any equity or convertible securities issuances below $0.397 without subsequent stockholder approval.

First and Second Bridge Notes Covenants

The Bridge Notes define event of default as certain events which include, but are not limited to, the suspension of trading of the Company s common stock on the NASDAQ exchange, failure to cure conversion failures or maintain sufficient shares of common stock available for conversion, failure to timely repay the Bridge Notes, failure to timely repay certain indebtedness exceeding $250,000, the occurrence of bankruptcy or similar events, the rendering of a final judgment against the Company in excess of $500,000 not covered by insurance, failure to receive the Elitech Funding, termination of the Share Exchange Agreement, failure to consummate the Business Combination by March 31, 2009, breaches of covenants, and default under the Company s material agreements.

Upon the occurrence of an event of default, the Bridge Note holders may require the Company to redeem all or a portion of the Bridge Notes at a redemption price in cash using a calculation set forth in the Bridge Notes. In addition, in the event of a change of control, the Company will have the right to redeem all of the Bridge Notes, and each Bridge Note holder will have the right to require the Company to redeem all or any portion of its Bridge Notes at a redemption price in cash using a calculation set forth in the Bridge Notes. Upon the occurrence of change in control transaction, the Company will be required to reaffirm it s obligations under the Bridge Notes following the transaction. In addition, the Company is required to confirm that the Notes will be convertible into either (i) common stock or the shares of publicly traded common stock of the Company or its successor entity, or (ii) if the Company or its successor entity is not a publicly traded company following the transaction, the Bridge Note Holders are to receive an equivalent amount of the securities or other cash or assets that the Bridge Note Holders would have received had they converted the Bridge Notes immediately prior to the consummation of the change of control transaction.

The Bridge Notes contain covenants which, among other things, restrict the Company and its subsidiaries ability to:

incur additional indebtedness other than in connection with existing indebtedness or certain permitted indebtedness;

grant liens on the Company s assets other than certain ordinary permitted liens;

make distributions on or repurchase shares of common stock;

transact businesses with its affiliates and to make investments in subsidiaries;

change the nature of the Company s businesses other than in respect of the Business Combination;

sell, convey or dispose of the Company s businesses or assets except for specified permitted asset dispositions; and

effect certain equity and debt financing that would result in a dilutive issuance except for certain permitted financing.

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In addition, the Company is not permitted to make any advance, loan, investment in or extend credit to its subsidiaries, except in the ordinary course of business and then not in an amount that exceeds, at any time, $90.0 million in the case of foreign subsidiaries, and $80.0 million in the case of domestic subsidiaries. Additionally, the Company has agreed that, after the date of the Financing, the net amount of advance, loan or investments made by the Company to its subsidiaries in any rolling three months period shall not exceed $250,000. Finally, the Company s Italian subsidiary must have an accounts receivable balance of at least 7.0 million at the end of each fiscal quarter, net of reserves, established in accordance with U.S. Generally Accepted Accounting Principles. At September 30, 2008 the Company was in compliance with the First and Second Bridge Note Covenants.

To secure the Company s obligations under the Bridge Notes, on August 14, 2008, the Company entered into a second lien security agreement with a collateral agent where the Company granted a second priority security interest in (i) substantially all of the assets of the Company, (ii) all of the Company s equity interests in its U.S. subsidiaries and (iii) 65% of the Company s equity interest in its non-U.S. subsidiaries (other than the Italian Subsidiary) and (iv) a first priority security interest in all of the Company s equity interests in its Italian subsidiary, subject to certain exclusions, which include (i) receivables sold pursuant to a factoring agreement with GE Capital Finance S.p.A. in Italy; (ii) assets transferred pursuant to, and intellectual property assets securing the obligations of the Company and its subsidiaries under, certain royalty sale transactions; (iii) cash collateral securing certain letters of credit; (iv) certain minority equity interests; and (v) assets subject certain permitted liens and certain other customary exclusions set forth in the terms of the Bridge Notes.

Restructuring of 9.75% Senior Secured Convertible Notes (New Exchange Notes)

In August 2008, the Company entered into an exchange agreement with each holder of the Company s outstanding New Notes. The holders agreed to exchange all their outstanding New Notes with an aggregate principal amount of $13,537,688 for an amended and restated 9.75% senior secured convertible notes in an aggregate principal amount of $13,537,688 (the Amended Notes) and a 9.75% Senior Secured Convertible Notes with an aggregate principal amount of $2,707,537 (the Additional Notes). The Amended Notes and Additional Notes are referred to herein collectively as the New Exchange Notes . The fair value allocated to the principal balance outstanding under the New Exchange Notes at September 30, 2008 is $8.3 million. Prior to entering into the New Exchange Notes agreement, the Company was in default on the New Notes.

The issuance of the New Exchange Notes were not subject to the registration requirements of the Act pursuant to Section 3(a)(9) promulgated thereunder. In addition, the exercise price of the warrants which were sold to the holders in connection with the issuance of 6.25% Unsecured Senior Convertible Notes (Debentures) in August 2007 were adjusted pursuant to the anti-dilution provision of such warrants to $0.397 as a result of the issuance of the Bridge Notes and the New Exchange Notes. The number of shares issuable upon exercise of such warrants was not adjusted. In addition, the Company agreed to pay the holders approximately $383,000 in legal fees that were incurred as a result of the issuance of the New Exchange Notes.

As a result of the issuance of the Bridge Notes, the initial conversion price of the Amended Notes was adjusted to $0.397 pursuant to the anti-dilution provisions in the New Notes, which were approved by stockholders of the Company in June 2008. The Additional Notes are convertible only after stockholder approval is obtained. Upon stockholder approval, the Additional Notes will be convertible initially into an aggregate of 5,683,328 shares of Common Stock at an initial conversion price of $0.4764 per share.

The New Exchange Notes have an identical interest rate and maturity date as the New Notes issued in March 2008 (see below). Interest expense recognized related to the New Exchange Notes for the nine months ended September 30, 2008 totaled $1.1 million. The financing costs of $731,000 are being amortized into interest expense over the term of the New Exchange Notes. As of September 30, 2008, we have amortized $110,000 of the financing costs. The remaining terms of the New Exchange Notes are substantially identical to the New Notes except for the following:

The New Exchange Notes do not contain the 20% redemption premium upon a change in control of the Company.

The Company is required to satisfy certain milestones relating to the Business Combination by certain dates, including filing of the proxy statement and gaining stockholder approval of the Business Combination. If these milestones are met the Company may defer its obligations to make interest and principal payments under the New Exchange Notes, including certain mandatory monthly and quarterly redemption payments and late charges. While the payments are deferred, interest is accrued at the event of default interest rate of 12.0% and late charges continue to accrue on all amounts so deferred (Principal and Interest Deferral).

The New Exchange Notes contain an automatic conversion provision that provides that, if at any time (i) the average closing price of the Common Stock for any ten trading days in any fifteen consecutive trading day period equals or exceeds 150% of the then-effective conversion price of the Amended Notes or the Additional Notes, as the case may be, and (ii) the Company satisfies certain specified equity conditions, then all outstanding principal amounts under the Amended Notes or the Additional Notes shall be converted into shares of Common Stock.

The Additional Notes do not contain certain mandatory redemption requirements as set forth in the New Notes and the Amended Notes, including monthly and quarterly redemption payments and redemption payments upon asset dispositions and subsequent placement by the Company.

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The New Exchange Notes provide that the failure of Elitech to provide Bridge Financing, termination of the Share Exchange Agreement, or failure to consummate of Business Combination by March 31, 2009 shall also constitute events of default.

The New Exchange Notes contain the Intercompany Advances Covenant and Italian Receivable Covenant.

The Company cannot pay interest under the Additional Notes in shares of Common Stock prior to stockholder approval.

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

Under Accounting Principles Board Opinion (APB) No. 26, *Early Extinguishment of Debt*, (APB 26), the difference between the New Exchange Notes principal amount of $16.2 million and the $11.1 million net carrying amount of the extinguished debt of the New Notes was recorded as a loss on extinguishment of debt in the third quarter of 2008. In addition, the Company recorded a $526,000 loss on the pro-rata share of unamortized debt issuance costs associated with the New Notes. These losses were offset by the write-off of the conversion rights of $2.6 million associated with the New Notes.

9.75% Senior Secured Convertible Notes (New Notes)

In March 2008, the Company entered into an exchange agreement with the holders of its 6.25% Unsecured Senior Convertible Notes (the Debentures) it issued in August 2007. The Company exchanged an aggregate $12,917,000 in principal amount of the Debentures for 9.75% Senior Secured Convertible Notes (the New Notes) with an aggregate principal amount of $15,500,400. The New Notes were initially convertible into an aggregate of 22,784,653 shares of common stock at a conversion price of $0.6803 per share. The exchange agreement was made pursuant to an exemption from a registration requirement under Section 3(a)(9) of the Act. Neither the New Notes nor shares of Common Stock were eligible for issuance upon conversion of the New Notes until they are registered under the Act.

Upon consummation of the Exchange Offer, the Debentures in an aggregate principal amount of $7.0 million remained outstanding. After the closing of the exchange agreement the conversion price of the remaining Notes and the exercise prices of certain warrants issued to the holders of the August 2007 Debt Financing were adjusted to $0.6803. The exchange offer triggered the anti-dilution clause in the warrants which resulted in issuing an additional 11.7 million warrants to the Holders. In addition, the Company agreed to pay Holders certain tax gross up payments and legal fees incurred as a result of the Second Exchange Offer.

In connection with this exchange offer the Holders agreed to allow the Company to pursue the sale of certain royalties. The Company also agreed to enter into a Second Supplemental Indenture (Indenture) between the Company and the Trustee for the purpose of making certain technical amendments to the Indenture in order to permit us to consummate the sale of certain royalties, and to revise the terms in the Indenture, including certain covenants, to conform to the terms of the New Notes.

The Company secured its obligations under the New Notes by entering into a Security Agreement to grant a security interest in substantially all of its assets and stock to the Holders of the New Notes. 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 the Company s obligations and obligations of the Company s 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. In addition, this Security Agreement contains customary representations, warranties and covenants.

As of September 30, 2008, the Company recorded $1.4 million in interest expense relating to the New Notes and the amortization of the financing costs. The remaining financing cost of $526,000 was expensed as a part of the loss on extinguishment of debt in August 2008.

The Holders of the New Notes had 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 the Company s election or the Holders election, the Company is also required to pay the present value of the future interest payments that would have been made if the conversion had not occurred.

