

NANOGEN INC
Form 10-Q
May 17, 2004
Table of Contents

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

FORM 10-Q

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

For the quarterly period ended March 31, 2004

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)

Edgar Filing: NANOGEN INC - Form 10-Q

Delaware
(State or other jurisdiction of
incorporation or organization)

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

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

92121
(Zip code)

(858) 410-4600

(Registrant's telephone number, including area code)

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

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

As of May 13, 2004, 34,025,094 shares of the Registrant's Common Stock were outstanding.

Table of Contents

NANOGEN, INC.

FORM 10-Q

INDEX

	Page
PART I. <u>FINANCIAL INFORMATION</u>	
Item 1. <u>Financial Statements:</u>	
<u>Consolidated Balance Sheets at March 31, 2004 (unaudited) and December 31, 2003</u>	3
<u>Consolidated Statements of Operations (unaudited) for the three months ended March 31, 2004 and 2003</u>	4
<u>Consolidated Statements of Cash Flows (unaudited) for the three months ended March 31, 2004 and 2003</u>	5
<u>Notes to Consolidated Financial Statements (unaudited)</u>	6
Item 2. <u>Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	13
Item 3. <u>Quantitative and Qualitative Disclosures About Market Risk</u>	20
Item 4. <u>Controls and Procedures</u>	20
PART II: <u>OTHER INFORMATION</u>	
Item 6. <u>Exhibits and Reports on Form 8-K</u>	21
<u>SIGNATURES</u>	22
<u>EXHIBIT INDEX</u>	23

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

	March 31,	December 31,
	2004	2003
	<u> </u>	<u> </u>
	(unaudited)	
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 32,030	\$ 8,550
Short-term investments	30,947	20,564
Receivables, net	2,333	1,415
Inventories, net	4,145	4,774
Other current assets	849	1,590
	<u> </u>	<u> </u>
Total current assets	70,304	36,893
Property and equipment, net	3,898	4,276
Acquired technology rights, net	2,232	2,508
Other assets, net	1,513	172
	<u> </u>	<u> </u>
	\$ 77,947	\$ 43,849
	<u> </u>	<u> </u>
LIABILITIES AND STOCKHOLDERS EQUITY		
Current liabilities:		
Accounts payable	\$ 170	\$ 290
Accrued liabilities	4,323	4,519
Deferred revenue	411	469
Current portion of capital lease obligations	580	743
	<u> </u>	<u> </u>
Total current liabilities	5,484	6,021
Capital lease obligations, less current portion	530	586
Other long-term liabilities	4,304	4,419
	<u> </u>	<u> </u>
Total long-term liabilities	4,834	5,005
Stockholders' equity:		
Convertible preferred stock, \$0.001 par value, 5,000,000 shares authorized; no shares issued and outstanding at March 31, 2004 (unaudited) and December 31, 2003		
Common stock, \$0.001 par value, 50,000,000 shares authorized; 31,209,615 and 24,867,325 shares issued and outstanding at March 31, 2004 (unaudited) and December 31, 2003, respectively	31	25
Additional paid-in capital	250,296	209,014
Accumulated other comprehensive income	11	1,136
Deferred compensation	(158)	(175)
Accumulated deficit	(181,629)	(176,255)

Edgar Filing: NANOGEN INC - Form 10-Q

Treasury stock, at cost, 500,189 shares at March 31, 2004 (unaudited) and December 31, 2003	(922)	(922)
Total stockholders' equity	67,629	32,823
	\$ 77,947	\$ 43,849

See accompanying notes.

Table of Contents

NANOGEN, INC.

CONSOLIDATED STATEMENTS OF OPERATIONS

(unaudited)

(in thousands, except per share data)

	Three months ended March 31,	
	2004	2003
Revenues:		
Product	\$ 1,132	\$ 228
License	152	
Sponsored research	375	375
Contract and grant	500	597
Total revenues	2,159	1,200
Costs and expenses:		
Cost of product sales	914	274
Research and development	4,348	4,710
Selling, general and administrative	3,575	4,066
Total costs and expenses	8,837	9,050
Loss from operations	(6,678)	(7,850)
Interest income, net	102	195
Other income/(expense)	(20)	27
Loss on sale of investments		(3,600)
Gain on foreign currency translation	1,221	
Minority interest in loss of consolidated subsidiary		548
Net loss	\$ (5,375)	\$ (10,680)
Net loss per share basic and diluted	\$ (0.20)	\$ (0.50)
Number of shares used in computing net loss per share basic and diluted	26,936	21,540

See accompanying notes.

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

	Three months ended	
	March 31,	
	2004	2003
Operating activities:		
Net loss	\$ (5,375)	\$ (10,680)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	854	980
Foreign currency translation gain	(1,221)	
Accretion related to short-term investments	39	53
Stock-based compensation expense		9
Interest capitalized on notes receivables from officers	15	
Minority interest in loss of consolidated subsidiary		(548)
Loss (gain) on sale of short-term investments	6	3,579
Changes in operating assets and liabilities:		
Receivables	(918)	349
Inventories	401	75
Other assets	317	252
Accounts payable	(119)	(138)
Accrued liabilities	(196)	(780)
Deferred revenue and other long-term liabilities	(179)	(113)
Net cash used in operating activities	(6,376)	(6,962)
Investing activities:		
Purchase of short-term investments	(14,654)	(1,551)
Proceeds from sale and maturities of short-term investments	4,223	11,439
Purchase of equipment, net	(120)	(433)
Funding of bridge notes receivable related to acquisition	(805)	
Net cash provided by (used in) investing activities	(11,356)	9,455
Financing activities:		
Principal payments on capital lease obligations	(219)	(240)
Issuance of common stock, net	41,288	
Net cash provided by (used in) financing activities	41,069	(240)
Effect of exchange rate changes	143	80
Net increase in cash and cash equivalents	23,480	2,333
Cash and cash equivalents at beginning of period	8,550	9,353
Cash and cash equivalents at end of period	\$ 32,030	\$ 11,686

Supplemental disclosure of cash flow information:		
Interest paid	\$ 33	\$ 52
Supplemental schedule of noncash investing and financing activities:		
Equipment acquired under capital leases	\$	\$ 49
Inventory transferred to fixed assets	\$ (122)	\$
Unrealized loss on short-term investments	\$ (10)	\$ 4,689
Acquisition of treasury stock in exchange for cancellation of officer note receivable	\$	\$ 212
Equity instruments issued in connection with employee benefit plan, non-employees services, and purchase of license rights, net	\$ (1)	\$ 112
Repayment of note receivable	\$	\$ 300

See accompanying notes.

Table of Contents

NANOGEN, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

(unaudited)

March 31, 2004

1. Basis of Presentation

The accompanying unaudited consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America for interim financial information and with the instructions to Form 10-Q and Article 10 of Regulation S-X. Accordingly, they do not include all of the information and disclosures required by accounting principles generally accepted in the United States of America for complete financial statements. The consolidated balance sheet as of March 31, 2004, consolidated statements of operations for the three months ended March 31, 2004 and 2003, and the consolidated statements of cash flows for the three months ended March 31, 2004 and 2003 are unaudited, but include all adjustments (consisting of normal recurring adjustments) which the Company considers necessary for a fair presentation of the financial position, results of operations and cash flows for the periods presented. The results of operations for the three months ended March 31, 2004 shown herein are not necessarily indicative of the results that may be expected for the year ending December 31, 2004.

