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 June 30, 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)

Delaware	**33-0489621**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
10398 Pacific Center Court, San Diego, CA	**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 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 August 12, 2004, 33,848,511 shares of the Registrant's Common Stock were outstanding.

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FORM 10-Q
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PART I. FINANCIAL INFORMATION
Item 1. Financial Statements
NANOGEN, INC.
CONSOLIDATED BALANCE SHEETS
(in thousands, except share data)

	June 30, 2004	December 31, 2003
	(unaudited)	
ASSETS		
Current assets:		
Cash and cash equivalents	$ 8,543	$ 8,550
Short-term investments	51,777	20,564
Receivables, net	1,860	1,415
Inventories, net	2,706	4,774
Other current assets	1,673	1,590
Total current assets	66,559	36,893
Property and equipment, net	7,372	4,276
Acquired technology rights, net	1,983	2,508
Other assets, net	1,549	172
Goodwill	10,462	—
	$ 87,925	$ 43,849
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 1,889	$ 290
Accrued liabilities	3,240	4,519
Deferred revenue	404	469
Current portion of capital lease obligations	552	743
Total current liabilities	6,085	6,021
Capital lease obligations, less current portion	545	586
Other long-term liabilities	5,451	4,419
Total long-term liabilities	5,996	5,005
Stockholders' equity:		
Convertible preferred stock, $0.001 par value, 5,000,000 shares authorized; no shares issued and outstanding at June 30, 2004 (unaudited) and December 31, 2003	—	—
Common stock, $0.001 par value, 50,000,000 shares authorized; 34,846,250 and 24,867,325 shares issued and outstanding at June 30, 2004 (unaudited) and December 31, 2003, respectively	34	25
Additional paid-in capital	271,645	209,014
Accumulated other comprehensive income	(226)	1,136
Deferred compensation	(170)	(175)
Accumulated deficit	(194,517)	(176,255)
Treasury stock, at cost, 500,189 shares at June 30, 2004 (unaudited) and December 31, 2003	(922)	(922)
Total stockholders' equity	75,844	32,823
	$ 87,925	$ 43,849

See accompanying notes.

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

	Three months ended June 30,		Six months ended June 30,	
	2004	2003	2004	2003
Revenues:				
Product sales	$ 477	$ 662	$ 1,609	$ 890
License fees	38	—	190	—
Sponsored research	125	375	500	750
Contracts and grant	478	657	978	1,254
Total revenues	1,118	1,694	3,277	2,894
Operating expenses:				
Cost of product sales	1,940	524	2,854	798
Research and development	4,040	4,483	8,388	9,193
Selling, general and administrative	4,234	4,130	7,809	8,196
Charge for acquired in-process research and development	3,758	—	3,758	—
Total operating expenses	13,972	9,137	22,809	18,187
Loss from operations	(12,854)	(7,443)	(19,532)	(15,293)
Interest income, net	129	113	231	308
Other income	(100)	11	(120)	43
Gain (loss) on sale of investments	(6)	32	(6)	(3,568)
Gain (loss) on sale on foreign currency translation	(17)	(11)	1,204	(16)
Loss on sale of fixed assets	(41)	(153)	(41)	(153)
Minority interest in loss of consolidated subsidiary	—	558	—	1,106
Net loss	$ (12,889)	$ (6,893)	$ (18,264)	$ (17,573)
Net loss per share – basic and diluted	$ (0.39)	$ (0.32)	$ (0.61)	$ (0.82)
Number of shares used in computing net loss per share – basic and diluted	32,798	21,543	29,870	21,492

See accompanying notes.

NANOGEN, INC.
CONSOLIDATED STATEMENTS OF CASH FLOWS
(unaudited)
(in thousands)

	Six months ended June 30	
	2004	**2003**
Operating activities:		
Net loss	$ (18,264)	$ (17,573)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	1,795	2,062
Charge for acquired in-process research and development	3,758	—
Inventory reserves	1,525	5
Loss on disposal of fixed assets	—	153
Accretion related to short-term investments	95	121
Foreign currency translation gain	(1,204)	—
Stock-based compensation expense	4	113
Minority interest in loss of consolidated subsidiary	—	(1,106)
Loss on sale of short-term investments	6	3,568
Changes in operating assets and liabilities:		
Receivables	(27)	(134)
Inventories	463	(800)
Other assets	(492)	(576)
Accounts payable	(4)	(539)
Accrued liabilities	(2,752)	(662)
Deferred revenue and other long-term liabilities	(65)	(129)
Net cash used in operating activities	(15,162)	(15,497)
Investing activities:		
Purchase of short-term investments	(38,591)	(5,112)
Acquisition of business, net of cash acquired	(1,370)	—
Funding of bridge notes receivable related to acquired business	(998)	
Proceeds from sale and maturities of short-term investments	7,126	17,705
Purchase of equipment, net	(149)	(720)
Acquired technology rights	—	(3)
Net cash provided by (used in) investing activities	(33,982)	11,870
Financing activities:		
Principal payments on capital lease obligations	(238)	(437)
Proceeds from development partner	441	—
Issuance of common stock, net	48,906	156
Net cash provided by (used in) financing activities	49,109	(281)
Effect of exchange rate changes	28	190
Decrease in cash and cash equivalents	(7)	(3,718)
Cash and cash equivalents at beginning of period	8,550	9,353
Cash and cash equivalents at end of period	$ 8,543	$ 5,635
Supplemental disclosure of cash flow information:		
Interest paid	$ 57	$ 103
Supplemental schedule of noncash investing and financing activities:		
Acquisition of business in exchange for common stock, including related assumption of stock options and warrants	$ 13,720	$ —
Warrant issued for research and development collaboration	$ —	$ 700
Unrealized loss on investments	$ (145)	$ (4,249)

See accompanying notes.

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 June 30, 2004, consolidated statements of operations for the three and six months ended June 30, 2004 and 2003, and the consolidated statements of cash flows for the six months ended June 30, 2004 and 2003 are unaudited, but include all adjustments (consisting of normal recurring adjustments, except for a $1.5 million inventory charge discussed elsewhere herein, and entries related to the acquisition of SynX Pharma Inc., including a $3.8 million charge to in-process research and development also discussed elsewhere herein) 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 and six months ended June 30, 2004 and 2003 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.

Basis of Consolidation

The accompanying unaudited consolidated financial statements include the accounts of: Nanogen, Inc.; its wholly-owned subsidiaries SynX Pharma Inc. ("SynX"), Nanogen Europe B.V. and Nanotronics, Inc.; as well as its majority owned subsidiary, Nanogen Recognomics (collectively, the "Company"). SynX's accounts and operating results are included beginning on April 21, 2004, the date of acquisition. All significant intercompany transactions have been eliminated.

Use of Estimates

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

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 June 30, (unaudited)		Six months ended June 30, (unaudited)	
	2004	2003	2004	2003
Net loss:				
As reported	$ (12,889)	$ (6,893)	$ (18,264)	$ (17,573)
Stock-based compensation expense under fair value based method	(1,238)	(957)	(2,182)	(1,984)
Pro forma net loss	$ (14,127)	$ (7,850)	$ (20,446)	$ (19,557)
Loss per share:				
As reported	$ (0.39)	$ (0.32)	$ (0.61)	$ (0.82)
Pro forma	$ (0.43)	$ (0.36)	$ (0.68)	$ (0.91)

The pro forma effect on net loss for the three and six months ended June 30, 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 related to 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 June 30, (unaudited)		Six months ended June 30, (unaudited)	
	2004	2003	2004	2003
Balance at beginning of period	$ 117	$ 180	$ 159	$ 190
Warranty additions	13	90	54	182
Payments to warranty service provider	(25)	(33)	(108)	(135)
Balance at end of period	$ 105	$ 237	$ 105	$ 237

2. Business Combination

On April 21, 2004, the Company acquired all the outstanding shares of SynX Pharma Inc. ("SynX") in an all-stock transaction by way of a court-approved plan of arrangement. Based in Toronto, Canada, SynX leverages proteomic and biomarker research to develop a line of point-of-care diagnostic tests. As a result of this acquisition, the Company expects to enter the point-of-care diagnostic market, initially using the research and development and products of SynX. Nanogen believes that the future markets for advanced diagnostics will include research and clinical reference labs as well as the point-of-care market. Historically, Nanogen has addressed the research and clinical reference lab market. In addition sales and marketing synergies are anticipated as SynX's line of point-of-care products may be sold into the clinical reference labs market. In the future, Nanogen anticipates developing microarray products to address all of these markets.

The results of operations of SynX have been included in the accompanying consolidated financial statements from the date of acquisition. The total cost of the acquisition is estimated as follows (in thousands, unaudited):

Nanogen common stock exchanged	$ 12,493
Assumption of warrants	865
Assumption of stock options	362
Bridge credit facility	998
Direct transaction costs	857
Total estimated purchase price	$ 15,575

The allocation of the above purchase price is preliminary (pending) receipt of such items as a final asset appraisal and final transaction related invoices) and estimated to be as follows (in thousands, unaudited):

Fair value of net tangible assets acquired	$ 1,061
Fair value of intangible assets acquired	4,052
Goodwill	10,462
Total estimated purchase price	$ 15,575

Purchased intangibles include in-process research and development of $3,758,000, and an indefinite lived asset related to acquired trade names of approximately $294,000. The $3.8 million assigned to acquired in-process research and development was recorded as an expense in the statement of operations for the three and six months ended June 30, 2004. Operations in a market niche that is complimentary and operational and technological synergies were among the factors that contributed to a purchase price resulting in the recognition of goodwill.

Pro Forma Information

The following unaudited pro forma information assumes that the April 21, 2004 acquisition of SynX occurred on January 1, 2004. The unaudited pro forma results have been prepared for comparative purposes only and do not purport to be indicative of the results of operations that would have actually resulted had the acquisition been in effect as of the periods indicated, or of future results of operations. The unaudited pro forma results for the three and six months ended June 30, 2004 and 2003, are as follows (in thousands, except per share data):

	Three months ended June 30, (unaudited)		Six months ended June 30, (unaudited)	
	2004	2003	2004	2003
Revenues	$ 1,147	$ 2,449	$ 3,561	$ 5,955
Net loss [1]	$ (13,818)	$ (8,590)	$ (21,248)	$ (19,450)
Loss per share (basic and diluted)	$ (0.42)	$ (0.37)	$ (0.69)	$ (0.84)

[1] Includes $3.8 million for the write-off of in-process research and development costs for the three and six months ended June 30, 2004.

3. Inventories

Inventories consist of the following (in thousands):

	June 30, 2004 (unaudited)	December 31, 2003
Raw materials	$ 1,234	$ 1,469
Work in process	2,303	1,745
Finished goods	3,288	4,043
	6,825	7,257
Reserve for excess and obsolete	(4,119)	(2,483)
	$ 2,706	$ 4,774

During the three months ended June 30, 2004, the Company increased its reserve related to its inventory of NanoChip® Molecular Biology Workstations and accessory items by $1,525,000. This charge is reflected as additional cost of sales during the period.

Finished goods includes $1.6 million and $1.7 million of NanoChip® Molecular Biology Workstations ("NanoChip® Workstations") at June 30, 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 June 30, 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 $134,000 and $197,000 at June 30, 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, related to instruments installed at customer sites where title has not transferred to the customer, totaled $735,000 at June 30, 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 June 30, 2004, the Company had commitments to purchase approximately $1.5 million in next generation instruments from Hitachi through January 31, 2005.

4. 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.

As a result of the SynX acquisition, the Company gained access to a cross-licensing agreement between Roche Diagnostics and SynX entered into in July 2003. The Company has a non-exclusive world-wide license in the field of point-of-care diagnostics relating to the development, manufacture and marketing of immunoassays for point-of-care diagnostics that detect the congestive heart failure marker NT-proBNP and granted Roche Diagnostics a non-exclusive world-wide license on the Company's improvement of the technology relating to the development, manufacture and marketing of immunoassays that detect the congestive heart failure marker NT-proBNP. As of June 30, 2004, the Company had a remaining obligation of $1 million under the agreement which was subsequently paid in July 2004. The estimated value of the license was included as a component of the $3.8 million acquired in-process research and development line item that was expensed upon consummation of the acquisition.

5. 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 June 30, (unaudited)		Six months ended June 30, (unaudited)	
	2004	2003	2004	2003
Comprehensive loss:				
Net unrealized gain / (loss) on short-term investments	$ (141)	$ 440	$ (145)	$ (4,249)
Foreign currency translation adjustment	(96)	115	(1,217)	195
Net loss	(12,889)	(6,893)	(18,264)	(17,573)
Comprehensive loss	$ (13,126)	$ (6,338)	$ (19,626)	$ (21,627)

6. Collaborative Alliances

Hitachi, Ltd.

Manufacturing Agreement

In June 2003, the Company entered into a manufacturing agreement with Hitachi for the manufacture of a new instrument being developed under the collaborative research agreement (described below). 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. As of June 30, 2004, the Company had a commitment to purchase approximately $1.5 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, 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 must 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.

Sponsored research revenue recognized under this agreement totaled $125,000 and $500,000 for the three and six months ended June 30, 2004, respectively, and $375,000 and $750,000 for the three and six months ended June 30, 2003, respectively. In accordance with SFAS No. 68, the Company records sponsored research revenue under this arrangement as expenses are incurred, in amounts 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 $4.9 million and $4.3 million at June 30, 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, Hitachi exercised its right to terminate the collaborative research agreement in accordance with the terms of the agreement. Hitachi's termination of this agreement did 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, Hitachi exercised 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 of 2004, the initial capital infusion of $5 million provided by Aventis to Nanogen Recognomics in June 2001 was 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 assume 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 and six months ended June 30, 2004, Nanogen Recognomics incurred approximately $76,000 and $1.3 million in operating expenses, respectively. Approximately $76,000 and $946,000 of the total expenses during the three and six month periods ended June 30, 2004, respectively, related to reorganization costs. These reorganization 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 not expected to be significant. For the three and six month periods ended June 30, 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 $558,000 and $1.1 million, respectively.

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 in the first quarter of 2004, realized the approximately $1.2 million in previously unrealized foreign currency translation gains during the first quarter of 2004. As a result of the discontinuance of business activity, there was no material gain or loss in the three month period ended June 30, 2004.

Princeton BioMeditech Corporation

In October 2001, the Company's wholly-owned subsidiary, SynX, entered into a development and manufacturing agreement with Princeton BioMeditech Corporation ("PBM"). PBM has the right to perform development, production and distribution functions for SynX's point-of-care product line, including the right to be SynX's exclusive producer of certain rapid assay diagnostic point-of-care products. Payment for PBM's services will be based on a defined percentage of the net sales price to customers of such products. In November 2002, SynX and PBM signed an exclusive agreement for Canadian distribution rights for PBM's LifeSign® brand point-of-care diagnostic products. SynX also distributes certain LifeSign® brand products in Europe.

7. 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 six months ended June 30, 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.

8. Stock Transactions

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.

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.

9. Related Party Transactions

Mr. Birndorf, Chief Executive Officer, owns an aircraft that is leased by a local charter aircraft company. For the six months ended June 30, 2004 and 2003, the Company paid approximately $0 and $50,000, 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 $0 and $28,000 as a result of the Company's use of Mr. Birndorf's aircraft during the six months ended June 30, 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.

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 identify such 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 acquisitions of businesses and technologies, 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 acquired companies,

businesses, collaborations, 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" elsewhere herein. 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 scientific disciplines 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 a 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 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.

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, (4) Nanogen's general purpose reagents and accessories used to facilitate assay and protocol development and validation on the NanoChip® Platform, (5) point-of-care diagnostic tests for myocardial infarction (obtained through the acquisition of SynX), and (6) point-of-care diagnostic tests for drugs of abuse (obtained through the acquisition of SynX). The Company also has several other ASRs and applications of its proprietary technology under development and (through the acquisition of SynX), is developing a pipeline of point-of-care tests, including tests for congestive heart failure, stroke and traumatic brain injury.

On April 21, 2004, the Company acquired all the outstanding shares of SynX Pharma Inc. ("SynX") in an all-stock transaction by way of a court-approved plan of arrangement. Based in Toronto, Canada, SynX leverages proteomic and biomarket research to develop a line of point-of-care diagnostic tests. The primary reason for the acquisition was to provide an initial entry into the point-of-care diagnostic market for Nanogen. Nanogen believes that the future markets for advanced diagnostics will include research and clinical reference labs as well as the point-of-care market. Nanogen addresses the research and clinical reference lab market and SynX provides the basis for addressing the point-of-care market. In addition sales and marketing synergies are anticipated as SynX's line of point-of-care products may be sold into the clinical reference labs market. In the future, Nanogen anticipates developing microarray products to address all of these markets. Through the acquisition of SynX, the Company gained access to a worldwide license to the CHF marker NT-proBNP (N-terminal pro-hormone brain natriuretic peptide) from Roche Diagnostics to develop a test for the point-of-care market. We believe the new Nexus Dx(TM) product will offer substantial improvements over other CHF diagnostics, including stability at room temperature and quicker results, and will enable health professionals to provide an enhanced level of care. Analysts predict the BNP market will have above-average growth and will reach approximately US $300 million by 2005 as use increases internationally.

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 June 30, 2004, had an accumulated deficit of $194.5 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 and six months ended June 30, 2004, as well as for the year ended December 31, 2003, product related revenue was a primary driver of total 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 will continue to be more product driven as certain research collaboration agreements expire and we introduce new products 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, including the CHF product and diagnostics related to infectious disease, the type of acquisition program our potential customers may choose, whether and when new products are successfully developed and introduced by us or our competitors, and the achievement of milestones under our collaborative agreements 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 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 debts, inventories, investments, goodwill and other 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 and point-of-care diagnostic tests are 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 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. The Company provides

product warranty coverage for the Workstation over the period of the contract and the fair value of the warranty is recognized ratably over the warranty period. 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).

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 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 $139,000 and $197,000 at June 30, 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 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, as well as provide reserves for estimated sales discounts below cost, 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

We have intangible assets, including goodwill and 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 and six months ended June 30, 2004, product revenue totaled $477,000 and $1.6 million compared to $662,000 and $890,000 for the three and six months ended June 30, 2003. Product revenue during the periods presented includes sales and rental payments related to our NanoChip® Molecular Biology Workstation, as well as sales of NanoChip® Cartridges, reagents, point-of-care diagnostics, and product warranty agreements. We offer our Molecular Biology Workstation and related 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. Product revenue during the three months ended June 30, 2004 was negatively impacted by performance issues with our CFTR ASR (related to cystic fibrosis), one of our largest molecular testing markets for clinical laboratories. We continue to make improvements to our CFTR ASR to address these issues. In the meantime, we shifted our primary sales force emphasis to the research and clinical research laboratories where our molecular biology workstation is used for research and assay development purposes. Research labs were our first customers and we have continued to sell to them even as we added clinical laboratories to our sales efforts. We anticipate that the majority of our product revenue in the next six months will come from these research laboratory customers.