The New Notes contained customary events of default provisions, including without limitation related to failure to pay the 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 the Company s 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 New Notes), the interest rate under the New Notes will increase to 12.0% per annum.

The Company determined that the initial fair value of the conversion rights of the New Notes was $2.8 million and separated this amount from the host debt contract and recorded it as a derivative liability. This resulted in a reduction of the initial notional carrying amount of the New Note as an unamortized discount which would be accreted over the term of the New Notes using the effective interest method. The fair value of the embedded derivative is accounted for in a similar manner to the embedded derivates that are associated with the August 2007 Debentures.

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Under EITF 96-19, the Company determined that the March 2008 modification of the original definitive agreement was substantial since the discounted cash flows that would have occurred under the modified portion of the Debentures differed by greater than 10% from the discounted cash flows associated with the New Notes. Thus the modification of debt under the New Notes 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, $2.0 million was recorded in the same manner as a result of the issuance of the additional warrants for 11.7 million shares triggered by the anti-dilution clause in the warrants, as well as a pro-rata share of unamortized debt issuance costs, $964,000, associated with the Notes. These losses were offset by the write-off of a pro-rata share of the conversion rights, $703,000, associated with the extinguished debt.

6.25% Unsecured Senior Convertible Notes (Debentures)

In August 2007, the Company 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 common stock. The Debentures bear interest at 6.25% per annum and interest is accrued and payable on a quarterly basis. Upon conversion whether at the Company s election or the debt holders election, the Company is also required to pay the present value of the future interest payments that would have been made if the conversion had not occurred. The Company received net proceeds of approximately $18.5 million from the sale of the Debentures 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 the Company s 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 Debentures and exercise prices of the related warrants were adjusted to $0.6803 per share pursuant to the terms of the exchange offer, and in August 2008, the conversion price of the Debentures and exercise price of the related warrants were further adjusted to $0.397 per share pursuant to the terms of the restructuring of the New Notes.

If, at any time after the two year anniversary of the issuance date of the Debentures, the last closing sale price of the Company s common stock exceeded $2.22 for any twenty out of thirty consecutive trading days, the Company has the right, subject to compliance with certain conditions, to require the Holders of the Debentures to convert all or any portion of the conversion amount of the Debentures into shares of common stock at the then applicable conversion price, subject to certain limitations on beneficial ownership.

The maturity date of the Debentures was 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 Debentures were not secured by any of the Company s assets or assets of its subsidiaries, except that the Company obtained a $7.3 million letter of credit. The Company has deposited $7.3 million in a trust as collateral for this letter of credit.

The Debentures contained 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 the Company s 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 Debentures), the interest rate under the Notes will increase to 12.0% per annum.

So long as the Company satisfies certain milestones relating to the Business Combination by certain dates, including filing of the proxy statement and stockholder approval of the Business Combination, then the Company s obligations to make interest and principal payments are deferred. While such payments are deferred, interest is accrued at the Event of Default interest rate (12% per annum) and late charges are accrued on all amounts so deferred. On September 30, 2008 the Company has elected to defer the interest and principal payments and thus is subject to the Event of Default interest rate and the applicable penalty rate of 12% per annum.

The Debentures contained provisions, that in connection with a change of control transaction, the holders of the Debentures will have the right to require the Company to redeem all of the Holders Debentures at a redemption price in cash.

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

the Company s common stock.

The Company evaluated the Debentures 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, the Company identified the detachable warrants and the conversion rights as derivative financial instruments which are required to be recorded as liabilities.

In August 2007, the Company allocated the fair value of the proceeds received from the Debentures between the underlying debt instruments, conversion rights, and the detachable warrants. At inception, the Company determined that the fair value of the detachable warrants was $6.4 million and the conversion rights were $6.6 million. These amounts 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 an unamortized discount which will be accreted over the term of the Debentures using the effective interest method. The Company recorded $1.3 million in non-cash interest expense relating to the accretion of this discount as of September 30, 2008.

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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 rights. 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 Debentures, and the conversion rights on the Debentures, New Notes, the New Exchange Notes and Bridge Notes (the Notes) are primarily affected by the Company s stock price, but are also affected by the Company s stock price volatility, expected life and interest rates. The Company recorded approximately $3.8 million of other income as of September 30, 2008 related to the change in the fair value of the warrants and the conversion features on the various Notes. This change in fair value was driven by adjustments of the conversion price of the various 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 decrease in the Company s stock price from the end of 2007 to the end of the third quarter. Assuming the Company s stock volatility, expected life and the interest rates remain constant, the fair value of the warrants will increase and the Company will recognize a charge to earnings if the price of the stock increases. If the price of the Company s stock decreases and stock price volatility, expected life and the risk-free interest rates remain constant, the fair value of the warrants will decrease and the Company will recognize income in its Statement of Operations.

6. Stock Award Activity

Stock Option Grants

Approximately 2.2 million stock options subject to time based vesting were granted during the nine months ended September 30, 2008, and the weighted average estimated fair value of stock options granted during the same period was $0.30 per share. At September 30, 2008, total unrecognized estimated compensation cost related to non-vested stock options was $2.2 million, excluding options with performance-based vesting, and is expected to be recognized over a weighted-average period of 3.12 years as of September 30, 2008.

Performance options

In December 2006, the Company issued 990,000 performance options to the Company s executives and key members of management, of which 785,000 options remain outstanding as of September 30, 2008. In June 2007, the Company issued 1,950,000 performance options to the Company s executives and key members of management, of which 1,522,500 options remain outstanding as of September 30, 2008. In March 2008, the Company issued an additional 1,860,000 performance options, all of which remain outstanding as of September 30, 2008. These options vest if these individuals meet specific performance targets and align the interest of the Company s employees with specific internal goals over a wide-range of the Company s operations.

In August 2008, the Company issued 3,925,000 performance options, all of which remain outstanding as of September 30, 2008, to the Company s executive officers. The vesting schedule on these options is designed to retain key personnel through the completion of the Company s business combination with Elitech and through the integration period following the closing of the business combination. In the event the business combination is not consummated prior to June 30, 2009, the option shares will terminate and cease to be outstanding. In addition, each vested option share will terminate and cease to be outstanding on August 17, 2019 or earlier if the executive officer ceases to be employed by the Company.

As of September 30, 2008, the Company has evaluated the probability and timing of vesting of the performance options, and recorded $127,000 and $176,000 in expense during the three and nine months ending September 30, 2008, respectively. The Company 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, depending upon the level of achievement of a performance goal. The Company determined the grant date fair value of each December 2006, June 2007, March 2008 and August 2008 performance option grants was $1.77, $1.02, $0.30 and $0.23 respectively. As of September 30, 2008, there is an aggregate unrecognized compensation expense of $4.8 million related to these performance options.

Restricted Stock Units

As of September 30, 2008, the Company had 203,000 non-vested restricted stock units outstanding that were granted to employees in previous years with a weighted-average grant date fair value of $3.17 and an aggregated unrecognized compensation expense of $180,000.

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

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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 nine months ended September 30, 2008, there were 53,343 shares issued under the ESPP plan.

Share-Based Payments

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2008	2007	2008	2007
Cost of product sales	$ 14	$ 7	$ 58	$ 176
Research and development	116	203	371	758
Selling, general and administrative	304	537	1,033	2,104
Total stock-based compensation expense	$ 434	$ 747	$ 1,462	$ 3,038

7. Related Party Transaction

Consulting Agreement with Board Member

In October 2006, the Company signed a consulting agreement with Mr. Dreismann, one of the Company s Board of Directors members. Mr. Dreismann received $22,000 and $56,000 in compensation under this agreement in the three and nine months ended September 30, 2008. The consulting agreement ended in the third quarter of 2008.

Fisher Development Agreement

In February 2008, the Company entered into a distribution and license agreement with Fisher under which the Company 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. There was approximately $281,000 and $997,000 of revenue recognized under this agreement in the three and nine months ended September 30, 2008, respectively.

8. Stock Transaction

On February 5, 2007, the Company entered into a placement agency agreement with Ascendiant Securities, LLC (Ascendiant) relating to the offering of stock pursuant to an effective shelf registration statement. Under the placement agency agreement, Ascendiant agreed to act as the Company s placement agent in connection with the issuance and sale of common stock and warrants to purchase shares of common stock, on a best efforts basis, to certain institutional investors. The Company 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 the Company sold 4,916,667 shares of common stock and 983,333 warrants to purchase shares of common stock for net proceeds of approximately $7.2 million.

9. Assignment of Royalties

In September 2006, the Company entered into an agreement with Drug Royalty LP2 (DRT) under which the Company assigned rights to a royalty stream 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 million (Royalty Agreement). In connection with the Royalty Agreement, the Company was required to make payments to DRT if the royalties assigned to DRT did not exceed certain minimum annual amounts. In 2006 the Company recorded the $20 million payment as a liability. The Company continued to record revenue for amounts received from ABI under the license agreement. The Company recorded interest expense and a reduction of the liability to DRT as the payments were received from ABI under the license agreement and were remitted to DRT under the Royalty Agreement. As of March 28, 2008, the carrying value of the liability to DRT under the Royalty Agreement was approximately $17.6 million.

On March 28, 2008, the Company 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 the Company is no longer required to make minimum payments to DRT.

On March 28, 2008, the Company entered into a new royalty interest assignment agreement (2008 Royalty Interest Assignment Agreement) with DRT in which the Company received an up-front payment of $9.9 million, net of transaction costs, in exchange for assigning the royalty rights under the same license agreement with ABI to DRT for the period of January 1, 2012 through the end of the Company s license agreement with ABI.

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The Company believes that it has potential remaining obligations which may be more than insignificant and given that the royalty performance is lengthy under the 2008 Royalty Interest Assignment Agreement, under Staff Accounting Bulletin No. 104 (SAB 104), the Company has deferred recognition of amounts received under the agreement and will amortize the revenue over the term of the agreement.

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

10. Fair Value Measurement

The Company adopted SFAS No. 157 effective after 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 the Company s 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 the Company 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

The Company measures fair value using the procedures set out below for all assets and liabilities measured at fair value. When available, the Company will use quoted market prices to determine fair value, and classify 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 the Company s 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:

Liabilities

The Company uses significant unobservable inputs to determine the fair value, shown as a Level 3 on the hierarchy, for common stock warrants and the conversion feature of convertible debt at September 30, 2008.