For more complete financial information, these financial statements, and notes thereto, should be read in conjunction with the audited consolidated financial statements for the year ended December 31, 2003 included in the Nanogen, Inc. Annual Report on Form 10-K for the year ended December 31, 2003, filed with the Securities and Exchange Commission.

Use of Estimates

The preparation of financial statements in conformity with accounting principles generally accepted in the United States requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and related disclosures at the date of the financial statements, and the amounts of revenues and expenses reported during the period. Actual results could differ from those estimates.

Net Loss per Share

The Company computes net loss per share in accordance with Statement of Financial Accounting Standards (SFAS) No. 128, Earnings per Share. Under the provisions of SFAS No. 128, basic net income (loss) per share is computed by dividing the net income (loss) available to common stockholders for the period by the weighted average number of common shares outstanding during the period. Diluted net income (loss) per share is computed by dividing the net income (loss) for the period by the weighted average number of common shares outstanding during the period and in the periods they are dilutive, common equivalent shares for outstanding stock options and warrants computed using the treasury stock method. The weighted average common shares outstanding during the period does not include those shares issued pursuant to the exercise of stock options prior to vesting and shares issued under the Company's 401K benefit plan 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.

Stock-Based Compensation

The Company measures compensation cost related to stock option plans using the intrinsic value method and provides pro forma disclosures of net loss and loss per common share as if a fair value based method had been applied. Accordingly, compensation cost for stock options is measured as the excess, if any, of the fair value of the Company's common stock at the date of grant over the amount an employee must pay to acquire the stock and is amortized over the vesting period.

Table of Contents**NANOGEN, INC.****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS****(unaudited)****March 31, 2004**

Had the compensation cost for the Company's stock-based compensation plans been determined based on the fair value at the grant dates for awards under those plans, the Company's net loss and loss per common share would have been as follows (in thousands, except for loss per share):

	Three months ended March 31,	
	(unaudited)	
	2004	2003
	_____	_____
Net loss:		
As reported	\$ (5,375)	\$ (10,680)
Stock-based compensation expense under fair value based method	(922)	(997)
	_____	_____
Pro forma net loss	\$ (6,297)	\$ (11,677)
	_____	_____
Loss per common share:		
As reported	\$ (.20)	\$ (.50)
Pro forma	\$ (.23)	\$ (.54)

The pro forma effect on net loss for the three months ended March 31, 2004 and 2003 is not necessarily indicative of potential pro forma effects on results for future years.

Warranty

The Company provides product warranty coverage under direct sale and reagent rental transactions of NanoChip® Molecular Biology Workstations. Additionally, the Company provides warranty coverage on products that are placed at customer sites under programs such as development site arrangements. A liability is recorded at the time products are shipped. Changes in the Company's warranty liability were as follows (in thousands):

Three months ended March 31,	
(unaudited)	
2004	2003
_____	_____

Edgar Filing: NANOGEN INC - Form 10-Q

Balance at beginning of period	\$ 159	\$ 190
Warranty additions	41	92
Cash payments	(83)	(102)
	<u> </u>	<u> </u>
Balance at end of period	\$ 117	\$ 180
	<u> </u>	<u> </u>

2. Inventories

Inventories consist of the following (in thousands):

	March 31,	December 31,
	2004	2003
	<u> </u>	<u> </u>
	(unaudited)	
Raw materials	\$ 1,127	\$ 1,469
Work in process	1,966	1,745
Finished goods	3,361	4,043
	<u> </u>	<u> </u>
	6,454	7,257
Reserve for excess and obsolete	(2,309)	(2,483)
	<u> </u>	<u> </u>
	\$ 4,145	\$ 4,774
	<u> </u>	<u> </u>

Table of Contents

NANOGEN, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

(unaudited)

March 31, 2004

Finished goods includes \$1.6 million and \$1.7 million of NanoChip[®] Molecular Biology Workstations (NanoChip[®] Workstations) at March 31 2004 and December 31, 2003, respectively, that are installed at customer sites where title has not transferred to the customer. The majority of these instruments are placed at customer sites under development site agreements. Under these arrangements, a NanoChip[®] Workstation is placed at a customer site for a period normally between six and twelve months for the purpose of developing content and optimizing assays which may result in the creation or enhancement of intellectual property that the Company may license in the future. The customer has the option to purchase the NanoChip[®] Workstation during the period of the arrangement or at its expiration. The Company provides warranty for these NanoChip[®] Workstations as well as insures them during the development site period. Development site customers are normally required to purchase any cartridges to be used on the instrument from the Company during the development site period. As of March 31, 2004, the Company had a total of 20 NanoChip[®] Workstations under agreements whereby the Company retains title to the Workstation. The Company classifies this inventory as consignment inventory and includes this within finished goods. The Company accrues refurbishment costs for each unit included in consignment inventory for the purpose of resale in the event the unit is returned under this arrangement. This reserve totaled \$173,000 and \$197,000 at March 31, 2004 and December 31, 2003, respectively. In addition, the Company has recorded a reserve related to the older production units that may be deemed obsolete or may be sold to the customer at a discount due to the depreciation of the unit during the development site period. This reserve totaled \$770,000 at March 31, 2004 and \$1.1 million at December 31, 2003.

The Company's manufacturing agreement with Hitachi, Ltd. (Hitachi) requires that the Company provide annual purchase commitments to Hitachi for the next generation of NanoChip[®] Workstations. As of March 31, 2004, the Company had commitments to purchase approximately \$1.9 million in next generation instruments from Hitachi for shipments of product through January 31, 2005.

3. Licensed Technology

The Company has acquired various licenses to technologies which are incorporated into certain of the Company's current products or products under development. The Company capitalizes the cost (which includes cash and equity consideration) in conjunction with the acquisition of these licenses and amortizes the cost over the expected life of the product.

4. Comprehensive Loss

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

**Three months ended March 31,
(unaudited)**

Edgar Filing: NANOGEN INC - Form 10-Q

	<u>2004</u>	<u>2003</u>
Comprehensive loss:		
Net unrealized gain / (loss)	\$ (4)	\$ (4,689)
Foreign currency translation adjustment	(1,125)	80
Net loss	<u>(5,375)</u>	<u>(10,680)</u>
Comprehensive loss	<u>\$ (6,504)</u>	<u>\$ (15,289)</u>

Table of Contents

NANOGEN, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

(unaudited)

March 31, 2004

5. Collaborative Alliances

Hitachi, Ltd.

Manufacturing Agreement

In January 2000, the Company executed an agreement with Hitachi, Ltd., effective as of December 15, 1999, for the full-scale commercial manufacturing and distribution of the NanoChip[®] Molecular Biology Workstation in specified research markets. Hitachi, Ltd.'s Instrument Group provides technology and technical support to aid in the manufacturing of the NanoChip[®] Molecular Biology Workstation's components.

Hitachi, Ltd. has the right to be the sole distributor of NanoChip[®] Molecular Biology Workstations in Japan. Hitachi, Ltd. also has the non-exclusive right to distribute NanoChip[®] Cartridges in Japan. Under this arrangement, the Company receives a royalty for NanoChip[®] Molecular Biology Workstations sold by Hitachi, Ltd. in Japan. The Company retains the right to distribute, directly or through others, NanoChip[®] Molecular Biology Workstations outside of Japan. In addition, the Company manufactures NanoChip[®] Cartridges at its San Diego, California facility for distribution worldwide. The Company also retains the right to form other manufacturing and distribution agreements.