Sponsored Research. For the three and six month periods ended June 30, 2004, revenues from sponsored research totaled $125,000, and $500,000, respectively, compared to $375,000 and $750,000 for the three and six months ended June 30, 2003, respectively. 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 and six months ended June 30, 2004 and 2003 represents revenue earned in connection with our development agreement entered into in July 2000 with Hitachi. During August 2003, the Company received written notification from Hitachi that Hitachi was terminating the research collaboration agreement in accordance with the terms of that agreement. Funding by Hitachi under the collaboration agreement was completed during the three months ended June 30, 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 $478,000 and $978,000, respectively, and $657,000 and $1.3 million, respectively, for the three and six months ended June 30, 2004 and 2003. The decrease in revenues for the three months ended June 30, 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 $1,940,000 and $2,854,000 for the three and six months ended June 30, 2004, respectively, compared to $524,000 and $798,000 for the three and six months ended June 30, 2003, respectively. Gross margins on product sales revenue were negative 306% and negative 77% for the three and six months ended June 30, 2004, respectively, compared to 21% and 10% for the three and six months ended June 30, 2003. Cost of product sales for the three and six months ended June 30, 2004 were negatively impacted primarily by increased inventory reserves for excess instruments, underabsorbed overhead costs due to underutilized capacity and manufacturing scrap. The inventory reserve, recorded in the three month period ended June 30, 2004, was $1,525,000 and related primarily to the write down of excess Molecular Biology Workstations and accessory items in our inventory that could potentially not be saleable or could become obsolete, primarily as a result of the performance issues with our CFTR ASR and corresponding shifting of sales force emphasis from the clinical laboratory market to the research market. 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. 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 and six months ended June 30, 2004, research and development expenses totaled $4.0 million and $8.4 million, respectively, compared to $4.5 million and $9.2 million, respectively, for the three and six months ended June 30, 2003. 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 and six months ended June 30, 2004, research and development activities primarily related to the development of new ASRs and new instrumentation products. We anticipate research and product development costs to remain at similar levels experienced in the current quarter as the savings resulting from the restructuring of Nanogen Recognomics into a non-operating entity (i.e. substantial discontinuation of business activity) has been offset by the addition of SynX.

Selling, General and Administrative Expenses. For the three and six months ended June 30, 2004, selling, general and administrative expenses totaled $4.2 million and $7.8 million, respectively, compared to $4.1 million and $8.2 million, respectively, for the three and six months ended June 30, 2003. 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 six months ended June 30, 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 period. The increase in selling, general, and administrative expense for the three months ended June 30, 2004 as compared to the same period during the prior year is primarily the result of the inclusion of SynX operating results beginning on April 21, 2004 (the date of acquisition), offset by 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 period. We anticipate selling, general and administrative expenses to remain at similar levels experienced during the three months ended June 30, 2004 during the remainder of 2004.

Charge for Acquired In-Process Research and Development. The three and six month periods ended June 30, 2004 include a $3.8 million non-cash charge related to the write-off of acquired in-process research and development resulting from the SynX acquisition and represent current research and development projects in process. There were no acquisitions during the same periods in 2003.

Interest Income, Net. For the three and six months ended June 30, 2004, net interest income totaled $129,000 and $231,000, respectively, compared to $113,000 and $308,000, respectively, for the three and six months ended June 30, 2003. The increase in net interest income for the three months ended June 30, 2004 is primarily a result of higher average cash and investment balances. The decrease in net interest income during the six month period is primarily a result of lower yields on outstanding cash and investment balances. As a result of a net cash use from operations, average cash and investment balances are expected to decrease and we expect a corresponding decrease in net interest income is subsequent quarters.

Gain on Foreign Currency Translation.

During the three and six months ended June 30, 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, totaled $0 for each of the three and six months ended June 30, 2004, compared to $558,000 and $1.1 million for the three and six months ended June 30, 2003, 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 June 30, 2004, we had $60.3 million in available cash, cash equivalents and short-term investments, compared to $29.1 million at December 31, 2003. The increase is primarily due to $41.4 million in gross proceeds from the sale of common stock during the six months ended June 30, 2004. Also during 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 $5.5 million related to the exercise of stock options. These sources of cash were partially offset by cash used in operations as well as transaction costs related to the acquisition of SynX.

Net cash used in operating activities was $15.2 million and $15.5 million for the six months ended June 30, 2004 and 2003, respectively. During both periods cash use was 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 hemochromotosis, and the other ASRs and other products recently introduced by Nanogen; and legal fees relating to establishing, maintaining and defending our intellectual property portfolio. In addition, the period ended June 30, 2004 included the operating cost of SynX from the date of acquisition, April 21, 2004. The majority of SynX's costs were associated with the commercialization of new products, including a point-of-care test for CHF, and the reduction of outstanding past due liabilities incurred prior to the date of acquisition.

Net cash used in investing activities was $34.0 million for the six months ended June 30, 2004, as compared to $11.9 million provided by investing activities for the six months ended June 30, 2003. We purchase short-term investments in order to enhance the yield on our cash balances, and in the six months ended June 30, 2004, a portion of the excess cash that resulted from the $41.4 million sale of common stock during the six months ended June 30, 2004 was invested. These securities mature from time to time or are sold to fund operating expenses. During the six months ended June 30, 2004, certain securities matured or were sold to help fund operating activities. In addition, $2.4 million of cash was used related to the acquisition of SynX, including the payment of transaction costs and a bridge funding made to SynX prior to the completion of the acquisition.

We have funded some of our equipment acquisitions and leasehold improvements through capital leasing facilities. As of June 30, 2004, we have approximately $1.7 million available on an equipment line of credit which expires in December 2004.

Net cash provided by financing activities for the six months ended June 30, 2004 was $49.1 million as compared to cash use of $281,000 for the six months ended June 30, 2003. The funding for the six months ended June 30, 2004 primarily relates to $41.4 million in gross proceeds from the March and April 2004 sale of common stock. During the six months ended June 30, 2004, 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 $5.5 million related to the exercise of stock options.

Our manufacturing agreement with Hitachi, Ltd. requires that we provide annual purchase commitments to Hitachi for NanoChip® Molecular Biology Workstations. As of June 30, 2004, we had commitments to purchase approximately $1.5 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, point-of-care product sales, 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.

FACTORS THAT MAY AFFECT RESULTS

An investment in our common stock involves a high degree of risk. Our business, financial condition or results of operations could be harmed by any of these risks. The risks and uncertainties described below are not the only ones we face. Additional risks not presently known to us or other factors not perceived by us to present significant risks to our business at this time also may impair our business operations.

Risks Related to Our Business

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

We are at an early stage of development. As of June 30, 2004, we had only a limited product offering that includes our NanoChip® System (which consists of our NanoChip® Molecular Biology Workstation and NanoChip® Cartridge), NanoChip® Cartridge, various ASRs for detection of gene mutations associated with diseases such as cystic fibrosis, general purpose reagents and accessories to facilitate assay and protocol development and validation on the NanoChip Platform and, through our acquisition of SynX, point-of-care diagnostic tests for myocardial infarction and drugs of abuse. All of our other platforms and ASRs and other potential products are under development. Our NanoChip® System, ASRs or our other products may not be successfully developed or commercialized on a timely basis, or at all. If we are unable, for technological or other reasons, to complete the development, introduction or scale-up of manufacturing of our new products, or if our products do not achieve a significant level of market acceptance, we would be forced to curtail or cease operations.

We are also party to transactions known as reagent rentals and cost-per-test agreements. Under these types of transactions, we place 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 as of June 30, 2004 require customer acceptance of our CFTR ASRs as a pre-condition to the customer's commitment to purchase the instrument. Our CFTR ASRs may be utilized by customers to develop and validate tests for the detection of mutations in the CFTR gene associated with cystic fibrosis. These reagent rentals and cost-per-test agreements might have an adverse impact on our short-term instrument sales revenue and cash flow as the revenues and cash received under these agreements are over the life of the contract, as reagents are shipped to the customer. 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.

Lack of market acceptance of our technology would harm us.

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 charge and reduce the value of our product inventory to its net realizable value. In June 2004 and September 2003 we took an accounting charges of $1.5 million and $829,000, respectively, to reduce product inventory to its estimated net realizable value. If actual future demand or market conditions are less favorable than those projected by us, additional inventory write-downs may be required. Market acceptance will depend on many factors, including our ability to:

- convince prospective strategic partners and customers that our technology is an attractive alternative to other technologies;
- manufacture products in sufficient quantities with acceptable quality and at an acceptable cost; and
- sell, place and service sufficient quantities of our products.

In addition, our technology platform could be harmed by limited funding available for product and technology acquisitions by our customers, internal obstacles to customer approvals of purchases of our products and market conditions in general.

Performance issues with our products may also harm market acceptance of our products and reduce our revenues. During the three months ended June 30, 2004, we experienced performance issues with our CFTR ASR which negatively impacted our revenue. Certain of the clinical research laboratories using our CFTR ASR experienced validation rates and repeat rates which were not satisfactory, increasing their costs and labor associated with the tests. We are in the process of making improvements to our CFTR ASR to address these issues. Nonetheless, we may not be able to address these issues to the satisfaction of our clinical laboratory customers and they may decide to adopt alternative products or may not resume purchases of our CFTR ASR.

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, joint venture partners, 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.

In August 2003, Hitachi, Ltd. exercised its right to terminate the research collaboration agreement it has with us. The agreement terminated during the second quarter of 2004. Our manufacturing and distribution agreements with Hitachi remain in place. In October 2001, SynX entered into a development and manufacturing agreement with Princeton BioMeditech Corporation ("PBM") which granted PBM exclusive rights to develop and manufacture certain point-of-care products of SynX, as well as rights to share in the profits of such products. As a result, our success in the point-of-care market is dependent upon PBM's ability to perform under the agreement. In June 2001, we formed a new company, Nanogen Recognomics GmbH, with Aventis Research and Technologies & Co. KG, in which we own 60% of the stock of Nanogen Recognomics and Aventis R&T owns the remaining 40%. Nanogen Recognomics seeks to combine our NanoChip® technology and Aventis R&T's intellectual property and expertise in synthetic oligonucleotide chemistry and advanced molecular biology to develop new products and applications for the NanoChip® System. In February 2004, the shareholders of Nanogen Recognomics decided to convert Nanogen Recognomics into a non-operating holding company to attempt to commercialize its intellectual property through licensing and sales transactions.

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.

Past and future acquisitions could be difficult to integrate, disrupt our business, dilute the ownership interests of our stockholders and harm our operating results

If appropriate opportunities become available, we may attempt to acquire businesses, technologies, services or products that we believe are a strategic fit with our business. In April 2004 we completed our acquisition of SynX Pharma Inc., a point-of-care diagnostic company. The process of integrating SynX or any other acquired business, technology, service or product requires significant efforts and expenditures, including the coordination of information technologies, research and development, sales and marketing, administration and manufacturing. Additionally, SynX is located in Canada and because our facilities are physically separated, 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 acquired companies and businesses successfully, we may not be able to meet our expectations of future results of operations. 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.

Factors that will affect the success of our acquisitions include:

- presence or absence of adequate internal controls and/or significant fraud in the financial systems of acquired companies;
- the ability to retain key employees
- competitive factors, including technological advances attained by competitors and patents granted to, or contested by competitors, which would result in increased efficiency in their ability to compete against us;
- the ability of the combined company to increase sales of all such companies' products; and
- the ability of the combined company to operate efficiently and achieve cost savings.

Even if we are able to successfully integrate our acquired operations, we may never realize the anticipated benefits of the SynX acquisition or any other acquisition. Our failure to achieve synergies could have a material adverse effect on the business, results of operations and financial condition of the combined company. 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 have a history of net losses. We expect to continue to incur net losses and we may not achieve or maintain profitability.

Since our inception, we have incurred cumulative net losses which, as of June 30, 2004, total approximately $194.5 million. Moreover, our negative cash flow and losses from operations will continue for the foreseeable future. We may never generate sufficient product revenue to become profitable. We also expect to have quarter-to-quarter fluctuations in revenues, expenses and losses, which fluctuations could be significant. The amount and timing of product revenue recognition and cash flow may depend on whether potential customers for the NanoChip® System choose to enter into sales, reagent rentals, cost-per-test or development site transactions. We believe our future operating results may be subject to quarterly fluctuations due to a variety of factors, including, but not limited to, market acceptance of the NanoChip® System and potential products under development, including the CHF product and diagnostics related to infectious disease, the type of acquisition program our potential customers may choose, whether and when new products are successfully developed and introduced by us or our competitors, and the achievement of milestones under our collaborative agreements 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.

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

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

We will need to raise more money to continue the research and development necessary to further develop our current products to bring our products to market and to further our manufacturing and marketing capabilities. We may seek additional funds through public and private stock offerings, arrangements with corporate partners, borrowings under lease lines of credit or other sources. If we cannot raise more money, we will have to reduce our capital expenditures, scale back our development of new products, 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 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 or QSRs and obtaining necessary regulatory clearances or approvals;
  - filing, prosecuting, defending and enforcing patent claims and litigation; and
  - the scope and results of our future clinical trials, if any.

Additional capital may not be available on terms acceptable to us, or at all. Any additional equity financing would likely be dilutive to stockholders, and debt financing, if available, may include restrictive covenants and require significant collateral.

Competing technologies may adversely affect us.

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

- health care and other companies that manufacture laboratory-based tests and analyzers;
- diagnostic and pharmaceutical companies;
- companies developing drug discovery technologies;
- companies developing molecular diagnostic tests; and
- companies developing point-of-care diagnostic tests.

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

In addition, several development-stage companies are currently making or developing products that compete with or will compete with our potential products. Our competitors may succeed in developing, obtaining approval from the U.S. Food and Drug Administration 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 and maintaining 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.

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 Proprietary Information, Inventions, and Dispute Resolution 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. We may in the future receive notices claiming infringement from third parties as well as invitations to take licenses under third-party patents. 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. In addition, these actions may subject us to potential liability for damages. 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. One such interference has recently been declared between U. S, Patent 6,461,828 owned by our Canadian subsidiary, SYN-X Pharma, and a patent application owned by Biosite Incorporated ("Biosite"). The count of the interference is directed to a method for predicting cardiac mortality in a patient using pairs of biological markers. Among the markers within the scope of the count are pro-BNP and troponin I, markers which are the basis of a product being developed by SYN-X for the prognosis of congestive heart failure. Even though Biosite is the senior party in the interference because of its earlier filing date, the Company believes that it will be able to prove an earlier date of invention and thus prevail in the interference. However, if Biosite prevails it may obtain a patent having claims corresponding exactly or closely to the count of the interference. If that were to occur, the Company would be precluded from marketing in the United States a product for predicting cardiac mortality using the markers within the scope of any claim obtained by Biosite. We may in the future become subject to other USPTO interference proceedings to determine the priority of inventions. In addition, laws of some foreign countries do not protect intellectual property to the same extent as do laws in the U.S., which may subject us to additional difficulties in protecting our intellectual property in those countries.

We are aware of U.S. and European patents and patent applications owned by Oxford Gene Technologies. We have opposed one allowed European patent that had broad claims to array technology for analyzing a predetermined polynucleotide sequence. Oxford Gene's position with respect to the opposed patent is that the claims relate to what it terms the "diagnostic mode." Those claims have now been narrowed before the Opposition Division of the European Patent Office to the point that, if these claims remain final before the European Patent Office, we believe they would not be infringed by our technology. In the oral proceedings before the Opposition Division on November 13, 14, and 15, 2001, the Division determined that the claims' language must be limited to arrays with "smooth, impermeable" surfaces. The case is currently on appeal. If the decision of the Opposition Division is successfully appealed by Oxford Gene and the original claims are reinstated, or if an application relating to arrays is issued in another country with claims as broad as the original European patent, we could be subject to infringement accusations that could delay or preclude sales of some or all of our anticipated diagnostic products.

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

In December 2002, Oxford Gene Technologies filed a complaint against us in the United States District Court for the District of Delaware claiming that we infringe U.S. Patent No. 6,054,270 entitled "Analytical Polynucleotide Sequences." In April 2003, we filed an answer to the complaint that denied that we infringe this patent. In October 2003, we entered into a settlement agreement with Oxford Gene Technologies pursuant to which the lawsuit was dismissed by Oxford Gene Technology without prejudice. If the litigation were to be reinitiated, significant attorneys' costs and fees could result. Although it is our position that Oxford Gene's assertions of infringement have no merit, neither the outcome of any further litigation nor the amount and range of potential fees can be assessed. No assurances can be given that we would prevail in any future lawsuits or that we could successfully defend ourselves against any future claims.

The regulatory approval process is expensive, time consuming, uncertain and may prevent us from obtaining required approvals for the commercialization of our products.

The manufacturing, labeling, distribution and marketing of any diagnostic products we may develop will be subject to regulation in the U.S. and other countries. These regulations could subject us to several problems such as:

- failure to obtain necessary regulatory approvals or clearances for our products on a timely basis, or at all;
- delays in receipt of or failure to receive approvals or clearances;
- the loss of previously received approvals or clearances;
- limitations on intended uses imposed as a condition of approvals or clearances; or
- failure to comply with existing or future regulatory requirements.

In the U.S., the Food and Drug Administration, or FDA, regulates as medical devices most test systems, kits and reagents that are marketed for human in vitro diagnostic use. Pursuant to the Federal Food, Drug, and Cosmetic Act, the FDA regulates the preclinical and clinical testing, design, safety, effectiveness, manufacture, labeling, distribution and promotion of medical devices. We will not be able to commence marketing or commercial sales in the U.S. of these products until we receive an exemption, clearance or approval from the FDA, which can be a lengthy, expensive and uncertain process. We have not applied for FDA or other regulatory approvals with respect to any of our current products or products under development. We may experience difficulties that could delay or prevent the successful development, introduction and marketing of proposed products. Regulatory clearance or approval of any proposed products may not be granted by the FDA or foreign regulatory authorities on a timely basis, if at all. Noncompliance with applicable FDA requirements can result in:

- criminal prosecution, civil penalties, other administrative sanctions or judicially imposed sanctions, such as injunctions;
- recall or seizure of products;
- total or partial suspension of production; and
- failure of the government to grant premarket clearance or premarket approval for devices or withdrawal of marketing clearances or approvals once granted.

The FDA also has the authority to request the recall, repair, replacement or refund of the cost of any regulated device that may eventually be manufactured or distributed by us. Any devices manufactured or distributed by us pursuant to FDA clearance or approvals are subject to thorough and continuing regulation by the FDA and certain state agencies, including the California Department of Health Services.

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

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

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

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

We, Hitachi or PBM or any of our contract manufacturers could encounter manufacturing difficulties, including those relating to:

- the ability to scale up manufacturing capacity;
- production yields;
- quality control and assurance; or
- shortages of components or qualified personnel.

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

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

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

We currently rely on one manufacturer of our Workstation and for certain future generations of the Workstation and other hardware products, one manufacturer for our point-of-care products, and only we manufacture our NanoChip® Cartridges, and our ASRs and most of our other products, which may delay the manufacture and shipment of our products to customers.

We have signed an exclusive manufacturing agreement with Hitachi to manufacture certain of our second generation Workstations and other hardware products to be developed. We have retained exclusive rights pursuant to each agreement to manufacture the NanoChip® Cartridges. Pursuant to the manufacturing agreements and the collaboration agreement, each party is obligated to provide the other with certain notice periods if such party determines to curtail or terminate the manufacturing relationship. Nevertheless, while alternative manufacturers of our Workstation and other products currently exist, 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.