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 September 30, 2008 (in thousands):

	Quoted prices in active markets for identical assets (Level 1)	Significant other observable inputs (Level 2)	Significant unobservable inputs (Level 3)	Total value in consolidated balance
Common stock warrants	$	$	$ 3,605	$ 3,605
Conversion feature of convertible debt			5,227	5,227
Total liabilities at fair value	$	$	$ 8,832	$ 8,832

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

The Company measures certain assets and liabilities at fair value on a non-recurring basis. Therefore, these assets and liabilities 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).

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11. Consolidation of Nanogen Point-of-Care Manufacturing Operations

On May 23, 2008 the Company announced that it was taking steps to reduce costs and improve margins of the rapid testing products by consolidating point of care manufacturing operations. The consolidation includes the transfer of current operations in Toronto, Canada to the Company s San Diego facility and the cessation of manufacturing operations in Canada. In accordance with FASB 146, *Accounting for Costs Associated with Exit or Disposal Activities* , because the Company continues to use the facility for non-manufacturing activities, the Company has not accrued any cease-to-use costs associated with the lease of the facility. The current facility lease in effect on the Toronto facility allows the Company to terminate the lease in 2012.

Below is a summary of the charges recorded as of September 30, 2008 (in thousands):

	September 30, 2008 (Unaudited)
Fixed asset impairment charges	$ 973
Severance charges	638
	$ 1,611

These charges were allocated to cost of product sales and operating expenses in the category for which the asset was intended for use. The allocation of these charges was recorded as follows: $926,000 in cost of product sales, $324,000 in research and development, and $361,000 in selling, general and administrative costs. The Company also expects to incur $75,000 of additional severance charges through the end of 2008.

12. Subsequent Events

On October 15, 2008 the Company received $1.0 million of funding from Elitech pursuant to the bridge financing agreement entered into in August 2008 to issue and sell the Second Bridge Notes. For further details on the Bridge Notes, see Note 5.

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 and anticipated cost reduction from business restructuring 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 December 31, 2007.

Our Business a general description of our business, our technologies and the actions we have taken to develop our business to help the reader better understand our objectives, areas of focus, various strategic investments, relationships and agreements we have entered into after December 31, 2007.

Results of Operations an analysis of our consolidated results of operations for the three and nine months ended September 30, 2008 and September 30, 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 to generate the liquidity required to support our current and planned operations.

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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.

Summary:

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

On August 14, 2008, Financiére Elitech S.A.S. (Elitech), a private French diagnostics company and we announced a definitive agreement to combine the two companies. The Board of Directors of the combined company will consist of seven members, four of whom will be designated by Elitech and three of whom will be designated by us. We believe the combination will create a global provider of products to the molecular, point-of-care, clinical chemistry and microbiology diagnostics markets with expected first year revenues of more than $150 million and positive Earnings Before Income Taxes Depreciation and Amortization (EBITDA). This transaction combines our technology leadership in molecular and point-of-care diagnostics markets with the strong revenue and profit base stemming from Elitech s global manufacturing, sales and distribution of In Vitro Diagnostic Products (IVD) for the clinical chemistry and microbiology markets. The Board of Directors of both companies unanimously approved the agreement to combine the two companies.

On August 14, 2008, we entered into an exchange agreement with each holder of all outstanding 9.75% Senior Secured Convertible Notes that we issued in March 2008, pursuant to which we exchanged such notes with an Amended and Restated Senior Secured Convertible Notes with an aggregate principal amount of $13,537,687 (Amended Notes) and another Senior Secured Convertible Notes with an aggregate principal amount of $2,707,537 (Additional Notes). The Amended Notes are convertible initially into 34,099,967 shares of common stock at an initial conversion price of $0.476 per share and the Additional Notes are convertible initially into 5,683,328 shares of common stock at an initial conversion price of $0.397 per share. The Amended Notes and Additional together are referred to as the New Exchange Notes . The New Exchange Notes have an annual interest rate of 9.75%. The New Exchange Notes required a security interest in substantially all of the assets of the Company and certain of its subsidiaries. Upon closing of the exchange agreement, the conversion price of the remaining Debentures and the exercise prices of related warrants issued to the Note holders were adjusted to $0.397. The $7.0 million in restricted cash balance is secured by a $7.0 million letter of credit required by the Debentures financing agreement and remains in place under the exchange agreement.

On August 14, 2008, we entered into a bridge financing agreement. The first part of the bridge financing agreement was with holders of the New Exchange Notes and the second part of the bridge financing agreement was an agreement with Elitech.

Under the first part of the bridge financing agreement, we agreed to issue an aggregate of $5.0 million of secured convertible notes (the First Bridge Notes), which are initially convertible into an aggregate of 12,594,458 shares of common stock at an initial conversion price of $0.397 per share. The First Bridge Notes will mature upon the earlier of (i) May 15, 2009 or (ii) the fifth business day following the consummation of the Business Combination, subject to extension under certain circumstances. The First Bridge Notes bear interest at 20.0% per annum, payable quarterly in arrears commencing on September 30, 2008. The interest is to be paid in cash or by adding the remaining amount of interest due to the outstanding principal amount of the First Bridge Notes (the Capitalized Interest). Upon and during the occurrence of an Event of Default, the interest rate under the First Bridge Notes will increase to 25.0% per annum. In addition, in the event that any payment of principal or other amounts payable under the First Bridge Notes or other transaction documents in the First Bridge Financing are not paid when due, such past due amounts are subject to a late charge of 15% per annum from the date due until paid.

Under the second part of the bridge financing agreement, we agreed to issue $3.0 million of secured convertible notes (the Second Bridge Notes) to Elitech. We expect to issue such notes in three stages during the fourth quarter of 2008. The first issuance was $1.0 million on October, 15, 2008, the second issuance of $1.0 million is expected on or prior to November 15, 2008 and $1.0 million on or prior to December 31, 2008. The Second Bridge Notes will mature upon the earlier of (i) May 15, 2009 or (ii) the fifth business day following the consummation of the Elitech business combination. The Second Bridge Notes bear interest at 20.0% per annum, payable quarterly in arrears commencing on September 30, 2008. The interest is to be paid in cash or added to the Capitalized Interest amount. Upon and during the occurrence of an event of default, the interest rate

under the Second Bridge Notes will increase to 25.0% per annum. In addition, in the event that any payment of principal or other amounts payable under the Second Bridge Notes or First Bridge Financing are not paid when due, such past due amounts are subject to a late charge of 15% per annum from the date due until paid.

On June 5, 2008 we announced that we had been awarded a new $10.4 million, two-year contract from the U.S. Centers for Disease Control and Prevention (CDC) to develop a multi-analyte molecular diagnostic assay for influenza. The molecular diagnostic test will be developed in partnership with the Medical College of Wisconsin and HandyLab Inc. The new test is expected to be significantly more sensitive than current rapid flu tests and is expected to be conducted in less than half the time of current molecular tests.

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On May 23, 2008 we announced that we were taking steps to reduce costs and improve margins of our rapid testing products by consolidating our point of care manufacturing operations. The consolidation includes the transfer of current operations in Toronto, Canada to our San Diego facility and the cessation of manufacturing operations in Canada and was completed by September 30, 2008.

On March 28, 2008 we entered into an agreement with Drug Royalty LP2 (DRT) where they purchased for $10.0 million all future royalties generated by our license with Applied Biosystems (ABI) for the use of our MGB technology (minor groove binder technology). This agreement modified certain terms in our September 2006 agreement with DRT, where we received $20.0 million from them for the assignment of the MGB royalty rights through December 31, 2011.

On March 14, 2008 we entered into agreements with the holders of the Debentures which were issued on August 27, 2007 to restructure the indebtedness. We agreed to exchanged $12.9 million in principal amount of the Debentures for 9.75% Senior Secured Convertible Notes (New Notes) due in 2010 with an aggregate principal amount of $15.5 million. The New Notes were convertible initially into an aggregate of approximately 22,784,000 shares of common stock at an initial conversion price of $0.6803 per share. The terms of the New Notes provided 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 Debentures, secured by a $7.0 million letter of credit. In connection with the exchange agreement, we granted a collateral agent on behalf of the holders of the New Notes a security interest in substantially all of the assets of the Company. Upon closing of the agreement, the conversion price of the remaining Debentures and the exercise prices of related warrants issued in the August 2007 debt financing were adjusted to $0.6803. In addition, this agreement triggered the anti-dilution clause in the warrants issued concurrently with the Debentures which resulted in an increase in the number of outstanding warrants by 11.7 million shares.

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 had remained small and we could 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 eliminate the micro array platform, we have been able to enhance financial performance and predictability. We expected that this restructuring would lower our cash used in operating activities by at least $15 million and from the period of September 30, 2007 to September 30, 2008 we lowered cash used in operating activities by approximately $24.5 million. Of the $24.5 million in lower cash use from operating activities, $10.0 million was from a one time sale of royalty rights to DRT. Despite the loss of a majority of our micro array revenue, we expect our 2008 revenues to significantly exceed our 2007 revenues. Under SFAS No. 144, *Accounting for the Impairment or Disposal of Long-Lived Assets* we have not classified the micro array business as discontinued operations in the statements of operations and certain related assets and liabilities because of our continued involvement in the business through the fourth quarter of 2008.

In the remainder of 2008, 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 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.

Markets

We participate in two major *in vitro* diagnostic markets: the molecular diagnostic market and the point-of-care rapid test 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 rapid test 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.

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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 us or our 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.

In 2008, we have worked to develop both our direct distribution and distributor network for our PCR product lines by entering into distribution agreements, such as with A. Menarini Diagnostics S.r.l., a division of The Menarini Group, the leading Italian pharmaceutical and diagnostics group, that will provide us the ability to have greater access to the Molecular Diagnostic Market.

In June 2008, we were awarded a new $10.4 million, two-year contract from the U.S. Centers for Disease Control and Prevention (CDC) to develop a multi-analyte molecular diagnostic assay for influenza. The molecular diagnostic test will utilize our proprietary assay system and will be developed in partnership with the Medical College of Wisconsin and HandyLab Inc. It will be significantly more sensitive than current rapid flu test and is expected to be conducted in less than half the time it takes to run current molecular tests.

Point of Care Diagnostics

POC products accounted 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.

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 in the US and Europe. The whole blood version of the CHF product has been CE-marked and will be launched in Europe during the fourth quarter of 2008. In the US, clinical trials to support a 510(k) are in process and the whole blood version is expected to be commercialized in the first half of 2009. This product addresses a large opportunity. The product target is licensed from Roche and is produced by Princeton Biomeditech (PBM). 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. The reader is supplied by PBM.