In June 2003, the Company entered into another manufacturing agreement with Hitachi for the manufacture of a new instrument being developed under the collaborative research agreement (described below). Pursuant to the 2003 manufacturing agreement, Hitachi will manufacture the new instrument, when development is completed, exclusively for the Company for worldwide distribution. Once production instruments are received by the Company, the Company is required to meet certain annual purchase commitments for the new instrument.

Pursuant to our manufacturing agreements with Hitachi, the Company is required to provide annual purchase commitments to Hitachi for the next generation of NanoChip[®] Workstations. As of March 31, 2004, the Company had a commitment to purchase approximately \$1.9 million in next generation instruments from Hitachi through January 31, 2005.

Research Collaboration Agreement

In July 2000, the Company executed an agreement with Hitachi, Ltd., Nissei Sangyo Co. Ltd. and Hitachi Instruments Service Co. Ltd. of Japan (collectively, Hitachi) to develop, manufacture and distribute additional potential products based on the parties' proprietary technologies,

Edgar Filing: NANOGEN INC - Form 10-Q

potentially including, among other things, reduced-size instruments for genetic testing, integrated amplification and point-of-care detection. Pursuant to the terms of the agreement, the Company is liable to repay to Hitachi fifty percent of all funding provided by Hitachi over an indefinite period of time. Repayment amounts are determined as a percentage of the Company's gross NanoChip® Cartridge sales until the liability is paid in full. Hitachi has the right to be the exclusive distributor of collaboration products in Japan and, based upon the attainment of minimum sales targets to be mutually agreed upon, in other Asian countries. The Company retains the exclusive right to distribute collaboration products outside of these countries.

Sponsored research revenue recognized under this agreement totaled \$375,000 in each of the three month periods ending March 31, 2004 and 2003. In accordance with SFAS No. 68, the Company records sponsored research revenue under this arrangement as expenses are incurred not exceeding scheduled payments under the agreement. The Company records a long-term liability for fifty percent of the funds received from Hitachi upon the receipt of such funds. The amount owed to Hitachi for proceeds received under this agreement was \$4.3 million and \$4.4 million at March 31, 2004 and December 31, 2003, respectively. The current portion of the long-term liability remains immaterial as payment amounts due under this obligation are determined as a percentage of the Company's gross NanoChip® Cartridge sales which have not been significant to date. As such, the Company has classified the entire balance of this liability as long-term.

In August 2003, the Company received written notice from Hitachi exercising their right to terminate the collaborative research agreement in accordance with the terms of the agreement. Hitachi's exercise of its right to

Table of Contents

NANOGEN, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

(unaudited)

March 31, 2004

terminate this agreement does not accelerate the repayment due Hitachi for the fifty percent of Hitachi provided funding. Based on joint discussions, Nanogen and Hitachi have determined to focus their joint efforts on the development and manufacture of a new instrument. Nanogen and Hitachi will continue to be jointly responsible for development of the new instrument. Hitachi is responsible for world-wide manufacturing of the instrument. Nanogen is responsible for development of assays and for marketing and sales except in Japan.

Service Agreement

In October 2000, the Company entered into an agreement with Hitachi for the service by Hitachi of the NanoChip[®] Molecular Biology Workstations in the United States after their sale or placement by the Company with the Company's customers. The Company pays an agreed-upon amount to Hitachi for annual service for each Workstation covered under the agreement. Nanogen amortizes the cost of the warranty agreement over the service period. As the Company provides the first year of warranty at no charge to the customer, the Company defers the portion of the Workstation sale revenue that relates to the warranty agreement. This deferred revenue is then amortized into revenue ratably over the annual service period. In subsequent years, the customer can pay an annual service fee to the Company and the Company will in turn pay Hitachi the annual service amount as specified in the agreement. The amount charged to the customer by the Company is based upon the cost of the service (i.e. the payment to Hitachi) plus an industry accepted profit margin for comparable service on similar types of products. Both the service revenue and the service expense are amortized ratably over the service period, generally one year.

In March 2004, the Company received written notice from Hitachi to exercise its right to terminate the service agreement in accordance with the terms of the agreement. Hitachi will continue to service existing field units for a period of six months from the date of notice, at which time the responsibility for servicing units will transfer back to the Company.

Aventis Research and Technologies

In June 2001, the Company entered into agreements with Hoechst AG (Aventis) to create a new company, Nanogen Recognomics GmbH (Nanogen Recognomics). Nanogen Recognomics was established to develop new products and applications for the NanoChip[®] system. Nanogen Recognomics is sixty percent owned by the Company and forty percent owned by Aventis and is based in Frankfurt, Germany. As a result of the agreements, Nanogen Recognomics owns several patent applications filed jointly by the Company and Aventis and the Company has licensed certain aspects of its NanoChip[®] technology to Nanogen Recognomics. Aventis retains the right to utilize the former Aventis patent portfolio in fields outside of Nanogen Recognomics.

During the first quarter, the initial capital infusion of \$5 million provided by Aventis to Nanogen Recognomics in June 2001 had been depleted. As a result, in February 2004, the shareholders of Nanogen Recognomics decided to reorganize into a non-operating holding company and therefore, discontinue all the business activities. The Company is required pursuant to the original joint venture agreement to take over

Edgar Filing: NANOGEN INC - Form 10-Q

reorganization costs and the Company may restructure Nanogen Recognomics to hold the original patents contributed by Aventis and any jointly owned patents. The restructured company will collect royalties, if any, and pay the equity owners accordingly. Our exclusive commercialization license will continue for 10 years after restructuring.

The results of operations for Nanogen Recognomics are fully consolidated in the Company's financial statements. During the three months ended March 31, 2004, Nanogen Recognomics incurred approximately \$300,000 in operating expenses, as well as approximately \$870,000 in reorganization costs of which approximately \$750,000 is reported as a liability as of March 31, 2004. These costs and expenses are reflected as research and development costs in the statement of operations. The Company will expense future reorganization costs as incurred. Such costs are expected to total approximately \$300,000, and the majority of the reorganization is expected to be completed by the end of the second quarter 2004. For the three month period ended March 31, 2003, the total operating loss of Nanogen Recognomics is reflected as a reduction of the minority interest in consolidated subsidiary liability account and totaled approximately \$550,000.

Table of Contents

NANOGEN, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

(unaudited)

March 31, 2004

The functional currency of Nanogen Recognomics is the Euro. As a result of the increasing value of the Euro versus the U.S. Dollar during the period from inception of Nanogen Recognomics through February 2004, the time the shareholders decided to reorganize, we had recorded cumulative unrealized gains on foreign currency translation of approximately \$1.2 million. In accordance with Statement of Financial Accounting Standards No. 52, *Foreign Currency Translation* and its related interpretations, the Company, upon discontinuance of its business activity, realized the approximately \$1.2 million in previously unrealized foreign currency translation gains.

Transgenomic, Inc.

In January 2004, the Company entered into an agreement with Transgenomic, Inc. (Transgenomic) for the distribution of the Company's NanoChip® Molecular Biology Workstation in selected Western European countries. Transgenomic's European marketing and sales organization will market, sell and service the instrument.