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

As of June 30, 2004, we had 32 total employees in our worldwide sales and marketing group.

Developing, training and monitoring this sales and marketing force has required and will further require capital and time expenditures by us and certain of our employees. The size of our sales and marketing force may not result in corresponding numbers of sales or placements of the NanoChip® System nor increased product revenues associated with such sales or placements or our ASRs, point-of-care diagnostic products or other products. We may be required to increase or decrease the size of the sales and marketing force as deemed necessary and such increases or decreases in staff will require additional capital and time expenditures by us and our employees.

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

We expect that a portion of our sales will be made outside the United States. A successful international effort will require us to develop relationships with international customers and partners. We may not be able to identify, attract or retain suitable international customers and distribution partners. As a result, we may be unsuccessful in our international expansion efforts. Furthermore, expansion into international markets will require us to continue to establish and expand foreign sales and marketing efforts, hire additional sales and marketing personnel and maintain good relations with our foreign customers and distribution partners.

International operations involve a number of risks not typically present in domestic operations, including:

- currency fluctuation risks;
- changes in regulatory requirements;
- costs and risks of deploying the NanoChip® System, ASRs, point-of-care diagnostics, and other products in foreign countries;
- licenses, tariffs and other trade barriers;
- political and economic instability, including the war on terrorism;
- difficulties in staffing and managing foreign offices;
- costs and difficulties in establishing and maintaining foreign distribution partnerships;
- potentially adverse tax consequences; and
- the burden of complying with a wide variety of complex foreign laws and treaties.

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

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

We may have significant product liability exposure.

We face an inherent business risk of exposure to product liability and other claims in the event that our technologies or products are alleged to have caused harm. These risks are inherent in the testing, manufacturing and marketing of our products. 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. A successful product liability claim or series of claims could have an adverse effect on our business, financial condition and results of operations.

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 year ended December 31, 2003, the turnover rate at all levels at Nanogen was 25%. For the years ended December 31, 2002 and 2001 the turnover rates at Nanogen were 29% and 31%, respectively. During the six month period ended June 30, 2004, we experienced a turnover rate equivalent to approximately 26% annualized. Turnover at these rates may, and if they continue, will adversely affect us.

The turnover rates above exclude the impact of reductions in workforce. In April 2003, we reduced our workforce by approximately 20% and incurred a severance charge of approximately $500,000 in the second quarter. Also, in October 2002, we reduced our workforce by approximately 10% and incurred severance charges of approximately $290,000 during the fourth quarter of fiscal 2002. Continued layoffs could have an adverse effect on us.

Health care reform and restrictions on reimbursement may limit our returns on potential products.

Our ability to earn sufficient returns on our products will depend in part on the extent to which reimbursement for our products and related treatments will be available from:

- government health administration authorities;
- private health coverage insurers;
- managed care organizations; and
- other organizations.

If appropriate reimbursement cannot be obtained, we could be prevented from successfully commercializing our potential products.

There are efforts by governmental and third party payors to contain or reduce the costs of health care through various means. We expect that there will continue to be a number of legislative proposals to implement government controls. The announcement of proposals or reforms could impair our ability to raise capital. The adoption of proposals or reforms could impair our business.

Additionally, third party payors are increasingly challenging the price of medical products and services. If purchasers or users of our products are not able to obtain adequate reimbursement for the cost of using our products, they may forego or reduce their use. Significant uncertainty exists as to the reimbursement status of newly approved health care products, and whether adequate third party coverage will be available.

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:

- the results of our premarket studies and clinical trials or those of our collaborators or competitors or for DNA testing in general;
- evidence of the safety or efficacy of our potential products or the products of our competitors;

- the announcement by us or our competitors of technological innovations or new products;
- the announcement by us of acquisitions by customers of our NanoChip® System, ASRs or our other products;
- announcements by us of government grants or contracts or of failure to obtain such government 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;
- the ability to obtain necessary licenses;
- changes or announcements in reimbursement policies;
- developments with our subsidiaries and collaborators;
- changes in or announcements relating to acquisition programs for our products, including the expiration or continuation of our development site agreements;
- period-to-period fluctuations in sales, inventories and our operating results;
- market conditions for life science stocks, nanotechnology stocks and other stocks in general;
- purchases by Nanogen pursuant to our stock repurchase program;
- changes in estimates of our performance by securities analysts and the loss of coverage by one or more securities analysts;
- the announcement by us of any stock repurchase plan, any purchases made thereunder by us and any cessation of the program by us;
- changes in the United States' war on terrorism and other geopolitical and military situations in which the country is involved; and
- changes in the price of petroleum, heating oil and any other raw materials that we use at our facilities.

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 approve some transactions and to take some stockholder actions, including the calling of a special meeting of stockholders and the amendment of any of the anti-takeover provisions contained in our certificate of incorporation.

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.

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 Canadian and Netherlands subsidiaries is the U.S. dollar, and the euro for our German subsidiary. 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 Recognomics, our German majority owned 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, was approximately $5.8 million at June 30, 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.

PART II - OTHER INFORMATION

Item 4. Submission of Matters to a Vote of Security Holders

(a) On June 9, 2004, the Registrant held its Annual Meeting of Stockholders.

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

Name of Nominee	No. of Votes For	No. of Votes Withheld
Val Buonaiuto	24,827,029	260,254

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

(c) (1) The proposal to amend the Company's 1997 Stock Incentive Plan to increase the number of shares reserved for issuance thereunder by 1,100,000 was approved with 6,620,093 shares voting in favor, 1,667,842 shares voting against, and 105,750 shares abstaining. There were 16,693,598 shares classified as broker non-votes.

(2) The proposal to amend the Company's Employee Stock Purchase Plan to increase the number of shares reserved for issuance thereunder by 150,000 was approved with 7,544,654 shares voting in favor, 753,487 shares voting against, and 95,544 shares abstaining. There were 16,693,598 shares classified as broker non-votes.

(3) The appointment of Ernst & Young LLP as independent auditors of the Company for the fiscal year ending December 31, 2004 was ratified with 24,896,173 shares voting in favor, 109,626 shares voting against, and 81,484 shares abstaining.

Item 6. Exhibits and Reports on Form 8-K

(a) Exhibits

Exhibit No.	Description
10.1	Offer letter dated April 30, 2004 between David Ludvigson and the Company.
10.2†	Cross License Agreement on NT-proBNP dated July 17, 2003 between SynX Pharma Inc. and Roche Diagnostics GmbH.
10.3†	Development and Manufacturing Agreement dated October 9, 2001 between SynX Pharma Inc. and Princeton BioMeditec Corporation.
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.

† 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.

(b) Reports on Form 8-K

(i) On May 3, 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 quarter year ended March 31, 2004.

(ii) On May 6, 2004, we filed a Current Report on Form 8-K to the SEC under Item 2 thereof, including the Company's press release announcing the completion of the acquisition of SynX Pharma Inc.

(iii) On June 3, 2004, we filed a Current Report on Form 8-K to the SEC under Item 5 thereof, including the Company's press release announcing the that David Ludvigson was appointed President and Chief Operating officer, replacing Bruce Huebner.

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 August 16, 2004

/s/ HOWARD C. BIRNDORF

Howard C. Birndorf
Chairman of the Board, Executive Chairman and
Chief Executive Officer

Date August 16, 2004

/s/ NICHOLAS J. VENUTO

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

NANOGEN, INC.
EXHIBIT INDEX

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

Exhibit 10.1

April 30, 2004

Mr. David G. Ludvigson
19431 San Marcos Road
Saratoga, CA 95070

Dear David:

On behalf on Nanogen Inc. ("Nanogen"), I am pleased to revise your employment arrangement and offer you the position of President and Chief Operating Officer with Nanogen Inc. on the terms outlined in this letter effective as of June 1, 2004.

You will be located in our San Diego office, and as President and Chief Operating Officer, will be responsible for all business activities for Nanogen. You will continue to devote your full-time efforts to these responsibilities and you will be compensated at an annual base rate of $300,000 per annum payable in equal, semi-monthly increments. You will continue to report to me in my role as CEO of Nanogen.

As President and Chief Operating Officer, you will continue to be a participant in Nanogen's Executive Incentive Compensation Plan. As part of this plan, you will be eligible for an annual bonus of up to 55% of your annual salary composed as follows: you may earn up to 30% of your annual salary, based on annual milestones as mutually agreed upon between you and me, subject to Board of Directors' approval; you may also earn up to 25% of your annual salary, based solely on the discretion of the Board of Directors.

As a regular employee of Nanogen, you will continue to participate in Company-sponsored benefits. At present, these include full medical, dental, life and long-term disability insurance coverage for yourself with the option to include your family with a minimal contribution. In addition, you will continue to be eligible to participate in our 401(k) plan and our 125 Flexible Benefits Program. You will be entitled to four weeks annual vacation.

Upon approval of the Nanogen Compensation Committee, you will be entitled to purchase 300,000 shares of Nanogen common stock at fair market value, as determined by the closing price of Nanogen common stock on such date of approval. The purchase will be made through either the signing of Nanogen's current form of Stock Purchase Agreement or Stock Options Agreement as provided in Nanogen's Stock Options Plan. These shares shall vest ratably on a monthly basis over the four-year period starting on the date of approval by the Compensation Committee. Vesting of the shares will be accelerated in the event of a change of control of Nanogen, as defined in this letter.

In recognition of your efforts and new role, Nanogen will pay you a one-time bonus of $150,000 upon approval by the Compensation Committee of the Board of Directors. This bonus shall be taxable to you and shall not be considered or offset to any degree by Nanogen in determining relocation expense reimbursement or bonuses to be paid under Nanogen's Executive Incentive Compensation Plan.

As part of this arrangement, you will be expected to relocate to the San Diego area. Reimbursement of your relocation expenses shall be in accordance with the Nanogen Executive Relocation Policy.

Effect of Change in Control

> Transaction Bonus. In the event of a transaction involving a Change in Control, in a transaction approved by the Company's Board of Directors, which transaction results in the receipt by the Company's stockholders of consideration with a value representing, in the sole judgment of the Board of Directors, a significant premium over the average of the closing prices per share of the Company's common stock as quoted on the Nasdaq National Market for 20 trading days ending one day prior to the public announcement of such transaction (a "Change in Control Transaction"), you shall be paid a Transaction Bonus at the closing of such a transaction in the amount equal to two (2) times 50% of your Base Salary in effect immediately preceding the closing of such a transaction. You shall also be paid said Transaction Bonus if the Company enters into a transaction approved by the Board of Directors which is not a Change in Control Transaction, but which, nonetheless, involves a significant change in the ownership of the Company or the composition of the Board of Directors of the Company, and which results in significant additional value for the Company's stockholders, as determined by the Board of Directors in its sole discretion and as specifically designated a significant event by the Board of Directors. In the event you receive a Transaction Bonus, no bonus under the Executive Incentive Compensation Plan will be paid to you in the year in which such Transaction Bonus is paid.

Vesting of Stock Options. If the Company enters into a transaction which is a Change in Control Transaction, then all of your stock options received before the date of the transaction shall become exercisable in full and all of the shares of the common stock of the Company awarded to you under the Company's 1997 Stock Incentive Plan (or any subsequent plan) shall become fully vested. If the Company enters into a transaction which is not a Change in Control Transaction but which is a Significant Event, then the Board of Directors may, in its sole discretion, determine that all, or a portion, of the Executive's stock options received before the effective date of the transaction shall become exercisable in full and all, or a portion, of the shares of the common stock of the Company awarded to Executive under the Company's 1997 Stock Incentive Plan (or any subsequent plan) shall become fully vested.

Definition. "Change in Control" shall mean the occurrence of any of the following events:

- The consummation of a merger or consolidation of the Company with or into another entity or any other corporate reorganization, if more than 50% of the combined voting power of the continuing or surviving entity's securities outstanding immediately after such merger, consolidation or other reorganization is owned by persons who were not stockholders of the Company immediately prior to such merger, consolidation or other reorganization;
- A change in the composition of the Board, as a result of which fewer than one-half of the incumbent directors are directors who either:
  - Had been directors of the Company 24 months prior to such change; or
  - Were elected, or nominated for election, to the Board with the affirmative votes of at least a majority of the directors who had been directors of the Company 24 months prior to such change and who were still in office at the time of the election or nomination; or
  - Any "person" (as such term is used in sections 13(d) and 14(d) of the Exchange Act) by the acquisition or aggregation of securities is or becomes the beneficial owner, directly or indirectly, of securities of the Company representing 50% or more of the combined voting power of the Company's then outstanding securities ordinarily (and apart from rights accruing under special circumstances) having the right to vote at elections of directors (the "Base Capital Stock"); except that any change in the relative beneficial ownership of the Company's securities by any person resulting solely from a reduction in the aggregate number of outstanding shares of Base Capital Stock, and any decrease thereafter in such person's ownership of securities, shall be disregarded until such person increases in any manner, directly or indirectly, such person's beneficial ownership of any securities of the Company. Thus, for example, any person who owns less than 50% of the Company's outstanding shares, shall cause a Change in Control to occur as of any subsequent date if such person then acquires an additional interest in the Company which, when added to the person's previous holdings, causes the person to hold more than 50% of the Company's outstanding shares.

The term "Change in Control" shall not include the Company's initial public offering or a transaction, the sole purpose of which is to change the state of the Company's incorporation.

Employment with Nanogen is not for a specific term and can be terminated by you or by the Company at any time for any reason, with or without cause and with or without notice. However, Nanogen agrees to prepare and execute a severance agreement with you in the event of termination of your employment for any reason other than Cause or if you terminate your employment with Nanogen for Good Reason. Under such severance agreement, Nanogen or its successor shall pay you six (6) months of your base annual compensation and cover your health insurance benefit plan for 6 months. As used herein, "Cause" shall mean any act that violates this agreement or the employment policies of Nanogen or any willful misconduct by you that may result in harm to Nanogen or its employees, directors or customers. The term "Good Reason" shall mean a material reduction, which is not corrected within thirty (30) days by Nanogen after receipt of notice from you, in your duties, reduction in compensation except as part of, and at the same percentage as, an across the board reduction of the compensation of the senior management team, and relocation of your office more than thirty (30) miles from your original place of employment with Nanogen.

The terms of this letter supercede and replace any other agreement between you and Nanogen. The terms of your employment cannot be changed except by an agreement in writing signed by you and an authorized representative of Nanogen.

Sincerely yours,
/s/ HOWARD C. BIRNDORF

Howard C. Birndorf

I accept the terms and conditions set forth in this letter.

/s/ DAVID G. LUDVIGSON

David G. Ludvigson

Exhibit 10.2

NOTE: Portions of this Exhibit are the subject of a Confidential Treatment Request by the Registrant to the Securities and Exchange Commission (the "Commission"). Such portions have been redacted and are marked with a "[***]" in place of the redacted language. The redacted information has been filed separately with the Commission.

CROSS-LICENSE_AGREEMENT on NT - proBNP

between

Syn-X Pharrna, Inc.
1 Marrnac Drive
Toronto, Ont. M9W lE7
Canada

- hereinafter referred to as "Syn-X" -

and

Roche Diagnostics GmbH
Sandhofer Strasse 116
D-68305 Mannheim

- hereinafter referred to as "RDG"

This Cross License Agreement on proBNP (hereinafter referred to as "Agreement") is entered into by and between Roche Diagnostics GmbH, a German company having its principal place of business at Sandhofer Strasse 116**,** D-68305 Mannheim, Germany (hereinafter referred to as "RDG"), and Syn-X Pharma, Inc., having its principal place of business at 1 Marmac Drive, Toronto, Ontario M9W lE7, Canada (hereinafter referred to as "Syn-X").

RECITALS

WHEREAS, RDG - the sole and exclusive licensor of certain RDG Licensed Patent Rights (as defined in Sect. 1.14) - controls worldwide intellectual property relating to the cardiovascular marker proBNP (as defined in Sect. 1. 16); and

WHEREAS, Syn-X is in the diagnostics business and is desirous of developing, manufacturing and selling proBNP immunoassays on their Point of Care system; and

WHEREAS, Syn-X desires to obtain a non-exclusive license under RDG's Licensed Patent Rights for proBNP to develop, manufacture, use and sell such proBNP immunoassays, and RDG is willing to grant Syn-X such license; and

WHEREAS, Syn-X is the owner of certain Syn-X Licensed Patent Rights (as defined in Sect. 1.20) relating to the cardiovascular marker proBNP (as defined in Sect. 1. 16); and

WHEREAS, RDG desires to obtain a non-exclusive license under Syn-X's Licensed Patent Rights for proBNP to develop, manufacture, use and sell proBNP immunoassays, and Syn-X is willing to grant RDG such license; and

WHEREAS, the Parties wish to cross-license their respective patent rights as provided in the Settlement Agreement (as defined in Sect. 1.18);

NOW, THEREFORE, in consideration of the recitals and the mutual covenants and obligations contained herein, RDG and Syn-X agree as follows:

ART. 1 DEFINITIONS

1.1 "Affiliate" shall mean:

a) an organization, which directly or indirectly controls a Party to this Agreement;

b) an organization, which is directly or indirectly controlled by a Party to this Agreement;

c) an organization, which is controlled, directly or indirectly, by the ultimate parent company of a Party.

Control as per a) to c) is defined as owning fifty percent or more of the voting stock of a company or having otherwise the power to govern the financial and the operating policies or to appoint the management of an organization.

With respect to RDG the term "Affiliate" shall not include Genentech, Inc., 1 DNA Way, South San Francisco, California 94080-4990, U.S.A. ("Genentech") nor Chugai Pharmaceutical Co., Ltd, 1-9, Kyobashi 2-chome, Chuo-ku, Tokyo, 104-8301, Japan ("Chugai"), respectively, unless RDG opts for such inclusion of Genentech and/or Chugai by giving written notice to Syn-X.

1.2 "Combination Product" shall mean a Syn-X Licensed Product sold in combination with any other products and/or services, whether packaged together or separately, in particular a Syn-X Licensed Product designed to also measure other parameters, whether packaged together or separately, if such Syn-X Licensed Product and such other products and/or services are offered for Sale at a one unit price.

1.3 "Confidential Information" shall mean the terms and conditions of this Agreement and all written information and data provided by a Party to the other hereunder and marked "Confidential" or a reasonable equivalent thereof or, if disclosed orally, visually or in some other form, is summarized in writing, is identified as "Confidential" and is provided to the other Party within thirty (30) days of such disclosure, except any portion thereof which:

a) is known to the recipient, as evidenced by its written records, before receipt thereof under this Agreement;

b) is disclosed to the recipient without restriction after acceptance of this Agreement by a Third Party who has the right to make such disclosure;

c) is or becomes part of the public domain through no breach of this Agreement; or

d) is independently developed by or for the recipient, as evidenced by its written records, by individuals or entities without reference to the information disclosed hereunder.

Notwithstanding the above, Syn-X herewith agrees that RDG is entitled to provide to its exclusive licensor all the information necessary to be disclosed by RDG to its licensor to fulfill its contractual obligations agreed upon in the agreement under which RDG received the right to grant the license under RDG Licensed Patent Rights, provided such licensor agrees to keep such information confidential pursuant to the terms of this Agreement.