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Infectious Disease as part of a competitive contract awarded by the CDC; we are developing pandemic influenza tests that detect and differentiate the various strains of influenza and can also detect potential pandemic strains. These products incorporates proprietary technology that we believe will provide significant improvements in sensitivity and precision 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. We expect to enter clinical trials in the 2008/2009 influenza season.

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 point of care platform developed for the infectious disease project offers an opportunity to develop point of care assays not possible using existing technologies. The rapid POC area is dominated by lateral flow solutions that lack sensitivity and precision 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 including additional infectious disease diagnostics under our collaboration with HX 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 September 30, 2008 and 2007

Revenues

The following table summarizes our revenues for the quarters ended September 30, 2008 and 2007 (in thousands):

	For the three months ended September 30,			For the nine months ended September 30,		
	2008	2007	Difference	2008	2007	Difference
Product sales	$ 7,819	$ 5,549	$ 2,270	$ 23,861	$ 16,927	$ 6,934
License fee and royalty income	1,514	1,833	(319)	4,772	5,132	(360)
Contracts and grant	4,428	986	3,442	8,744	6,277	2,467
Total	$ 13,761	$ 8,368	$ 5,393	$ 37,377	$ 28,336	$ 9,041

We sell the following: real-time PCR molecular products in the molecular diagnostic market (real-time molecular products), rapid tests assays used in emergency care (point of care), and a limited amount of micro array instruments and the associated consumables (micro array). In the nine months ended September 30, 2008, product revenue consisted of 83% real-time molecular products, 12% point-of-care products and the remaining 5% is related to the micro array business. The increase in product sales revenue for the three and nine months ended September 2008 as compared to the same periods in 2007 is primarily due to overall increased revenues in the real time product line as well as in the point of care business.

The future: In the remainder of 2008 we expect revenue to continue to increase significantly as compared to 2007 despite the winding down of our micro array product line.

The whole blood congestive heart failure test, which is expected to be commercialized in Europe in the last quarter of 2008 and in the US during the first half of 2009, will significantly expand the potential market and revenue generating capability of the product.

License fee and royalty revenue is generated by licensing our intellectual property rights to third parties. The majority of our license fee and royalty revenue is related to the deferred revenue recognized under the March 2008 contract with DRT. The decrease in license fees and royalty revenues in the three and nine months ended September 2008 as compared to the same periods in 2007 is primarily due to lower royalty revenues recognized under the March 2008 contract with DRT versus revenue recognized under the original September 2006 agreement with ABI.

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The future: In March 2008, we entered into an agreement with DRT to sell all future royalties generated under the ABI license agreement from January 1, 2012 through the end of the license agreement for an upfront payment of $10.0 million. In addition, for our assignment of the MGB royalty rights to DRT through December 31, 2011, DRT agreed to release the Company s required minimum royalty payments potentially due to DRT. We expect in the remainder of 2008 that revenues will continue at approximately $1.0 million per quarter.

In addition, with our growing intellectual property profile of 198 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 represents funding by various federal, state and private agencies earned through our research and development efforts awarded through contracts and grants. The increase in contract and grant revenues in the three and nine months ended September 30, 2008 as compared to the same period in 2007 is primarily due to the June 2008 contract with the CDC for influenza diagnostic assay research and the February 2008 Fisher agreement to develop molecular testing products which was offset by lower billings under our December 2006 CDC contract to develop a pandemic influenza test.

The future: The recognition of revenue under contracts and grants will vary from quarter to quarter and may result in significant fluctuations in operating results from year to year depending on the timing of the scientific results, quantity of agreements and reimbursement rates negotiated for our development contracts. As a result, our future contract and grant revenue will be significantly impacted by whether or not we are awarded with additional contracts which in large part depends on the results of our scientific research efforts.

As of September 30, 2008, we have recognized approximately $6.7 million of the contracted $6.7 million under the CDC contract for influenza diagnostic assay research. This contract can be extended to a total of $12.5 million based on reaching certain benchmarks. We have recognized approximately $1.8 million of the contracted $10.4 million with the CDC for a two year research project, beginning June 2008, for a multi-analyte molecular diagnostic assay for influenza. In February 2008, Fisher agreed to fund development programs related to certain molecular testing products on a cost incurred basis. If we successfully launch any new products from these development programs, Fisher has agreed to certain minimum purchases over a six-year period.

Cost and expenses

Cost of product sales (in thousands):

	For the three months ended September 30,			For the nine months ended September 30,		
	2008	2007	Difference	2008	2007	Difference
Cost of product sales	$ 4,466	$ 8,705	$ (4,239)	$ 14,783	$ 18,064	$ (3,281)

Cost of product sales relates to the expenses associated with manufacturing our products. These expenses include materials, labor, and various overhead costs as well as charges for excess capacity and inventory impairment charges. Cost of product sales in the three and nine months ended September 30, 2008 as compared to the same periods in 2007 have decreased primarily due to the wind down of our micro array business which resulted in significant impairments in 2007 and the consolidation of our point-of-care manufacturing operations which lowered our cost of product sales.

The future: In the remainder of 2008 we expect our cost of product sales to increase in line with the increase in product sales revenue. In 2009 and beyond, we expect to achieve cost savings on the production of our POC products due to the closure of our Toronto production facility in the third quarter of 2008 and the use of PBM to produce our new CHF product.

Research and development expenses (in thousands):

	For the three months ended September 30,			For the nine months ended September 30,		
	2008	2007	Difference	2008	2007	Difference
Research and development	$ 4,768	$ 7,540	$ (2,772)	$ 13,710	$ 21,598	$ (7,888)

Research and development relates to the expenses associated with our efforts to develop products for commercialization and the expenses incurred while conducting reimbursable research and development under contractual agreements with various federal, state and private entities. The decrease in research and development costs in the three and nine months ending September 30, 2008 as compared to the same periods of 2007 is primarily due to the elimination of research and development costs related to the micro array business , as well as consolidating certain development projects into our San Diego facilities, the deconsolidation of Jurilab in the second half of 2007.

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The future: In the remainder of 2008, 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 September 30,			For the nine months ended September 30,		
	2008	2007	Difference	2008	2007	Difference
Selling, general and administrative expenses	$ 8,036	$ 9,167	$ (1,131)	$ 25,093	$ 29,253	$ (4,160)

Selling, general and administrative (SG&A) expenses relate to the costs associated with promoting and selling our products and the administrative costs required to support the Company s operations. The decreases in the three and nine months ended September 30, 2008 as compared to the same periods of 2007 was primarily due to the savings resulting from exiting the micro array business, consolidation of marketing efforts into our San Diego facilities as well as a reduction in our administrative and marketing staff.

The future: We expect in the remainder of 2008 that our SG&A expenditures as a percentage of revenue will trend lower than the percentage increases in our revenue. We also anticipate our costs will further decline as a percentage of revenue as we continue to reduce expenses and further focus our business on real time molecular and point of care products as a result of our exit of the micro array business.

Amortization of purchased intangible assets (in thousands):

	For the three months ended September 30,			For the nine months ended September 30,		
	2007	2006	Difference	2007	2006	Difference
Amortization of purchased intangible assets	$ 707	$ 733	$ (26)	$ 2,350	$ 2,260	$ 90

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 the amortization expense on purchased intangibles to remain consistent at the current level. However, amortization expense may also be impacted by potential future business combinations.

Other income (expense)

	For the three months ended September 30,			For the nine months ended September 30,		
	2008	2007	Difference	2008	2007	Difference
Interest income	$ 154	$ 188	$ (34)	$ 631	$ 757	$ (126)
Interest expense	(3,135)	(1,439)	(1,696)	(6,341)	(3,438)	(2,903)
Other income (expense)	37	27	10	325	(26)	351
Loss on extinguishment of debt	(3,050)		(3,050)	(15,295)		(15,295)
Warrant and conversion rights valuation adjustment	4,185	5,426	(1,241)	3,126	5,436	(2,310)
Gain (loss) on deconsolidation of VIE		12,686	(12,686)		12,686	(12,686)
Gain (loss) on foreign currency translation	33	(12)	45	10	(26)	36
Total	$ (1,776)	$ 16,876	$ (18,652)	$ (17,544)	$ 15,389	$ (32,933)

The increase in interest expense is primarily related to the convertible debt offerings in August 2007 and restructured in March and August 2008 and the bridge financing agreement in August 2008. The loss on extinguishment of debt and the change in the warrant valuation adjustment amount related to the restructuring of our convertible debt in March and August of 2008. The decrease in warrant valuation changed was primarily a result of the repricing of the warrants from $1.14 to $0.397. The change in the warrant valuation adjustment is also due to the quarterly remeasurement of fair value of our outstanding warrants using the methodology prescribed by EITF 00-19 *Accounting for Derivative Financial Instruments Indexed to, and Potentially Settled in, a Company s Own Stock* . The gain on deconsolidation of VIE in 2007 represents the losses in Jurilab, a variable interest entity, which were allocated to the noncontrolling interests at which time the initial fair value of their interests had been reduced to zero with no comparable charges in 2008.

Liquidity and capital resources

Short-term and long-term liquidity

At September 30, 2008 we have cash and cash equivalents of approximately $1.7 million. We will need to raise additional funds through financing transactions in order to continue to support our planned operations through December 31, 2008. Without access to this financing, on terms acceptable to us, we may have to curtail or cease operations and product development that will

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materially alter our current business strategy. Under the Second Bridge Note agreement with Elitech, we agreed to issue an aggregate of $3.0 million in convertible debt to Elitech through the remainder of 2008 to fund our operations. We received funds from the first issuance of $1.0 million on October 15, 2008, and expect to receive an additional $1.0 million on or prior to November 15, 2008 and $1.0 million on or prior to December 31, 2008.