6. Litigation

In September 2002, the Company entered into a settlement agreement with CombiMatrix Corp. (CombiMatrix) and Dr. Donald Montgomery concluding pending litigation in the U.S. District Court for the Southern District of California. Pursuant to the settlement agreement, Nanogen agreed to drop its claims against CombiMatrix and Dr. Montgomery that include certain causes of action relating to U.S. patent Nos. 6,093,302 and 6,280,595 (the patented technology) that were assigned by Dr. Montgomery, an ex-Nanogen employee, to CombiMatrix in 1995 and assertions relating to other matters. In exchange, CombiMatrix agreed to pay \$1.0 million as a reimbursement of legal costs; issue 4,016,346 shares of CombiMatrix tracking common stock that as of December 18, 2002 became publicly tradable on the Nasdaq National Market and were initially valued upon receipt at \$10.8 million, which represents seventeen and one-half percent (17.5%) of its outstanding common stock; and make royalty payments of twelve and one-half percent (12.5%) on sales of products by either CombiMatrix or its affiliates that incorporate the patented technology. Of the \$1.0 million due the Company, \$500,000 was paid in October 2002 and the remaining \$500,000 was paid in September 2003. Also, as part of the settlement agreement, CombiMatrix and Dr. Montgomery agreed to drop their counterclaims against Nanogen and CombiMatrix retained sole ownership of the patented technology. In February 2003, the Company sold 3,000,000 shares of CombiMatrix common stock for net proceeds totaling \$4.5 million and recognized a loss of approximately \$3.6 million during the three months ended March 31, 2003. The remainder of the shares were sold in the second half of 2003.

In December, 2002, Oxford Gene Technologies (OGT) filed a complaint against the Company in the United States District Court for the District of Delaware claiming that Nanogen infringes U.S. Patent No. 6,054,270 (the 270 Patent) entitled Analyzing Polynucleotide Sequences. In April 2003, Nanogen filed an answer to the complaint that denies that it infringes the 270 Patent. In October, 2003, the Company and OGT entered into a settlement agreement pursuant to which the lawsuit was dismissed by OGT without prejudice.

7. Stock Transactions

In January 2003, the Compensation Committee of the Board of Directors approved the issuance of common stock pursuant to the Company's Stock Bonus Plan. During the three months ended March 31, 2003, the Company issued 71,610 shares of common stock under the Plan valued at approximately \$112,000 based on the value of the shares at the date of issuance. No shares were issued under the Stock Bonus Plan during the three months ended March 31, 2004.

Table of Contents

NANOGEN, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

(unaudited)

March 31, 2004

In September 2003, the Company entered into agreements to sell common stock and warrants to several accredited investors for aggregate potential gross proceeds of approximately \$16 million. During the initial closing in September 2003, Nanogen received \$7 million in gross proceeds through the sale of 2,121,211 newly issued shares of its common stock at a negotiated discount price of \$3.30 per share. The investors received warrants to purchase additional shares of common stock as follows: 1,103,032 shares at an exercise price of \$4.14 per share exercisable until March 18, 2004; 530,305 shares at an exercise price of \$4.75 per share exercisable until September 18, 2004; and 424,243 shares at an exercise price of \$4.75 per share exercisable until September 18, 2008. During the three months ended March 31, 2004, 1,103,032 shares were issued pursuant to exercises of the \$4.14 warrants resulting in gross proceeds of approximately \$4.6 million. As of March 31, 2004, all of the \$4.75 warrants were outstanding.

In March 2004, the Company sold 4.25 million shares of its common stock to institutional investors at a price of \$7.94 per share, for gross proceeds of approximately \$33.7 million. After deducting fees and expenses, the Company received approximately \$31.5 million from the sale.

In April 2004, the Company sold 900,000 shares of its common stock to institutional investors at a price of \$8.60 per share, for gross proceeds of approximately \$7.7 million. After deducting fees and expenses, the Company received approximately \$7.4 million from the sale.

During the three months ended March 31, 2004, approximately 950,000 stock options were exercised resulting in gross proceeds of approximately \$4.9 million to the Company. There were no exercises during the three months ended March 31, 2003.

8. Related Party Transactions

In January 2004, the Vice-President of Operations' employment with the Company terminated, and pursuant to the terms of his employment agreement, a severance payment of \$110,000 was made.

Mr. Birndorf, Chief Executive Officer, owns an aircraft that is leased by a local charter aircraft company. For the three months ended March 31, 2004 and 2003, the Company paid approximately \$0 and \$25,000, respectively, to the local charter aircraft company for the Company's use of Mr. Birndorf's aircraft for business related travel. Mr. Birndorf receives approximately \$1,250 per hour of usage when his aircraft is leased to outside parties. Mr. Birndorf received approximately \$0 and \$15,000 as a result of the Company's use of Mr. Birndorf's aircraft during the three months ended March 31, 2004 and 2003, respectively. The Company believes that the terms of the charter arrangements are comparable to those that could be obtained from unrelated third parties.

9. Subsequent Events

Acquisition of SynX Pharma Inc.

On April 21, 2004, the Company completed its acquisition of SynX Pharma Inc. (SynX) in an all-stock transaction by way of a court-approved plan of arrangement. SynX is now a wholly owned subsidiary of Nanogen. The transaction was valued at Canadian \$16.3 million (approximately U.S. \$12.2 million). Nanogen also made available to SynX a secured line of credit of Canadian \$2.0 million (approximately U.S. \$1.5 million) to fund working capital needs prior to closing. Approximately Canadian \$1 million of the line of credit was utilized prior to closing. Pursuant to the plan of arrangement each SynX shareholder received 0.123 shares of Nanogen common stock per SynX common share. Accordingly, approximately 1.6 million shares of Nanogen common stock are issuable to former SynX shareholders and to holders of replacement warrants and options. In addition, the CDN\$3.5 million principal amount of subordinated secured debentures of SynX (together with unpaid interest) were retired in exchange for approximately 300,000 shares of Nanogen common stock.

Table of Contents

NANOGEN, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

(unaudited)

March 31, 2004

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

This report includes forward-looking statements about our business and results of operations that are subject to risks and uncertainties that could cause our actual results to vary materially from those reflected in the forward-looking statements. These risks and uncertainties include possible delays in the introduction of new products, customer acceptance of existing products, price competition, the actions of competitors, infringement of intellectual property rights and licenses of the Company or others, the effects of government regulation, both foreign and domestic, availability of funded research and government contracts and grants, preservation of productive relationships with our manufacturer and collaborator Hitachi and our distributors, ability to manage our capital resources and other factors. Words such as believes, anticipates, plans, estimates, future, could, may, should, expect, envision, potentially, variations of such words and similar expressions are intended to be forward-looking statements. The forward-looking statements contained in this Form 10-Q may include, but are not limited to, statements about matters including the following: (i) the development of the markets and demand for our products and services; (ii) our product development plans and anticipated activities designed to pursue these plans, including collaborations and other corporate partnering arrangements; (iii) our ability to derive substantial revenues from sales of products and consumable cartridges and reagents and continuing revenues from reagent rental agreements; (iv) the ability of our product platform to affect the market and become an industry standard; (v) our ability to generate license and other fee revenue in the future; (vi) the amounts we invest in research and development activities in the future; (vii) future levels of selling, general and administrative expenses and other expenses associated with our business; (viii) future levels of interest income; (ix) any amounts we may be able to realize from the liquidation of our investments, including our investments in short-term securities; (x) operating results of joint ventures and other corporate partnering arrangements; (xi) the amounts and timing of our contractual obligations and capital commitments; and (xii) our future capital needs and our ability to fund those needs. Factors that could cause or contribute to these differences include those discussed below under the caption *Factors that May Affect Results* and elsewhere in this Quarterly Report on Form 10-Q and which are described in our Annual Report on Form 10-K for the year ended December 31, 2003. Readers are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date hereof. We disclaim any intent or obligation to update these forward-looking statements.