1.4 "Contract Reporting Period" shall mean a period of three (3) consecutive months starting on the first day of the calendar year and each successive three (3) consecutive month period, except that the first Contract Reporting Period shall begin on the Effective Date and shall end on December 31,2003.

1.5 "Contract Year" shall mean a period of twelve (12) consecutive months during the term of this Agreement, which begins on January 1 each year, except that the first Contract Year shall begin on the Effective Date and shall end on December 31, 2003.

1.6 "Distributor" shall mean a distributor appointed by Syn-X or its Affiliates in the Territory or parts thereof for the marketing, Sales and/or promotion of Syn-X Licensed Products.

1.7 "Effective Date" shall mean the last date on which a Party executes this Agreement.

1.8 "Improvements" shall mean substantial proBNP-related developments, discoveries and/or inventions made by Syn-X, whether or not patentable, and in particular technical refinings, technological know-how, additions, ameliorations, amendments and/or modifications which improve or otherwise offer advantages in respect of the development and/or use and/or performance and/or manufacture of products for the determination of proBNP but excluding those related to assay formats, detectable labels, instrumentation, packaging and the like.

1.9 "Licensed Patent Rights" shall mean RDG Licensed Patent Rights and/or Syn-X Licensed Patent Rights.

1.10 "Licensed proBNP Test" shall mean [***]

1.11 "Net Sales" shall mean [***].

"B" is the list selling price of the other products when sold separately, during the royalty period being considered.

(ii) If the Combination Product contains other products which are not sold or not offered for sale separately in a particular market or during the royalty period being considered, the Net Sales of that Combination Product shall be determined as Sales of a Syn-X Licensed Product alone.

1.12 "Party" shall mean either Syn-X or RDG and "Parties" shall mean both Syn-X and RDG.

1.13 "RDG Licensed Field" shall mean [***]

1.14 "RDG Licensed Patent Rights" shall mean patents and patent applications listed in Exhibit A and which are either licensed by RDG or owned by RDG and all substitutions, extensions, reexaminations, reissues, renewals, divisionals, continuations, or continuations-in-part therefore or thereof, and all foreign counterparts of the foregoing. Exhibit A shall be updated from time to time by RDG.

1.15 "RDG Licensed Product" shall mean any product (including, without limitation, a diagnostic kit or packaged assay in its entirety, any component part of a diagnostic kit or packaged assay, any human in-vitro diagnostic assay or research-use-only assay, any investigational-use-only assay, or any Analyte Specific Reagents (ASRs) or General Purpose Reagents (GPRs)) sold by RDG, the development, manufacture, offering, distribution, use, import, export or sale of which, but for the license granted hereunder would infringe one (1) or more Valid Syn-X Claims in the country in which such product is developed, manufactured, offered, distributed, sold, imported, exported or used.

Calibrators, controls, standalone and universal reagents sold separately and even without the sublicense granted hereunder not infringing one (1) or more Valid Syn-X Claims in the country in which such calibrators, controls, standalone and universal reagents are developed, manufactured, offered, distributed, sold, imported, exported or used are not RDG Licensed Products.

1.16 "proBNP" shall mean the N-terminal pro brain natriuretic peptide.

1.17 "Sale" or "sale" or "sold" shall mean to sell, hire, let, rent, lease or otherwise dispose of to a Third Party for monetary or other valuable consideration, or consume in the performance of a service for a Third Party for monetary or other valuable consideration.

1.18 "Settlement Agreement" shall mean the Settlement Agreement between the Parties and Syn-X Pharma, U.S.A., LL.C. and Roche Diagnostics Corporation on even date herewith.

1.19 "Syn-X Licensed Field" shall mean [***]

1.20 "Syn-X Licensed Patent Rights" shall mean patents and patent applications listed in Exhibit B and which are owned by Syn-X or Syn-X is the exclusive licensor, and all substitutions, extensions, reexaminations, reissues, renewals, divisionals, continuations, or continuations-in-part therefore or thereof, and all foreign counterparts of the foregoing. Exhibit B shall be updated from time to time by Syn-X.

1.21 "Syn-X Licensed Product" shall mean any product (including, without limitation, a diagnostic kit or packaged assay in its entirety, any component part of a diagnostic kit or packaged assay, any human in-vitro diagnostic assay or research-use-only assay, any investigational-use-only assay, or any Analyte Specific Reagents (ASRs) or General Purpose Reagents (GPRs» sold by Syn-X, the development, manufacture, offering, distribution, use, import, export or sale of which, but for the license granted hereunder would infringe one (1) or more Valid RDG Claims in the country in which such product is developed, manufactured, offered, distributed, sold, imported, exported or used.

Calibrators, controls, standalone and universal reagents sold separately and even without the sublicense granted hereunder not infringing one (1) or more Valid RDG Claims in the country in which such calibrators, controls, standalone and universal reagents are developed, manufactured, offered, distributed, sold, imported, exported or used are not Syn-X Licensed Products.

1.22 "Territory" shall mean all countries worldwide.

1.23 "Third Party" shall mean a natural person, corporation, partnership, joint venture, trust, any governmental authority or other business entity or organization, and any other recognized organization other than the Parties and/or their Affiliates.

1.24 "Valid RDG Claim" shall mean a claim of an issued and unexpired patent or patent application included in RDG Licensed Patent Rights, which claim has not been withdrawn, cancelled or disclaimed, or held invalid or unenforceable by a final unappealable or unappealed order of a court or agency of competent jurisdiction, or which has not been admitted by the patentee to be invalid or unenforceable.

1.25 "Valid Syn-X Claim" shall mean a claim of an issued and unexpired patent or patent application included in Syn-X Licensed Patent Rights, which claim has not been withdrawn, cancelled or disclaimed, or held invalid or unenforceable by a final unappealable or un appealed order of a court or agency of competent jurisdiction, or which has not been admitted by the patentee to be invalid or unenforceable.

ART. 2 GRANT OF RIGHTS BY RDG

2.1 Grant. RDG hereby grants to Syn-X, subject to the terms and conditions set forth herein, a non-exclusive license, under the RDG Licensed Patent Rights to use, have used, develop, have developed, make, have made, possess, import, have imported, export, have exported, market, have marketed, offer for sale, have offered for sale, sell and have sold or otherwise distribute Syn-X Licensed Products under its own trademark and/or trade name in the Syn-X Licensed Field throughout the Territory.

2.2 Syn-X shall not be entitled to grant sub-licenses to Third Parties but Syn-X shall be entitled to grant sublicenses to its Affiliates under the terms and conditions of this Agreement. Such sublicense shall terminate automatically if sublicensed Affiliate no longer qualifies as an Affiliate. Syn-X shall be responsible for compliance of its sublicensed Affiliate with all obligations under this Agreement. In case of a grant of such sublicense to its respective Affiliates or its termination Syn-X will inform RDG immediately. Sales to a distributor are not considered a sub-license event.

2.3 Syn-X and its Affiliates shall not set up any arrangement with a Third Party for supply or manufacture of components of Syn-X Licensed Products to such Third Party which by its nature would grant such Third Party rights to sell Syn-X Licensed Products on its own behalf to Third Parties.

ART. 3 GRANT OF RIGHTS BY SYN-X

3.1 Grant. Syn-X hereby grants to RDG, subject to the terms and conditions set forth herein, a non-exclusive license, under the Syn-X Licensed Patent Rights to use, have used, develop, have developed, make, have made, possess, import, have imported, export, have exported, market, have marketed, offer for sale, have offered for sale, sell and have sold or otherwise distribute RDG Licensed Products under its own trademark and/or trade name in the RDG Licensed Field throughout the Territory.

3.2 RDG shall not be entitled to grant sub-licenses to Third Parties but RDG shall be entitled to grant sublicenses to its Affiliates under the terms and conditions of this Agreement. Such sublicense shall terminate automatically if sublicensed Affiliate no longer qualifies as an Affiliate. RDG shall be responsible for compliance of its sublicensed Affiliate with all obligations under this Agreement. In case of a grant of such sublicense to its respective Affiliates or its termination RDG will inform Syn-X immediately.

3.3 RDG and its Affiliates shall not set up any arrangement with a Third Party for supply or manufacture of components of RDG Licensed Products to such Third Party which by its nature would grant such Third Party rights to sell RDG Licensed Products on its own behalf to Third Parties.

ART. 4 ROYALTIES AND PAYMENT TERMS

4.1 In consideration for the rights, covenant and license granted above under Art. 2 and for RDG's agreement to the other terms and conditions hereof, Syn-X shall pay to RDG the following:

4.1.1 [***]

4.1.2 [***]

4.1.3 [***]

4.1.4 [***]

4.2 [***]

4.3 Terms of Payment. [***]

4.4 [***]

4.5

4.6 Reports. Syn-X is obliged to transmit to RDG within forty-five (45) days from the end of every Contract Reporting Period a written report showing [***] . The written report or the nil returns shall be sent to the following address:

[***]

4.7 [*******]

[***]

4.8 The obligations to pay shall only be fulfilled on the day on which the relevant amount of money is credited to the aforesaid account.

ART. 5 [***]

5.1

5.2

ART. 6 DEVELOPMENT, REGISTRATION AND MARKETING OF LICENSED PRODUCTS

6.1 Syn-X shall:

use all commercially reasonable efforts to develop and market Syn-X Licensed Products;

market only Syn-X Licensed Products which meet RDG's worldwide Standard Performance Criteria and Specifications of such Syn-X Licensed Product as defined in Exhibit C.

These obligations of Syn-X represent a substantial part of this Agreement.

6.2 [***]

6.3 [***] Prior to the first commercial Sale of Syn-X Licensed Product, Syn-X shall prove in writing to RDG that its Syn-X Licensed Products meet RDG's worldwide Standard Performance Criteria and Specification as defined in Exhibit 'C.

ART. 7 IMPROVEMENTS

7.1 Throughout the term of this Agreement, Syn-X shall promptly inform RDG in writing of any Improvements, whether patentable or not.

7.2 [***]

7.3 [***]

7.4 [***]

*** Certain information on this page has been omitted and filed separately with the Commission pursuant to a request for Confidential Treatment.

ART. 8 BOOKS AND RECORDS

8.1 Procedures. Syn-X shall keep full and accurate accounting records of Net Sales of Syn-X Licensed Products in sufficient detail to determine the royalties payable to RDG. Such records, together with all necessary supporting data, shall be kept at Syn-X's offices at the address set forth above or such other address as Syn-X may indicate in writing to RDG. Upon reasonable notice to Syn-X, RDG shall have the right during normal business hours to have an independent certified public accountant, selected by RDG and reasonably acceptable to Syn-X, audit on a confidential basis Syn-X's records pertaining to Syn-X Licensed Product to verify the royalties payable pursuant to this Agreement; provided, however, that such audit shall not (a) take place more frequently than once in a Contract Year, or (b) cover records for more than the preceding five (5) Contract Years. An adjustment in payment shall be made upon demonstration of any underpayment or overpayment.

8.2 Cost of Audits. The fees and expenses of an audit requested by RDG pursuant to Sect. 8.1 shall be borne by RDG; provided, however, that if any audit reveals that Syn-X underpaid the royalties due to RDG under this Agreement as to the period being audited by more than five percent (5 %) of the amount that was payable for such period, then Syn-X shall in addition to paying immediately to RDG any such deficiency, reimburse RDG for the cost of such audit.

8.3 Retention Period. Syn-X shall retain all books and records required to be maintained hereunder for five (5) years from the date of the royalty payment to which they pertain.

ART. 9 REPRESENTATIONS AND WARRANTIES

9.1 Intellectual Property Warranties by RDG. Each Party represents and warrants to the other Party as of the date of execution of this Agreement the following:

a) There are no suits, claims or proceedings pending or threatened against either Party or its licensor or any of its Affiliates that that Party is aware of in any court or by or before any governmental body or agency with respect to the respective Licensed Patent Rights other than those which are subject to the Settlement Agreement between the Parties of even date herewith;

b) Each Party controls all right, title and interest in and to the respective Licensed Patent Rights and each Party has the right to grant the non-exclusive license herein and to enter into the obligations of this Agreement;

c) Each Party's control over the respective Licensed Patent Rights has not been obtained by it through any fraudulent activity or misrepresentation; and

d) There are no Third Party obligations which would adversely affect each Party's performance under this Agreement.

9.2 Consequential Damages. Neither Party shall be liable to the other Party for any indirect, special, or consequential damages for any cause of action a Party may have against the other Party arising hereunder.

9.3 Patent Validity Actions. If either Party brings or prosecutes by itself, or either directly or indirectly assists any Third Party in any proceedings relating to the validity, enforceability, inventorship, ownership, control or licensing of any of the respective Licensed Patent Rights, the other Party may, upon thirty (30) days written notice, terminate the license rights granted to the prosecuting Party hereunder in any or all countries. For purposes of this Section "assist" shall not include any information that either Party is required or obligated to disclose or provide as a matter of law.

9.4 Either Party shall inform the other Party about revocation, invalidation, rejection, and abandonment of any respective License Patent Right and shall provide the other Party with an amended Exhibit.

ART. 10 PATENT INFRINGEMENT

Each Party shall provide to the other all non-confidential and non-privileged information in its possession concerning any infringement of Licensed Patent Rights by a Third Party within thirty (30) days of becoming aware of such infringement. If, during the term of this Agreement, either Party becomes aware that any Third Party is infringing any Valid RDG or Syn-X Claims in a country where a Valid RDG or Syn-X Claim exists it shall notify the other Party to this Agreement. The respective patent owner or exclusive licensor shall have sole discretion in the decision to institute legal proceedings against such Third Party and the other Party shall provide such assistance as the patent owner of exclusive licensor may reasonably request.

ART. 11 CONFIDENTIALITY AND PUBLIC ANNOUNCEMENTS

11.1 Confidentiality. It is contemplated that in the course of the performance of this Agreement each Party may disclose from time to time Confidential Information to the other Party. Each Party agrees (a) not to use Confidential Information received from the other for any purpose other than the performance of its obligations hereunder, and (b) not to disclose Confidential Information so received to any Third Party, except as is required by a court or governmental authority. In the event that such disclosure to a Third Party becomes necessary or required, the disclosing Party shall give to the Party from whom the Confidential Information was received the greatest practical prior written notice so as to permit the latter to take all possible action to perfect and/or safeguard its rights in the Confidential Information. The obligations of the Parties relating to Confidential Information shall expire five (5) years after termination of this Agreement. Any Third Party that receives Confidential Information in accordance with the terms of this Sect. 11.1 shall first be required to consent in writing to the same restrictions as defined in this Sect. 11.1 before any disclosure of Confidential Information is made to such Third Party.

11.2 Public Announcements. Neither Party shall make any public announcement concerning the transactions contemplated herein or to make any public statement which includes the name of the other Party or any of its Affiliates, or otherwise use the name of the other Party or any of its Affiliates in any public statement or document, except as may be required by law or judicial order (and then only following consultation with the other Party), without the written consent of the other Party.

11.3 Notice to licensor. Not withstanding any other terms of this Agreement, RDG retains the right to notify its licensor of the RDG Licensed Patent Rights of RDG's intent to grant a license under RDG Licensed Patent Rights to Syn-X pursuant to this Agreement. RDG shall also be allowed to supply to said licensor all information necessary to satisfy its obligations, i.e. Syn-X's Net Sales of Syn-X Licensed Products and the royalties payable to RDG, subject to such licensor agreeing to keep such information confidential consistent with the terms of this Agreement.

ART. 12 TERM AND TERMINATION

12.1 Term. This Agreement shall commence on the Effective Date and each Party's license shall remain in effect until the last to expire patent included in the respective Licensed Patent Rights licensed to that Party, unless otherwise terminated earlier by operation of law or by acts of the Parties in accordance with the terms of this Agreement.

[***]

ART. 13 INDEMNIFICATION

13.1 Indemnification by RDG. RDG shall indemnify, defend and hold harmless Syn-X and its officers, directors, employees, agents and representatives (hereinafter referred to as "Syn-X Indemnitees") from and against any and all liabilities, claims, demands, actions, suits, losses, damages, costs, and expenses (including reasonable attorneys' fees) based on a Third Party claim which in turn is based upon or arises out of RDG's gross negligence, willful or deliberate misconduct, recklessness, or breach of any covenant, agreement, representation or warranty made by RDG in this Agreement provided that RDG shall not be required to indemnify Syn-X or any Syn-X Indemnitee to the extent it arises from the development, manufacture, offering, distribution, sale, import, export or use of Syn-X Licensed Products hereunder, Syn-X's gross negligence, willful or deliberate misconduct, or recklessness, Syn-X's breach of this Agreement, or any other matter for which Syn-X is responsible to indemnify RDG pursuant to Sect. 11.2.

13.2 Indemnification by Syn-X. Syn-X shall indemnify, defend, and hold harmless RDG and its officers, directors, employees, agents and representatives (hereinafter referred to as "RDG Indemnitees") from and against any and all liabilities, claims, demands, actions, suits, losses, damages, costs, and expenses (including reasonable attorneys' fees) based on a Third Party claim which in turn is based upon or arising out of (i) the development, manufacture, offering, distribution, sale, import, export or use of Syn-X Licensed Products hereunder, and (ii) Syn-X's gross negligence, willful or deliberate misconduct, recklessness, breach of any covenant, agreement, representation, or warranty made by Syn-X in this Agreement; provided that Syn-X shall not be required to indemnify RDG or any RDG Indemnitee to the extent that it arises from RDG's gross negligence, willful or deliberate misconduct, or recklessness, RDG's breach of this Agreement or any other matter for which RDG is responsible to indemnify Syn-X pursuant to Sect. 11.1.

13.3 Conditions of Indemnification. If either Party proposes to seek indemnification from the other under the provisions of this Article 12, it shall notify the other Party within fifteen (15) business days of receipt of notice of any such claim or suit and shall cooperate fully with the other Party in the defense of such claims or suits. No settlement or compromise shall be binding on a Party hereto without its prior written consent.

13.4 Termination of Indemnification Obligations. All obligations for indemnification on the part of a Party hereto shall expire two (2) years from the date of termination of this Agreement, except with respect to claims already notified to the other Party prior to the end of such two (2) year period.

ART. 14 TRADE NAMES, TRADEMARKS AND LABELING

14.1 Either Party acknowledges that all trademarks, trade names, and trade dress of the other Party that shall accompany or shall be affixed to Syn-X or RDG Licensed Products during the term of this Agreement are the property of the labeling Party. Neither Party shall claim or obtain any rights in any such trademarks, trade names, or trade dress of the other Party and shall take no action that shall in any way impair the other Party's right, title, and interest in and to such trademarks, trade names, and trade dress and shall not use for its own benefit or for the benefit of any Third Party any such trademarks, trade names, and trade dress during or after the term of this Agreement unless such trademark, trade name or trade dress is being used in conflict with applicable laws and regulations. This shall not preclude either Party from using or claiming rights to a trademark, trade name or trade dress in existence at the time of the Effective Date of this Agreement.

14.2 Labeling. the Parties shall consult regarding the appropriate labeling of patent numbers of the respective Licensed Patent Rights that should be noted on the packaging of the licensed product within ninety (90) days of execution of this Agreement, or in the case of products not currently on the market, at least ninety (90) days prior to commercialization of such licensed product by the other Party. Syn-X shall print on the packaging and the package insert of Syn-X Licensed Products the words "Manufactured under license from Roche Diagnostics GmbH".