The following is a summary of our key liquidity measures as of September 30, 2008 and December 31, 2007 (in thousands):

	September 30, 2008	December 31, 2007	Difference
Cash and cash equivalents	$ 1,689	$ 5,806	$ (4,117)
Short-term investments, available for sale		1,450	(1,450)
Total cash and cash equivalents and short-term investments, available for sale	$ 1,689	$ 7,256	$ (5,567)
Current assets	$ 24,619	$ 26,184	$ (1,565)
Current liabilities	(46,099)	(26,371)	(19,728)
Working capital	$ (21,480)	$ (187)	$ (21,293)

Our cash and cash equivalents and short-term investments, available for sale decreased by $5.6 million, while our working capital decreased by $21.2 million, at September 30, 2008 as compared to December 31, 2007. The decrease in working capital was primarily due to an increase in current liabilities resulting from the increase in current debt financing. In addition, current liability balances include $5.3 million of deferred revenue balances, liabilities related to convertible debt conversion features of $5.2 million and common stock warrants of $3.6 million, all of which represent non-cash liabilities. The decrease in cash and cash equivalents and short term investments, available for sale, is primarily due to cash usage for operations during the period. Going forward, with our exit from the micro array business, we believe we can use less cash and achieve higher margins with our other product lines as we focus on further reducing costs and work to increase sales to achieve cash flow break even.

From our inception to September 30, 2008, we have financed our operations primarily by:

- Issuing our stock and warrants
- Bridge financing agreements
- Issuing secured and unsecured 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

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

Cash used in operating, investing and financing activities for the nine months ended September 30, 2008 and 2007 is as follows (in thousands):

	September 30, 2008	September 30, 2007
Net cash used in operating activities	$ (6,086)	$ (30,577)
Net cash used in investing activities	(218)	(881)
Net cash provided by financing activities	$ 2,339	$ 27,383

Operating activities

Net cash used in operating activities for the nine months ended September 30, 2008 and 2007 primarily related to our net losses and changes in working capital. The decrease in cash used in operating activities in the nine months of 2008 as compared to the same period of 2007 primarily related to a $10 million sale of certain royalty rights, non-cash charges related to extinguishment of debt as well as cost savings due to our exit from the micro array business and the deconsolidation of Jurilab.

Investing activities

Net cash used in investing activities in the nine months ended September 30, 2008 primarily related to net proceeds from the sale of short-term investments offset by the purchase of equipment and technology rights. Net cash used in investing activities in the nine months ended September 30, 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).

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Capital spending is essential to our product innovation initiatives and maintaining our operational capabilities. Therefore in the first nine months of 2008 and 2007 we used cash to purchase $1.9 million and $1.8 million, respectively, in property and equipment to support the development of our product lines.

Financing activities

Due to our negative cash flows from operations, we remain dependent on equity, debt financing or other non-dilutive sources of financing to fund our operations. In the fourth quarter of 2008, we plan on funding our operations with a combination of collecting receivables from our product sales and with issuance of our Second Bridge Notes.

On February 5, 2007, we entered into a placement agency agreement with Ascendiant Securities, LLC (Ascendiant) relating to the offering of stock pursuant to an effective shelf registration statement. Under the placement agency agreement, Ascendiant 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.

On March 14, 2008 we entered into agreements with the holders of our 6.25% Convertible Notes due in 2010 (the Debentures) 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 Debentures with the Company s 9.75% Senior Secured Convertible Notes due in 2010 (New Notes) with an aggregate principal amount of $15.5 million. The New Notes are convertible initially into an aggregate of approximately 22,784,000 shares of common stock at an initial conversion price of $0.6803 per share. The terms of the New Notes provided for the mandatory payment of the principal in specified periodic installments as well restrict certain asset disposition and financing transactions. An aggregate of $7.0 million remained as restricted cash under the New Notes which is 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 New Notes a security interest in substantially all of the assets of the Company. Upon closing of the agreement, the conversion price of the remaining Debentures and the exercise prices of related warrants issued in the August 2007 debt financing were adjusted to $0.6803. In addition, this agreement triggered the anti-dilution clause in the warrants issued concurrently with the Debentures which resulted in an increase in the number of outstanding warrants by 11.7 million shares.

On August 14, 2008, we entered into an exchange agreement with each holder of all outstanding 9.75% Senior Secured Convertible Notes that we issued in March 2008 with an Amended and Restated Senior Secured Convertible Notes with an aggregate principal amount of $13,537,687 (Amended Notes) and another Senior Secured Convertible Notes with an aggregate principal amount of $2,707,537 (Additional Notes). The Amended Notes are convertible initially into 34,099,967 shares of common stock at an initial conversion price of $0.397 per share and the Additional Notes are convertible initially into 5,683,328 shares of common stock at an initial conversion price of $0.397 per share. The Amended Notes and Additional together are the New Exchange Notes . The New Exchange Notes have an annual interest rate of 9.75%. The $7.0 million in restricted cash balance secured by a $7.0 million letter of credit required by the 6.25% Unsecured Senior Convertible Notes (Debentures) financing agreements will remain under the exchange agreement. The New Exchange Notes required a security interest in substantially all of the assets of the Company. Upon closing of the exchange agreement, the conversion price of the remaining Debentures and the exercise prices of related warrants issued to the Note holders were adjusted to $0.397.

On August 14, 2008, in conjunction with the exchange agreement described above, we entered into a bridge financing agreement. The first part of the bridge financing agreement was with the holders of the New Exchange Notes and the second part of the bridge financing agreement was an agreement with Elitech.

Under the first bridge financing agreement we issued an aggregate of $5.0 million in secured convertible note (the First Bridge Notes). The First Bridge Notes were initially convertible into an aggregate of 12,594,458 shares of common stock at an initial conversion price of $0.397 per share. The First Bridge Notes will mature upon the earlier of (i) May 15, 2009 or (ii) the fifth business day following the consummation of the Business Combination, subject to extension under certain circumstances. The First Bridge Notes bear interest at 20.0% per annum, payable quarterly in arrears commencing on September 30, 2008. The interest is to be paid in cash or by adding the remaining amount of interest due to the outstanding principal amount of the First Bridge Notes (the Capitalized Interest). Upon and during the occurrence of an Event of Default, the interest rate under the First Bridge Notes will increase to 25.0% per annum. In addition, in the event that any payment of principal or other amounts payable under the First Bridge Notes or other transaction documents in the First Bridge Financing are not paid when due, such past due amounts are subject to a late charge of 15% per annum from the date due until paid. The principal amount of the First Bridge Notes together with any accrued, unpaid interest and any late charges will be convertible at the option of the First Bridge Note Holders, at any time following their issuance, into shares of Common Stock at the initial conversion price of $0.397 per share, subject to certain limitations on beneficial ownership. Upon conversion of the First Bridge Notes the Company is required to pay the net present value of total interest over the term of the First Bridge Notes calculated at a 6.25% discount rate, subject to certain limitations. The conversion prices are subject to certain adjustments

including full ratchet anti-dilution protection for the First Bridge Notes in respect of any equity or convertible securities issuances below $0.397 without subsequent stockholder approval. We received approximately $4.7 million, net of debt issuance costs, in proceeds under this agreement.

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Under the second bridge financing agreement we issued $3.0 million in secured convertible notes (the Second Bridge Notes) to Elitech. We expect to issue the convertible debt in three stages during the fourth quarter of 2008. We issued the first $1.0 million on October 15, 2008 and expect to issued $1.0 million on or prior to November 15, 2008 and $1.0 million on or prior to December 31, 2008. The Second Bridge Notes will mature upon the earlier of (i) May 15, 2009 or (ii) the fifth business day following the consummation of the Elitech combination. The Second Bridge Notes bear interest at 20.0% per annum, payable quarterly in arrears commencing on September 30, 2008. The interest is to be paid in cash or by adding the remaining amount of interest due to the outstanding principal amount of the Second Bridge Notes. Upon and during the occurrence of an event of default, the interest rate under the Second Bridge Notes will increase to 25.0% per annum. In addition, in the event that any payment of principal or other amounts payable under the Second Bridge Notes or First Bridge Financing are not paid when due, such past due amounts are subject to a late charge of 15% per annum from the date due until paid. The principal amount of the Second Bridge Notes together with any accrued and unpaid interest and any late charges will be convertible at the option of Elitech, at any time following their issuance, into shares of Common Stock at the initial conversion price of $0.397 per share, subject to certain limitations on beneficial ownership. Upon conversion of Second Bridge Notes we are required to pay the net present value of total interest over the term of the Second Bridge Notes calculated at a 6.25% discount rate, subject to certain limitations. The conversion prices are subject to certain adjustments including full ratchet anti-dilution protection for the First Bridge Notes in respect of any equity or convertible securities issuances below $0.397 without subsequent stockholder approval.

Off Balance Sheet Arrangements

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 the Remainder of 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.

While we believe that we will be successful in generating additional working capital through a combination of the $3.0 million from the Second Bridge Notes expected to be fully funded on or before December 31, 2008, 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 will 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 the 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 New Exchange Notes, we are required to use a portion of the proceeds of certain financings to redeem the New Exchange 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.

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

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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 $36.1 million in the nine months ending September 30, 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 $436.7 million as of September 30, 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 $38.9 million of goodwill on our September 30, 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.

Goodwill is recorded as the difference, if any, between the aggregate consideration paid for an acquisition and the fair value of the net tangible and intangible assets acquired. In accordance with SFAS No. 142, *Goodwill and Other Intangible Assets* (SFAS 142), we test goodwill for impairment on an annual basis in the fourth quarter or more frequently if we believe indicators of impairment exist. This testing requires that we make judgments to identify our reporting units which significantly affects our valuation analysis. In addition, we test goodwill for possible impairment if events occur or circumstances indicate that the carrying amount of goodwill may not be recoverable. We assess potential impairments to goodwill assets when there is evidence that events or circumstances indicate that the recorded value of an asset (the carrying amount) may not be recovered. These assessments are based on judgments and estimates of the materiality of various on-going events and circumstances related to the asset. Indicators of impairment may include, but are not limited too:

- a significant adverse change in legal factors or in the business climate;
- a significant decline in our stock price or the stock price of comparable companies;
- a significant decline in our projected revenue or earnings growth or cash flows;
- an adverse action or assessment by a regulator;
- unanticipated competition;
- a loss of key personnel; and
- a more-likely-than-not expectation that a reporting unit or a significant portion of a reporting unit will be sold or otherwise disposed of

In the fourth quarter we will test our goodwill for potential impairment. 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. We generally determine the fair value of our 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, we perform 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.

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.

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

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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.