Overview

Nanogen was founded on the vision of integrating multiple sciences to develop diagnostic products. Through advances in genomic and pharmaceutical research, we believed that diagnostics and therapeutics would become closely linked. Further, we believed that by using electronics, we could develop a highly accurate and flexible set of products that would facilitate the analysis of complex genetic relationships and the correlation to disease and therapies. This vision in turn led to the definition of the Company's mission: to become a leading provider of high quality innovative advanced diagnostic products and services to patients, providers and pharmaceutical companies.

Nanogen currently develops and commercializes molecular diagnostics products and tests for the gene-based testing market for sale primarily in the United States, Europe and the Pacific Rim. By integrating microelectronics and molecular biology into a core proprietary technology platform, the Company seeks to establish the unique, open-architecture design of its primary products, the NanoChip[®] Molecular Biology Workstation and the NanoChip[®] Cartridge (collectively, the NanoChip[®] System), as the standard platform for molecular identification and analysis. In furtherance of its mission to become a leading supplier of advanced diagnostics testing products, Nanogen is developing a broad menu of Analyte Specific Reagents (ASRs) and other commercial applications for the NanoChip[®] System. The Company continually conducts

Edgar Filing: NANOGEN INC - Form 10-Q

research and development by itself and with third parties, to improve the NanoChip® System and to extend its technology to other applications such as biodefense, forensics, drug discovery and pharmacogenomics.

Table of Contents

Nanogen believes that its technology platform provides a key advantage over conventional manual and mechanical platforms in that it provides an accurate, simple, versatile and cost-effective integrated microelectronic system that is capable of improving the quality of molecular diagnostic testing while reducing the overall cost of such testing. At the heart of Nanogen's technology is a silicon chip called the NanoChip[®] Electronic Microarray. Each Electronic Microarray has 100 microlocations or test sites upon which genetic tests can be conducted. DNA or RNA is moved and concentrated by controlling the electric current at each test site, improving accuracy, speed and flexibility. This electronic concentration of molecules greatly accelerates molecular binding at each test site. In addition, our technology allows the simultaneous analysis of multiple test results, or multiplexing, from a single sample. Current applications of the NanoChip[®] Electronic Microarray include single nucleotide polymorphisms (SNPs), short tandem repeats (STRs), insertions, deletions and other mutation analyses.

The Company's current commercially available products include (1) the NanoChip[®] Molecular Biology Workstation, an automated, multi-purpose instrument primarily used for DNA-based analyses, (2) the NanoChip[®] Cartridge, which incorporates the NanoChip[®] Electronic Microarray and provides a flexible tool for the rapid identification and precise analysis of biological test samples containing charged molecules, (3) various ASRs for detection of gene mutations associated with diseases such as cystic fibrosis and (4) Nanogen's general purpose reagents and accessories used to facilitate assay and protocol development and validation on the NanoChip[®] Platform. The Company also has several other ASRs and applications of its proprietary technology under development. The Company provides technical support and field applications assistance to service and support its customers.

In addition, in April 2004, we completed the acquisition of SynX Pharma Inc., a point-of-care diagnostics company based in Ontario, Canada. SynX currently markets point-of-care diagnostic tests for myocardial infarction in Europe and Canada, and infectious diseases and drugs of abuse in Canada. SynX is preparing to commercialize a diagnostic product for congestive heart failure (CHF). We expect the acquisition will provide us with a pipeline of complementary products in order to expand our market share in the *in vitro* diagnostics market and augments our technology platform for developing advanced diagnostic products.

Since commencing operations in 1993, we have applied substantially all of our resources to our research and development programs. We have incurred losses since inception and, as of March 31, 2004, had an accumulated deficit of \$(181.6) million. We expect to continue to incur significant losses over at least the next few years as we attempt to further commercialize our products as well as expand the menu of applications for our current products.

For the three months ended March 31, 2004 as well as for the year ended December 31, 2003, product related revenue was the largest category of revenue. While we recognized revenue from product sales during the years ended December 31, 2002, and 2001, our main sources of revenues during those fiscal years were payments under our sponsored research agreements, contracts and grants and, in 2002, a license fee valued at \$10.8 million received from a litigation settlement with CombiMatrix Corp. We believe that in future periods, our revenue base will continue to be more product driven as certain research collaboration agreements expire and new products are introduced to the marketplace. We believe our future operating results may be subject to quarterly fluctuations due to a variety of factors, including, but not limited to, market acceptance of the NanoChip[®] System and potential products under development, the type of acquisition program our potential customers may choose, whether and when new products are successfully developed and introduced by us or our competitors, and the achievement of milestones under our collaborative agreements with Hitachi and various government agencies. The recognition of revenue under contracts, grants and sponsored research agreements will be subject to significant fluctuations in both timing and amount and therefore our results of operations for any period may not be comparable to the results of operations for any other period.

Critical Accounting Policies and Estimates

This Management's Discussion and Analysis of Financial Condition and Results of Operations discusses our consolidated financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States. The preparation of these financial

Edgar Filing: NANOGEN INC - Form 10-Q

statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. On an on-going basis, we evaluate our estimates and judgments, including those related to bad

Table of Contents

debts, inventories, investments, intangible assets, service obligations and contingencies. We base our estimates and judgments on historical experience and on various other factors that we believe to be reasonable under the circumstances. Actual results may differ from these estimates under different assumptions or conditions.

We believe the following critical accounting policies, among others, affect our more significant judgments and estimates used in the preparation of our consolidated financial statements:

Revenue recognition

Product revenue is generated by the sale of commercial products and services under various sales programs to the end user or through distribution channels. Revenue is recognized in accordance with the Securities and Exchange Commission's Staff Accounting Bulletin No. 101, Revenue Recognition in Financial Statements and is recorded as follows:

The Company sells NanoChip® Molecular Biology Workstations under various commercial programs such as; direct sale, reagent rental programs, and cost-per-reportable agreements. Additionally, the Workstations are placed with potential customers under development site programs that may ultimately result in one of the above commercial transactions. The Company sells Workstations direct to the end user and to distributors. Revenue from the sale of consumables is recognized upon shipment (f.o.b. shipping point) as the Company does not sell consumables with a right of return.

Revenue from the direct sale of NanoChip® Molecular Biology Workstations is recognized following receipt of a purchase order, shipment (f.o.b. shipping point) of product, and transfer of title when sold directly to the end user or to a distributor. In transactions where a right-of-return exists, revenue is deferred until acceptance has occurred and the period for the right-of-return has lapsed. The NanoChip® Molecular Biology Workstation is sold with a one year warranty contract. The fair value of the warranty is recorded as deferred revenue and recognized ratably over the warranty period included in the customer contract. The fair value of the warranty is based on the renewal price paid by the same customer. This renewal price for the maintenance contract is consistent for all customers. The Company includes the estimated cost of product warranty in deferred revenue and recognizes as revenue over the warranty period.