ART. 15 MISCELLANEOUS

15.1 Entire Agreement. This Agreement, together with the exhibits, constitutes the entire agreement between the Parties concerning the subject matter hereof and supersedes all written or oral prior agreements or understandings with respect thereto.

15.2 Amendment or Modification. Any modification of or amendment to this Agreement must be made in writing. The same applies to any agreement waiving the written form.

15.3 Severability. Should any provision of this Agreement be or become invalid, then the Parties hereto shall substitute for such invalid provision a new valid provision, which in economic effect comes closest to the invalid provision that it can be reasonably assumed that the Parties would have concluded this Agreement including such new provision. In case such new provision cannot be found, the invalidity of any provision of this Agreement shall not affect the validity of this Agreement as a whole, unless the invalid provision is of such essential importance to this Agreement that it is to be reasonably assumed that the Parties would not have concluded this Agreement without the invalid provisions.

15.4 Assignment. neither Party shall not assign this Agreement in whole or in part without the prior written consent of the other Party which consent shall not unreasonably be withheld. Any permitted assignee shall assume all obligations of its assignor under this Agreement. No assignment shall relieve either Party of responsibility for the performance of any accrued obligation that it has hereunder.

15.5 Independent Contractor. The relationship of RDG to Syn-X is that of independent contractor. In no event shall either Party hold itself out to others or allow itself to be considered the agent, employee, or representative of the other Party.

15.6 Notices. All notices hereunder shall be in writing and shall be delivered personally, mailed by overnight delivery, registered or certified mail, postage prepaid, mailed by express mail service or given by facsimile, to the following addresses of the respective Party:

If to RDG: Roche Diagnostics GmbH
Legal Department
Sandhofer Strasse 116
D-68305 Mannheim
Germany
Facsimile Number: [***]

With copy to: Roche Diagnostics GmbH
Licensing Department
Sandhofer Strasse 116
D-68305 Mannheim
Facsimile Number: [***]

If to Syn-X: Syn-X Pharma, Inc.
1 Marmac Drive
Toronto, Ont. M9W lE7
Canada

15.7 Force Majeure. Any delay in the performance of any of the duties or obligations of either Party under this Agreement caused by an event outside the affected Party's reasonable control shall not be considered a breach of this Agreement, and the time required for performance shall be extended for a period equal to the period of such delay. Such events shall include, without limitation: acts of God; riots; embargoes; labor disputes, including strikes, lockouts, job actions, or boycotts; fires; explosions; earthquakes; floods; shortages of material or energy; or other unforeseeable causes beyond the reasonable control and without the fault or gross negligence of the Party so affected. The Party so affected shall give prompt notice to the other Party of such cause and shall take whatever reasonable steps are necessary to relieve the effect of such cause as rapidly as possible.

15.8 Binding Effect. This Agreement shall be binding upon and shall inure to the benefit of the Parties hereto and their respective assignees and successors in interest.

15.9 Waiver. No waiver or modification of any of the terms of this Agreement shall be valid unless in writing and signed by an authorized representative of the Parties. Failure by either Party to enforce any rights under this Agreement shall not be construed as a waiver of such rights, nor shall a waiver by either Party in one or more instances be construed as constituting a continuing waiver or as a waiver in other instances.

15.10 Exhibits. All exhibits that are attached to this Agreement are incorporated herein by reference.

15.11 Headings. The headings used in this Agreement are for convenience and reference purposes only and shall not affect the meaning or interpretation of this Agreement.

15.12 Counterparts. This Agreement may be executed in two (2) original counterparts, each of which shall be deemed an original, but both of which together shall constitute one and the same instrument.

15.13 Affiliate Compliance. Either Party guarantees that its Affiliates shall comply with the terms and conditions of this Agreement, and either Party remains liable directly to the other Party for any breach thereof.

ART. 16 APPLICABLE LAW - VENUE - ARBITRATION

16.1 Applicable Law. This Agreement shall be governed and construed in accordance with the laws of Germany without reference to its laws of conflict and without regard to the 1980 UN Convention on the International Sale of Goods.

16.2 Disputes and Arbitration. All disputes, controversies and differences which may arise between the Parties hereto in respect of this Agreement shall tried to be settled amicably through mutual consultation within thirty (30) days of a written settlement request of either Party.

Any dispute or claim which may arise out of or in connection with this Agreement or the breach, termination or validity thereof shall be settled by final and binding arbitration pursuant to the Rules of the German Institution of Arbitration (DIS e.V.; www.dis-arb.de) as thereinafter provided:

a) The arbitral tribunal shall consist of one (1) or three (3) arbitrators. If the Parties cannot agree on one arbitrator, each Party shall nominate in the request for arbitration and the answer thereto one arbitrator and both arbitrators will then jointly appoint the third arbitrator as chairman of the arbitral tribunal. The chairman of the arbitral tribunal shall be a lawyer who has, at least, 15 years of experience with a law firm or who was a judge of a court of general jurisdiction. If one Party fails to nominate its arbitrator or the Parties' arbitrators cannot agree on the person to be named for the chairman within sixty (60) days, the German Institution of Arbitration shall make the necessary appointments for arbitrator or chairman.

b) The place of arbitration shall be in Frankfurt (Germany) and the arbitral proceedings shall be held in the English language.

c) The award of the arbitral tribunal shall be final and judgement upon such an award may be entered in any competent court or application be made to any competent court for juridical acceptance of such an award and order of enforcement.

IN WITNESS WHEREOF, each Party has caused this Agreement to be executed on its behalf by its duly authorized officer as of the Effective Date.

Roche Diagnostics GmbH /

/s/ H. J. NEUER
By: H. J. Neuer
Title: Licensing Manager
Date: July 3, 2003

/s/ CLAUDIA BOCKSTIEGEL
By: Claudia Bockstiegel,
Title: Legal Counsel
Date: July 3, 2003

Syn-X Pharma, Inc.

/s/ GEORGE JACKOWSKI
By: George Jackowski
Title: Chairman & CEO
Date: July 17, 2003

/s/ ROD WILSON
By: Rod Wilson
Title: President
Date:

EXHIBIT A
RDG Licensed Patent Rights

Medinnova patent rights exclusively licensed to RDG

Country	Application *No.*/ Publication No.	Application Date	Patent No.	Grant Date
Great Britain (priority application)	9211686.2	03.06.1992		
Australia	*43405/93*	02.06.1993	667223	
Canada	2136961	02.06.1993		
Japan	6-500364	02.06.1993		
EP designated countries:	93913278.3	02.06.1993	0 648 228	04.11.1998
Austria				
Belgium				
Denmark				
France				
Germany				
Great-Britain				
Ireland				
Italy				
Luxembourg				
Netherlands				
Spain				
Sweden				
Switzerland				
USA	*08/338558*	02.06.1993	5,786,163	28.07.1998

EXHIBIT A - continued

RDG patent rights

Country	Application No./ Publication No.	Application Date	Patent No.	Grant Date
Case 18931				
High sensitive				
NTproBNP assay				
Gennany (priority application)	19903489.3	29.01.1999		
Australia	25451/00	27.01.2000		
Canada	2359667	27.01.2000		
China	00803234.3/1339107	27.01.2000		
EP	00903642.7/1 151 304	27.01.2000		
Hungary	P0105195	27.01.2000		
Israel	144062	27.01.2000		
Japan	2000-596377	27.01.2000		
Mexico	007637	27.01.2000		
New Zealand	512762	27.01.2000		
Norway	20013698	27.01.2000		
Poland		27.01.2000		
Russia	2001123936	27.01.2000		
South Africa	2001/6193	27.01.2000	2001/6193	31.07.2002
South-Korea	01-7009587	28.01.2000		
U.S.A.	09/890442	27.01.2000		
Case 21299				
Cardiac risc assessment using				
CRP, proBNP and TnT/I				
US (priority application)	60/380413	14.05.2003		

EXHIBIT B
Syn-X Licensed Patent Rights

[***]

*** Certain information on this page has been omitted and filed separately with the Commission pursuant to a request for Confidential Treatment.

Exhibit C

Performance Criteria and Specifications of SynX Licensed Products

[***]

*** Certain information on this page has been omitted and filed separately with the Commission pursuant to a request for confidential treatment.

Exhibit 10.3

NOTE: Portions of this Exhibit are the subject of a Confidential Treatment Request by the Registrant to the Securities and Exchange Commission (the "Commission"). Such portions have been redacted and are marked with a "[***]" in place of the redacted language. The redacted information has been filed separately with the Commission.

THIS DEVELOPMENT AND MANUFACTURING AGREEMENT (the "Agreement") is executed as of this 9th day of October, 2001, by and between PRINCETON BIOMEDITECH CORPORATION, a New Jersey corporation ("PBM"), having its principal place of business at 4242 U.S. Route 1, Monmouth Junction, New Jersey 08852, and SYN.X PHARMA, INC., an Ontario corporation ("SYN.X"), having its principal place of business at 6354 Viscount Road, Mississauga, Ontario L4VIH3 Canada. PBM and SYNX are individually referred to herein as a "Party" and collectively referred to herein as the "Parties".

RECITALS

A. SYN.X has developed, and is in the process of further developing, certain unique, proprietary biomarkers and protein targets for the diagnosis of congestive heart failure, insulin resistance, Alzheimer's disease, traumatic brain injury and other various diseases, excluding stroke.

B. PBM has expertise in further developing biomarkers and protein targets for their commercial use in rapid assay, point of care, diagnostic test products, and in producing rapid assay, point of care diagnostic test products utilizing such biomarkers and protein targets.

C. SYN.X and PBM wish to work together to advance their common goal of developing, producing and distributing point of care rapid assay products produced by PBM utilizing biomarkers and protein targets supplied by SYN.X.

NOW, THEREFORE, in consideration of the foregoing premises, which are incorporated into and made a part of this Agreement, and of the mutual covenants which are set forth herein, the Parties hereby agree as follows:

ARTICLE 1
DEFINITIONS

1.1 "Affiliate" means any person or entity which directly or indirectly, through one or more intermediaries, controls, is controlled by, or is under common control with, a Party. "Control" means the legal or beneficial ownership of 50% or more of the voting or equity interests or the power or right to direct the management and affairs of the entity.

1.2 "Customer" shall mean any purchaser of POC Rapid Assays.

1.3 "cGMP" shall mean current good manufacturing practices related to diagnostic pharmaceutical products under applicable laws, rules and regulations in all relevant jurisdictions, including without limitation the guidelines of good manufacturing practices determined by the FDA and the equivalent European regulatory body.

1.4 "FDA" means the United States Food and Drug Administration, or any successor entity.

1.5 "FD & C Act" shall mean the United States Federal Food, Drug and Cosmetic Act, as amended.

1.6 "Panel" shall mean a POC Rapid Assay containing one or more analyte(s).

1.7 "PBM" shall mean Princeton BioMeditech Corporation, as identified above, and its Affiliate entities.

1.8 "Quantitative Reader" shall mean a quantitative reader that will be incorporated into all of the POC Rapid Assays, to be developed by a third party under license or contract from PBM.

1.9 "Reagents" shall mean biomarkers and protein targets developed and produced by SYN.X for the diagnosis of congestive heart failure, insulin resistance, Alzheimer's disease, traumatic brain injury and other various diseases, excluding stroke. The term "Reagents" shall also include all other biomarkers and protein targets developed and produced by SYN.X (other than for stroke) for which there shall be application in the point of care diagnostic products.

1.10 "Regulatory Approval" shall mean, with respect to any country or jurisdiction, all FDA, FDA-counterpart, governmental and regulatory registrations and approvals (including, but not limited to, approvals of all POC Rapid Assay labeling and POCkaging) required for the marketing, distribution and sale of the POC Rapid Assays in such country or jurisdiction.

1.11 "POC Rapid Assays" shall mean rapid assay diagnostic point of care products, utilizing Reagents; provided, however, that "POC Rapid Assays" shall not include devices for test procedures performed in a hospital's central clinical laboratory or in a reference laboratory setting. In addition, "POC Rapid Assays" shall not include any assay that can be used on any instrument with random access capability and/or any instrument with the ability to analyze multiple samples.

1.12 "POC Rapid Assay Specifications" shall mean the standards and specifications for the manufacture of the POC Rapid Assays, as developed and agreed to by the Parties, as amended from time to time, and shall be appended to and form part of this Agreement.

1.13 "Reagent Specifications" shall mean the standards and specifications for the manufacture of the Reagents, as developed and agreed to by the Parties, as amended from time to time, and shall be appended to and form part of this Agreement.

1.14 "SYN.X" shall mean SYN.X Pharma, Inc., as identified above, and its Affiliate entities.

ARTICLE 2
PRODUCT DEVELOPMENT

2.1 Research and Development of Reagents by SYN.X: Reagent Specifications: Clinical Trials.

a) SYN.X agrees to continue to conduct research and development with respect to the Reagents and to work and cooperate with PBM in the development of Reagents that the Parties shall reasonably each agree are suitable for use by PBM in the production of POC Rapid Assays in commercial quantities. The final decision as to which marker Reagents shall be developed into POC Rapid Assays shall be in the sole discretion of SYN.X.

b) SYN.X agrees to take such measures as it deems necessary and appropriate with respect to obtaining and maintaining patent protection for the Reagents in such jurisdictions as SYN.X in its sole discretion may determine.

c) SYN.X agrees to take such measures as it believes reasonable to develop scientific interest in the Reagents, through obtaining publication of research and other articles in scientific journals and publications, giving papers and other similar measures, in its sole discretion.

d) SYN.X agrees from time to time to supply PBM with such quantities of each Reagent as is reasonably required to enable PBM to produce sample POC Rapid Assays for the clinical trials and other studies to be conducted by SYN.X.

e) SYN.X agrees to conduct all such clinical trials and other testing of each Reagent as is reasonably required in order to obtain Regulatory Approval for the marketing and sale of POC Rapid Assays from the Regulatory Authorities in any jurisdiction in which the Parties desire that POC Rapid Assays shall be marketed and sold.

f) SYN.X agrees to be primarily responsible, working and cooperating with PBM, for the development of manufacturing and other specifications to be met by each batch of Reagent to be supplied by SYN.X for commercial use by PBM in the production of POC Rapid Assays (the "Reagent Specifications").

g) SYN.X agrees to fund [***] % of the direct, actual development cost of a Quantitative Reader, up to a maximum of $[***], as provided for by Section 2.2(f) hereof.

h) SYN.X agrees to work and cooperate with PBM (who shall have primary responsibility) in the development of each POC Rapid Assay to be produced by PBM utilizing Reagents supplied by SYN.X (the "POC Rapid Assay Specifications").

i) To the extent not covered by the above, SYN.X agrees to work and cooperate with PBM in taking all steps reasonably necessary to permit the commercial development of POC Rapid Assays produced by PBM utilizing Reagents supplied by SYN.X.

j) SYN.X agrees that all of its activities with respect to the research and development of Reagents, obtaining and maintaining patent and other intellectual property protection for the Reagents, conducting clinical and other trials, and its other activities working and cooperating with PBM as contemplated in this Section 2.1, shall be at the sole cost and expense of SYN.X.

*** Certain information on this page has been omitted and filed separately with the Commission pursuant to a request for Confidential Treatment.

2.2 Further Development by PBM: POC Rapid Assay Specifications: Regulatory Approvals.

a) PBM agrees to conduct such research and development as is reasonably required in order to produce POC Rapid Assays utilizing Reagents supplied by SYN.X, and in connection therewith, to further develop and to optimize for its commercial use in producing POC Rapid Assays, in cooperation with SYN.X, the Reagents developed by SYN.X.

b) PBM agrees to supply SYNX with sufficient quantities of sample POC Rapid Assays as is reasonably necessary for SYN.X to conduct the clinical trials and other studies required in order to obtain Regulatory Approval for the POC Rapid Assays.

c) Utilizing clinical trial and other data to be supplied by SYN.X, PBM agrees to use its best efforts to obtain Regulatory Approval for the production of POC Rapid Assays at PBM's facility, from such regulatory authorities as the Parties from time to time determine is desirable.

d) PBM agrees to work and cooperate with SYN.X in the development of the Reagent Specifications.

e) PBM agrees to be primarily responsible, working and cooperating with SYN.X, for the development of the POC Rapid Assay Specifications to be met by each POC Rapid Assay produced by PBM utilizing Reagents supplied by SYN.X.

f) PBM agrees to use commercially reasonable best efforts to complete by March 31, 2002 the development work of a reasonably priced Quantitative Reader for the first POC Rapid Assay to be developed by the parties, provided that the parties have finalized the POC Rapid Assay Specifications for such product by no later than January 1, 2002. SYN.X agrees to provide [***] % of the actual, direct development costs of such Quantitative Reader, up to a maximum of $[***] USD.

g) To the extent not covered by the above, PBM agrees to work and cooperate with SYN.X in taking all steps reasonably necessary to permit the commercial development of POC Rapid Assays produced by PBM utilizing Reagents supplied by SYN.X.

h) PBM agrees that all of its activities with respect to the development of POC Rapid Assays, the production of sample POC Rapid Assays for the clinical and other trials to be conducted by SYN.X, the obtaining of Regulatory Approval for POC Rapid Assays, the development of specifications, and the other activities working and cooperating with SYN.X as contemplated in this Section 2.2, shall be at the sole cost and expense of PBM.

i) PBM shall use its commercially reasonable best efforts to secure, within 24 months of the effective date hereof, additional, appropriately qualified manufacturing capability for POC Rapid Assays. Such additional manufacturing capability shall be adequately qualified to produce the POC Rapid Assays in accordance with all current standards, guidelines and regulations determined by the responsible authorities, including, without limitation, the FDA and any European Community or European Union directives relating to medical devices and in vitro diagnostic medical devices. Notwithstanding anything herein to the contrary, PBM shall not be required to have such additional manufacturing capability be operational until such time as the volume of orders to be produced by PBM under this Agreement make it commercially reasonable to add such additional manufacturing capability.

ARTICLE 3
COMMERCIAL PRODUCTION OF REAGENTS AND POC RAPID ASSAYS

3.1 SYN.X to Supply ReaGents Exclusively to PBM.

a) SYN.X shall not, directly or indirectly, supply, provide, sell, distribute, or deliver Reagents for use in point of care rapid assay products to any person other than PBM except to the extent set forth in Section 3.3 hereof. Nothing herein shall be deemed to preclude SYN.X from supplying, providing, selling or distributing Reagents that are used in rapid assay products utilized in a hospital's central clinical laboratory or in a reference laboratory setting or in rapid assay products that can be used in any instrument with random access capability and/or any instrument with the ability to analyze multiple samples.

*** Certain information on this page has been omitted and filed separately with the Commission pursuant to a request for Confidential Treatment.

b) SYN.X shall produce, deliver and supply to PBM, FOB PBM's production facility, on a timely basis, sufficient quantities of Reagents that shall meet the Reagent Specifications, so as to enable PBM to produce POC Rapid Assays that meet the POC Rapid Assay Specifications.

c) Prior to the initial delivery by SYN.X to PBM of Reagents for the production of POC Rapid Assays for commercial sale, the Parties shall discuss and shall mutually agree upon reasonable procedures applicable to the supplying of Reagents by SYN.X to PBM. The Parties may from time to time supplement, revise, modify and amend such procedures.

d) SYN.X shall be compensated for its activities hereunder as set forth elsewhere in this Agreement including without limitation Article 5 hereof.