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

Valuation of 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 and August 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 $3.1 million of other income in 2008 related to the change in the fair value of the warrants and the conversion feature. As of September 30, 2008, the fair value of the warrants and conversion features was determined to be $8.8 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), 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) collectability 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 $5.9 million of inventory reserves as of September 30, 2008, with a net ending inventory balance of approximately $2.6 million. Given the inherent unpredictability of 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, FASB Interpretation No. 48 (FIN No. 48) *Accounting for Uncertainty in Income Taxes an interpretation of Statement of Financial Accounting Standards (SFAS) No. 109*, prescribed 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, 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

Consulting Agreement with Board Member

In October 2006, we signed a consulting agreement with Mr. Dreismann, one of our Board of Directors members. Mr. Dreismann received $22,000 and $56,000 in compensation under this agreement in the three and nine months ended September 30, 2008. The consulting agreement ended in the third quarter of 2008.

ThermoFisher Development Agreement

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 ThermoFisher. 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 were approximately $378,000 and $672,000 of sales under this agreement in the three and nine months ended September 30, 2008, respectively.

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 basis. Upon commercial launch of the new products, Fisher has agreed to certain minimum purchases over a six-year period. There were approximately $281,000 and $997,000 of revenue recognized under this agreement in the three and nine months ended September 30, 2008, respectively.

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 is minimal as we do not have short-term investment holdings other than an auction rate security which has no carrying value at September 30, 2008 as it is considered impaired.

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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 $7.6 million at September 30, 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 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 September 30, 2008, our disclosure controls 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.

(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 nine months of 2008, including:

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

- adding detailed review procedures over accounting close activities, including inventory valuation analysis, and search for unrecorded liabilities.

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

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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 September 30, 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 September 30, 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 additional cash to continue our planned operations through December 31, 2008 and beyond. Our independent registered public accounting firm has included a modification to its audit report regarding substantial doubt about our ability to continue as going concern 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 bridge notes, 9.75% senior secured convertible notes issued in August and March 2008 (the New Exchange Notes and the New Notes , respectively) and 6.25% senior convertible notes issued in August 2007 (the Notes) contain restrictive covenants that limit our ability to raise capital through additional financing unless we obtain consent from holders of these 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 New Exchange Notes, we are required to use a portion of the proceeds of certain financings to redeem the New Notes. Any additional equity financing will be dilutive to stockholders, and debt financing, if available, may include restrictive covenants and require significant collateral.

Furthermore, on August 15, 2008, we completed the initial closing of our $8.0 million bridge financing in which we received $5.0 million of gross proceeds, while the remaining $3.0 million will be funded by Elitech in three stages during the fourth quarter of 2008 as follows: $1.0 million on or prior to October 15, 2008, $1.0 million on or prior to November 15, 2008 and $1.0 million on or prior to December 31, 2008. We received the first $1.0 million funding on October 15, 2008. If Elitech is unable to provide us with the remaining balance of such funding or if the funding is not provided in a timely manner, it will have a material adverse effect on our financial conditions and our ability to continue our operations. Such failure will also cause an event of default under our convertible notes which will jeopardize our financial viability.

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

Since our inception, we have incurred cumulative net losses which, as of September 30, 2008, total approximately $436.7 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

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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 September 30, 2008, we had only a limited product offering that includes real-time PCR products and point-of-care diagnostic tests for cardiac disease. 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.

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 a non-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.

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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.

On March 14, 2008 we entered into agreements with the holders of our 6.25% Convertible Notes due in 2010 (the Debentures) 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 in 2010 (New Notes) with an aggregate principal amount of $15.5 million. The New Notes are convertible initially into an aggregate of approximately 22,784,000 shares of common stock at an initial conversion price of $0.6803 per share. The terms of the New Notes provided for the mandatory payment of the principal in specified periodic installments as well restrict certain asset disposition and financing transactions. An aggregate of $7.0 million remained as restricted cash under the New Notes which is 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 New Notes a security interest in substantially all of the assets of the Company. Upon closing of the agreement, 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. In addition, this agreement triggered the anti-dilution clause in the warrants issued concurrently with the Debentures which resulted in an increase in the number of outstanding warrants by 11.7 million shares.

On August 14, 2008, we entered into an exchange agreement with each holder of our outstanding 9.75% Senior Secured Convertible Notes that we issued in March 2008 with an Amended and Restated Senior Secured Convertible Notes with an aggregate principal amount of $13,537,687 (Amended Notes) and another Senior Secured Convertible Notes with an aggregate principal amount of $2,707,537 (Additional Notes). The Amended Notes are convertible initially into 34,099,967 shares of common stock at an initial conversion price of $0.397 per share and the Additional Notes are convertible initially into 5,683,328 shares of common stock at an initial conversion price of $0.397 per share. The Amended Notes and Additional together are called the New Exchange Notes . The New Exchange Notes have an annual interest rate of 9.75%. The $7.0 million in restricted cash balance secured by a $7.0 million letter of credit required by the Debentures financing agreements will remain under the exchange notes agreement. The New Exchange Notes required a security interest in substantially all of the assets of the Company. Upon closing of the exchange agreement, the conversion price of the remaining Debentures and the exercise prices of related warrants issued to the Note holders were adjusted to $0.397.

On August 14, 2008, we entered into a bridge financing agreement. The first part of the bridge financing agreement was with the holders of the New Exchange Notes and the second part of the bridge financing agreement was an agreement with Elitech.

Under the first bridge financing agreement we issued an aggregate of $5.0 million of senior secured convertible bridge notes (the First Bridge Notes). The First Bridge Notes were initially convertible into an aggregate of 12,594,458 shares of common stock at an initial conversion price of $0.397 per share. The First Bridge Notes will mature upon the earlier of (i) May 15, 2009 or (ii) the fifth business day following the consummation of the Business Combination, subject to extension under certain circumstances. The First Bridge Notes bear interest at 20.0% per annum, payable quarterly in arrears commencing on September 30, 2008. The interest is to be paid in cash or by adding the remaining amount of interest due to the outstanding principal amount of the First Bridge Notes (the Capitalized Interest). Upon and during the occurrence of an Event of Default, the interest rate under the First Bridge Notes will increase to 25.0% per annum. In addition, in the event that any payment of principal or other amounts payable under the First Bridge Notes or other transaction documents in the First Bridge Financing are not paid when due, such past due amounts are subject to a late charge of 15% per annum from the date due until paid. The principal amount of the First Bridge Notes together with any accrued, unpaid interest and any late charges will be convertible at the option of the First Bridge Note Holders, at any time following their issuance, into shares of Common Stock at the initial conversion price of $0.397 per share, subject to certain limitations on beneficial ownership. Upon conversion of the First Bridge Notes the Company is required to pay the net present value of total interest over the term of the First Bridge Notes calculated at a 6.25% discount rate, subject to certain limitations. The conversion prices are subject to certain adjustments including full ratchet anti-dilution protection for the First Bridge Notes in respect of any equity or convertible securities issuances below $0.397 without subsequent stockholder approval. We received approximately $4.7 million, net of debt issuance costs, under this agreement.

Under the second bridge financing agreement we issued an aggregate of $3.0 million of senior secured convertible note (the Second Bridge Notes). We expect to issue the Second Bridge Notes in three stages during the fourth quarter of 2008. We issued the first $1.0 million on October 15, 2008 and expect to issued $1.0 million on or prior to November 15, 2008 and $1.0 million on or prior to December 31, 2008. The Second Bridge Notes will mature upon the earlier of (i) May 15, 2009 or (ii) the fifth business day following the consummation of the Elitech combination. The Second Bridge Notes bear interest at 20.0% per annum, payable quarterly in arrears commencing on September 30, 2008. The interest is to be paid in cash or by adding the remaining amount of interest due to the outstanding principal amount of the Second Bridge Notes. Upon and during the occurrence of an event of default, the interest rate under the Second Bridge Notes will increase to 25.0% per annum. In addition, in the event that any payment of

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principal or other amounts payable under the Second Bridge Notes or First Bridge Financing are not paid when due, such past due amounts are subject to a late charge of 15% per annum from the date due until paid. The principal amount of the Second Bridge Notes together with any accrued and unpaid interest and any late charges will be convertible at the option of Elitech, at any time following their issuance, into shares of Common Stock at the initial conversion price of $0.397 per share, subject to certain limitations on beneficial ownership. Upon conversion of Second Bridge Notes we are required to pay the net present value of total interest over the term of the Second Bridge Notes calculated at a 6.25% discount rate, subject to certain limitations. The conversion prices are subject to certain adjustments including full ratchet anti-dilution protection for the First Bridge Notes in respect of any equity or convertible securities issuances below $0.397 without subsequent stockholder approval.

As a result of this transaction, we increased the total amount of convertible debt outstanding, as well as the amount of interest payments. Furthermore, we have agreed to make the following redemption payments:

- 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 New Exchange 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, transfer 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 New Exchange 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 New Exchange 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 New Exchange Notes, we may have to restructure or limit our operations. Our indebtedness could have significant additional negative consequences, including, but not limited to:

- 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 our debt obligations.

Our liquidity position is constrained by the operating losses from our business. In addition, we are not able to pay interest on our convertible debt obligations with shares of our common stock if the valuation of our stock is below $0.397 per share or if we do not satisfy certain equity conditions set forth in the convertible debt convertible obligations, 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 New Exchange Notes and Bridge 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 New Exchange Notes. As a result, we may not have sufficient funds to make the required interest, redemption and principal payments on the convertible debt obligations 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 debt payment obligations 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.

In connection with the execution of share exchange agreement (the Share Exchange Agreement) for the business combination with Elitech, holders of our convertible notes agreed to restructure such notes so that interest payments, as well as certain monthly and quarterly mandatory redemption payments, under such notes will be deferred as long we meet certain specified milestone events relating to the closing of the business combination, including the filing of a proxy statement/prospectus and stockholder approval of the business combination in a timely manner. There is no guarantee that Nanogen will be able to meet these milestone requirements, and failure to do so will reinstate our obligation s to make cash payments on interest, as well as certain monthly and quarterly redemption, payments due under such notes, including late charges and penalty, unless we obtain a waiver from holders of notes representing two-thirds of outstanding principal amount of such notes. There is no guarantee that we will be able to obtain such waiver, and if not, we may not have sufficient cash on hand to make these payments, in which case it will cause a default under the notes and jeopardize our financial viability.

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

To secure our obligations under our convertible debt obligations, 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 our convertible debt obligations, 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.

Certain of our convertible debt obligations 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.

Our convertibles debt obligations allow the holders to require us to repay the debt obligation 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 convertible debt obligations, as well as specified change of control transactions. In such a situation, we may be required to repay all or part of the convertible debt obligations, 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 pay the full amount in cash, any such payment could leave us with little or no working capital for our business. We have not established a sinking fund for payment of our debt obligations, nor do we anticipate doing so.