The Company also recognizes revenue from the sale of the NanoChip® System under reagent rental and cost-per-reportable transactions whereby customers pay a premium for consumable products (NanoChip® Cartridges or ASRs) over a number of years that is intended to cover the sales price of the NanoChip® Workstation, consumables and warranty. Under a reagent rental transaction, the customer commits to purchasing a fixed number of consumable products on a periodic basis for a specified period of time (i.e. a certain number of cartridges for a certain number of years). Revenue for the Workstation, consumables and warranty under reagent rental transactions is recognized as consumable products are shipped, over a period of generally two to five years, depending on the specific customer arrangement as they may vary by customer. The Company reclassifies the recorded value of the Workstation from inventory to fixed assets, recognizing the depreciation expense as cost of sales ratably over the period of the arrangement. Under a cost-per-reportable transaction, the customer agrees to purchase a certain number of consumable products on a periodic basis determined by the customer's volume of reported test results (to third parties) from the use of consumable products. The Company recognizes revenue under this type of transaction at the time the Company receives evidence of the customer's test results reported to third parties. Under these arrangements, the Company provides product warranty coverage for the Workstation over the period of the contract. Under both of these sale transactions, the fair value of the warranty is recognized ratably over the warranty period included in the customer contract. The cost of sales related to the consumables is recorded in line with the revenue (i.e., as consumables are shipped or consumed, depending on the terms of the contract).

Edgar Filing: NANOGEN INC - Form 10-Q

The Company also places NanoChip[®] Molecular Biology Workstations at customer sites under programs, such as development site arrangements, where title of the NanoChip[®] Workstation does not transfer to the customer. No revenues are recognized at the time of placement under these agreements. These arrangements are for a period normally between six and twelve months for the purpose of developing content and optimizing assays that may result in the creation or enhancement of intellectual property that the Company may license in the future. In addition, a primary intent of the program is for the customer to purchase the NanoChip[®] Workstation during the period of the arrangement or at its expiration. The Company provides a warranty for these NanoChip[®] Workstations as well as insures them during the development site period. Warranty expense is recorded ratably over the period of

Table of Contents

the arrangement within selling, general, and administrative (SG&A) expenses. Development site customers are normally required to purchase any consumables to be used on the instrument from the Company during the development site period. The Company classifies this inventory of workstations as consignment inventory and includes this within finished goods. The Company records a reserve for the refurbishment costs, recorded within SG&A, for each unit included in consignment inventory for the purpose of resale in the event the unit is returned under this arrangement. This reserve totaled approximately \$173,000 and \$197,000 at March 31, 2004 and December 31, 2003, respectively, and is included in accrued liabilities. In addition, the Company has recorded a reserve related to the older production units that may be deemed obsolete or sold to the customer at a discount due to the age of the unit during the development site period. Transactions under these types of programs do not result in the recognition of revenue, however, if the customer elects to purchase the NanoChip[®] Workstation at any time, sales revenue is recognized upon receipt of a non-cancelable purchase order. Cost of sales for the Workstation is provided for at the time revenue is recognized.

Workstations sold to distributors are sold outright with title transferring at point of shipment (i.e. f.o.b. shipping point) without a right of return. Workstations are sold at a discount to the standard sales price (but not below the cost of manufacturing the instrument) and without warranty coverage.

Sponsored research and contract and grant revenue are generally recorded as the costs and expenses to perform the research are incurred. Under certain arrangements, revenue is recorded ratably over the term of the arrangement as funding is provided for contractually on a scheduled basis. Payments received in advance under these arrangements are recorded as deferred revenue until the expenses are incurred. Continuation of certain sponsored research, contracts and grants are dependent upon the Company achieving specific contractual milestones.

License fees include nonrefundable fees generated from the licensing of the Company's technology. Revenue is recognized immediately when the Company has no further obligation to perform and collections are reasonably assured.

Bad debts

We maintain allowances for doubtful accounts for estimated losses resulting from the inability of our customers to make required payments. We record additions to our reserve based on specific analysis of each customer's balance due us. If the financial condition of our customers were to deteriorate, resulting in an impairment of their ability to make payments, additional allowances would be required.

Inventory

We reduce the carrying value of our inventory, including NanoChip[®] Molecular Biology Workstations placed under development site arrangements, for estimated obsolescence or non-marketability after considering future purchase commitments, the potential impact of next generation instruments, and based upon assumptions about future demand and market conditions. If actual future demand or market conditions are less favorable than those projected by us, additional inventory write-downs may be required.

Intangible Assets

Edgar Filing: NANOGEN INC - Form 10-Q

We have intangible assets related to acquired technology rights. The determination of related estimated useful lives and whether or not these assets are impaired involves significant judgments. Impairment is measured by a comparison of the carrying amount of an asset to the future net cash flows that are expected to be generated by the asset. If such assets are considered to be impaired, the impairment to be recognized is measured by the amount by which the carrying amount of the assets exceeds the fair value of the assets. Changes in strategy and/or market conditions could significantly impact these judgments and require adjustments to recorded asset balances.

Results of Operations

Product Revenue. For the three months ended March 31, 2004, product revenue totaled \$1.1 million compared to \$228,000 for the three months ended March 31, 2003. Product revenue during the three months ended March 31, 2004 included the sale of seven NanoChip® Molecular Biology Workstations of which two were development site agreement conversions, as well as sales of NanoChip® Cartridges, reagents and warranty revenue. Product revenue

Table of Contents

during the three months ended March 31, 2003 included the sale of one partial unit as well as sales of NanoChip® Cartridges, reagents and warranty revenue. All revenue recorded related to sales of our NanoChip® Molecular Biology Workstation for the three months ended March 31, 2004 and 2003 resulted from outright sales transactions where title of the instrument passed to the customer. We offer our products to customers under several different types of acquisition programs, some of which pass title of the instrument to the customer and some of which do not pass title to the customer. Our product revenue may vary from year to year due to, among other things, the types of acquisition programs our potential customers may choose.

Sponsored Research. For each of the three month periods ended March 31, 2004 and 2003, revenues from sponsored research totaled \$375,000. Revenues are primarily recorded under these arrangements as expenses are incurred. Payments received in advance under these arrangements are recorded as deferred revenue until the expenses are incurred. Sponsored research revenue recognized during the three months ended March 31, 2004 and 2003 represents revenue earned in connection with our development agreement entered into in July 2000 with Hitachi. We are currently on schedule with project milestones and expect sponsored research revenue from the collaboration to continue at their current level through May 2004. During August 2003, the Company received written notification from Hitachi that Hitachi is terminating the research collaboration agreement in accordance with the terms of that agreement. Funding by Hitachi under the collaboration agreement is expected to terminate in May 2004.

Contracts and Grants. We fund some of our research and development efforts through contracts and grants awarded by various federal and state agencies. Revenues are recognized under these contracts and grants as expenses are incurred, and totaled \$500,000 and \$597,000, respectively, respectively, for the three months ended March 31, 2004 and 2003. The decrease in revenues for the three months ended March 31, 2004 compared to the same period in 2003 is primarily related to the completion of two government contracts.