3.2 PBM as Exclusive Producer of POC Rapid Assays.

a) PBM shall be SYN.X's sole and exclusive producer of POC Rapid Assays, directly and indirectly, and SYN.X shall not authorize or permit any other person, directly or indirectly, to produce POC Rapid Assays.

b) PBM and SYN-X shall not sell, distribute or transfer POC Rapid Assays to any person except in accordance with the terms and conditions of this Agreement.

c) Neither SYN.X nor PBM shall, directly or indirectly, produce, purchase, procure, supply, sell, distribute, or deliver POC Rapid Assays except under the terms and conditions of this Agreement.

d) PBM shall produce, POCkage, deliver and supply to SYN.X or Customers, as the case may be, FOB PBM's production facility, on a timely basis, POC Rapid Assays for commercial use. Such POC Rapid Assays shall meet the POC Rapid Assay Specifications, as well as any written specifications agreed to between PBM and SYN.X and/or the Customer.

e) Prior to the initial delivery by PBM of POC Rapid Assays for commercial sale, the Parties shall discuss and shall mutually agree upon reasonable procedures applicable to the production, POCkaging and distribution of POC Rapid Assays. Without limiting the foregoing, PBM shall not be required by the terms of this Agreement or otherwise to produce POC Rapid Assays in production runs that are smaller than [***] units.

1) PBM shall be compensated for its activities hereunder as set forth elsewhere in this Agreement including without limitation Article 5 hereof.

g) In allocating its manufacturing capacity, PBM agrees to give preference to manufacturing the POC Rapid Assays at its Princeton manufacturing site.

3.3 Exceptions to PBM's Servine as Exclusive Producer of POC Rapid Assays.

a) **POC Rapid Assay Quality Problem**. Notwithstanding Sections 3.1 and 3.2, SYNX, subject to the provisions of this Agreement, may produce, or arrange for third parties to produce P~C Rapid Assays if SYN.X is able to reasonably establish that PBM has failed to produce POC Rapid Assays that meet the POC Rapid Assay Specifications (a "POC Rapid Assay Quality Problem"); provided, however, that SYN.X shall have given written notice to PBM of same, and that PBM shall have failed to cure same within 60 days after receipt of such written notice; and provided further, that in the event of an uncured POC Rapid Assay Quality Problem, third parties may supply only such POC Rapid Assays as to which there shall be a POC Rapid Assay Quality Problem, and that as soon as PBM shall not have a POC Rapid Assay Quality Problem, PBM shall resume supplying such POC Rapid Assays. SYN.X's rights under this Section 3.3(a) shall not arise to the extent to which PBM is able to reasonably establish that the POC Rapid Assay Quality Problem is attributable, in whole or in part, to defects or deviations in the Reagents supplied by SYN.X or to other act of SYN.X or a Customer. Nothing in this Section 3.3(a) shall be deemed to grant SYN.X a license in any of PBM's intellectual property or the intellectual property relied upon by PBM in producing POC Rapid Assays. PBM shall give prompt written notice to SYNX whenever PBM encounters a POC Rapid Assay Quality Problem that it reasonably expects could affect the timely and satisfactory discharge of its obligations under this Agreement.

*** Certain information on this page has been omitted and filed separately with the Commission pursuant to a request for Confidential Treatment.

b) **Inability to Supply**. PBM shall give SYN.X prompt written notice (in any event, not later than 15 days after PBM's receipt of a purchase order) in the event that PBM reasonably anticipates that it will be unable to supply any of the POC Rapid Assays upon the date specified in a purchase order. Notwithstanding Sections 3.1 and 3.2, SYN.X, subject to the provisions of this Agreement, may produce, or arrange for third parties to produce, such POC Rapid Assays as PBM is unable to supply to SYN.X or Customers, as the case may be, within 60 days of the required delivery date, the quantities of POC Rapid Assays complying with the POC Rapid Assay Specifications as ordered by SYN.X pursuant to Article IV herein (a "POC Rapid Assay Supply Problem"). SYN.x's rights under this Section 3.3(b) shall not arise to the extent to which PBM is able to reasonably establish that the POC Rapid Assay Supply Problem is attributable, in whole or in part, to defects, deviations or delay in the Reagents supplied by SYN.X or to other act of SYN.X or a Customer including without limitation a failure by SYN.X to comply with the provisions of Section 4.1 or 4.2 hereof. In respect of any particular order as to which there is a POC Rapid Assay Supply Problem, SYN.X may, in its sole discretion, in respect of that particular order, direct PBM to obtain the POC Rapid Assays complying with the POC Rapid Assay Specifications from an alternate supplier reasonably acceptable to SYN.X, within 90 days. Any additional direct costs that SYN.X may incur due to such inability to supply on the part of PBM shall be borne by PBM; provided, however, that PBM shall not be liable for any of SYN.X's lost profits, consequential damages, indirect or special damages, or any other damages other than such direct damages. Nothing in this Section 3.3(b) shall be deemed to grant SYN.X a license in any of PBM's intellectual property or the intellectual property relied upon by PBM in producing POC Rapid Assays.

3.4 <u>Exceptions to SYN.X Serving as the Exclusive Supplier of the Reagents.</u>

a) **Reagent Quality Problem.** Notwithstanding Sections 3.1 and 3.2, PBM, subject to the provisions of this Agreement, may produce, or arrange for third parties to produce Reagents in the event that PBM is able to reasonably establish that SYN.X has failed to produce Reagents that meet the Reagent Specifications (a "Reagent Quality Problem"); provided, however, that PBM shall have given written notice to SYN.X of same, and that SYN.X shall have failed to cure same within 60 days after receipt of such written notice; and provided further, that in the event of an uncured Reagent Quality Problem, third parties may supply only such Reagent as to which there shall be a Reagent Quality Problem, and that as soon as SYN.X shall not have a Reagent Quality Problem, SYN.X shall resume supplying such Reagent. PBM's rights under this Section 3.4(a) shall not arise to the extent to which SYN.X is able to reasonably establish that the Reagent Quality Problem is attributable, in whole or in part, to defects or deviations in the POC Rapid Assay supplied by PBM or to other act of PBM or a Customer. Nothing in this Section 3.4(a) shall be deemed to grant PBM a license in any of SYN-X's intellectual property or the intellectual property relied upon by SYN.X in producing Reagents. SYN.X shall give prompt written notice to PBM whenever SYN.X encounters a Reagent Quality Problem that it reasonably expects could affect the timely and satisfactory discharge of its obligations under this Agreement.

b) **Inability to Supply.** SYN.X shall give PBM prompt written notice in the event that SYN.X reasonably anticipates that it will be unable to supply Reagents upon an agreed date. Notwithstanding Sections 3.1 and 3.2, PBM, subject to the provisions of this Agreement, may produce, or arrange for third parties to produce Reagents in the event that SYN.X is unable to supply to PBM within 60 days of the agreed delivery date the quantities of Reagents complying with the Reagent Specifications as is necessary for the production of POC Rapid Assays that PBM is to produce under the provisions of Article 4 hereof (a "Reagent Supply Problem"). PBM's rights under this Section 3.4(b) shall not arise to the extent to which SYN.X is able to reasonably establish that the Reagent Supply Problem is attributable, in whole or in part, to defects, deviations or delay in the P~C Rapid Assays produced by PBM or to other act of PBM or a Customer. In respect of any particular order, PBM may, in its sole discretion, in respect of that particular order, direct SYN.X to obtain the Reagent complying with the Reagent Specifications from an alternate supplier reasonably acceptable to PBM, within 90 days. Any additional direct costs that PBM may incur due to such inability to supply on the part of SYNX shall be borne by SYN.X; provided, however, that SYN.X shall not be liable for any of PBM's lost profits, consequential damages, indirect or special damages, or any other damages other than such direct damages. Nothing in this Section 3.4(b) shall be deemed to grant PBM a license in any of SYN-X's intellectual property or the intellectual property relied upon by SYN.X in producing Reagents.

ARTICLE 4
FORECASTING, ORDERING, PACKAGING AND SHIPPING

4.1 Forecasts.

a) **Long Term Forecasts.** Once commercial production of POC Rapid Assays is set to commence, SYN.X shall provide to PBM no later than 30 days before the first day of every calendar quarter during the Term of this Agreement, a rolling quarterly forecast of the quantities of POC Rapid Assays that SYN.X intends to order during the next four calendar quarters. Such forecasts shall represent the most current estimates for planning purposes, but shall not be purchase commitments.

b) **Short Term Forecasts.** Once commercial production of POC Rapid Assays is set to commence, SYN.X shall provide to PBM no later than 90 days prior to the first day of each succeeding calendar quarter a rolling forecast of the quantities of POC Rapid Assays that SYN.X intends to order by month, during the next calendar quarter. Such forecasts shall constitute binding commitments of SYN.X to order and PBM to supply at least 80% of the number of POC Rapid Assays designated, pursuant to firm orders issued in accordance with the terms of this Agreement.

4.2 Purchase Orders

SYN.X shall order P~C Rapid Assays by written purchase orders specifying the quantity of POC Rapid Assays and the delivery date on which such quantity is required. SYN.X shall submit each such written purchase order at least 30 days in advance of the required delivery date. PBM shall use reasonable efforts to meet any request of SYN.X for delivery of POC Rapid Assays in less than 30 days, and further, PBM will attempt to accommodate any changes requested by SYN.X in delivery schedules for P~C Rapid Assays following PBM's receipt of purchase orders from SYN.X Upon receipt of each purchase order by PBM, PBM shall supply the quantity of POC Rapid Assays designated therein within the time for delivery set out therein. Should PBM be unable to supply such quantity of POC Rapid Assays by the designated delivery date of any purchase order, PBM shall so advise SYN.X within 10 days of receipt of such purchase order, and the provisions of Section 3.3(b) shall apply. The terms and conditions of this Agreement shall be paramount to the terms and conditions of any purchase order, should there be any variance.

4.3 Packaging and Labeling

POC Rapid Assays shall be packaged and labeled in accordance with all relevant requirements of the jurisdiction into which they are being distributed, as well as in accordance with SYN.X's requirements as communicated to PBM from time to time.

4.4 Delivery and Shipping Terms

Delivery by PBM of the POC Rapid Assays shall be FOB PBM's manufacturing site, in accordance with the shipping and handling instructions specified by SYN.X in each purchase order. Title to the POC Rapid Assays shall pass to SYN.X at the time of proper delivery of the POC Rapid Assays to SYN.X's designated carrier for shipment at the place of shipment. All P~C Rapid Assays shall be shipped to SYN.X or Customers, as the case may be, in appropriate shipping containers as agreed by the Parties.

4.5 Raw Materials and Components

PBM shall provide, at its cost and expense all raw materials, components, and other resources required in connection with production of the POC Rapid Assays in accordance with the POC Rapid Assay Specifications, except that the Reagents shall be supplied by SYN.X at its sole cost and expense. PBM represents and warrants to SYN.X that PBM currently has access to, and during the entire term of this Agreement will make all commercially reasonable efforts to maintain access to, sufficient supplies of raw materials, utilities, container/closure systems, packaging materials, labor, and all other items required to perform the services and supply the P~C Rapid Assays required of PBM hereunder without interruption, unless otherwise provided for by this Agreement. PBM agrees to conduct audits of its suppliers of raw materials and components of the P~C Rapid Assays on a regular basis to monitor whether such suppliers are producing the raw materials and components in accordance with all applicable laws, rules and regulations, including but not limited to the requirements of cGMP, and to determine whether such suppliers will continue to be able to supply a sufficient quantity and quality of such raw materials and components. Upon request, PBM will supply SYN.X will certificates stating that any related supplier complies with all such laws, rules and regulations. SYN.X represents and warrants to PBM that SYNX currently has access to, and during the entire term of this Agreement will make all commercially reasonable efforts to maintain access to, sufficient supplies of raw materials, utilities, container/closure systems, packaging materials, labor, and all other items required to perform the services and supplied the Reagents required of SYN.X hereunder without interruption, unless otherwise provided for by this Agreement.

ARTICLE 5
PAYMENT; PRICING; DISTRIBUTION

5.1 Allocation of Net Sales Price and Payment.

a) For sales of P~C Rapid Assays to Customers within the United States, SYN.X shall receive [***]%, and PBM shall receive [***]%, of the "Net Sales Price" of the P~C Rapid Assay. "Net Sales Price" shall be the POC Rapid Assay's selling price to the Customer FOB PBM's facility, net of taxes, freight, returns, allowances, rebates and such other items as the Parties may from time to time agree. Such allocation of the Net Sales Price assumes that PBM is to bear the cost of industry-standard packaging. Any deviation from such standard packaging resulting in additional costs will be borne by the distributor or equally by PBM and SYN.X in each case, and will be reflected in an increase in the price from the standard price.

b) For sales of P~C Rapid Assays to Customers outside of the United States, SYN.X shall receive [***]%, and PBM shall receive [***]%, of the Net Sales Price (as defined above) of the P~C Rapid Assays. Such allocation of the Net Sales Price assumes that PBM is to bear the cost of industry-standard packaging. Any deviation from such standard packaging resulting in additional costs will be borne by the distributor or equally by PBM and SYN.X in each case, and will be reflected in an increase in the price from the standard price.

c) PBM may invoice SYN.X upon shipment for amounts due to PBM under this Agreement, and SYN.X shall make payment to PBM not later than 60 days after shipment. Interest on unpaid amounts due to PBM shall accrue commencing upon the 61th day after shipment at the rate of 0.75% per month. PBM may refuse to ship further POC Rapid Assays to any Customer in the event that SYN.X shall not make full payment on or prior to such 60th day, and any such refusal to supply POC Rapid Assays shall not give rise to any right in SYN.X to terminate or modify this Agreement. All payments to PBM shall be USD. Risk of payment by the Customer for sales by SYN.X and its Affiliates shall be solely with SYN.X and its Affiliates.

d) SYN.X may invoice PBM upon shipment for amounts due to SYN.X under this Agreement, and PBM shall make payment to SYN.X not later than 60 days after shipment. Interest on unpaid amounts due to SYN.X shall accrue commencing upon the 61th day after shipment at the rate of 0.75% per month. SYN.X may refuse to ship further Reagents to PBM in the event that PBM shall not make full payment on or prior to such 60th day, and any such refusal to supply Reagents shall not give rise to any right in PBM to terminate or modify this Agreement. All payments to SYN.X shall be USD. Risk of payment by the Customer for sales by PBM and its Affiliates shall be solely with PBM and its Affiliates.

5.2 Distribution

a) The Parties shall from time to time jointly determine and agree in advance upon the terms and conditions for the sale and distribution of POC Rapid Assays, and each Party may from time to time present for each other's prior approval proposed agreements for the sale and distribution of POC Rapid Assays to nonaffiliated third parties. Only SYN.X may grant or sell any distribution right for any POC Rapid Assay, subject to the terms and conditions hereof.

No Party shall have the right to veto any such proposed agreement unless the other Party shall present, not later 90 days after having been advised in writing of the material terms of such proposed agreement, a more suitable third party distributor. A more suitable third party distributor would be one which presents a clearly superior opportunity for the distribution of POC Rapid Assays, on the basis of more than merely equal or more favorable commercial terms, for example, superior marketing and distribution capability.

Payments to SYNX for the grant of exclusive distribution rights shall not be included in determining whether a third party is a more suitable third party distributor, nor shall any loss of distribution revenue or distribution profit by PBM and/or its Affiliates nor the costs of terminating existing resale agreements, resulting from the termination, loss or absence of PBM's and/or its Affiliates' distribution rights, be taken into account in the determination of whether a third party is a more suitable third party distributor.

*** Certain information on this page has been omitted and filed separately with the Commission pursuant to a request for Confidential Treatment.

b) SYN.X and PBM shall each have the right, directly and through their respective Affiliates, to sell and distribute POC Rapid Assays; provided that PBM shall not have such right to the extent to which it is excluded by any exclusive distribution agreement entered into by SYN.X; and provided further that neither PBM nor any Affiliate may sell or distribute POC Rapid Assays to any reseller or wholesaler or other third party distributor; and provided further that PBM shall not have such right to the extent to which SYN.X has presented a non-exclusive third party distributor from whom the Parties as a whole shall obtain a better distribution opportunity as compared to the distribution opportunity presented by such third party distributor combined with distribution by PBM and its Affiliates.

c) Where PBM and/or its Affiliates distribute POC Rapid Assays under Section 5.2(b) hereof, PBM and/or its Affiliates shall have the right to purchase POC Rapid Assays at a Net Sales Price that is the most favorable cost basis agreed to with any Customer of POC Rapid Assays, or at a specifically agreed price between the Parties deemed necessary to promote the POC Rapid Assays or to penetrate into new markets or to compete against similar competing product(s). Revenues earned through distribution of POC Rapid Assays by PBM and/or its Affiliates, net of the Net Sales Price, taxes, freight, returns, allowances, rebates and other agreed items ("Net Distribution Revenues") shall be shared on the following basis: (i) Net Distribution Revenues earned on sales outside of the United States: [***]% to PBM or its Affiliates, as the case may be, and [***] % to SYN.X; and (ii) Net Distribution Revenues earned on sales within the United States:. [***]% to PBM and its Affiliates, as the case may be, and [***]% to SYN.X.

d) In the event that SYN.X sells or grants distribution rights or otherwise agrees to sell or distribute POC Rapid Assays on terms that provide for a Net Sales Price of less than $[***] (US D) per Panel outside of the U.S., or less than $[***] (USD) per Panel within the U.S., PBM shall receive an allocation of such selling price under Section 5.1 hereof as if the Net Sales Price yielded thereby were $[***] (USD) per Panel outside of the U.S. or $[***] (USD) per Panel within the U.S. Such $[***] and $[***] respective prices may be increased in PBM's sole discretion at the end of every three year period of this Agreement by the amount of the increase in PBM's actual cost of manufacturing multiplied by the rate of inflation as reflected in the Consumer Price Index.

ARTICLE 6
OWNERSHIP OF INTELLECTUAL PROPERTY; LICENSES; CONFIDENTIALITY

6.1 <u>Intellectual Property.</u>

a) Nothing in this Agreement shall be deemed to give PBM any rights in, right to use or license in any of SYN.X's existing or future intellectual property, including without limitation patents, confidential information, technology, production methods and procedures, know-how and the like (collectively "Intellectual Property"), except as explicitly provided herein.

b) Nothing in this Agreement shall be deemed to give SYN.X any rights in, right to use or license in any of PBM's existing or future Intellectual Property, except as explicitly provided herein.

c) Any Intellectual Property exclusively developed after the date hereof by SYN.X shall remain the sole and exclusive property of SYN.X.

d) Any Intellectual Property exclusively developed after the date hereof by PBM shall remain the sole and exclusive property of PBM.

e) Any Intellectual Property that is jointly or cooperatively developed by the Parties after the date hereof shall be jointly owned to the extent of the respective contributions thereto (the "Jointly Owed Intellectual Property"). Each Party hereby grants to the other a fully paid-up, perpetual exclusive license to all licensing and commercialization rights in such Jointly Owed Intellectual Property for the field pertaining to the other party's business (the "Field-Exclusive Jointly Owned Intellectual Property License"). Any Party may transfer the Jointly Owned Intellectual Property, as well as the Field-Exclusive Jointly Owned Intellectual Property License, in connection with the sale of all or substantially all of its assets. The parties shall share equally in the cost of and responsibility for patent filing, maintenance and enforcement, and shall cooperate fully in any such endeavor.