In addition, we have granted holders of our convertible debt obligations a first priority security interest in substantially all of our assets and stock of our subsidiaries to secure our obligations under the convertible debt obligations. 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 Debentures in a cash collateral account for the purpose of securing the letter of credit issued in favor of the holders of the Debentures. 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 NASDAQ 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 or there is no threat of such suspension by NASDAQ. 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 October 22, 2008 was $0.22 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 convertible debt obligations.

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.

Certain of our convertible secured debt obligations 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 convertible secured debt obligations 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 convertible debt obligations further restrict us from additional borrowing without permission of the note holders whose consent cannot be assured.

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

Our Debentures, New Exchange Notes and Bridge Notes contain a conversion feature. The conversion features of the Debentures and New Exchange 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 convertible debt note holders, who may be unwilling to provide such consent.

We have agreed, for so long as any New Exchange Notes, Debentures and Bridge 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 Company s convertible debt obligations 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 convertible debt obligations 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 or that we will obtain the necessary stockholder approval. 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 convertible debt obligations may limit our ability to expand our operations and capitalize on our business opportunities.

The terms of the convertible debt obligations include restrictive covenants which limit our ability to borrow money, create liens, dispose of assets, transact businesses with affiliates, effect equity and debt financing, advance loan credit to its subsidiaries 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 Bridge Financing, New Exchange Notes and Debentures limit our ability to capitalize on these opportunities.

Conversion of the debt obligations and exercise of related warrants and issuance of shares of common stock in payment of interests on the convertible debt obligations 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 convertible debt obligations and related warrants, respectively, and the issuance of shares of common stock in payment of interests on the convertible debt obligations, could significantly dilute the ownership interests of existing stockholders. The restructuring transaction completed in August 2008 also increased substantially the number of shares that may be issued upon conversion of the convertible debt obligations by lowering the initial conversion price of the convertible debt obligations from $0.6803 per share to $0.397 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 convertible debt obligations may encourage short selling by market participants because the conversion of the convertible debt obligations 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 contracts totaling $6.7 million 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. We have recognized approximately $1.8 million of the contracted $10.4 million with the CDC for a two year research project, beginning June 2008, for a multi-analyte molecular diagnostic assay for influenza. 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.

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If we fail to regain compliance with the minimum bid price requirement under NASDAQ rules, we could lose our listing on the NASDAQ Capital Market, and the loss of listing will result in an event of default under our Notes.

Our common stock was initially 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 had 180 calendar days, or until May 27, 2008, to regain compliance with the minimum bid requirement under NASDAQ rules. As the Company has not regained compliance by May 27, 2008, we requested and received approval from NASDAQ staff to transfer our common stock to the NASDAQ Capital Market. Our common stock satisfied all criteria, other than compliance with the minimum bid price requirement, for this initial inclusion on the NASDAQ Capital Market. As part of the transfer of our common stock to the NASDAQ Capital Market we were granted an additional 180 calendar days, or until the end of November 2008, to comply with the minimum bid price requirement.

As a result of recent turmoil in the financial market, on October 16, 2008, NASDAQ Stock Market issued new rules suspending enforcement of its $1.00 minimum bid price requirement for listed companies through Friday, January 16, 2009. As a result of the rule change, on October 22, 2008 NASDAQ notified us that we will now have until February 26, 2009 to regain compliance of the minimum bid price requirement. We can regain compliance, either during the suspension or during the compliance period resuming after the suspension, by achieving a $1.00 closing bid price for a minimum of 10 consecutive trading days.

There is no guarantee that we will be able to regain compliance of the minimum bid price requirement under NASDAQ rules prior to the February 26, 2009 deadline. 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 October 22, 2008 was $0.22 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;
- The assumption of certain known and unknown liabilities of the acquired companies; and
- Difficulties in retaining key relationships with employees, customers, partners and suppliers of the acquired company.

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

Future acquisitions could also result in potentially dilutive issuances of equity securities, the incurrence of debt, contingent liabilities and/or amortization expenses related to certain intangible assets and increased operating expenses, which could adversely affect our results of operations and financial condition. Further, any additional equity financing, debt financing, or credit facility used for such acquisition may not

be on satisfactory terms, and any such financing or facility may place restrictions on our business. In addition, to the extent that the economic benefits associated with any of our acquisitions diminish in the future, we may be required to record additional write downs of goodwill, intangible assets or other assets associated with such acquisitions, which would adversely affect our operating results.

We may not realize the benefits that we anticipate from our 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

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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.

On May 23, 2008 we announced that we were taking steps to reduce costs and improve margins of our rapid testing products by consolidating our point of care manufacturing operations. The consolidation includes the transfer of current operations in Toronto, Canada to our San Diego facility and the cessation of manufacturing operations in Canada by the end of 2008. We have determined that the manufacturing facility will continue to be used until the end of September 2008, after which time we will only use a small portion of the facility and will actively seek a subtenant to occupy a larger portion of the premises. The current facility lease in effect on our Toronto facility allows us to terminate the lease in 2012.

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.

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.

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

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.

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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. In July 2008, we filed a document with the FDA outlining our plan for compliance with the FDA s ASR guidance. 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, and 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.

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

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

On July 17, 2007, our Point-of-Care Division received a warning letter from the FDA following an earlier inspection of the division s facility in Toronto, Canada in February 2007. The letter cited violation of the FDA s Current Good Manufacturing Practice requirements of the Quality System Regulations with respect to the manufacture, packing and installation of products in our cardiac business: Cardiac STATus, Decision Point and i-Lynx. Subsequent to our decision to close our manufacturing operations in the Toronto facility in the third quarter of 2008, we have informed the FDA of our decision, and we have received a closeout notification from the FDA on these violations.

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

We manufactured the majority of our products sold in 2008. 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 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.

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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.

In addition, we rely on outside vendors to extend short term credits to us for purchases of raw materials to manufacture our products. Due to our liquidity constraint, we may not be able to meet our payment obligations timely, or at all, under these vendor payables, and vendors may refuse to extend credit to us if we do not make timely payments. If we fail to obtain credits from such vendors, we will not be able to purchase materials needed to manufacture our products, which may force us to curtail or cease our operations.

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

We anticipate that our products, including our ASRs and most of our other products will be manufactured and introduced by us and third parties, if any, based on forecasted demand and that we will seek to purchase components and materials in anticipation of the actual receipt of purchase orders from our customers. Lead times for materials and components to be included in our products vary significantly and may depend on factors such as the business practices of each specific supplier and the terms of the particular contracts, as well as the overall market demand for such materials and components at any given time. Also, we often rely on our own and third party forecasted demand for various products and the accuracy of such forecasts may depend on a number of factors, including but not limited to, government reports and recommendations for certain genetic testing, regulatory burdens, competitive products, the nature and effectiveness of our products, the timing and extent of the introduction of our products into the marketplace and other factors. If the forecasts are inaccurate, we could experience fluctuations in excess inventory of our products, or shortages of critical components or products, either of which could cause our business to suffer.

We currently rely on one manufacturer 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 the company may have a material adverse effect on our business. To the extent we have adverse developments 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.

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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.

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.

In May 2008 we have announced the consolidation of our point-of-care manufacturing operations into our San Diego facility. This will result in a reduction of approximately 20% of our workforce. We will have incurred approximately $1.6 million as of September 30, 2008 for fixed asset impairments and severance charges.

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

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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.

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 Capital 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;

changes in or announcement of business combination plans;

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;

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

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

announcements by us of involvement in litigation;

developments concerning our patents or other proprietary rights or those of our competitors, including other litigation or patent office proceedings;

loss of key board, executive, management or other personnel or the increase or decrease in size of our sales and marketing staff;

governmental regulatory actions or the failure to gain necessary clearances or approvals;

our ability to obtain necessary licenses;

changes or announcements in reimbursement policies;

developments with our subsidiaries and collaborators;

changes in or announcements relating to acquisition programs for our products, including the expiration or continuation of our development site agreements;

market conditions for life science stocks, nanotechnology stocks and other stocks in general;

changes in estimates of our performance by securities analysts and the loss of coverage by one or more securities analysts;

the announcement by us of any stock repurchase plan, any purchases made thereunder by us and any cessation of the program by us; and

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

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.

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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.

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.

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.

Risks Relating to the Proposed Business Combination

The following risk factors relate to the proposed business combination between Nanogen and Elitech that was announced on August 14, 2008. Unless indicated otherwise, references to we, us and our in the risk factors under Risks Relating to the Proposed Business Combination refer to the operations of the combined company as it would exist following the business combination.

After the business combination, we will need to modify our finance and accounting systems, procedures and controls to incorporate the operations of Elitech, which modifications may be time consuming and expensive to implement, and there is no guarantee that we will be able to do so successfully.

As a public reporting company, we are required to comply with the Sarbanes-Oxley Act of 2002 and the related rules and regulations of the Securities and Exchange Commission (the SEC), including Section 404 of the Sarbanes-Oxley Act of 2002 relating to internal control over financial reporting. Although we believe that we currently have adequate finance and accounting

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systems, procedures and controls for our business on a standalone basis, after the business combination we will need to upgrade the existing, and implement additional, procedures and controls to incorporate the operations of Elitech, which has not been subject to the SEC s rules prior to the proposed business combination. These updates may require significant time and expense, and there can be no guarantee that we will be successful in implementing them. Furthermore, certain Nanogen s managerial, financial and accounting personnel are expected to terminate their employment with us soon after the business combination. The loss of these personnel could limit our ability to successfully complete these updates. If we are unable to complete the required modifications to our internal control reporting or if our independent registered public accounting firm is unable to provide us with an unqualified report as to the effectiveness of our internal control over financial reporting, investors could lose confidence in the reliability of our internal control over financial reporting, which could have a material adverse effect on our stock price.

If we are not successful in integrating our organizations, we may not be able to operate efficiently after the business combination.

Achieving the benefits of the business combination will depend in part on the successful integration of Nanogen s and Elitech s technical and business operations and personnel in a timely and efficient manner. The integration process requires coordination of personnel, product development, manufacturing, marketing and sales functions, and involves the integration of systems, applications, policies, procedures, business processes and operations. This process may be difficult and unpredictable because of possible conflicts and differing opinions on business, scientific and regulatory matters. Moreover, the integration of the two companies will present challenges resulting from the transatlantic nature of the combined company. If we cannot successfully integrate our technical and business operations and personnel, our operations, profitability and stock price may be adversely affected.

We may fail to realize the anticipated synergies, cost savings and other benefits expected from the business combination, which could adversely affect our business operations and the value of our stock.

The success of the business operation of the combined company will depend in part on our ability to realize the anticipated revenue opportunities and cost savings from the business combination. Our management believes that operational synergies in the combined company are expected in areas of overlapping business functions such as sales, marketing and finance, and that improvement in gross margin will be achieved through optimization of manufacturing and distribution in both U.S and European markets. Our management expects that during the first full year after the business combination, the combined company will achieve approximately $150 million in annual revenue and be EBITDA positive. There can be no assurance, however, that we can successfully combine the two companies to realize the anticipated synergy, or that such revenue opportunities and gross margin improvement will be achieved. If we are not able to successfully attain these objectives, the anticipated benefits of the business combination may not be realized fully or at all or may take longer to realize than expected. The combination of the two companies businesses, even if achieved in an efficient, effective and timely manner, may not result in better combined results of operations and financial condition than would have been achieved by each company independently.

Integrating our companies may divert management s attention away from our operations.

The successful integration of Nanogen s and Elitech s technical and business operations and personnel may place a significant burden on our management and internal resources. The diversion of management s attention and any difficulties encountered in the transition and integration process could result in delays in our product development programs and could otherwise harm our business, financial condition and operating results.

We expect to incur significant costs integrating the companies into a single business, which may adversely affect our financial results and operations and diminish the benefit of the business combination.

We expect to incur significant costs integrating Nanogen s and Elitech s technical and business operations and personnel, which include but are not limited to costs for:

- employee redeployment, relocation or severance;
- conversion of information systems;

combining administrative teams and processes;

reorganization of facilities and disposition of excess facilities; and

relocation or disposition of excess equipment.

In addition, there may be costs associated with the consolidation and integration of operations that cannot be estimated accurately or anticipated at this time. If the total costs of the business combination exceed our estimates or expectation, or if the benefits of the business combination do not exceed the total costs of the business combination, the financial results of the combined company could be adversely affected.

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Failure to complete the business combination could adversely affect Nanogen s stock price and Nanogen s and Elitech s future business and operations, and such failure may cause Nanogen to default on its obligation to make interest, principal and other payments under its convertible notes

The business combination is subject to the satisfaction of closing conditions, including approval by Nanogen s stockholders, achievement of certain earnings target by Nanogen, securing of financing for the combined company, preparation and delivery of audited financial statement by Elitech and others. Neither Nanogen nor Elitech can assure you that all of these closing conditions will be satisfied and that the business combination will be successfully completed. In the event that the business combination is not consummated, Nanogen and Elitech may be subject to many risks, including the costs related to the business combination, such as legal, accounting and advisory fees, which must be paid even if the business combination is not completed, and the payment by either Elitech or Nanogen of a termination fee under certain circumstances. In addition, the failure to consummate the business combination would undermine Nanogen s ability to continue as a going concern and to achieve profitability in its business operation, which could cause the price of Nanogen s stock to decline.

In connection with the execution of share exchange agreement (the Share Exchange Agreement) for the business combination, holders of Nanogen s 9.75% Senior Secured Convertible Notes and 6.25% Senior Convertible Notes agreed to restructure such notes so that interest payments, as well as certain monthly and quarterly mandatory redemption payments, under such notes will be deferred as long as Nanogen meets certain specified milestone events relating to the closing of the business combination, including the filing of a proxy statement/prospectus and stockholder approval of the business combination in a timely manner. There is no guarantee that Nanogen will be able to meet these milestone requirements, and failure to do so will reinstate Nanogen s obligation s to make cash payments on interest, as well as certain monthly and quarterly redemption, payments due under such notes, including late charges and penalty. Nanogen may not have sufficient cash on hand to make these payments, in which case, it will cause a default under these notes.

We expect that the combined company will need to raise additional capital to implement and execute on its business plan. If the combined company is successful in raising capital through the sale of common stock, it will dilute the combined company s existing stockholders, and if we are unsuccessful in raising additional capital, we may not be able to implement or execute on our business plan and our results of operations may suffer.

If the business combination is completed, the combined company may seek to raise additional capital through the sale of its securities. It is expected that the offering proceeds, if raised, would be used, among other things, to retire certain convertible debt of Nanogen, including $12.4 million of outstanding senior secured convertible notes of Nanogen, and to implement and execute on the business plan of the combined company. Any such sale of stock will reduce the proportionate ownership and voting power of stockholders of the combined company and may result in a reduction of the market price of Nanogen s common stock. If we are unable to raise additional capital on acceptable terms, or at all, our liquidity may suffer as assumed debts mature and the combined company may be limited in its ability to execute its business plan, which will negatively affect both results of operations and our stock price.

Because the number of shares Nanogen common stock to be issued to Elitech stockholders in the business combination is based in part on the value of Nanogen common stock prior to closing, if the market price of Nanogen common stock declines, the number of shares issued to Elitech stockholders may increase, which will result in additional dilution to existing Nanogen stockholders .

Under the Share Exchange Agreement, Nanogen agrees to issue an aggregate number of shares of its common stock to Elitech stockholders equal to the greater of (i) 58.7% of the fully diluted outstanding shares of the combined entity and (ii) such number of shares of equivalent to a market value of 66.5 million (based on the closing price of Nanogen Common Stock on the fifth trading day prior to closing), *provided that* such number of shares shall not exceed 68.7% of fully diluted outstanding shares of the combined company. As such, if the market price of Nanogen common stock declines, Nanogen may be required to issue additional shares of its common stock in order to ensure that Elitech stockholders receives a minimum consideration of 66.5 million, which will result in a higher percentage of ownership by Elitech stockholders. Issuance of such additional shares will result in an increased and significant dilution of the voting interests of existing stockholders. In addition, the minimum consideration of 66.5 million will be determined based on the Euro-dollar currency exchange rate at the time of closing, thus any significant fluctuation in the Euro-dollar currency exchange rate may have a material impact on the aggregate number of shares to be issued to Elitech stockholders.

The value of common stock of the combined company will fluctuate.

The market price of common stock of the combined company when the business combination is completed may vary from their current market prices at the date of this Form 10-Q. For example, during the 12-month period ended on September 30, 2008, the high and low sales prices for Nanogen common stock ranged from $1.02 to $0.24.

Future variations may be the result of various factors, which may include but are not limited to:

delisting, or risk of delisting, of Nanogen common stock from the NASDAQ Capital Market;

changes in the business, operations or prospects of Nanogen or Elitech;

any issues or difficulties arising with respect to the companies products or programs;

governmental and/or litigation developments and/or regulatory considerations;

market assessments as to whether and when the business combination will be completed;

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uncertainty caused by intellectual property disputes and the impact of competition on the sales of the companies products;

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

loss of key board, executive, management or other personnel or the increase or decrease in size of our sales and marketing staff; and

general market and economic conditions

In recent years, the stock market in general, and the securities of biotechnology companies in particular, have experienced extreme price and volume fluctuations. These market fluctuations may adversely affect the market price of common stock of the combined company. The market price of common stock of the combined company upon and after the consummation of the business combination could be lower than the market price of Nanogen common stock on the date of the Share Exchange Agreement or the current market price.

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

On August 14, 2008, we entered into securities purchase agreements with holders of our 9.75% Senior Secured Convertible Notes pursuant to which we sold and issued an aggregate of $5.0 million in principal amount of the First Bridge Notes, initially convertible into an aggregate of 12,594,458 shares of our common stock at an initial conversion price of $0.397 per share. Also on August 14, 2008, we entered into a securities purchase agreement with Elitech, pursuant to which we issued and sold an aggregate principle amount of $3.0 million of our Second Bridge Notes (together with the First Bridge Notes, the Bridge Notes) to Elitech.

The closing of the sale of the First Bridge Notes occurred on or about August 15, 2008. We received net proceeds of approximately $4.15 million from the sale of the First Bridge Notes, after deducting estimated offering expenses payable by the Company. The closings of the sale of the Second Bridge Notes, will occur in three stages during the fourth quarter of 2008 as follows: $1.0 million on or prior to October 15, 2008, $1.0 million on or prior to November 15, 2008 and $1.0 million on or prior to December 31, 2008. We received the first $1.0 million on October 15, 2008.

We used the proceeds of sales of the Bridge Notes for general corporate purposes.

The Bridge Notes were issued and sold pursuant to an exemption from the registration requirements of the Securities Act of 1933, as amended provided under Section 4(2) of the Act, and Rule 506 promulgated thereunder.

ITEM 3. DEFAULTS UPON SENIOR SECURITIES

Not applicable

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

Not applicable

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. This review has been extended to include the Form 10-Q for the period ended March 31, 2008. On September 12, 2008 we resolved all the SEC comments related to our reporting requirements.

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.

ITEM 6. EXHIBITS

Exhibit No.	Description
10.1	Guaranty, dated as of August 21, 2008, between Nanogen Advanced Diagnostics, S.r.l. and Portside Growth & Opportunity Fund, as collateral agent.
10.2	Pledge as Collateral on Quota of a Limited Liability Company, dated as of September 15, 2008, between Nanogen, Inc. and Portside Growth & Opportunity Fund, as collateral agent.
10.3	Pledge as Collateral on Quota of a Limited Liability Company, dated as of September 15, 2008, between Nanogen, Inc. and Portside Growth & Opportunity Fund, as collateral agent.
10.4**	Letter, dated September 15, 2008, from Nanogen Advanced Diagnostics S.r.l. to Portside Growth & Opportunity Fund, regarding pledging the balance of Nanogen Advanced Diagnostics S.r.l. s bank account.
10.5**	Letter, dated September 16, 2008, from Portisde Growth & Opportunity Fund to Nanogen Advanced Diagnostics S.r.l., regarding pledging the balance of Nanogen Advanced Diagnostics S.r.l. s bank account.
10.6**	Letter, dated September 15, 2008, from Nanogen Advanced Diagnostics S.r.l. to Portside Growth & Opportunity Fund, regarding pledging the balance of Nanogen Advanced Diagnostics S.r.l. s bank account.
10.7**	Letter, dated September 16, 2008, from Portisde Growth & Opportunity Fund to Nanogen Advanced Diagnostics S.r.l., regarding pledging the balance of Nanogen Advanced Diagnostics S.r.l. s bank account.
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.

English translation of original Italian document.

** 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: November 14, 2008

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

Date: November 14, 2008

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