Cost of Product Sales and Gross Margins. Cost of product sales totaled \$914,000 and \$274,000 for the three months ended March 31, 2004 and 2003, respectively. Gross margins on product sales revenue were 19.2% and negative 20% for the three months ended March 31, 2004 and 2003, respectively. Cost of product sales for the three months ended March 31, 2004 were negatively impacted by a reserve for excess and obsolete inventory totaling \$140,000, underabsorbed overhead costs due to underutilized capacity and manufacturing scrap. The inventory reserve relates primarily to obsolete raw materials in our inventory that could potentially not be saleable or could become obsolete. Costs of product sales during the three months ended March 31, 2003 were negatively impacted by a reserve for excess instrument inventory and related accessory items, lower sales volume, underabsorbed overhead costs due to underutilized capacity, and manufacturing scrap as a result of lower yields on new products released into production. As we are still in the early stages of commercialization, we expect to continue to incur significant costs associated with excess production capacity within our manufacturing facility in 2004. For the three months ended March 31, 2004 and 2003, gross margins were impacted by sales of NanoChip® Workstations to certain customers under various discount programs, and by sales to distributors that are at a discount. Gross margins in future periods may be further impaired by minimum product royalties or potential adjustments made to reflect the impairment of intangible assets related to products sold. The sale of NanoChip® Workstations is directly related to the successful validation of assays developed and implemented by clinical laboratories based on our ASRs. Should the successful validation or rate of adoption by clinical laboratories vary from our estimates, gross margins could be impacted by additional reserves for obsolete and slow moving inventory.

Research and Development Expenses. For the three months ended March 31, 2004 and 2003, research and development expenses totaled \$4.3 million and \$4.7 million, respectively. During these periods, research and development expenses included the cost of salaries and benefits for scientific, engineering and operations personnel, costs associated with improving and refining our current products as well as development of potential new products and protocols, lab supplies, consulting, travel, facilities, and other expenditures associated with our research and product development activities. For the three months ended March 31, 2004 and 2003, research and development activities primarily related to the development of new ASRs and new instrumentation products. We anticipate research and product development costs to decline from amounts experienced during the three months ended March 31, 2004 as a result of the restructuring of Nanogen Recognomics into a non-operating entity (i.e. substantial discontinuation of business activity). This decline does not include the future impact of the acquisition of SynX discussed elsewhere herein under the heading Subsequent Events .

Table of Contents

Selling, General and Administrative Expenses. For the three months ended March 31, 2004 and 2003, selling, general and administrative expenses totaled \$3.6 million and \$4.1 million, respectively. Selling, general and administrative expenses include salaries, benefits, consulting, travel and other expenditures related to executive, legal, finance, human resources, sales and marketing personnel. In addition, these expenses include costs related to enhancing and maintaining our intellectual property portfolio. The decline in selling, general, and administrative expense for the three months ended March 31, 2004 as compared to the same period during the prior year is primarily the result of decreased expenditures associated with the launch of products, reduced costs related to maintaining and enhancing our intellectual property portfolio, and other cost reduction measures taken during the quarter. We anticipate selling, general and administrative expenses to remain at similar levels experienced during the three months ended March 31, 2004, excluding the future impact of the acquisition of SynX discussed elsewhere herein under the heading Subsequent Events .

Interest Income, Net. For the three months ended March 31, 2004 and 2003, net interest income totaled \$102,000 and \$195,000, respectively. The decrease in net interest income is a result of lower average cash and investment balances as well as lower yields on outstanding cash and investment balances during the three months ended March 31, 2004. As a result of increased average cash and investment balances that resulted from the net proceeds from the sale of common shares totaling \$33.7 million and \$7.7 million in March 2004 and April 2004, respectively, we expect net interest income to increase in subsequent quarters during 2004 as compared to the first quarter.

Gain on Foreign Currency Translation.

During the three months ended March 31, 2004, the Company recognized a gain of \$1.2 million related to a previously unrealized gain for foreign currency translation of its Nanogen Recognomic s subsidiary financial statements. In February 2004, the Company and the minority shareholder of Nanogen Recognomics decided to reorganize Nanogen Recognomics and discontinue all its business activities. In accordance with Statement of Financial Accounting Standards No. 52, Foreign Currency Translation, and its related interpretation the Company recognized the gain of \$1.2 million as all the business activities of this subsidiary have been discontinued.

Minority Interest in Loss of Consolidated Subsidiary. The minority interest in losses relating to our majority-owned subsidiary, Nanogen Recognomics GmbH, for the three months ended March 31, 2004 and 2003, totaled \$0 and \$548,000, respectively. Through December 2003, the losses were funded by the investment from minority interest investor and are therefore offset against the minority interest balance in its balance sheet. Subsequently, any losses incurred are recognized solely by the Company and are reflected in the consolidated net loss.

Liquidity and Capital Resources

At March 31, 2004, we had \$63.0 million in available cash, cash equivalents and short-term investments, compared to \$29.1 million at December 31, 2003. The increase is primarily due the initial \$33.7 million in gross proceeds from the March 2004 sale of common stock. Also during the three months ended March 31, 2004, the Company received \$4.6 million in gross proceeds from the exercise of warrants related to a financing that originally closed in September 2003, and approximately \$4.9 million related to the exercise of stock options. These sources of cash were partially offset by cash used in operations.

Net cash used in operating activities was \$6.4 million and \$7.0 million for the three months ended March 31, 2004 and 2003, respectively, and primarily related to costs associated with commercializing our products, including the expansion, development and support of our sales and marketing organization; the procurement of inventory pursuant to our manufacturing arrangement with Hitachi, Ltd; support of our continuing research and development efforts including development of the ASRs which may be used by customers to develop tests for the detection of mutations in the CFTR gene associated with cystic fibrosis, the ASRs for mutations in the HFE gene associated with the hereditary

Edgar Filing: NANOGEN INC - Form 10-Q

hemochromatosis, and the other ASRs and other products recently introduced by Nanogen; and legal fees relating to establishing, maintaining and defending our intellectual property portfolio.

Net cash used in investing activities was \$11.4 million for the three months ended March 31, 2004, as compared to \$9.5 million provided by investing activities for the three months ended March 31, 2003. We purchase short-term investments in order to enhance the yield on our cash balances, and in the three months ended March 31, 2004, a portion of the excess cash that resulted from the \$33.7 million sale of common stock was invested. These securities mature from time to time or are sold to fund operating expenses. During the three months ended March 31, 2003, certain securities matured or were sold to help fund operating activities.

We have funded some of our equipment acquisitions and leasehold improvements through capital leasing facilities. As of March 31, 2004, we have approximately \$1.9 million available on an equipment line of credit which expires in December 2004.

Table of Contents

As of March 31, 2004, the acquisition of SynX had not been completed. Included in the definitive agreements signed in February 2004, was a provision whereby the Company agreed to provide bridge funding up to Canadian \$2 million for SynX's operating use prior to closing. As of March 31, 2004, the Company had advanced approximately Canadian \$1.1 million to SynX. As of April 21, 2004, the date of acquisition, the Company had advanced approximately Canadian \$1.6 million to SynX. We intend to invest approximately \$6-8 million to fund the operations and product development programs of SynX.

Net cash provided by financing activities for the three months ended March 31, 2004 was \$41.1 million as compared to cash use of \$240,000 for the three months ended March 31, 2003. The funding for the three months ended March 31, 2004 primarily relates to the initial \$33.7 million in gross proceeds from the March 2004 sale of common stock. The Company also received \$4.6 million in gross proceeds from the exercise of warrants related to a financing that closed in September 2003, and approximately \$4.9 million related to the exercise of stock options.

Our manufacturing agreement for the Molecular Biology Workstation with Hitachi, Ltd. requires that we provide annual purchase commitments to Hitachi for NanoChip® Molecular Biology Workstations. As of March 31, 2004, we had commitments to purchase approximately \$1.9 million in NanoChip® Workstations from Hitachi for shipments of product through January 2005.