6.2 Licenses

a) SYN.X hereby grants to PBM a license to SYN.X's intellectual property rights in the Reagents and the POC Rapid Assays to manufacture the POC Rapid Assays in accordance with the POC Rapid Assay Specifications, subject to the terms and conditions of this Agreement, for the sole and exclusive purpose of incorporating the Reagents into P~C Rapid Assays.

b) PBM hereby grants to SYN.X a license to PBM's intellectual property rights, if any, in the POC Rapid Assays, to distribute, use and sell the POC Rapid Assays throughout the world, subject to the terms and conditions of this Agreement.

6.3 Confidential Information.

a) During the term of this Agreement and for a period of three (3) years thereafter, the receiving party (the "Receiving Party") shall maintain in confidence all Confidential Information, as defined in Section 6.3 (b) below, and shall not use, disclose or grant use of such Confidential Information except as expressly authorized in this Agreement. The Receiving Party may disclose the Confidential Information, as authorized hereunder, only to those employees or consultants of the Receiving Party who agree to be bound by the terms of this Section 6.3. The Receiving Party shall use the strictest standard of care which is practical to ensure that such employees do not disclose or make any unauthorized use of the Confidential Information. The Receiving Party shall promptly notify the Disclosing Party upon discovery of any unauthorized use or disclosure of the Confidential Information.

b) As used in this Agreement, the term "Confidential Information" shall mean any information, either enabling or disabling, including the terms of this Agreement, any batch record, any order or other commercial relationship between the Parties, know-how, trade secret, research, inventions, patented or patentable subject matter, patent applications, data, process, technique, algorithm, program, design, drawing, future development, scientific, manufacturing, marketing, business plan, financial or personnel matter relating to the disclosing party (the "Disclosing Party"), its present or future products, sales, suppliers, employees, investors or business, whether in oral, written, graphic, or electronic form and whether received from the Disclosing Party or a third party. The term "Confidential Information" shall include, without limitation (i) any cost information related to the manufacture of the Reagents and/or POC Rapid Assays, and (ii) the Reagent Specifications and/or POC Rapid Assay Specifications.

c) The term "Confidential Information" shall not be deemed to include information which the Receiving Party can demonstrate by competent written proof: (i) is now, or hereafter becomes, through no act or failure to act on the part of the Receiving Party, generally known or available; (ii) is known by Receiving Party at the time of receiving such information as evidenced by its records; (iii) is hereafter furnished to the Receiving Party by a third party, as a matter of right and without restriction or disclosure; or (iv) is the subject of written permission to disclose provided by the Disclosing Party. Further, the obligations of confidentiality under this Article shall not apply to the extent that the Receiving Party is required to disclose information in support of a product approval application or by an order or regulation of a governmental agency or in the course of litigation, provided that in all cases the Receiving Party shall give the other party prompt notice of the pending disclosure and shall seek an order maintaining the confidentiality of the information.

ARTICLE 7
REPRESENTATIONS AND WARRANTIES

7.1 Existence and Power.

Each Party hereby represents and warrants to the other Party that such party (a) is duly organized, validly existing and in good standing under the laws of the state and country in which it is organized; (b) has the power and authority and the legal right to own and operate its property and assets, to lease the property and assets it operates under lease, and to carryon its business as it is now being conducted; and (c) is in compliance with all requirements of applicable law, except to the extent that any noncompliance would not materially adversely affect such party's ability to perform its obligations under the Agreement.

7.2 Authorization and Enforcement of Obligations.

Each Party hereby represents and warrants to the other Party that such party (a) has the power and authority and the legal right to enter into the Agreement and to perform its obligations hereunder and thereunder and (b) has taken all necessary action on its part to authorize the execution and delivery of the Agreement and the performance of its obligations hereunder. The Agreement has been duly executed and delivered on behalf of such party, and constitutes a legal, valid, binding obligation, enforceable against such party in accordance with its terms.

7.3 No Consents.

Each Party hereby represents and warrants to the other Party that all necessary consents, approvals and authorizations of all governmental authorities and other persons required to be obtained by such party in connection with the Agreement have been obtained.

7.4 No Conflict.

Each Party hereby represents and warrants to the other Party that the execution and delivery of the Agreement and the performance of such party's obligations hereunder and thereunder (a) do not conflict with or violate any requirement of applicable laws or regulations or any material contractual obligations of such party and (b) do not materially conflict with, or constitute a material default or require any consent under, any material contractual obligation of such party. The Parties shall not in any event enter into any agreement or arrangement with any other party that would prevent or in any way interfere with their obligations pursuant to this Agreement.

7.5 Compliance with Laws.

Each Party shall comply with regulations, requirements and laws of any and all applicable state, provincial and local authorities and agencies, including without limitation all laws and regulations which are applicable to the transportation, storage, use, handling and disposal of hazardous materials. The Parties shall maintain during the term of this Agreement all governmental permits, including without limitation health, safety and environmental permits, necessary for the conduct of the actions and procedures that they undertake pursuant to this Agreement.

7.6 Documentation.

The Parties shall keep complete, accurate and authentic accounts, notes, data and records of the work performed under this Agreement. Each party shall maintain complete and adequate records pertaining to the methods and facilities used for the manufacture, processing, testing, packing, labeling, holding and distribution of the *POC* Rapid Assays in accordance with the applicable laws and regulations.

7.7 Limited Warranty.

a) SYN.X warrants that the Reagents to be delivered hereunder will (i) be manufactured by SYN.X in accordance with the agreed-upon manufacturing procedures and (ii) conform to the Reagent Specifications agreed to at the time of delivery. PBM's remedies and SYN.X's liability with respect to this warranty are set forth below.

b) PBM represents and warrants that the POC Rapid Assays to be delivered hereunder will (i) be manufactured by PBM in accordance with all applicable rules and regulations and cGMP, (ii) be manufactured in accordance with the agreed-upon manufacturing procedures (iii) conform to the POC Rapid Assay Specifications agreed to at the time of delivery, and will not be (iv) adulterated or misbranded within the meaning of the FD & C Act, (v) an article that may not be introduced into interstate commerce under the provisions of Sections 404 or 505 of the FD & C Act, (vi) manufactured, sold or shipped in violation of any agreement, judgment, order or decree to which PBM is a party or otherwise (vii) manufactured, sold or shipped in violation of any applicable federal, provincial, state or local law, rule, regulation or ordinance in any material respect. SYN.X's remedies and PBM's liability with respect to this warranty are set forth below.

c) PBM represents and warrants that there is no claim, suit, proceeding, or other investigation pending, or to the actual knowledge of PBM, overtly threatened against PBM which is likely to prevent or materially interfere with PBM's performance under this Agreement or materially adversely affect the rights of SYN.X hereunder.

d) PBM represents and warrants that neither it nor any member of its staff has been disqualified or debarred by the FDA for any purpose. If during the term of this Agreement, PBM becomes aware that any member of its staff is or is about to become disqualified or debarred, PBM will provide immediate written notice of same to SYN.X .

e) PBM represents and warrants to SYN.X that it owns the rights to the intellectual property and any technology required to manufacture the POC Rapid Assays, except for the Reagents.

7.8 Remedies.

a) Reagents supplied by SYNX to PBM which do not conform to the Reagent Specifications shall be replaced by SYN.X at SYN.X's sole cost and expense. This remedy is available only if such nonconformance was not caused by PBM's misuse, unauthorized modifications, neglect, improper testing or improper storage, transportation, use beyond any dating provided, accident, fire or other hazard.

b) POC Rapid Assays which do not conform to the POC Rapid Assay Specifications shall be replaced by PBM at PBM's sole cost and expense, not to be deducted from the Net Sales Price. This remedy is available only if such nonconformance was not caused by the Customer's misuse, unauthorized modifications, neglect, improper testing or improper storage, transportation, use beyond any dating provided, accident, fire or other hazard.

ARTICLE 8
SPECIFICATIONS

8.1 Certificate of Analysis

PBM shall furnish to SYN.X with each shipment of POC Rapid Assays a certificate of analysis reflecting that such POC Rapid Assays meet the POC Rapid Assay Specifications.

8.2 Notice of Failure to Meet Specifications

PBM shall promptly notify SYN.X, at least within 72 hours, of the discovery of any batch or lot of POC Rapid Assays, which has previously been approved in accordance with the procedures set forth herein, which does not meet the POC Rapid Assay Specifications. PBM shall provide in such notice details concerning the nature of any such failure to meet the POC Rapid Assay Specifications. PBM shall make, at its sole expense, such further internal investigations of any failure to meet the POC Rapid Assay Specifications as is appropriate under the circumstances and otherwise consistent with its obligations hereunder. The liability for costs associated with any such batch or lot of POC Rapid Assays shall be determined in accordance with Section 9.1 below (Claims), with the exception of the requirement that SYN.X provide written notice of rejection within 30 days.

8.3 Specification Changes: PBM

In the event that PBM is required to change the POC Rapid Assay Specifications pursuant to applicable law, rule, or regulation or in response to the order or request of a governmental authority or regulatory body, PBM shall promptly advise SYN.X in writing of any such change.

8.4 Specification Changes: SYN.X

In the event that SYN.X is required to change the Reagent Specifications pursuant to applicable law, rule, or regulation or in response to the order or request of a governmental authority or regulatory body, SYN.X shall promptly advise PBM in writing of any such change.

ARTICLE 9
CLAIMS

9.1 Claims

In the event that any of the POC Rapid Assays delivered to SYN.X or Customers, as the case may be, pursuant to this Agreement by PBM fails to conform with any warranty set forth herein relating to quality and/or the POC Rapid Assay Specifications, SYN.X may reject such POC Rapid Assays by giving written notice to PBM within 30 days after SYN.X's receipt of such POC Rapid Assays, either from PBM or on return from Customer. Any notice given under this provision must specify the manner in which the POC Rapid Assay fails to conform with the POC Rapid Assay Specifications. If there is a disagreement between the Parties as to whether any POC Rapid Assay meets the POC Rapid Assay Specifications, then samples and/or batch records, as appropriate, from the batch that is in dispute will be submitted promptly for testing and evaluation to an independent third party (including a third party testing laboratory) as shall be agreed to in writing by both Parties. Should the Parties be unable to agree on an independent third party testing laboratory, an arbitrator shall be appointed under the arbitration provisions of this Agreement for the sole purpose of choosing such an independent third party testing laboratory. The determination of such third party as to whether such POC Rapid Assay meets the POC Rapid Assay Specifications will be final and binding. If it is determined that the nonconformity is due to

damage to the POC Rapid Assay caused solely by SYN.X or its agents, or which occurs subsequent to the proper delivery of such POC Rapid Assay to the carrier for shipment, PBM shall have no liability to SYN.X with respect to such nonconformity and the cost of any testing and evaluation by a third party shall be borne by SYN.X If the nonconformity is caused by a defect in manufacturing, the cost of any testing or evaluation by a third party shall be borne by PBM and, at SYN.X's election, PBM shall at its option replace or repair such nonconforming POC Rapid Assay within 60 days of such determination at no additional cost to SYN.X, or in lieu of replacement, credit SYN.X's account or reimburse SYN.X for the price invoiced or paid for such nonconforming POC Rapid Assay.

9.2 Disposition of Nonconforming POC Rapid Assay

In any case in which SYN.X expects to make a claim against PBM with respect to damaged or otherwise non-conforming POC Rapid Assays, SYN.X shall not dispose of such POC Rapid Assays for 6 months after notifying PBM in writing of such damage or nonconformance without written authorization and instructions from PBM to either dispose of such POC Rapid Assays or to return them to PBM.

ARTICLE 10
AUDITS, COMPLAINTS, REGULATORY MATTERS

10.1 Performance of Audits.

SYN.X and PBM shall each have the right, at their sole respective expense, to conduct an Audit, upon thirty (30) calendar days' written notice to the other Party, during such Party's normal business hours, of all records, documents, processes, procedures, and facilities directly associated with the manufacture, processing, packaging, sales and distribution of Reagents or the POC Rapid Assays, as the case may be, as well as with the receipt, storage, and issuance of raw materials, labeling and packaging components, and ingredients thereof. Notwithstanding the immediately preceding sentence, in the event of a rejection of by one Party of the product supplied by the other Party because of a failure to meet specifications, then the rejecting party shall have an additional right to conduct an Audit under the provisions of this Article. In no event shall an Audit exceed two (2) days in duration unless mutually agreed in writing by the parties. Each Party warrants that all inspections and Audits hereunder shall be carried out in a manner that does not unreasonably interfere with the other Party's normal and ordinary conduct of business and that insures the continued confidentiality of such other Party's other business and technical information. Audits may be conducted by no more than two (2) representatives of a Party. Any such representatives shall be qualified in terms of auditing skill to conduct Audits, shall execute a written agreement to maintain in confidence all information obtained during the course of any such Audit except for disclosure to the senior representatives of such Party, and shall comply with the normal security at the manufacturing site.

10.2 Audit Feedback.

Within thirty (30) days of completing any Audit hereunder, the auditing Party shall submit to the audited Party a written report outlining its findings and/or observations from any such Audit. If deficiencies are discovered during an Audit that could, in the auditing Party's reasonable opinion, prevent the audited Party from satisfying the requirements of cGMP obligations hereunder, and the audited Party in good faith disputes the observations or conclusions of the auditing Party, then the Parties shall promptly enter into good faith discussions to resolve their differences. If the Parties fail to resolve their differences within thirty (30) days, then the disputed points shall be resolved by submitting same to a mutually agreeable Third Party consultant in the same manner and under parameters similar to those contemplated under Article 9 for disputes related to nonconforming POC Rapid Assays. That is, the Parties shall be bound by the decision of the Third Party consultant and the Party in error shall bear the costs and expenses of the Third Party consultant. If both Parties are in error, they shall share the costs equally. If the audited Party does not, in good faith, dispute the observations made during any Audit it shall promptly correct those deficiencies at its own cost, and shall notify the auditing Party in writing when those deficiencies are corrected.

10.3 Regulatory Matters.

a) **General Compliance.** The parties shall jointly determine and conduct all regulatory strategies, proceedings and communications. SYN.X shall have primary responsibility for creating all regulatory documents other than those pertaining to manufacturing. PBM shall have primary responsibility for creating all regulatory documents pertaining to manufacturing. Where possible, the parties shall endeavor to have a distributor pay registration and regulatory costs pertaining to the jurisdiction of such distributor. Where this is not possible, the parties shall split such costs equally. PBM shall, at its sole expense, comply with all federal, state, and local laws, regulations, and standards and specifications applicable to production of the POC Rapid Assays and its performance of PBM's obligations hereunder.

b) **Marking.** All POC Rapid Assays produced hereunder shall comply with all requirements relating to marking, packaging and labeling for the relevant jurisdictions into which they shall be sold. Without limiting the foregoing, all POC Rapid Assays shall be marked as a SYN.X product, manufactured by PBM, except for private label sales.

c) **Validations and Qualifications.** PBM shall concurrently perform process and cleaning validation, analytical methods validation, and installation/operating qualification, and calibration of all equipment and facilities utilized in the manufacture, packaging, testing, storing, and release of POC Rapid Assays. Such validations, qualifications, and calibrations are to be in accordance with all current regulations determined by the responsible authorities (in particular, without limitation, the regulations of the FDA and any European Community or European Union directives relating to medical devices and in vitro medical devices), and PBM shall, through effective control procedures, ensure all such validations, qualifications, and calibrations will be current. In general, PBM shall, at all times in the performance of its obligations hereunder, comply with its standard operating procedures for the POC Rapid Assays

d) **Batch Records.** PBM shall develop and manufacture POC Rapid Assays in compliance with all cGMP including preparation and maintaining of all Batch History Records. SYN.X shall develop and manufacture Reagents in compliance with all cGMP including preparation and maintaining of all Batch History Records. Both PBM and SYN.X shall make these Records available to the other party during their Audits.

e) **Notice of Warnings. Etc.** PBM will notify SYN.X promptly of any warning (including any FDA Form 483), citation, indictment, claim,. lawsuit, or proceeding issued or instituted by any federal, state, or local governmental entity or agency against PBM if, and only to the extent that, the manufacture of POC Rapid Assays hereunder is affected, or of any revocation of any license or permit issued to PBM, but only to the extent that such license or permit relates to PBM's performance of its obligations hereunder.

f) **POC Rapid Assays Reviews. Reports.** PBM will conduct annual product reviews for the POC Rapid Assays, which shall include trend analysis of critical process parameters when reasonably available as well as a review of stability, reserve samples, complaints, in-process variances, rejections, investigations and process changes. Further, PBM agrees to timely compile, for the POC Rapid Assays, all data reasonably necessary for SYNX to file Annual Reports and other periodic reports with the FDA, in accordance with applicable laws, rules, and regulations, relative to the POC Rapid Assays. SYN.X will conduct annual product reviews for the Reagents, which shall include trend analysis of critical process parameters when reasonably available as well as a review of stability, reserve samples, complaints, and adverse drug reports, in-process variances, rejections, investigations and process changes. Further, SYN.X agrees to timely compile, for the Reagents, all data reasonably necessary for PBM to file Annual Reports and other periodic reports with the FDA, in accordance with applicable laws, rules, and regulations, relative to the Reagents.

g) **Stability.** PBM will be responsible for taking and maintaining any necessary quality control stability samples for the POC Rapid Assays, testing stability samples on a timely basis, and providing SYN.X on an annual basis, and as otherwise reasonably requested by SYN.X, with stability data. PBM will initiate a stability failure investigation on any stability test failure promptly (but at least within seventy-two [72] hours) of learning of any such deviation. PBM will notify SYN.X promptly (but at least within seventy-two [72] hours) upon its actual discovery of objective evidence of a stability failure with regard to the POC Rapid Assays. SYN.X will be responsible for taking and maintaining any necessary quality control stability samples for the Reagents, testing stability samples on a timely basis, and providing PBM on an annual basis, and as otherwise reasonably requested by SYN.X, with stability data. SYNX will initiate a stability failure investigation on any stability test failure promptly (but at least within seventy-two [72] hours) of learning of any such deviation. PBM will notify SYN.X promptly (but at least within seventy-two [72] hours) upon its actual discovery of objective evidence of a stability failure with regard to the POC Rapid Assays.

10.4 Inspections.

In the event the manufacturing facility producing POC Rapid Assays hereunder is inspected by representatives of any federal, state, or local regulatory agency in connection with the manufacture of the POC Rapid Assays, PBM shall notify SYN.X promptly (but at least within seventy-two [72] hours) upon learning of such inspection, and shall supply SYN.X with copies of any correspondence or portions of correspondence which relate to the POC Rapid Assays. In the event the manufacturing facility producing Reagents hereunder is inspected by representatives of any federal, state, or local regulatory agency in connection with the manufacture of the Reagents, SYN.X shall notify PBM promptly (but at least within seventy-two [72] hours) upon learning of such inspection, and shall supply PBM with copies of any correspondence or portions of correspondence which relate to the Reagents.

10.5 Correspondence.

a) **Correspondence Received by PBM**. PBM shall promptly (and in any event, within three (3) business days of the date of receipt of notice) notify SYN.X in writing of, and shall provide SYN.X with copies of, any correspondence and other documentation received or prepared by PBM in connection with any of the following events: (i) receipt of a regulatory letter, warning, or similar item, from the FDA or any other regulatory authority in connection with the manufacture, packaging, and storage of the POC Rapid Assays and; (ii) any regulatory comments relating to the manufacture of the POC Rapid Assays requiring a response or action by PBM.

b) **Correspondence received by SYN.X**. SYN.X shall promptly (and in any event, within three (3) business days of the date of receipt of notice) notify PBM in writing of, and shall provide PBM with copies of, any correspondence and other documentation received or prepared by SYN.X in connection with any of the following events: (i) receipt of a regulatory letter, warning, or similar item, from the FDA or any other regulatory authority in connection with the manufacture, packaging, and storage of the Reagents and; (ii) any regulatory comments relating to the manufacture of the Reagents requiring a response or action by SYN.X; (iii) customer complaints.

ARTICLE 11
RECALLS

PBM or SYN.X shall notify other party promptly if any batch of POC Rapid Assays supplied by PBM pursuant to this Agreement is alleged or proven to be the cause of a recall, market withdrawal, or correction, and the Parties shall cooperate in the handling and disposition of such recall, market withdrawal, or correction. PBM and SYN.X shall jointly bear the cost of all recalls, market withdrawals, or corrections of POC Rapid Assays supplied by PBM pursuant to this Agreement. SYN.X and PBM shall maintain records of all sales of POC Rapid Assays and Customers sufficient to adequately administer a recall, market withdrawal or correction for the longer of five (5) years after termination or expiration of this Agreement or the period required by applicable law.

ARTICLE 12
INDEMNIFICATION

12.1 Indemnity

a) Each Party shall indemnify, defend and hold harmless the other Party from and against any and all damages incurred by or asserted against the Party of whatever kind or nature, because of a third party claim that the manufacture, use or sale of intellectual property, to the extent arising from any patent right or know-how of the Party, infringes any patent or other intellectual property rights of any third parties.

b) Except in the event that such claims, suits, losses, damages, costs, fees or expenses arise or result from any negligent or wrongful act or omission of PBM or the failure of the POC Rapid Assays to meet the POC Rapid Assay Specifications, SYN.X agrees to indemnify, hold harmless and defend PBM and PBM's directors, officers, employees and agents, and the directors, officers, employees and agents of any PBM parent, subsidiary or related company (the "PBM Indemnities") from and against any and all claims, suits, losses, damages, costs, fees and expenses resulting from or arising out of SYN.X's use, handling, distribution, marketing or sale of the P~C Rapid Assays by any person other than a PBM Indemnity, including without limiting the generality of the foregoing any damages, losses or liabilities whatsoever with respect to death or injury to the person or damage to property, provided that PBM provides SYN.X with prompt notice of any such claim and the exclusive ability to defend (with the reasonable cooperation of PBM) or settle any such claim.

c) Except in the event that such claims, suits, losses, damages, costs, fees or expenses arise or result from any negligent or wrongful act or omission of SYN.X or the failure of the Reagents supplied by SYN.X to meet the Reagent Specifications, then PBM agrees to indemnify, hold harmless and defend SYN.X and SYN.X's directors, officers, employees and agents, and the directors, officers employees and agents of any SYN.X parent, subsidiary or related company (the "SYNX Indemnities") from and against any and all claims, suits, losses, damages, costs, fees and expense resulting from or arising out of its manufacture of the P~C Rapid Assays, its transportation, storage, use, handling and disposal of hazardous materials related to such manufacture, or the possession or use of the P~C Rapid Assays by any person other than a SYN.X Indemnity, including, without limiting the generality of the foregoing, any damages, losses or liabilities whatsoever with respect to death or injury to person or damage to property, provided that SYN.X provides PBM with prompt notice of any such claim and the exclusive ability to defend (with the reasonable cooperation of SYN.X) or settle any such claim.

d) In the event that the parties cannot in good faith agree as to the application of subsections (a), (b) or (c) above to any particular loss or claim, the parties may (i) after the Executives' Meetings provided for by Section 14.2 hereof, proceed to arbitration, or, alternatively, in each party's sole discretion, (ii) conduct separate defenses of such claim and each party shall be relieved of its obligation to tender to the indemnifying party the exclusive ability to defend such claim or suit as a condition of indemnification.

12.2 Expenses.

No party shall be required to pay over to another amounts called for under this Article until the final resolution of the claim, action, suit or proceeding from which the right to such payment arose.

12.3 Payments

All amounts payable under this Article 12 shall be paid promptly after receipt by the indemnifying Party of written notice from the indemnified Party stating that such Indemnified Amounts have been incurred, the amount thereof and of the related indemnity payment and substantiation of such amount and such indemnity payment; provided, however, any disputed amounts shall be due and payable promptly after such amounts are finally determined to be owing by the indemnifying Party to the indemnified Party.

12.4 Conduct of Litigation.

a) Each Party indemnified under the provisions of this Agreement, upon receipt of written notice of any claim, or the service of a summons or other initial legal process upon it in any action instituted against it, in respect of the agreements contained in this Agreement, shall promptly give written notice of such claim, or the commencement of such action, or threat thereof to the Party from whom indemnity shall be sought hereunder; provided, however, the failure to provide such notice within a reasonable period of time shall not relieve the indemnifying Party of any of its obligations hereunder except to the extent the indemnifying Party is prejudiced by such failure;

b) The indemnifying Party shall be entitled at its own expense to participate in the defense of such claim or action, or, if it shall elect, to assume such defense, in which event such defense shall be conducted by counsel chosen by such indemnifying Party, which counsel may be any counsel reasonably satisfactory to the indemnified Party against whom such claim is asserted, or who shall be the defendant in such action, and such indemnified Party shall bear all fees and expenses of any additional counsel retained by it;

c) Notwithstanding the immediately preceding paragraph, if the named parties in such action (including impleaded parties) include the indemnified and the indemnifying Parties, and the indemnified Party has been advised by counsel that there may be a conflict between the positions of the indemnifying Party and the indemnified Party in conducting the defense of such action, or that there are legal defenses available to such indemnified Party different from or in addition to those available to the indemnifying Party, then the indemnified Party shall be entitled, at its election, to conduct such separate defense as is necessary to protect its own interests, at its own expense, if it is determined by agreement of the indemnifying Party and the indemnified Party or by a court of competent jurisdiction that the indemnified Party is entitled to indemnification hereunder for the Indemnified Amounts giving rise to such action;

d) If the indemnifying Party shall elect not to assume the defense of such claim or action, such indemnifying Party shall reimburse such indemnified Party for the reasonable fees and expenses of any counsel retained by it, and shall be bound by the results obtained by the indemnified Party in respect of such claim or action if it is determined by agreement of the indemnifying Party and the indemnified Party or by a court of competent jurisdiction that the indemnified Party is entitled to indemnification hereunder for the Indemnified Amounts giving rise to such action; provided, however, that no such claim or action shall be settled without the written consent of the indemnifying Party.

12.5 Survival of Indemnification Obligations.

The provisions of this Article shall survive the expiry or termination of this Agreement.

12.6 Disclaimer of Consequential Damages.

In no event shall either Party be liable to the other for incidental, special, or consequential damages, including, but not limited to, any claims for damages based upon lost profits.

ARTICLE 13
TERM; TERMINATION

13.1 Term.

This Agreement shall be effective for a period of twenty (20) years from and after the date of the execution of this Agreement, and shall thereafter automatically renew for successive terms of five (5) years unless terminated by either Party unless no less than one year's notice of non-renewal shall be given prior to such 20th year anniversary or any 5th year anniversary thereafter.

13.2 Surviving Obligations.

Expiration of this Agreement shall not (a) affect any other rights of any Party which may have accrued up to the date of such expiration or (b) relieve the Parties from their obligation to pay sums due in respect of POC Rapid Assays delivered prior to expiration of this Agreement. In addition, without limiting the foregoing, the provisions of Article 1, Sections 3.1 (d), 3.2(f), 5.1, 5.2(c) and Articles 6, 7, 9, 11, 12, 13, 14 and 15 shall survive the termination or expiration of this Agreement.

13.3 Events of Default.

The following events shall entitle a Party to terminate this Agreement, upon 30 days written notice to the other:

a) In the event either of the Parties commits a material breach of its respective obligations under this Agreement, and said breach is not cured within ninety (90) days after receipt of a written notice specifying said breach, then the non-breaching Party may terminate this Agreement upon delivery to the breaching Party of a written notice of termination prior to the breach being cured; provided, however, that the Parties shall conduct no less than two Executives' Meetings during such ninety (90) day period;

b) if the other Party ceases for any reason to carryon business (but not as the result of a merger, acquisition or reorganization with one or more entities whether in a single transaction or a series of transactions) or convenes a meeting of its creditors or has a receiver or manager appointed in respect of substantially all of its assets or is the subject of an application for an administration order or of any proposal for a voluntary arrangement or enters into liquidation (whether compulsorily or voluntarily) or undergoes any analogous act or proceedings under the laws of any relevant jurisdiction; or

c) the enactment of any law, order or regulation by a governmental unit that would render it impossible for the other Party to perform its obligations hereunder.

13.4 Expiry: Termination: Consequences.

a) Upon expiry or termination of this Agreement, whichever is sooner (but in the case of termination, only if directed by the terminating Party in the notice of termination), PBM shall manufacture and ship, and SYN.X shall purchase in accordance with the provisions hereof, any and all quantities of POC Rapid Assays ordered by SYN.X pursuant to this Agreement prior to the date on which such notice is given. All amounts owed by SYN.X to PBM up to and including the effective date of termination, shall become immediately due and payable.

b) Expiry or termination of this Agreement shall not relieve the Parties of any obligation accruing prior to the effective date of such expiration or termination.

ARTICLE 14
ARBITRATION

14.1 Binding Arbitration.

Except for issues relating to indemnification, confidentiality, competition and intellectual property rights, or disputes relating to whether the POC Rapid Assays meet the POC Rapid Assay Specifications or the Reagents meet the Reagent Specifications, any and all disputes, controversies, differences, claims or the like between the parties under, arising out of or related to this Agreement, or the performance, enforcement, breach, termination or validity of this Agreement (collectively, "Disputes") which cannot be resolved by mutual agreement among the executives of the Parties shall be submitted to final and binding arbitration in accordance with the terms of this Agreement. Any situation not expressly covered by this Agreement shall be decided in accordance with the UNCITRAL Model Rules of conciliation and arbitration then prevailing. The arbitration shall be commenced when one party serves the other with a written demand to arbitrate. The number of arbitrators shall be 3, one of whom is selected by each of the Parties, and the third to be selected by the other 2 arbitrators.

14.2 Executives' Meetings.

Prior to making any demand for arbitration, the Parties agree that there shall be at least two face to face meetings (each such meeting an "Executives' Meeting") attended by the senior representatives of the Parties. Whenever there shall be a requirement under this Agreement for two Executives' Meetings, at least one of such meeting shall be held being in Toronto or such other place in Canada or the United States as may be designated by SYN.X, and at least one such meetings shall be held in Princeton, or such other place in the United States or Canada as may be designated by PBM.

14.3 Arbitration Location.

Any arbitration initiated by a written demand of PBM shall be conducted in Toronto, Ontario, Canada, or such other place in Canada as shall be agreeable to SYN.X in its sole discretion. Any arbitration initiated by the written demand of SYN.X shall be conducted in Mercer County, New Jersey USA, or such other place in the United States as shall be agreeable to PBM in its sole discretion. The Parties consent to the personal jurisdiction of the courts in each such location for any cause arising out of or otherwise related to this arbitration, its conduct and its enforcement.

14.4 Language of Arbitration.

Any arbitration shall be conducted in the English language and documents and submissions shall be in the English language.

14.5 Choice of Law.

This Agreement will be governed and interpreted in accordance with the laws of the State of New Jersey and the federal laws of the United States applicable therein, without regard to the conflict of laws principles thereof. To the extent to which any judicial proceeding is commenced under this Agreement in accordance with the provisions of Section 14.1 hereof, it shall be brought in the courts of the Province of Ontario, and the Parties attorn to such exclusive jurisdiction of the courts of the Province of Ontario.

14.6 Award Enforcement.

Each Party agrees to abide by the award rendered in any arbitration conducted pursuant to this Article 14 and agrees that the courts may award full faith and credit to such judgment in order to enforce such award.

14.7 Costs.

Each Party shall bear its own legal fees, including costs and expenses.

ARTICLE 15
MISCELLANEOUS

15.1 Use of Name.

No right, express or implied, is granted by this Agreement to any Party to use in any manner the name of the other or any other trade name or trademark of the other in connection with the performance of this Agreement.

15.2 Independent Parties.

The Parties are not employees or legal representatives of the other Parties for any purpose. No Party shall have the authority to enter into any contracts in the name of or on behalf of any other Party.

15.3 English Language.

This Agreement has been prepared in the English language and the English language shall control its interpretation.

15.4 Notice.

All notices required or permitted to be given under this Agreement shall be in writing and deemed to have been received upon the earlier of confirmation of actual receipt and may be sent by (a) hand delivery; (b) overnight courier, or (c) confirmed telecopy, in each case addressed to the address first set forth above.

15.5 Severability.

In the event any provision of this Agreement is held to be invalid or unenforceable, the valid or enforceable portion thereof and the remaining provisions of this Agreement will remain in full force and effect.

15.6 Waiver.

Any waiver (express or implied) by any Party of any breach of this Agreement shall not constitute a waiver of any other or subsequent breach.

15.7 Entire Agreement.

This Agreement and the exhibits attached hereto, constitute the entire, final, complete and exclusive agreement between the Parties and supersede all previous agreements or representations, written or oral, with respect to the subject matter of this Agreement. All information to be kept confidential under any earlier agreements between any Party shall be maintained by the receiving party under the obligations set forth in Article 5 of this Agreement. This Agreement may not be modified or amended except upon mutual agreement of the Parties in writing signed by a duly authorized representative of SYNX and PBM.

The terms and conditions set forth herein constitute the final, complete, exclusive and entire agreement between SYN.X and PBM with respect to the subject matter hereof. Any term or condition in any order, confirmation or other document furnished by SYN.X or PBM which is in any way inconsistent with the terms set forth herein is hereby expressly rejected.

15.8 Assignability: Binding on Successors.

Neither this Agreement nor any of the rights hereunder may be assigned by either Party except upon the prior written consent of the other Party, except in the event of a merger, corporate reorganization, or a sale of all or substantially all of the assets of the business of a party relating to the subject matter hereof. This Agreement shall be binding upon, and inure to the benefit of, the successors, executors, heirs, representatives, administrators and assigns of the Parties hereto.

15.9 Force Majeure.

No Party shall be liable to the other for its failure to perform any of its obligations under this Agreement, except for payment obligations, during any period in which such performance is delayed or does not occur because such performance is rendered impracticable or impossible due to circumstances beyond its reasonable control, including without limitation earthquakes, governmental or regional regulation, fire, flood, labor difficulties, strikes, interruption of supply of key raw materials, civil disorder, and acts of God, provided that the Party experiencing the delay promptly notifies the other Party of the delay; the nature thereof and the extent to which the affected party will be unable to fulfill its obligations hereunder. Each Party further agrees to use reasonable efforts to mitigate the affects of the Force Majeure event as quickly as possible and to give the other prompt written notice when it is again able to fully perform such obligations. Notwithstanding the foregoing, nothing herein shall be deemed to modify the provisions of Articles 2 or 3 hereof.

15.10 Termination as a Result of a Force Majeure Event.

If as a result of a Force Majeure event, a Party is unable to fully perform its obligations hereunder for any consecutive period of 180 days, the other Party shall have the right to terminate this Agreement in its entirety, upon providing written notice to the nonperforming Party, such termination to be effective 30 days from the date hereof.

15.11 Publicity.

No Party will make any announcement or other public announcement concerning the existence and terms of this Agreement without the consent of the other Party, excepting only for such disclosures as may be required by applicable law or regulation.

15.12 Captions.

The Parties agree that the headings in this Agreement are used for the convenience of the Parties only and are not intended to be used in the interpretation of the Agreement.

15.13 Counterparts.

This Agreement may be executed in counterparts with the same force and effect as if each of the signatories had executed the same Instrument. Signatures may be transmitted by facsimile.

IN WITNESS WHEREOF, the Parties have executed this Agreement effective the date first set forth above.

PRINCETON BIOMEDITECH CORPORATION

By: /s/ JEMO KANG

Name: Jemo Kang

SYNXPHARMA, INC.

By: /s/ AARON DAVIDSON

Name: Aaron Davidson

Exhibit 31.1

NANOGEN, INC.

CERTIFICATIONS REQUIRED BY
RULE 13a-14(a) OF THE SECURITIES EXCHANGE ACT OF 1934

CERTIFICATIONS

I, Howard C. Birndorf, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Nanogen, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a 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 by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the registrant and have:

   a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   b) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   c) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

August 16, 2004

/s/ HOWARD C.BIRNDORF

Howard C. Birndorf
Chief Executive Officer

Exhibit 31.2

NANOGEN, INC.

CERTIFICATIONS REQUIRED BY
RULE 13a-14(a) OF THE SECURITIES EXCHANGE ACT OF 1934

CERTIFICATIONS

I, David Ludvigson, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Nanogen, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a 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 by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the registrant and have:

   a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   b) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   c) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

August 16, 2004

/s/ DAVID LUDVIGSON

David Ludvigson
President, Chief Operating Officer, Chief Financial Officer and Treasurer

Exhibit 32.1

NANOGEN, INC.

CERTIFICATIONS REQUIRED BY
RULE 13a-14(a) OF THE SECURITIES EXCHANGE ACT OF 1934

I, Howard C. Birndorf, Chief Executive Officer of Nanogen, Inc., a Delaware corporation (the "Company"), hereby certify that, based on my knowledge:

(1) The Company's Quarterly Report on Form 10-Q for the quarter ended June 30, 2004 (the "Report") fully complies with the requirements of Section 13(a) of the Securities Exchange Act of 1934, as amended; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and result of operations of the Company.

August 16, 2004

/s/ HOWARD C.BIRNDORF

Howard C. Birndorf
Chief Executive Officer

Exhibit 32.2

NANOGEN, INC.

CERTIFICATIONS REQUIRED BY
RULE 13a-14(a) OF THE SECURITIES EXCHANGE ACT OF 1934

I, David Ludvigson, President, Chief Operating Officer, Chief Financial Officer and Treasurer of Nanogen, Inc., a Delaware corporation (the "Company"), hereby certify that, based on my knowledge:

(1) The Company's Quarterly Report on Form 10-Q for the quarter ended June 30, 2004 (the "Report") fully complies with the requirements of Section 13(a) of the Securities Exchange Act of 1934, as amended; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and result of operations of the Company.

August 16, 2004

/s/ DAVID LUDVIGSON

David Ludvigson
President, Chief Operating Officer, Chief Financial Officer and Treasurer