We are a party to development site agreements with various entities and to license agreements under which we acquired rights to pay license fees, annual minimum royalties or product royalties for any customer owned or licensed intellectual property used to develop any Nanogen commercial products. None of these agreements individually are considered material.

We are also party to transactions known as reagent rentals and cost-per-test agreements. Under these types of transactions, we place a workstation at a customer site with no upfront cost to the customer. The value of the instrument is typically recaptured through a contracted stream of future reagent sales, sold at a premium to cover the cost of the system. Many of our reagent rentals and cost-per-test agreements entered into to date require customer acceptance of our CFTR ASRs as a pre-condition to this commitment. These reagent rentals and cost-per-test agreements might have a short-term adverse impact on our instrument sales revenue and cash flow as the revenues and cash received under these agreements are over the life of the contract, which is typically two to five years, as reagents are shipped to the customer.

We expect that our existing capital resources, combined with anticipated revenues from potential product sales, reagent rentals, leases or other types of acquisition programs for the NanoChip® System, sponsored research agreements, contracts and grants will be sufficient to support our planned operations for at least one year from the date of this filing. This estimate of the period for which we expect our available sources of liquidity to be sufficient to meet our capital requirements is a forward-looking statement that involves risks and uncertainties, and actual results may differ materially. Our future liquidity and capital funding requirements will depend on numerous factors including, but not limited to, commercial success of our products, or lack thereof, of our current products, the extent to which our products under development are successfully developed and gain market acceptance, the timing of regulatory actions regarding our potential products, the costs and timing of expansion of sales, marketing and manufacturing activities, prosecution and enforcement of patents important to our business and any litigation related thereto, the results of clinical trials, competitive developments, and our ability to maintain existing collaborations, our ability to enter into additional collaborative arrangements, our ability to realize the anticipated benefits of acquisitions, and transaction, integration and operating costs and expenses of acquisitions. We have incurred negative cash flow from operations since inception and do not expect to generate positive cash flow to fund our operations for at least the next several years. We may need to raise additional capital to fund our research and development programs, to scale-up manufacturing activities, to expand our sales and marketing efforts to support the commercialization of our products under development and otherwise to fund operations beyond the one-year period referenced above. Additional capital may not be available on terms acceptable to us, or at all. If adequate funds are not available, we may be required to curtail our operations significantly or to obtain funds through entering into collaborative agreements or other arrangements on unfavorable terms. Our failure to raise capital on acceptable terms when needed could have a material adverse effect on our business, financial condition or results of operations.

Table of Contents

Item 3. Quantitative and Qualitative Disclosures About Market Risk

Short-term investments. We invest our excess cash in short-term, interest-bearing investment-grade securities that primarily are held for the duration of the term of the respective instrument. We have not utilized derivative financial instruments, derivative commodity instruments or other market risk sensitive instruments, positions or transactions in any material fashion. Accordingly, we believe that, while the instruments we hold are subject to changes in the financial standing of the issuer of such securities, we are not generally subject to any material risks arising from changes in interest rates, foreign currency exchange rates, commodity prices, equity prices or other market changes that affect market risk sensitive instruments.

Foreign currency rate fluctuations. The functional currency for our Netherlands and German subsidiaries is the U.S. dollar and euro, respectively. The German subsidiary's accounts are translated from the euro to the U.S. dollar using the current exchange rate in effect at the balance sheet date for balance sheet accounts, and using the average exchange rate during the period for revenues and expense accounts. The effects of translation are recorded in accumulated other comprehensive income in the consolidated financial statements included herein. In certain instances, our subsidiaries conduct business with customers and vendors in euros or in other local European currencies. Exchange gains and losses arising from these transactions are recorded using the actual exchange rate differences on the date of the transaction. We have not taken any action to reduce our exposure to changes in foreign currency exchange rates, such as options or futures contracts, with respect to transactions with our European customers and vendors. In February 2004, the shareholders of Nanogen Recogomics, our German subsidiary, elected to reorganize as a non-operating entity. As a result of this reorganization, in accordance with Statement of Financial Accounting Standards No. 52, *Foreign Currency Translation*, the Company realized approximately \$1.2 million in foreign currency translation gains, previously unrealized. The net tangible assets of our subsidiaries, excluding intercompany balances, is \$1.7 million at March 31, 2004.

Item 4. Controls and Procedures

(a) Evaluation of Disclosure Controls and Procedures.

The Company's management, with the participation of the Company's Chief Executive Officer and Chief Financial Officer, evaluated the effectiveness the Company's disclosure controls and procedures as of the end of the period covered by this report. Based on that evaluation, the Chief Executive Officer and Chief Financial Officer concluded that the Company's disclosure controls and procedures as of the end of the period covered by this report have been designed and are functioning effectively to provide reasonable assurance that the information required to be disclosed by the Company in reports filed under the Securities Exchange Act of 1934 is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms. The Company believes that a controls system, no matter how well designed and operated, cannot provide absolute assurance that the objectives of the controls system are met, and no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, within a company have been detected.

(b) Change in Internal Control over Financial Reporting.

No change in the Company's internal control over financial reporting occurred during the Company's most recent fiscal quarter that has materially affected, or is reasonably likely to materially affect, the Company's internal control over financial reporting.

Table of Contents

PART II - OTHER INFORMATION

Item 6. Exhibits and Reports on Form 8-K

(a) Exhibits

<u>Exhibit No.</u>	<u>Description</u>
10.1	Offer letter dated May 8, 2003 between David Ludvigson and the Company.
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 Required by Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended.
32.2	Certifications of Chief Financial Officer Required by Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended.

(b) Reports on Form 8-K

- (i) On February 10, 2004, we furnished a Current Report on Form 8-K to the SEC under Item 5 thereof, including the Company's press release announcing that it had signed a definitive agreement to acquire SynX Pharma, Inc., a company organized and existing under the laws of the Province of Ontario.
- (ii) On February 18, 2004, we furnished a Current Report on Form 8-K to the SEC under Item 12 thereof, including the Company's press release announcing financial results for the year ended December 31, 2003.
- (iii) On March 4, 2004, we furnished a Current Report on Form 8-K to the SEC under Item 5 thereof, including unaudited pro forma combined financial statements reflecting the impact of the then proposed acquisition of SynX Pharma Inc. using the purchase method of accounting.
- (iv) On March 9, 2004, we furnished a Current Report on Form 8-K to the SEC, filing the placement agency agreement with respect to a prospectus supplement filed on March 5, 2004 with the Securities and Exchange Commission under Item 5 thereof and our press release announcing the sale of common stock under Item 9 thereof.

Table of Contents

NANOGEN, INC.

SIGNATURES

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

NANOGEN, INC.

Date May 14, 2004

/s/ HOWARD C. BIRNDORF

**Howard C. Birndorf
Chairman of the Board, Executive Chairman and**

Chief Executive Officer

Date May 14, 2004

/s/ NICHOLAS J. VENUTO

**Nicholas J. Venuto
Senior Director, Finance
(Chief Accounting Officer)**

Table of Contents

NANOGEN, INC.

EXHIBIT INDEX

<u>Exhibit No.</u>	<u>Description</u>
10.1	Offer letter dated May 8, 2003 between David Ludvigson and the Company.
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 Required by Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended.
32.2	Certifications of Chief Financial Officer Required by Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended.