FORM 10-Q

Quarterly report pursuant to sections 13 or 15(d)

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FILER

GEN PROBE INC

CIK:**820237**| IRS No.: **330044608** | State of Incorp.:**DE** | Fiscal Year End: **1231**
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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

(Mark One)

[✓] Quarterly Report Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

For the quarterly period ended June 30, 2004

OR

[ ] Transition Report Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

Commission File Number 0-21872

GEN-PROBE INCORPORATED

(Exact name of registrant as specified in its charter)

Delaware	**33-0044608**
(State or other jurisdiction of incorporation or organization)	*(I.R.S. Employer Identification Number)*

10210 Genetic Center Drive
San Diego, CA 92121
(Address of principal executive offices)

(858) 410-8000
(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 July 30, 2004, there were 49,604,009 shares of the registrant' s common stock, par value $0.0001 per share, outstanding.

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Item 1. Financial Statements

GEN-PROBE INCORPORATED

CONSOLIDATED BALANCE SHEETS

(In thousands, except share and per share data)

	June 30, 2004 (unaudited)	December 31, 2003
Current assets:		
Cash and cash equivalents	$ 27,952	$ 35,973
Short-term investments	164,841	120,333
Trade accounts receivable, net of allowance for doubtful accounts of $714 and $717 at June 30, 2004 and December 31, 2003, respectively	17,827	15,158
Accounts receivable − other	6,939	2,555
Inventories	27,649	15,096
Deferred income taxes	9,490	10,979
Prepaid expenses and other current assets	11,480	8,783
Total current assets	266,178	208,877
Property, plant and equipment, net	67,063	65,478
Capitalized software, net	24,723	24,872
Goodwill	18,621	18,621
Other assets	6,397	6,893
Total assets	$ 382,982	$ 324,741
Current liabilities:		
Accounts payable	10,825	9,250
Accrued salaries and employee benefits	10,579	11,670
Other accrued expenses	5,317	6,085
Income taxes payable	14,218	6,191
Deferred revenue	10,775	6,681
Total current liabilities	51,714	39,877
Deferred income taxes	6,926	6,850
Deferred revenue	5,333	5,667
Deferred rent	313	323
Minority interest	2,013	1,649
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, $.0001 par value per share; 20,000,000 shares authorized, none issued and outstanding	–	–
Common stock, $.0001 par value per share; 200,000,000 shares authorized, 49,590,728 and 48,721,560 shares issued and outstanding at June 30, 2004 and December 31, 2003, respectively	5	5
Additional paid-in capital	228,019	212,586
Deferred compensation	(1,283)	(538)
Accumulated other comprehensive income	474	343
Retained earnings	89,468	57,979
Total stockholders' equity	316,683	270,375
Total liabilities and stockholders' equity	$ 382,982	$ 324,741

See accompanying notes to consolidated financial statements.

GEN-PROBE INCORPORATED

CONSOLIDATED STATEMENTS OF INCOME

(In thousands, except per share data)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2004	2003	2004	2003
Revenues:				
Product sales	$ 52,600	$ 46,299	$ 107,630	$ 89,919
Collaborative research revenue	7,007	3,840	13,738	5,737
Royalty and license revenue	1,618	543	16,343	1,194
Total revenues	61,225	50,682	137,711	96,850
Operating expenses:				
Cost of product sales	13,164	11,055	27,028	23,974
Research and development	15,896	16,422	34,315	27,655
Marketing and sales	6,578	5,892	13,390	10,547
General and administrative	7,476	5,391	14,759	10,017
Total operating expenses	43,114	38,760	89,492	72,193
Income from operations	18,111	11,922	48,219	24,657
Other income (expense):				
Minority interest	(83)	–	(179)	–
Interest income	186	426	1,026	883
Interest expense	(4)	(29)	(13)	(43)
Other income (expense), net	(78)	59	(136)	66
Total other income (expense)	21	456	698	906
Income before income taxes	18,132	12,378	48,917	25,563
Income tax expense	6,371	4,229	17,428	8,760
Net income	$ 11,761	$ 8,149	$ 31,489	$ 16,803
Net income per share[(1)]:				
Basic	$ 0.24	$ 0.17	$ 0.64	$ 0.35
Diluted	$ 0.23	$ 0.17	$ 0.62	$ 0.35
Weighted average shares outstanding[(1)]:				
Basic	49,302	47,650	49,103	47,624
Diluted	51,402	48,466	51,200	48,059

(1) All share and per share amounts reflect the 2-for-1 stock split implemented as a 100% stock dividend in September 2003.

See accompanying notes to consolidated financial statements.

GEN-PROBE INCORPORATED

CONSOLIDATED STATEMENTS OF CASH FLOWS

(In thousands)

	Six Months Ended June 30,	
	2004	2003
Operating activities		
Net income	$ 31,489	$ 16,803
Adjustments to reconcile net income to net cash provided by operating activities:		
Depreciation and amortization	8,361	7,922
Stock compensation charges	199	–
Loss on disposal of property and equipment	27	58
Deferred rent	(10)	1
Stock option income tax benefits	2,220	–
Deferred revenue	3,760	1,789
Deferred income taxes	1,662	153
Minority interest	249	–
Changes in assets and liabilities:		
Accounts receivable	(6,460)	(2,423)
Inventories	(12,546)	(39)
Prepaid expenses and other current assets	(2,696)	(2,244)
Accounts payable	1,565	(989)
Accrued salaries and employee benefits	(1,091)	(740)
Other accrued expenses	(1,412)	(71)
Income taxes payable	8,066	(1,597)
Net cash provided by operating activities	33,383	18,623
Investing activities		
Proceeds from sales and maturities of short-term investments	108,958	22,729
Purchases of short-term investments	(153,173)	(40,663)
Purchases of property, plant and equipment	(8,824)	(6,143)
Capitalization of software development costs	(270)	(983)
Capitalization of patent costs	(284)	(298)
Other assets	(394)	(90)
Net cash used in investing activities	(53,987)	(25,448)
Financing activities		
Proceeds from issuance of common stock	12,269	1,964
Net cash provided by financing activities	12,269	1,964
Effect of exchange rate changes on cash	314	–
Net increase (decrease) in cash and cash equivalents	(8,021)	(4,861)
Cash and cash equivalents at the beginning of the period	35,973	43,118
Cash and cash equivalents at the end of the period	27,952	38,257
Supplemental disclosure of cash flow information:		
Cash paid (received) for:		
Interest	$ 9	$ 37
Income taxes	$ 6,587	$ 10,241

See accompanying notes to consolidated financial statements.

Notes to the Consolidated Financial Statements (unaudited)

Note 1 − Basis of presentation

The accompanying interim consolidated financial statements of Gen-Probe Incorporated ("Gen-Probe" or the "Company") at June 30, 2004, and for the three and six month periods ended June 30, 2004 and 2003, are unaudited and have been prepared in accordance with accounting principles generally accepted in the United States for interim financial information. Accordingly, they do not include all of the information and footnotes required by generally accepted accounting principles for complete financial statements. In management' s opinion, the unaudited financial statements include all adjustments, consisting only of normal recurring accruals, necessary to state fairly the financial information therein, in accordance with generally accepted accounting principles. Interim results are not necessarily indicative of the results which may be reported for any other interim period or for the year ending December 31, 2004.

These unaudited consolidated financial statements and footnotes thereto should be read in conjunction with the audited financial statements and footnotes thereto contained in the Company' s Annual Report on Form 10-K for the year ended December 31, 2003.

Note 2 − Reporting periods

The Company operates and reports on fiscal periods ending on the Friday closest to the end of the month except for year-end, which closes December 31. For ease of presentation, the quarterly reporting periods are deemed to end on March 31, June 30 and September 30. The three months ended March 31, 2004 and six months ended June 30, 2004 included three more business days compared to the same periods in the prior year.

Note 3 − Summary of significant accounting policies

Principles of consolidation

The consolidated financial statements of the Company include the accounts of the Company and its subsidiaries, Gen-Probe Sales and Services, Inc., Gen-Probe Canada, Inc., Gen-Probe UK Limited and Molecular Light Technology Limited and its subsidiaries. All intercompany transactions and balances have been eliminated in consolidation.

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 amounts reported in the consolidated financial statements. These estimates include assessing the collectibility of accounts receivable and the valuation of inventories and long-lived assets. Actual results could differ from those estimates.

Foreign currency translation

The functional currency of the Company' s majority owned subsidiary, Molecular Light Technology Limited and its subsidiaries, is the British pound. Accordingly, all balance sheet accounts of this subsidiary are translated into United States dollars using the exchange rate in effect at the balance sheet date, and revenues and expenses are translated using the average exchange rates in effect during the period. The gains and losses from foreign currency translation of this subsidiary' s financial statements are recorded directly as a separate component of stockholders' equity under the caption "Accumulated other comprehensive income."

Reclassifications

Certain prior year amounts have been reclassified to conform with the current year presentation.

Note 4 − Stock-based compensation

In June 2004, the Company granted 20,000 shares of restricted common stock to its chief executive officer under the 2003 Incentive Award Plan of Gen-Probe Incorporated (the "2003 Plan"), resulting in deferred compensation of $839,000 associated with this grant. The deferred compensation is being amortized to expense over the vesting period of the restricted stock.

The Company measures compensation expense for its employee stock-based compensation using the intrinsic value method and provides pro forma disclosures of net income and earnings per common share as if the fair value methods had been applied in measuring compensation expense. Under the intrinsic value method, compensation cost for employee stock awards is recognized as the excess, if any, of the deemed fair value for financial reporting purposes of the Company' s common stock on the date of grant over the amount an employee must pay to acquire the stock.

Pro forma information regarding net income is required to be disclosed in interim financial statements by Statement of Accounting Standards ("SFAS") No. 148, and has been determined as if the Company had accounted for its employee stock options and employee stock purchase plan under the fair value method of SFAS No. 123. The fair value for employee stock options was estimated at the dates of grant using the minimum value option pricing model from the stock option plan inception date in 2000 through September 15, 2002 and the Black-Scholes pricing model for all option grants made subsequent to that date. The following weighted average assumptions were used:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2004	2003	2004	2003
Risk free interest rate	3.60 %	2.27 %	3.19 %	2.38 %
Dividend yield	0 %	0 %	0 %	0 %
Volatility factor	64 %	50 %	66 %	50 %
Expected life (in years)	4	4	4	4
Resulting average fair value	$20.68	$6.70	$18.64	$6.24

The fair value of each purchase right issued under the Company' s Employee Stock Purchase Plan ("ESPP") for the three and six month periods ended June 30, 2004 and 2003 was estimated on the date of grant using the Black-Scholes pricing model. The following weighted average assumptions were used:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2004	2003	2004	2003
Risk free interest rate	1.0 %	1.0 %	1.0 %	1.0 %
Dividend yield	0 %	0 %	0 %	0 %
Volatility factor	66 %	54 %	59 %	54 %
Expected life (in years)	.50	.20	.50	.20
Resulting average fair value	$6.33	$1.80	$5.46	$1.80

Had compensation expense for stock-based compensation plans been determined based on the fair value method prescribed under SFAS No. 123, the Company' s net income and net income per share would have been as follows (in thousands, except per share data):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2004	2003	2004	2003
Net income:				
As reported	$11,761	$8,149	$31,489	$16,803
Stock-based employee compensation expense included in reported net income, net of related tax effects	33	–	55	–
Total stock based employee compensation expense determined under fair value based method for all awards, net of related tax effects	(2,397)	(234)	(4,289)	(418)
Pro forma net income	$9,397	$7,915	$27,255	$16,385
Net income per share:				
As reported				
Basic	$0.24	$0.17	$0.64	$0.35
Diluted	$0.23	$0.17	$0.62	$0.35
Pro forma				
Basic	$0.19	$0.17	$0.56	$0.34
Diluted	$0.18	$0.16	$0.53	$0.34

The pro forma effects on net income for the three and six month periods ended June 30, 2004 and 2003 are not likely to be representative of the effects on reported net income in future years. In management' s opinion, existing stock option valuation models do not provide a reliable single measure of the fair value of employee stock options that have vesting provisions and are not transferable. In addition, option valuation models require the input of highly subjective assumptions, and changes in such subjective assumptions can materially affect the fair value estimate of employee stock options.

Note 5 − Net income per share

The Company computes net income per share in accordance with SFAS No. 128, "Earnings Per Share," and SEC Staff Accounting Bulletin ("SAB") No. 98. Basic net income per share is computed based on the weighted average number of common shares outstanding during the period. Diluted net income per share is computed based on the weighted average number of shares of common stock and other dilutive securities outstanding during the period. Under the provisions of SAB No. 98, common shares issued for nominal consideration, if any, would be included in the per share calculations as if they were outstanding for all periods presented.

The following table sets forth the computation of net income per share (in thousands, except per share amounts):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2004	2003	2004	2003
Net income	$11,761	$8,149	$31,489	$16,803
Weighted average shares outstanding − Basic	49,302	47,650	49,103	47,624
Effect of dilutive common stock options outstanding	2,100	816	2,097	435
Weighted average shares outstanding − Diluted	51,402	48,466	51,200	48,059
Net income per share:				
Basic	$0.24	$0.17	$0.64	$0.35
Diluted	$0.23	$0.17	$0.62	$0.35

Dilutive securities include common stock options subject to vesting and unvested restricted stock. Potentially dilutive securities totaling 225,636 and 135,564 for the three months ended June 30, 2004 and 2003, and 307,086 and 179,200 shares for the six months ended June 30, 2004 and 2003, respectively, were excluded from the calculation of diluted earnings per share because of their anti-dilutive effect.

Note 6 − Comprehensive income

Comprehensive income is comprised of net income and other comprehensive income (loss), which includes certain changes in stockholders' equity such as foreign currency translation of our majority owned subsidiary' s financial statements and unrealized gains and losses on our available for sale securities.

Components of comprehensive income, net of income taxes, were as follows (in thousands):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2004	2003	2004	2003
Net income	$11,761	$8,149	$31,489	$16,803
Foreign currency translation adjustment	(412)	−	504	−
Change in unrealized gain (loss) on investments	(196)	150	(373)	206
Comprehensive income	$11,153	$8,299	$31,620	$17,009

Note 7 − Inventories

Net inventories are comprised of the following (in thousands):

	June 30, 2004	December 31, 2003
Raw materials	$7,540	$5,874
Work in progress	6,569	3,118
Finished goods	13,540	6,104
	$27,649	$15,096

Note 8 − Stockholders' equity

Number of authorized shares of common stock

On September 5, 2003, the Company' s Board of Directors authorized a two-for-one stock split implemented as a 100% stock dividend, effective September 30, 2003 for holders of record as of September 16, 2003 (the "Stock Split"). As a result of the Stock Split by stock dividend, the number of outstanding shares of the Company' s common stock and the number of shares of the Company' s common stock reserved under its equity compensation plans was doubled. On May 28, 2004, the Company' s stockholders approved an increase in the authorized number of shares of common stock under the Company' s Certificate of Incorporation from 100,000,000 to 200,000,000 shares.

Common stock

During the three and six months ended June 30, 2004, 514,118 and 809,647 options, respectively to purchase shares of the Company' s common stock were exercised by Gen-Probe employees at a weighted average exercise price of $13.42 and $13.22, respectively. The Company also issued 719 and 2,804 shares of restricted common stock at fair market value during the three and six months ended June 30, 2004, respectively to members of the Board of Directors as partial consideration for services rendered, resulting in an expense totaling $34,023 and $106,535, respectively, which was equal to the fair market value on the date of grants. Further, employees purchased 56,717 shares of the Company' s common stock at an average purchase price of $26.92 per share during the six months ended June 30, 2004, pursuant to the Company' s ESPP.

Note 9 - Litigation

The Company is a party to the following litigation and is currently participating in other litigation in the ordinary course of business. The Company intends to vigorously defend its interests in these matters. The Company expects that the resolution of these matters will not have a material adverse effect on its business, financial condition or results of operations. However, due to the uncertainties inherent in litigation, no assurance can be given as to the outcome of these proceedings. If any of these matters were resolved in a manner unfavorable to the Company, its business, financial condition and results of operations would be harmed.

Enzo Biochem, Inc.

In June 1999, the Company was sued by Enzo Biochem, Inc. in the United States District Court for the Southern District of New York. Enzo alleged that the Company and its former affiliates, as well as Becton Dickinson and bioMérieux, have willfully infringed United States patent no. 4,900,659, or the " '659 patent," through the manufacture and sale of products for the diagnosis of gonorrhea. The Company' s former affiliates and bioMérieux have been dismissed from the case by Enzo. The Company and Becton Dickinson remain as defendants. Enzo asserted a damage claim based on a contention that Enzo was entitled to a reasonable royalty on all sales of Gen-Probe products for the detection of *Neisseria gonorrhoeae* bacteria from June 1993 through trial. Revenues from tests for the detection of *Neisseria gonorrhoeae* have constituted a significant portion of Gen-Probe' s revenues during the relevant period. The Company believes that the claims of the '659 patent are invalid, unenforceable and may not be properly interpreted to cover its products. On July 27, 2004, the Court granted summary judgment in favor of the defendants and against Enzo, holding that the '659 patent is invalid based on an on-sale doctrine. Enzo has indicated that it plans to appeal the summary judgment to the United States Court of

Appeals for the Federal Circuit. The Company intends to vigorously defend the lawsuit. However, there can be no assurance that the case will be resolved in the Company' s favor.

Vysis, Inc.

In December 1999, the Company initiated litigation in the United States District Court for the Southern District of California against Vysis, now a subsidiary of Abbott Laboratories, seeking a declaratory judgment that the Company' s products were not covered by a Vysis patent that is the subject of a license granted by Vysis in favor of the Company and that the patent is invalid and unenforceable. In August 2002, following a jury trial, the District Court entered judgment in the Company' s favor, finding the Vysis patent invalid and finding that the patent does not cover Gen-Probe' s products. On September 3, 2002, Vysis filed a notice of appeal with the District Court. Further, on October 22, 2002 while Vysis' appeal was pending, the United States Patent & Trademark Office reissued the Vysis patent with amended claims. On October 22, 2002, the Company filed a second lawsuit in District Court to challenge the validity and scope of the reissued patent. On March 5, 2004, the Court of Appeals vacated the District Court' s August 2002 judgement in favor of the Company and directed the District Court to dismiss the case on the ground of lack of subject matter jurisdiction. The Company' s petition for rehearing and rehearing en banc (with the participation of all the judges) was denied by the Federal Circuit. In accordance with the denial, on July 14, 2004, the District Court dismissed the action with prejudice. The Company intends to file a petition for review by the United States Supreme Court of the lower court' s decision. There can be no assurances as to the final outcome of this litigation. The Company has at all times maintained the license with Vysis in full force and continued to make royalty payments under the license, pending final resolution of the litigation.

Bayer Corporation

In November 2002, the Company filed a demand for arbitration against Bayer Corporation, or Bayer, in the Judicial Arbitration & Mediation Services, Inc., or JAMS, office in San Diego, California related to the Company' s collaboration with Bayer for nucleic acid diagnostic tests for viral organisms. Under the terms of the collaboration agreement, Bayer acquired the exclusive right to distribute nucleic acid diagnostic tests designed and developed by Gen-Probe for the detection of HIV, hepatitis viruses and other specified viruses, subject to certain conditions. Gen-Probe' s demand for arbitration states that Bayer has failed to fulfill the conditions required to maintain exclusive distribution rights. The arbitration demand seeks confirmation that the agreement grants Gen-Probe, in the present circumstances, a co-exclusive right to directly distribute the viral diagnostic tests that are the subject of the agreement. Gen-Probe' s arbitration demand also seeks money damages due to Bayer' s failure to use commercially reasonable efforts to promote, market and sell viral diagnostic assays developed by Gen-Probe. In November 2003, Bayer filed a counterclaim for money damages based on alleged delays in the development of the TIGRIS system, alleged delays in the development of certain assays, and other claims. Bayer Healthcare LLC has also been added as a respondent and counterclaimant. The matter has been set for hearing beginning September 13, 2004. There can be no assurances as to the final outcome of the arbitration.

On March 17, 2004, the Company filed a patent infringement action in the United States District Court for the Southern District of California against Bayer Corporation and Bayer Healthcare LLC, alleging that Bayer' s bDNA nucleic acid tests for HIV and HCV infringe Gen-Probe' s U.S. patent no. 5,955,261, entitled "Method for Detecting the Presence of Group-Specific Viral mRNA in a Sample." Bayer' s bDNA tests are not covered by the collaboration agreement between the companies. Bayer has denied the allegations of infringement and alleged that the patent is invalid or unenforceable. No trial date has been set. There can be no assurances as to the final outcome of the litigation.

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

This report contains "forward-looking" statements within the meaning of the Private Securities Litigation Reform Act of 1995, which provides a "safe harbor" for these types of statements. To the extent statements in this report involve, without limitation, our expectations for growth, estimates of future revenue, expenses, profit, cash flow, balance sheet items or any other guidance on future periods, these statements are forward-looking statements. Forward-looking statements are not guarantees of performance. They involve known and unknown risks, uncertainties and assumptions that may cause actual results, levels of activity, performance or achievements to differ materially from any results, level of activity, performance or achievements expressed or implied by any forward-looking statement. We assume no obligation to update any forward-looking statements.

The following information should be read in conjunction with our June 30, 2004 consolidated financial statements and related notes thereto and with our consolidated financial statements and notes thereto for the year ended December 31, 2003 and the related "Management' s Discussion and Analysis of Financial Condition and Results of Operations" contained in our Annual Report on Form 10-K for the year ended December 31, 2003. We also urge you to review and consider our disclosures describing various risks that may affect our business, which are set forth under the heading "Risk Factors" in this report and in our Annual Report on Form 10-K for the

year ended December 31, 2003.

Overview

We are a global leader in the development, manufacture and marketing of rapid, accurate and cost-effective nucleic acid probe-based products used for the clinical diagnosis of human diseases and for the screening of donated human blood. We have over 21 years of nucleic acid detection research and product development experience, and our products, which are based on our patented nucleic acid testing, or NAT, technology, are used daily in clinical laboratories and blood collection centers in major countries throughout the world.

In September 2002, our common stock began trading on the Nasdaq National Market immediately after our former parent company, Chugai Pharmaceutical Co., Ltd. distributed all of its shares of our common stock to its shareholders. Since our spin-off into an independent, publicly traded company, we have achieved strong growth in both revenues and earnings due principally to the success of our blood screening products which are used to detect the presence of human immunodeficiency virus (type 1), or HIV-1, and hepatitis C virus, or HCV. Under our collaboration agreement with Chiron Corporation, or Chiron, we are responsible for the research, development, regulatory process and manufacturing of our blood screening products, while Chiron is responsible for marketing, sales, distribution and service.

During the three and six months ended June 30, 2004, we achieved strong financial results. Net income for the six month period ended June 30, 2004 was $31.5 million ($0.62 per diluted share), compared to $16.8 million ($0.35 per diluted share) in the same period of the prior year, an increase of 77% per diluted share. Total revenues for the six month period ended June 30, 2004 were $137.7 million, compared to $96.9 million in the same period of the prior year, an increase of 42%. Product sales for the period ended June 30, 2004 were $107.6 million, compared to $89.9 million in the same period of the prior year, an increase of 20%. During the six month period ended June 30, 2004, net income and total revenues included a contract milestone with Chiron and a license fee earned in connection with our cross-licensing agreement with Tosoh Corporation, or Tosoh. These amounts added approximately $0.17 to diluted earnings per share and $13.5 million to revenues.

Recent Events

The launch of the Tigris system was slower than expected early in the year, but picked up speed in the second quarter. Between assay revenues and instrument sales, we remain on track to achieve $5 million or more in TIGRIS-related revenue this year.

Clinical trials of the Procleix Ultrio blood screening assay on both the semi-automated and TIGRIS systems have been completed on schedule. Gen-Probe remains on track to file a Biologics License Application (BLA) for the assay in the third quarter of 2004.

The pivotal clinical trial of the Procleix WNV assay began on schedule in July 2004, and we remain on track to file a BLA for the assay in the first quarter of 2005. So far this mosquito season, the assay has intercepted 42 confirmed West Nile virus, or WNV, infected blood donations in nine states through ongoing screening under an Investigational New Drug, or IND. In addition, Gen-Probe expects to begin IND testing of the Procleix WNV assay on the fully automated TIGRIS system in August.

We successfully completed the process of transferring DiagnoCure' s first-generation assay for prostate cancer detection onto our APTIMA technology platform, and development work is proceeding well.

We have completed clinical trials to evaluate APTIMA Combo 2 to test for *Chlamydia trachomatis* and *Neisseria gonorrhoeae* from both Cytyc Corporation' s and TriPath Imaging Inc.' s liquid Pap transport media. The Pap test remains the most widely used screening test in the United States for the early detection of cervical cancer. Approximately 50 million Pap tests are performed annually in the United States, 80% of which are liquid-based. Testing for *Chlamydia trachomatis* and *Neisseria gonorrhoeae* from the liquid Pap medium would offer patients, physicians and laboratories convenient testing for several diseases from one sample, and further differentiate the superior performance of APTIMA Combo 2 in the widest range of specimen types. We intend to file for United States regulatory clearance later this year.

In December 2003, we signed a cross-licensing agreement with Tosoh, effective January 1, 2004, for certain NAT technologies in clinical diagnostics and other related fields. Under the agreement, we earned a $7.0 million license fee during the three months ended March 31, 2004.

In January 2004, we began United States clinical trials of the Procleix Ultrio assay on the fully automated, high-throughput TIGRIS instrument system, triggering a $6.5 million contract milestone payment from Chiron that we recognized during the three months ended March 31, 2004. During January 2004, the Procleix Ultrio assay, running on our semi-automated instrument system, received its

Community European, or CE, mark, which permitted Chiron to launch the product in the European Economic Area.

Revenues

We derive revenues from three primary sources: product sales, collaborative research revenue and royalty and license revenue. The majority of our revenues come from product sales, which consist primarily of sales of our NAT assays tested on the proprietary instruments that serve as the analytical platform for our assays. We recognize as collaborative research revenue payments we receive from Chiron for the products we provided under our collaboration agreements with Chiron prior to their regulatory approval and the payments we receive from Chiron, Bayer Corporation, or Bayer, and other collaboration partners, including the National Institutes of Health, or NIH, for research and development activities. Our royalty and license revenues reflect fees paid to us by third parties for the use of our proprietary technology. For the six months ended June 30, 2004, product sales, collaborative research revenues, and royalty and license revenues equaled 78%, 10% and 12%, respectively, of our total revenues of $137.7 million. For the same period in the prior year, product sales, collaborative research revenues, and royalty and license revenues, equaled 93%, 6% and 1%, respectively, of our total revenues of $96.9 million.

Product sales

Our primary source of revenue is the sale of clinical diagnostic products in the United States, which include our APTIMA Combo 2, PACE 2, AccuProbe and Amplified Mycobacterium Tuberculosis Direct Test product lines. During the six months ended June 30, 2004, we shipped approximately 10.8 million tests for the diagnosis of a wide variety of infectious microorganisms, including those causing sexually transmitted diseases, or STDs, tuberculosis, strep throat, pneumonia and fungal infections. The principal customers for our clinical diagnostics products include large reference laboratories, public health laboratories and hospitals located in North America, Europe and Japan.

Since 1999, we have supplied NAT assays for use in screening blood donations intended for transfusion. Our first blood screening assay detects HIV-1 and HCV in donated human blood. Our blood screening assays and instruments are marketed through our collaboration with Chiron under the Procleix and Ultrio trademarks. We recognize product sales from the manufacture and shipment of tests for screening donated blood, through our collaboration with Chiron, to blood bank facilities located in the countries where our products have obtained governmental approvals at a contractual transfer price. Blood screening product sales are then adjusted monthly corresponding to Chiron' s payment to us of amounts reflecting our ultimate share of net revenue from sales by Chiron to the end user, less the transfer price revenues previously recorded. Net sales are ultimately equal to the sales of the assays by Chiron to third-parties, less freight, duty and certain other adjustments specified in our agreement with Chiron, multiplied by our share of the net revenue, which was 43.0% with respect to sales of assays that include a test for HCV beginning the second quarter of 2002 upon implementation of commercial pricing, through April 6, 2003, after which our share of net revenues from sales of assays that include a test for HCV was adjusted to 47.5%. Effective January 1, 2004, our share of net revenues from commercial sales of assays that include a test for HCV was permanently changed to 45.75% under our agreement with Chiron. With respect to commercial sales of blood screening assays under our collaboration with Chiron that do not include a test for HCV, such as possible future commercial tests for WNV, we will continue to receive reimbursement for our manufacturing costs plus 50% of net revenues. Our costs related to these products primarily include manufacturing costs.

Collaborative research revenue

We have developed a NAT assay to detect HIV-1 and HCV in donated human blood and have also developed a semi-automated instrument system to conduct the test. These assays and instruments are marketed through our collaboration with Chiron under the Procleix name. In February 2002, the Food and Drug Administration, or FDA, approved the Procleix HIV-1/HCV assays.

In March 2003, we signed a definitive agreement with Chiron for the development and commercialization of the Procleix Ultrio assay. For the six month periods ended June 30, 2004 and 2003, we recognized $1.3 million and $2.8 million, respectively in reimbursements for expenses incurred related to the development of this assay. In January 2004, we commenced clinical trials of the Procleix Ultrio assay in the United States on our TIGRIS instrument. We have also developed a NAT assay to detect WNV, which is currently being used in clinical trials under an IND application. We expect to receive further reimbursement for certain costs incurred during the development of the Procleix Ultrio and WNV assays from Chiron and separately from the National Heart, Lung, and Blood Institute, a part of the NIH.

We have recorded revenues related to use of our blood screening products in the United States and other countries in which the

products have not received regulatory approval as collaborative research revenue, because price restrictions applied to these products prior to FDA license approval in the United States and similar approvals in foreign countries. For the six months ended June 30, 2004, we recognized $9.2 million in collaborative research revenue through our collaboration with Chiron from deliveries of WNV tests on a "cost recovery" basis. We expect to continue recognizing these sales as collaborative research revenue until FDA approval has been received, although there is no guarantee we ultimately will receive FDA approval.

Since 1996, we have been awarded contracts aggregating approximately $28.2 million by the NIH to develop NAT assays for screening donated blood for HIV-1, HCV, hepatitis B virus, or HBV, and WNV. To date, all payments due to us under these reimbursement contracts have been received and have been recorded as collaborative research revenues as reimbursable costs were incurred. As of June 30, 2004, the Company had approximately $0.2 million in reimbursements remaining under this contract, which will be recognized during the third quarter of 2004 as expenses are incurred.

We recognize collaborative research revenue over the term of our strategic alliance agreement with Chiron as reimbursable costs are incurred. The costs associated with the reported collaborative research revenue are reflected in our statements of income under the captions "Research and development," "Marketing and sales" and "General and administrative," based on the nature of the costs. We do not separately track the costs applicable to the blood screening development collaboration with Chiron and, therefore, are not able to quantify the direct costs associated with the collaborative research revenue.

Collaborative research revenue tends to fluctuate based on the amount of research services performed, delivery of assays on a "cost recovery" basis and the status of projects under collaboration. Due to the nature of our collaborative research revenues, results in any one period are not necessarily indicative of results to be achieved in the future. Our ability to generate additional collaborative research revenues depends, in part, on our ability to initiate, maintain and perform under relationships with potential and current collaborative partners. These relationships may not be established or maintained and current collaborative research revenue may decline.

Royalty and license revenue

We recognize non-refundable up-front license fees over the performance period of the applicable agreement or at the time that we have satisfied all substantive performance obligations under such agreement. We also receive milestone payments for successful achievement of contractual development activities. Milestone payments are recognized as revenue upon achievement of the milestone only if there are no remaining substantive performance obligations under such agreement and the amounts are non-refundable.

In December 2003, we entered into an agreement with Tosoh to cross-license intellectual property covering certain NAT technologies. The licenses, which were effective January 1, 2004, cover products in clinical diagnostics and other related fields. Under the agreement, Tosoh received non-exclusive rights to our proprietary Transcription-Mediated Amplification, or TMA, and rRNA technologies in exchange for two payments totaling $7.0 million, which was recognized as revenue in the first quarter of 2004. Additionally, Tosoh will pay us royalties on worldwide sales of any future products that employ our technologies licensed by Tosoh. We will gain access, in exchange for the payment of royalties, to Tosoh' s patented Transcription Reverse-Transcription Concerted, or TRC, amplification and Intercalation Activating Fluorescence, or INAF, detection technologies for use with our real time TMA technology.

Under the strategic alliance agreement we entered into with Chiron in June 1998, we have responsibility for research, development and manufacturing of the blood screening products covered by the agreement, while Chiron has responsibility for marketing, distribution and service of the blood screening products worldwide. During the first quarter of 2004, the Company recognized as royalty and license revenue, a $6.5 million milestone payment, as the Company began clinical trial tests of the Procleix Ultrio assay on the TIGRIS instrument in the United States. Additional payments of up to $10.0 million are due to us in the future under the agreement if we achieve certain other specified milestones relating to the development of the TIGRIS instrument. There is no guarantee we will receive any additional milestone payments under this agreement.

Royalty and license revenue may fluctuate in the future based on the nature of the related agreements and the timing of receipt of license fees and achievement of research and development milestones. Results in any one period are not necessarily indicative of results to be achieved in the future. In addition, our ability to generate additional royalty and license revenues will depend, in part, on our ability to market and capitalize on our technologies. We may not be able to continue to do so in the future and future royalty and license revenue may decline.

Cost of product sales

Cost of product sales includes direct material, direct labor, and manufacturing overhead associated with the production of inventory

on a standard cost basis. Indirect cost elements, which include manufacturing variances, purchase price variances, and allowances for scrap, etc., are also included as a component of cost of product sales, as well as certain related expenses, such as royalties, warranty, and instrument amortization.

In addition, we manufacture significant quantities of raw materials, development lots, and clinical trial lots of product prior to receiving FDA approval for commercial sale. During the six month periods ended June 30, 2004 and 2003, our manufacturing facilities produced development lots for WNV and Procleix Ultrio assays. The majority of the costs associated with these development lots are classified as research and development expense. The portion of a development lot that is manufactured to support In-Vitro Diagnostic, or IVD, sales abroad is capitalized and classified as cost of sales upon shipment.

Our blood screening manufacturing facility has operated below its capacity and will continue to operate below its capacity for the foreseeable future. A portion of this available capacity has been utilized for research and development activities, as new product offerings are identified for commercialization. As a result certain operating costs of our blood screening facility, together with other manufacturing costs for the production of pre-commercial development lot assays that are delivered under the terms of an IND application, are classified as research and development expense prior to FDA approval.

Effective January 1, 2004, our revenue sharing percentage with Chiron was decreased, from 47.5% to 45.75%. This change, combined with higher instrument costs, including the amortization of our capitalized software development costs (which we began to amortize in the second quarter of 2004) and related service costs attributed to the planned general commercial launch of our TIGRIS instrument, may result in lower future gross margin percentage levels. In addition, our non-military customers currently utilize pooled blood screening samples for testing. We anticipate that requirements for smaller pool sizes or ultimately individual donor testing, if and when implemented, could result in lower gross margin rates, as additional tests would be required to deliver the sample results, unless a corresponding increase in sales pricing is implemented. We are not able to accurately predict the extent to which our gross margin may be affected as a result of smaller pool sizes or individual donor testing because we do not know the ultimate selling price that Chiron, our distributor, would charge to the end user if smaller pool sizes or individual donor testing is implemented.

Research and development

We invest significantly in research and development as part of our ongoing efforts to accelerate the development of new products and technologies, particularly our TIGRIS instrument and our Procleix Ultrio and WNV assays for screening donated blood. Our research and development expenses consist of expenses associated with the development of proprietary products and instrument platforms, as well as expenses related to the co-development of new products and technologies in collaboration with our strategic partners. Research and development costs in total are expected to increase in the future due to new product development, clinical trial costs and clinical manufacturing costs; however, we expect our research and development expenses as a percentage of total revenues to decline in future years. The timing of clinical trials and development manufacturing costs is variable and is affected by product development activities and the regulatory process.

In connection with our research and development efforts, we have various license agreements, which provide us with rights to develop and market products using certain technologies and patent rights maintained by third parties. These agreements generally provide for a term that commences upon execution of the agreement and continues until expiration of the last patent related to the technologies covered by the license.

Research and development costs include the costs of raw materials, development lots and clinical trial lots of products that we manufacture. These costs are dependent on the status of projects under development and may vary substantially between quarterly or annual reporting periods. During the remainder of 2004, we expect to incur additional incremental costs associated with the manufacture of developmental lots and clinical trial lots for our blood screening products and with the TIGRIS instrument. Collaborative research revenues, if any, associated with these types of incurred costs have typically been realized in a period later than when incurred.

Critical accounting policies and estimates

Our discussion and analysis of our financial condition and results of operations is based on our consolidated financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States. The preparation of these financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, revenues and expenses and related disclosure of contingent assets and liabilities. On an ongoing basis, we evaluate our estimates, including those related to revenue recognition, the collectibility of accounts receivable, valuation of inventories, long-lived assets including patent costs

and capitalized software and income taxes. We base our estimates on historical experience and on various other assumptions that are believed to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities. Senior management has discussed the development, selection and disclosure of these estimates with the Audit Committee of our Board of Directors. Actual results may differ from these estimates under different assumptions or conditions.

We believe there have been no significant changes to our critical accounting policies and estimates as disclosed in Management' s Discussion and Analysis of Financial Condition and Results of Operations in our Annual Report on Form 10-K for the year ended December 31, 2003, except for the item(s) discussed below.

Capitalized software costs

We capitalize costs incurred in the development of computer software related to products under development after establishment of technological feasibility. These capitalized costs are recorded at the lower of unamortized cost or net realizable value and are amortized over the estimated life of the related product.. At June 30, 2004, capitalized software development costs related to our TIGRIS instrument totaled $24.7 million, net. We completed beta evaluations of this instrument for clinical diagnostic applications and undertook initial beta trials for blood screening applications in the third quarter of 2002 and we completed a clinical trial for a diagnostic application in June 2003. In December 2003, we received approval from the FDA for testing certain STDs on the TIGRIS instrument. We initiated clinical trials of our Procleix Ultrio assay on the TIGRIS instrument for a blood screening application in January 2004. If we are not able to successfully deliver this instrument to the marketplace and attain customer acceptance, the asset could be impaired and an adjustment to the carrying value of this asset would be considered by management at that time.

In accordance with SFAS No. 86, "Accounting for the Costs of Computer Software to Be Sold, Leased, or Otherwise Marketed," we began amortizing the capitalized software costs on a straight-line basis over 120 months during the second quarter of 2004, coinciding with the general release of TIGRIS instruments to our customers.

Results of Operations

The following table sets forth operating data as a percentage of total revenues on a comparable basis for the three and six month periods ended June 30, 2004 and 2003. The information for each of these periods is unaudited and has been prepared in accordance with accounting principles generally accepted in the United States for interim financial information. In the opinion of management, all necessary adjustments, consisting only of normal recurring accruals, have been included to fairly present the unaudited quarterly results when read in conjunction with our audited financial statements and related notes. Past operating results are not necessarily indicative of future results.

The following table sets forth unaudited operating data as a percentage of total revenues:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2004	2003	2004	2003
Total revenues	100 %	100 %	100 %	100 %
Product sales	86 %	91 %	78 %	93 %
Collaborative research revenue	11 %	8 %	10 %	6 %
Royalty and license revenue	3 %	1 %	12 %	1 %
Operating expenses:				
Cost of product sales	22 %	22 %	19 %	25 %
Research and development	26 %	32 %	25 %	29 %
Marketing and sales	11 %	12 %	10 %	11 %
General and administrative	12 %	11 %	11 %	10 %
Total operating expenses	71 %	77 %	65 %	75 %
Income from operations	29 %	23 %	35 %	25 %
Total other income (expense)	0 %	1 %	1 %	1 %
Income before income taxes	29 %	24 %	36 %	26 %
Income tax expense	10 %	8 %	13 %	9 %
Net income	19 %	16 %	23 %	17 %

Three Months Ended June 30, 2004 Compared to Three Months Ended June 30, 2003
(Percentages have been rounded to the nearest whole percentage)

Product sales

Product sales increased $6.3 million, or 14%, to $52.6 million during the three months ended June 30, 2004, from $46.3 million in the same period of the prior year. The increase was primarily the result of a $3.6 million increase in worldwide commercial sales of our Procleix blood screening products, a $1.1 million increase in STD product sales, primarily APTIMA, and a $1.6 million increase in sales of other diagnostic products. Procleix blood screening product sales represented $22.1 million, or 42% of product sales, for the three months ended June 30, 2004, compared to $18.5 million, or 40% of product sales, for the three months ended June 30, 2003.

We expect competitive pressures related to our STD and blood screening products to continue into the foreseeable future, primarily as a result of the introduction of competing products into the market and continuing pricing pressure, particularly with our STD products.

Collaborative research revenue

Collaborative research revenue increased $3.2 million, or 84%, to $7.0 million during the three months ended June 30, 2004, from $3.8 million in the same period of the prior year. The increase was primarily the result of a $4.7 million increase in firm support commitment payments in connection with the WNV tests provided to United States customers through our collaboration with Chiron. This increase was partially offset by a $0.6 million decrease in revenue for reimbursement from Chiron of our development costs incurred on the Procleix Ultrio assay and a $0.6 million decrease in revenue from the NIH to develop a NAT assay for the detection of WNV.

Royalty and license revenue

Royalty and license revenue increased $1.1 million to $1.6 million in the three months ended June 30, 2004, from $0.5 in the same period of the prior year. The increase was attributed to a $1.1 million increase in net license income from Bayer for the licensing of rights to certain patented technology.

Cost of product sales

Cost of product sales increased $2.1 million to $13.2 million, or 25% of product sales in the three months ended June 30, 2004, from $11.1 million, or 24% of product sales, in the same period of the prior year. The $2.1 million increase in cost of sales was principally attributed to the volume increase in product sales and the amortization of capitalized software development costs related to our TIGRIS instrument during the period. Cost of product sales may fluctuate significantly in future periods based on changes in production volumes for both commercially approved products and products under development or in clinical trials. Cost of product sales are also affected by manufacturing efficiencies, allowances for scrap or obsolete materials, additional costs related to initial production quantities of new products after achieving FDA approval, and contractual adjustments, such as instrumentation costs, instrument service costs and royalties.

Our gross profit margin on product sales decreased to 75% in the three months ended June 30, 2004, from 76% in the same period of the prior year due, in part, to the amortization of capitalized software development costs of $0.4 million, which began in the second quarter of 2004.

Research and development

Our research and development expenses include salaries and other personnel-related expenses, temporary personnel expenses, outside services, laboratory and manufacturing supplies, pre-commercial development lots and clinical evaluation trials. Research and development expenses decreased $0.5 million to $15.9 million, or 26% of total revenues, in the three months ended June 30, 2004, from $16.4 million, or 32% of total revenues, in the same period of the prior year. The decrease was primarily the result of a $4.5 million decrease in inventory used due to lower development lot production, which was partially offset by a $2.5 million increase in expenses resulting from higher staffing levels to support product development projects and a $1.1 million increase in expenses related to clinical trials for blood bank.

Marketing and sales

Our marketing and sales expenses include personnel costs, promotional expenses, and outside services. Marketing and sales expenses increased $0.7 million to $6.6 million, or 11% of total revenues, in the three months ended June 30, 2004, from $5.9 million, or 12% of total revenues, in the same period of the prior year. The increased spending principally included expenses to support increases in sales of our clinical diagnostic products, including a $0.2 million increase for printing and promotional costs related to the marketing of TIGRIS.

General and administrative

Our general and administrative expenses include personnel costs for finance, legal, public relations, human resources and business development, as well as professional fees, such as expenses for legal, patents and auditing services. General and administrative expenses increased $2.1 million to $7.5 million, or 12% of total revenues, in the three months ended June 30, 2004, from $5.4 million, or 11% of total revenues, in the same period of the prior year. The increased spending included a $1.1 million increase in expenses resulting from higher staffing levels, including expenses from our majority owned subsidiary, Molecular Light Technology Limited (acquired in August 2003), and a $0.6 million increase in patent and legal related expenses, primarily related to the ongoing Bayer arbitration.

Total other income (expense)

Other income (expense) generally consists of investment and interest income offset by interest expense on borrowing, minority interest, and other items. The net other income of $21,000 in the three months ended June 30, 2004 represented a $435,000 decrease from the net other income of $456,000 in the same period of the prior year. The decrease was primarily due to realized market losses in our investment portfolio of government bonds, coinciding with our recent shift in investment emphasis from U.S. Treasury bonds to tax free municipal bonds, bond interest rates increased approximately 100 basis points during the second quarter of 2004, resulting in market losses for lower yield bonds as they were sold. If these available for sale securities had been held to maturity, most of these realized market losses would have been recorded through stockholders' equity as other comprehensive income or loss. The Company expects to achieve a long term benefit with the tax free securities.

Income tax expense

Income tax expense increased to $6.4 million, or 35% of pretax income, in the three months ended June 30, 2004, from $4.2 million, or 34% of pretax income, in the same period of the prior year. The increased effective tax rate in 2004 is attributed to higher profits taxed at the combined Federal and state statutory tax rate of approximately 41%, partially offset by the benefit of Federal and state research and investment credits.

Six Months Ended June 30, 2004 Compared to Six Months Ended June 30, 2003
(Percentages have been rounded to the nearest whole percentage)

Product sales

Product sales increased $17.7 million, or 20%, to $107.6 million during the six months ended June 30, 2004, from $89.9 million in the same period of the prior year. The increase was primarily the result of a $10.1 million increase in worldwide commercial sales of our Procleix blood screening products, a $5.5 million increase in STD product sales, primarily APTIMA, and a $2.1 million increase in sales of our other diagnostic products. Procleix blood screening product sales represented $45.1 million, or 42% of product sales, for the six months ended June 30, 2004, compared to $35.0 million, or 39% of product sales, for the six months ended June 30, 2003.

Collaborative research revenue

Collaborative research revenue increased $8.0 million, or 140%, to $13.7 million during the six months ended June 30, 2004, from $5.7 million in the same period of the prior year. The increase was primarily the result of a $9.2 million increase in firm support commitment payments in connection with the WNV tests provided to United States customers through our collaboration with Chiron. Further, we recognized $0.5 million additional revenues from the NIH to develop a NAT assay for the detection of WNV. These increases were partially offset by a $1.5 million decrease in revenue for reimbursement from Chiron of our development costs incurred on the Procleix Ultrio assay. We recognized $1.3 million in revenue during the first quarter of 2003 for work performed during 2002 and 2001 in connection our collaboration with Chiron.

Royalty and license revenue

Royalty and license revenue increased $15.1 million to $16.3 million in the six months ended June 30, 2004, from $1.2 million in the same period of the prior year. The increase was attributed to $7.0 million in license fees earned from Tosoh as part of our non-exclusive licensing agreement relating to NAT technologies effective in January 2004, and $6.5 million in milestone revenue from Chiron as the Company began clinical trial testing in the United States of the Procleix Ultrio assay on the fully automated TIGRIS instrument. Additionally, we recognized $1.5 million in net license income from Bayer during the six months ended June 30, 2004 for the licensing of rights to certain patented technology.

Cost of product sales

Cost of product sales increased $3.0 million to $27.0 million, or 25% of product sales, in the six months ended June 30, 2004, from $24.0 million, or 27% of product sales, in the same period of the prior year. The $3.0 million increase in cost of sales was principally attributed to the volume increase in product sales and the amortization of capitalized software development costs.

Our gross profit margin on product sales increased to 75% in the six months ended June 30, 2004, from 73% in the same period of the prior year. The gross profit margin benefited from certain manufacturing costs absorbed by research and development for the production of pre-commercial development lots, partially offset by amortization of the TIGRIS instrument capitalized software which began in the second quarter of 2004.

Research and development

Our research and development expenses include salaries and other personnel-related expenses, temporary personnel expenses, outside services, laboratory and manufacturing supplies, pre-commercial development lots and clinical evaluation trials. Research and development expenses increased $6.6 million to $34.3 million, or 25% of total revenues, in the six months ended June 30, 2004, from $27.7 million, or 29% of total revenues, in the same period of the prior year. The increased spending was primarily the result of a $5.1 million increase in expenses resulting from higher staffing levels to support product development projects, a $2.0 million increase in expenses related to clinical trials for blood screening products and a $0.8 million increase in research and development expenses from our subsidiary, Molecular Light Technology Limited (acquired in August 2003), partially offset by a $1.6 million decrease in the unit costs of clinical lots produced for our WNV project.

Marketing and sales

Our marketing and sales expenses include personnel costs, promotional expenses, and outside services. Marketing and sales expenses increased $2.8 million to $13.4 million, or 10% of total revenues, in the six months ended June 30, 2004, from $10.5 million, or 11% of total revenues, in the same period of the prior year. The increased spending principally included a $2.1 million increase in salaries, benefits, commissions and other personnel related costs in our marketing and sales force to support increases in sales for our clinical diagnostic products, together with a $0.4 million increase for advertising and promotional costs related to the marketing of our TIGRIS instrument.

General and administrative

Our general and administrative expenses include personnel costs for finance, legal, public relations, human resources and business development, as well as professional fees, such as expenses for legal, patents and auditing services. General and administrative expenses increased $4.8 million to $14.8 million, or 11% of total revenues, in the six months ended June 30, 2004, from $10.0 million, or 10% of total revenues, in the same period of the prior year. The increased spending included a $2.3 million increase in expenses resulting from higher staffing levels, including expenses from our majority owned subsidiary, Molecular Light Technology Limited (acquired in August 2003), and a $1.7 million increase in patent and legal related expenses, primarily related to the ongoing Bayer arbitration.

Total other income (expense)

Other income (expense) generally consists of investment and interest income offset by interest expense on borrowing, minority interest, and other items. The net other income of $698,000 in the six months ended June 30, 2004 represented a $208,000 decrease from the net other income of $906,000 in the same period of the prior year. The decrease was primarily due to a $179,000 increase in minority interest expense from our subsidiary, Molecular Light Technology Limited, and a $115,000 decrease in realized foreign exchange rate losses from our sales to Canadian customers.

Income tax expense

Income tax expense increased to $17.5 million, or 36% of pretax income, in the six months ended June 30, 2004, from $8.8 million, or 34% of pretax income, in the same period of the prior year. The increased effective tax rate in 2004 is attributed to higher profits taxed at the combined Federal and state statutory tax rate of approximately 41%, partially offset by the benefit of Federal and state research and investment credits.

Liquidity and capital resources

Historically, we have financed our operations through cash from operations, cash received from collaborative research agreements, royalty and license fees, the private placement of debt and cash from capital contributions. At June 30, 2004, we had $192.8 million of cash and cash equivalents and short-term investments.

For the six months ended June 30, 2004, net cash provided by operating activities was $33.4 million, compared to $18.6 million in the same period of the prior year. The increase in net cash during the six months ended June 30, 2004 was principally the result of net income of $31.5 million, depreciation and amortization of $8.4 million and an $8.1 million increase in income taxes payable, partially offset by a $6.5 million increase in accounts receivable and a $12.5 million increase in inventory.

Our investing activities, which used cash of $54.0 million for the six months ended June 30, 2004, consisted of purchases, net of proceeds of $44.2 million for short-term investments and $8.8 million for capital expenditures. Our expenditures for capital additions vary based on the stage of development projects and may increase in the future related to the timing of development of new product opportunities and to support expansion of our facilities in connection with those opportunities. The average age of our property, plant and equipment is approximately five years, which gives us flexibility in planning capital expenditures.

Net cash provided by financing activities for the six months ended June 30, 2004, was the result of $12.3 million in proceeds from stock option exercises and purchases made through our Employee Stock Purchase Plan, or ESPP. Cash from financing activities will be affected by receipts from sales of stock under our ESPP and from the exercise of stock options. We expect fluctuations to occur throughout the year, as the amount and frequency of stock-related transactions are dependent upon the market performance of our common stock, together with other factors.

We have an unsecured bank line of credit agreement with Wells Fargo Bank, N.A., which expires in July 2005, under which we may borrow up to $10.0 million, subject to a “borrowing base formula,” at the bank’ s prime rate, or at LIBOR plus 1.0%. We have not taken advances against the line of credit since its inception. The line of credit agreement requires us to comply with various financial and restrictive covenants. Financial covenants include requirements as to tangible net worth, liabilities as a percentage of tangible net worth, the ratio of current assets to current liabilities, required minimum levels of earnings before interest, taxes, depreciation and amortization, the ratio of funded debt to earnings before interest, taxes, depreciation and amortization, and maximum levels of pre-tax and after tax losses. At December 31, 2003 and June 30, 2004, we were in compliance with all covenants and had no outstanding borrowings under this line of credit.

In July 2004, we commenced the construction of an additional building at our Genetic Center Drive location. This new building will consist of an approximately 291,000 square foot outside shell, with approximately 160,000 square feet built out with interior improvements. The additional space that will not initially be built out will allow for future expansion. The first phase of this project is estimated to take two years for completion and is currently estimated to cost approximately $45.0 million. These costs will be capitalized as incurred and depreciation will commence upon our completion and use, which is planned for early 2006.

We plan to implement a new Enterprise Resource Planning, or ERP, software system, which currently is estimated to represent an approximately $6.5 to $8.0 million expenditure. The majority of these costs will be capitalized and amortization will commence upon our placement of the new ERP system into service, which is currently planned for January 2005.

Further, we expect to incur approximately $10.0 million to purchase TIGRIS instruments that will be added to our installed base during 2004.

Contractual obligations and commercial commitments

In connection with the joint development of the Procleix HIV-1/HCV assay, and as a condition for Chiron' s agreement to pay for most of the clinical trial costs related to approval of that assay, we agreed to pay the costs related to the clinical trial for the next joint development project with Chiron. Our obligation is limited to the cost incurred for the previous joint clinical trial, which was approximately $4.1 million. As of June 30, 2004, we had incurred approximately $3.7 million of clinical trial expenses as a result of this obligation to Chiron and we anticipate that our obligation to pay these costs will satisfied during the second half of 2004.

In November 2003, we entered into a license and collaboration agreement with DiagnoCure under which we agreed to develop in collaboration with DiagnoCure, and we agreed to market, a test to detect a new gene marker for prostate cancer. Under the terms of the agreement, we agreed to pay DiagnoCure an upfront fee of $3.0 million, and future fees and contract development payments of up to $7.5 million over the next three years.

Our primary short-term needs for capital, which are subject to change, are for continued research and development of new products, costs related to commercialization of blood screening products and purchases of the TIGRIS instruments for placement with our customers. Certain research and development costs are funded under collaboration agreements with partners or agencies of the United States government. We anticipate additional funds from these sources as reimbursable costs are incurred, but these funds may not materialize and these relationships may not continue.

We believe that our available cash balances, anticipated cash flows from operations and available line of credit will be sufficient to satisfy our operating needs for the foreseeable future. However, we operate in a rapidly evolving and often unpredictable business environment that may change the timing or amount of expected future cash receipts and expenditures. Accordingly, we may in the future be required to raise additional funds through the sale of equity or debt securities or from additional credit facilities. Additional capital, if needed, may not be available on satisfactory terms, if at all. Furthermore, additional debt financing may contain more restrictive covenants than our existing debt.

We may from time to time consider the acquisition of businesses and/or technologies complementary to our business. We could require debt and/or equity financing if we were to engage in a material acquisition in the future. In August 2003, we filed a Form S-3 shelf registration statement with the SEC relating to the possible future sale of up to an aggregate of $150 million of debt and/or equity securities.

Risk Factors

The following information sets forth facts that could cause our actual results to differ materially from those contained in forward-looking statements we have made in this Quarterly Report and those we may make from time to time.

Our quarterly revenue and operating results may vary significantly in future periods and our stock price may decline.

Our operating results have fluctuated in the past and are likely to continue to do so in the future. Our revenues are unpredictable and may fluctuate due to changes in demand for our products, the timing of the execution of customer contracts and the initiation or termination of corporate collaboration agreements. Our product revenues, particularly in bloodscreening, may vary significantly from quarter to quarter based upon fluctuations in blood donations and reportable bloodscreening results. A significant portion of our costs also can vary substantially between quarterly or annual reporting periods. For example, the total amount of research and development costs in a period often depends on the amount of research and development costs we incur in connection with manufacturing developmental lots and clinical trial lots. We incurred substantial costs of manufacturing these lots in 2003 and the first half of 2004 and will continue to incur expense through the remainder of 2004 and beyond as we seek FDA approval of our Procleix Ultrio assay and the WNV assay. Moreover, a variety of factors may affect our ability to make accurate forecasts regarding our operating results. For example, our blood screening products and some of our clinical diagnostic products, such as APTIMA Combo 2, have a relatively limited sales history, which limits our ability to project future sales accurately. Our share of revenue from commercial sales of assays that test for HCV under our blood screening collaboration with Chiron decreased to 45.75% of net revenues as of January 1, 2004, as a result of the recent amendment to our collaboration agreement with Chiron. In addition, we base our internal projections of our international sales on projections prepared by our distributors of these products. Because of all of these factors, our operating results in one or more future quarters may fail to meet or exceed financial guidance we may provide from time to time and the expectations of

securities analysts or investors, which could cause our stock price to decline.

We are dependent on Chiron and other third parties for the distribution of some of our products. If any of our distributors terminates its relationship with us or fails to adequately perform, our product sales will suffer.

We rely on Chiron to distribute our blood screening products and Bayer to distribute some of our viral clinical diagnostic products. Commercial product sales by Chiron accounted for 33% of our total revenues for the six months ended June 30, 2004 and 37% of our total revenues for 2003. Our agreements with Chiron and Bayer will terminate in 2010 unless extended. Both the Chiron and Bayer agreements can be extended by the development of new products under the agreements, in which case they will expire upon the later of the end of the original term or five years after the first commercial sale of the last new product developed during the original term.

In February 2001, we commenced an arbitration proceeding against Chiron in connection with our blood screening collaboration. The arbitration related primarily to the propriety of various deductions from gross revenues made by Chiron prior to calculating Gen-Probe' s share of revenues and the parties' respective shares of revenues received from The American Red Cross prior to FDA approval of the Procleix HIV-1/HCV blood screening assay. Other disputed items included the parties' respective obligations in connection with clinical trials of the Procleix HIV-1/HCV blood screening assay and future assays, Chiron' s obligation to purchase blood screening assays in compliance with its forecasts and the parties' respective obligations with respect to royalties to be paid on a patent license from a third party. By December 2001, we negotiated a resolution to most of the disputed items, and in January 2002, we received $6.9 million in partial settlement of the claims. In the event that we or Chiron commence arbitration against each other in the future under the collaboration agreement, proceedings could delay or decrease our receipt of revenue from Chiron or otherwise disrupt our collaboration with Chiron, which could cause our revenues to decrease and our stock price to decline.

In November 2002, we initiated an arbitration proceeding against Bayer in connection with our clinical diagnostic collaboration. Under the terms of the collaboration agreement, Bayer acquired the exclusive right to distribute nucleic acid diagnostic tests designed and developed by us for the detection of HIV, hepatitis virus and other specified viruses, subject to specific conditions. Our demand for arbitration stated that Bayer has failed to fulfill the conditions required to maintain exclusive distribution rights. Accordingly, we are seeking confirmation that the agreement grants us, in the present circumstances, a co-exclusive right to directly distribute the viral diagnostic tests that are the subject of the agreement. Our arbitration demand also seeks money damages due to Bayer' s failure to use commercially reasonable efforts to promote, market and sell viral diagnostic assays developed by us. In November 2003, Bayer filed a counterclaim for money damages based on alleged delays in the development of the TIGRIS instrument and certain assays, and other claims. The matter has been set for hearing beginning on September 13, 2004. There can be no assurances as to the final outcome of the arbitration.

We rely upon bioMérieux for distribution of some of our products in most of Europe, Rebio Gen, Inc. for distribution of some of our products in Japan and various independent distributors for distribution of our products in other regions. Our distribution agreement with bioMérieux terminates on May 1, 2006, although it may terminate earlier under certain circumstances. The distribution rights revert back to Gen-Probe upon termination. Our distribution agreement with Rebio Gen, terminates on December 31, 2005.

If any of our distribution or marketing agreements is terminated, particularly our agreement with Chiron, and we are unable to enter into an alternative agreement or if we elect to distribute our products directly, we would have to invest in additional sales and marketing resources, including additional field sales personnel, which would significantly increase future selling, sales and marketing and general and administrative expenses. We may not be able to enter into new distribution or marketing agreements on satisfactory terms, or at all. If we fail to enter into acceptable distribution or marketing agreements or fail to market successfully our products, our product sales would decrease.

If we cannot maintain our current corporate collaborations and enter into new corporate collaborations, our product development could be delayed. In particular, any failure by us to maintain our collaboration with Chiron with respect to blood screening would have a material adverse effect on our business.

We rely, to a significant extent, on our corporate collaborators for the joint development and marketing of our products. If any of our corporate collaborators were to breach or terminate its agreement with us or otherwise fail to conduct their collaborative activities successfully and in a timely manner, the pre-clinical or clinical development or commercialization and subsequent marketing of the products contemplated by the collaboration could be delayed or terminated. We cannot control the amount and timing of resources our corporate collaborators devote to our programs or potential products. In addition, we expect to rely on our corporate collaborators for the commercialization of some of our products.

The continuation of any of our collaboration agreements may depend on the periodic renewal of our corporate collaborations. Our agreements with Chiron and Bayer will terminate in 2010 unless extended by the development of new products under the agreements, so that they will expire upon the later of the original term or five years after the first commercial sale of the last new product developed during the original term. Both collaboration agreements are also subject to termination prior to expiration upon a material breach by either party to the agreement.

If any of our collaboration agreements is terminated, or if we are unable to renew those collaborations on acceptable terms, we would be required to devote additional internal resources to product development or marketing or to terminate some development programs or seek alternative corporate collaborations. We may not be able to negotiate additional corporate collaborations on acceptable terms, if at all, and these collaborations may not be successful.

Market demand for our new TIGRIS instrument may be difficult to predict. If we are unable to deliver and support the TIGRIS instrument, we may be unable to retain our existing customers and attract new customers.

We believe the fully-automated TIGRIS instrument offers significant economic and technical advantages to customers. However, the TIGRIS instrument will be more expensive for customers to purchase or lease than our existing semi-automated instrument systems. The comparatively higher cost of this new instrument makes it difficult to accurately predict market demand. Because the commercial launch of the TIGRIS instrument is currently underway for use with our APTIMA Combo 2 assay, we do not have a history of TIGRIS instrument sales or leases on which to accurately base predictions of market demand.

Additionally, diagnostic instruments as innovative and complex as the TIGRIS instrument may require frequent service during the period of their initial introduction. We expect to bear the expense of such service costs for most customers. We do not have a history of providing service for TIGRIS instruments and our service costs will depend upon the ultimate reliability of the instrument in the field.

We face intense competition, and our failure to compete effectively could decrease our revenues and harm our profitability and results of operations.

The clinical diagnostics industry is highly competitive. Currently, the majority of diagnostic tests used by physicians and other health care providers are performed by large reference laboratories, public health laboratories and hospitals. We expect that these laboratories will compete vigorously to maintain their dominance in the diagnostic testing market. In order to achieve market acceptance of our products, we will be required to demonstrate that our products provide accurate, cost-effective and time saving alternatives to tests performed by traditional laboratory procedures and products made by our competitors.

In the markets for clinical diagnostic products, a number of competitors, including F. Hoffmann-La Roche Ltd. and its subsidiary, Roche Molecular Diagnostics, Inc., Abbott Laboratories, Becton Dickinson and Company and bioMérieux S.A., compete with us for product sales, primarily on the basis of technology, quality, reputation, accuracy, ease of use, price, reliability, the timing of new product introductions and product line offerings. In markets outside of the United States, other factors, including local distribution systems, complex regulatory environments and differing medical philosophies and product preferences, influence competition as well. Some of our competitors have, and in the future these and other competitors may have, significantly greater financial, marketing, sales, manufacturing, distribution and technological resources than us. Moreover, these companies may have substantially greater expertise in conducting clinical trials and research and development, greater ability to obtain necessary intellectual property licenses and greater brand recognition than we do. In addition, we have licensed some of our proprietary technology relating to certain clinical diagnostic and food pathogen applications for use on specific instruments to bioMérieux, and we may license other technologies to potential competitors in the future. As a result, we may in the future compete with bioMérieux and these other licensees for sales of products incorporating our technology. Our competitors may be in a stronger position to respond quickly to new or emerging technologies, may be able to undertake more extensive marketing campaigns, may adopt more aggressive pricing policies and may be more successful in attracting potential customers, employees and strategic partners than we are.

While our current products incorporate end-point detection methods, we believe that our competitors are developing “real time” or kinetic nucleic acid assays and are developing semi-automated instrument systems to perform real time assays. Our competitors may be further in the development process with respect to such assays and instrumentation then we are.

In the market for blood screening products, our primary competitor is Roche Molecular Systems, which received FDA approval of its Polymerase Chain Reaction, or PCR, based NAT tests for blood screening in December 2002. We also compete with assays developed internally by blood banks and laboratories based on PCR technology, an HCV antigen assay marketed by Ortho Clinical Diagnostics, a subsidiary of Johnson & Johnson, and immunoassay products from Abbott Laboratories. In the future, our blood screening products also may compete with viral inactivation technologies and blood substitutes.

Chiron, with whom we have entered into a collaboration agreement for our blood screening products, retains certain rights to grant licenses of the patents related to HCV and HIV to third parties in blood screening. Chiron has granted HIV and HCV licenses to Roche Molecular Systems in the blood screening and clinical diagnostics fields. Chiron has granted HIV and HCV licenses in the clinical diagnostic field to Bayer Healthcare LLC, which also has the right to grant certain additional HIV and HCV sublicenses in the field to third parties. Chiron has granted an HCV license to Abbott and an HIV license to Organon Teknika (now bioMeriuex). To the extent that Chiron grants additional licenses in blood screening or Bayer grants additional licenses in clinical diagnostics, further competition will be created for sales of HCV and HIV assays and these licenses could affect the prices that can be charged for our products.

Our profit margin on the sale of blood screening assays may decrease upon the implementation of individual donor testing.

We currently receive revenues from the sale of the Procleix HIV-1/HCV blood screening assay for use with pooled donor samples. In pooled testing, multiple donor samples are initially screened by a single test, however, Chiron sells our Procleix HIV-1/HCV assay to blood collection centers on a per donation basis. We expect the blood screening market to ultimately transition from pooled testing to individual donor testing. A greater number of tests will be required for individual donor testing than are now required for pooled testing. Under our collaboration agreement with Chiron, we bear the cost of manufacturing our Procleix HIV-1/HCV assay. The greater number of tests required for individual donor testing will increase our variable manufacturing costs, including costs of raw materials and labor. If the price per donor or total sales volume does not increase in line with the increase in our total variable manufacturing costs, our gross profit margins from sales of the blood screening assay may decrease upon the adoption of individual donor testing. We are not able to accurately predict the extent to which our gross profit margin may be negatively affected as a result of individual donor testing because we do not know the ultimate selling price that Chiron would charge to the end user if individual donor testing were implemented.

Because we depend on a small number of customers for a significant portion of our total revenues, the loss of any of these customers or any cancellation or delay of a large purchase by any of these customers could significantly reduce our revenues.

Historically, a limited number of customers has accounted for a significant portion of our total revenues, and we do not have any long-term commitments with these customers other than our collaboration agreement with Chiron. Our blood screening collaboration with Chiron accounted for 46% of our total revenues for the six months ended June 30, 2004 and 42% of our total revenues for 2003. Our blood screening collaboration with Chiron is largely dependent on two large customers in the United States, The American Red Cross and America' s Blood Centers, although we did not receive any revenues directly from those entities. Chiron was our only customer that accounted for greater than 10% of our total revenues for the six months ended June 30, 2004. In addition, Quest Diagnostics Incorporated, Laboratory Corporation of America Holdings and various state and city public health agencies accounted for an aggregate of 18% of our total revenues for the six months ended June 30, 2004 and 21% of our total revenues for 2003. Although state and city public health agencies are legally independent of each other, they tend to act similarly with respect to their product purchasing decisions. We anticipate that our operating results will continue to depend to a significant extent upon revenues from a small number of customers. The loss of any of our key customers, or a significant reduction in sales to those customers, could significantly reduce our revenues.

The intellectual property rights on which we rely to protect the technologies underlying our products may be inadequate to prevent third parties from using our technologies or developing competing products.

Our success will depend in part on our ability to obtain patent protection for, or maintain the secrecy of, our proprietary products, processes and other technologies for development of blood screening and clinical diagnostic products and instruments. Although we have 184 United States patents and 160 foreign patents, these patents, or any patents that we may own or license in the future, may not afford meaningful protection for our technology and products. The pursuit and assertion of a patent right, particularly in areas like nucleic acid diagnostics and biotechnology, involve complex determinations and, therefore, are characterized by substantial uncertainty. In addition, the laws governing patentability and the scope of patent coverage continue to evolve, particularly in biotechnology. As a result, patents might not issue from certain of our patent applications or from applications licensed to us. In addition, all of our existing patents will expire by May 1, 2021, and the patents we may obtain in the future also will expire over time.

The scope of any of our issued patents may not be broad enough to offer meaningful protection. In addition, others may challenge our current patents or patents we may obtain in the future and, as a result, these patents could be narrowed, invalidated or rendered unenforceable, or we may be forced to stop using the technology covered by these patents or to license technology from third parties. Moreover, the laws of some foreign countries may not protect our proprietary rights to the same extent as do the laws of the United States. Any patents issued to us or our strategic partners may not provide us with any competitive advantages, and the patents held by other parties may limit our freedom to conduct our business or use our technologies. Our efforts to enforce and maintain our intellectual

property rights may not be successful and may result in substantial costs and diversion of management time. Even if our rights are valid, enforceable and broad in scope, competitors may develop products based on technology that is not covered by our patents.

In addition to patent protection, we also rely on copyright and trademark protection, trade secrets, know-how, continuing technological innovation and licensing opportunities. In an effort to maintain the confidentiality and ownership of our trade secrets and proprietary information, we require our employees, consultants, advisors and others to whom we disclose confidential information to execute confidentiality and proprietary information agreements. However, it is possible that these agreements may be breached, invalidated or rendered unenforceable, and if so, there may not be an adequate corrective remedy available. Furthermore, like many companies in our industry, we may from time to time hire scientific personnel formerly employed by other companies involved in one or more areas similar to the activities we conduct. In some situations, our confidentiality and proprietary information agreements may conflict with, or be subject to, the rights of third parties with whom our employees, consultants or advisors have prior employment or consulting relationships. Although we require our employees and consultants to maintain the confidentiality of all confidential information of previous employers, we or these individuals may be subject to allegations of trade secret misappropriation or other similar claims as a result of their prior affiliations. Finally, others may independently develop substantially equivalent proprietary information and techniques, or otherwise gain access to our trade secrets. Our failure to protect our proprietary information and techniques may inhibit or limit our ability to exclude certain competitors from the market and execute our business strategies.

The diagnostic products industry has a history of patent and other intellectual property litigation, and we may be involved in costly intellectual property lawsuits.

The diagnostic products industry has a history of patent and other intellectual property litigation, and these lawsuits likely will continue. Because we produce and provide many different products and services in this industry, we have faced in the past, are currently facing, and may face in the future, patent infringement suits by companies that control patents for similar products and services or other suits alleging infringement of their intellectual property rights. In order to protect or enforce our intellectual property rights, we may have to initiate legal proceedings against third parties. Legal proceedings relating to intellectual property typically are expensive, take significant time and divert management' s attention from other business concerns. The cost of this litigation could adversely affect our results of operations, making us less profitable. Further, if we do not prevail in an infringement lawsuit brought against us, we might have to pay substantial damages, including treble damages, and we could be required to stop the infringing activity or obtain a license to use the patented technology.

We have been involved in a number of patent disputes with third parties, a number of which remain unresolved. Most recently, in February 2004, we filed a patent infringement action in the United States District Court for the Southern District of California alleging that Bayer' s bDNA nucleic acid tests for HIV and HCV infringe certain of our patents. In addition, we are in litigation with Enzo Biochem Inc. which claims that genetic sequences used in certain of our gonorrhea testing products infringe one of its patents. We are also in litigation with Vysis, Inc. regarding the validity of a Vysis' patent that Vysis asserts covers the target capture technology that we employ in some of our amplified NAT assays.

We may be subject to future product liability claims that may exceed the scope and amount of our insurance coverage, which would expose us to liability for uninsured claims.

While there is a federal preemption defense against product liability claims for medical products that receive premarket approval from the FDA, we believe that no such defense is available for our products that we market under a 510(k) clearance. As such, we are subject to potential product liability claims as a result of the design, development, manufacture and marketing of our clinical diagnostic products. Any product liability claim brought against us, with or without merit, could result in the increase of our product liability insurance rates. In addition, we would have to pay any amount awarded by a court in excess of our policy limits. Our insurance policies have various exclusions, and thus we may be subject to a product liability claim for which we have no insurance coverage, in which case, we may have to pay the entire amount of any award. In addition, insurance varies in cost and can be difficult to obtain, and we may not be able to obtain insurance in the future on terms acceptable to us, or at all. A successful product liability claim brought against us in excess of our insurance coverage, may require us to pay substantial amounts, which could harm our business and results of operations.

The adoption of the Financial Accounting Standards Board SFAS No. 142, "Goodwill and Other Intangible Assets" as of January 1, 2002 could adversely affect our future results of operations and financial position.

In June 2001, the Financial Accounting Standards Board issued SFAS No. 142, "Goodwill and Other Intangible Assets," which we adopted effective on January 1, 2002. Under the new rules, goodwill and intangible assets deemed to have indefinite lives will no longer be amortized but will be subject to annual impairment tests in accordance with the Statement. As of June 30, 2004, we had goodwill and

intangible assets valued at approximately $49.5 million, including $24.7 million of capitalized software relating to the TIGRIS instrument, which we began amortizing during the second quarter of 2004, and $6.2 million of capitalized patents and purchased intangibles that have been included in "Other assets" on the face of our balance sheet. At December 31, 2003, we performed our annual impairment tests of goodwill and indefinite lived intangible assets to determine if an impairment charge should be recognized under SFAS No. 142 and determined that there had been no impairments at that time. In the future, we will continue to test for impairment at least annually. These tests may result in a determination that the assets have been impaired. If at any time we determine that an impairment has occurred, we will be required to reflect the impaired value as a charge, resulting in a reduction in earnings in the quarter such impairment is identified and a corresponding reduction in our net asset value. A material reduction in earnings resulting from such a charge could cause us to fail to be profitable in the period in which the charge is taken or otherwise to fail to meet the expectations of investors and securities analysts, which could cause the price of our stock to decline.

Our future success will depend in part upon our ability to enhance existing products and to develop and introduce new products.

The market for our products is characterized by rapidly changing technology, evolving industry standards and new product introductions, which may make our existing products obsolete. Our future success will depend in part upon our ability to enhance our existing products and to develop and introduce new products, such as our NAT assay to detect WNV. For example, we believe that we will need to continue to provide new products that can detect a greater number of organisms from a single sample. We also believe that we must develop new assays that can be performed on automated instrument platforms, such as the TIGRIS instrument.

The development of new or enhanced products is a complex and uncertain process requiring the accurate anticipation of technological and market trends, as well as precise technological execution. In addition, the successful development of new products will depend on the development of new technologies. We will be required to undertake time-consuming and costly development activities and to seek regulatory approval for any new products. We may experience difficulties that could delay or prevent the successful development, introduction and marketing of these new products. Regulatory clearance or approval of any new products may not be granted by the FDA or foreign regulatory authorities on a timely basis, or at all, and the new products may not be successfully commercialized.

We expect to continue to incur significant research and development expenses, which may make it difficult for us to maintain profitability.

In recent years, we have incurred significant costs in connection with the development of our blood screening products and the TIGRIS instrument. We expect our expense levels to remain high in connection with our research and development as we continue to expand our product offerings and continue to develop products and technologies in collaboration with our strategic partners. As a result, we will need to continue to generate significant revenues to maintain profitability. Although we expect our research and development expenses as a percentage of revenue to decrease in future years, we may not be able to generate revenues and may not maintain profitability in the future. Our failure to maintain profitability in the future would cause the market price of our common stock to decline.

We may not have financing for future capital requirements, which may prevent us from addressing gaps in our product offerings or improving our technology.

Although historically our cash flow from operations has been sufficient to satisfy working capital, capital expenditure and research and development requirements, in the future we may need to incur additional debt or issue equity in order to fund these requirements as well as to make acquisitions and other investments. If we cannot obtain additional debt or equity financing on acceptable terms or are limited with respect to incurring additional debt or issuing equity, we may be unable to address gaps in our product offerings or improve our technology, particularly through strategic acquisitions or investments.

We may need to raise substantial amounts of money to fund a variety of future activities integral to the development of our business, including but not limited to the following:

for research and development to successfully develop our new technologies and products,

to conduct clinical trials,

to obtain regulatory approval for new products,

to file and prosecute patent applications and defend and assert patents to protect our technologies,

to retain qualified employees, particularly in light of intense competition for qualified scientists and engineers,

to manufacture additional products ourselves or through third parties,

to market different products to different markets, either through building our own sales and distribution capabilities or relying on third parties, and

to acquire new technologies, products or companies.

If we raise funds through the issuance of debt or equity, including without limitation through the issuance of equity or debt securities pursuant to our Form S-3 shelf registration statement that we filed on August 29, 2003 with the Securities and Exchange Commission relating to the possible future sale of up to an aggregate of $150 million of debt or equity securities, any debt securities or preferred stock issued will have rights, preferences and privileges senior to those of holders of our common stock in the event of a liquidation and may contain other provisions that adversely effect the rights of the holders of our common stock. The terms of the debt securities may impose restrictions on our operations. If we raise funds through the issuance of equity or debt convertible into equity, this issuance would dilute your ownership interest in us.

We expect to fund future acquisitions in part by issuing additional equity. If the price of our equity is unacceptably low or volatile due to market volatility or other factors, we may not be able to acquire other companies.

We have only one third-party manufacturer for each of our instrument product lines, which exposes us to increased risks associated with delivery schedules, manufacturing capability, quality assurance, quality and costs.

We have one third-party manufacturer for each of our instrument product lines. KMC Systems is our only manufacturer of the TIGRIS instrument. MGM Instruments, Inc. is the only manufacturer of our LEADER series of luminometers. We are dependent on these third-party manufacturers, and this dependence exposes us to increased risks associated with delivery schedules, manufacturing capability, quality control, quality assurance and costs. We have no firm long-term commitments from KMC Systems, MGM Instruments or any of our other manufacturers to supply products to us for any specific period, or in any specific quantity, except as may be provided in a particular purchase order. If KMC Systems, MGM Instruments or any of our other third-party manufacturers experiences delays, disruptions, capacity constraints or quality control problems in its manufacturing operations or becomes insolvent, then product shipments to our customers could be delayed, which would decrease our revenues and harm our competitive position and reputation.

Further, our business would be harmed if we fail to manage effectively the manufacturing of our products. Because we place orders with our manufacturers based on our forecasts of expected demand for our products, if we inaccurately forecast demand, we may be unable to obtain adequate manufacturing capacity or adequate quantities of components to meet our customers' delivery requirements, or we may accumulate excess inventories.

We may in the future need to find new contract manufacturers to increase our volumes or to reduce our costs. We may not be able to find contract manufacturers that meet our needs, and even if we do, qualifying a new contract manufacturer and commencing volume production is expensive and time consuming. For example, qualifying a new manufacturer of our TIGRIS instrument would take approximately twelve months. If we are required or elect to change contract manufacturers, we may lose revenues, and our customer relationships may suffer.

If we or our contract manufacturers are unable to manufacture our products or our instrument products in compliance with regulatory requirements, in sufficient quantities, on a timely basis and at acceptable costs, or fail to develop new or replacement systems, our ability to sell our products will be harmed.

We must manufacture our products in compliance with regulatory requirements, in sufficient quantities and on a timely basis, while maintaining product quality and acceptable manufacturing costs. Significant additional work will be required for scaling-up manufacturing of each new product prior to commercialization, and we may not successfully complete this work. Manufacturing and quality control problems have arisen and may arise as we attempt to scale-up our manufacturing of a new product, and we may not achieve scale-up in a timely manner or at a commercially reasonable cost, or at all. In addition, although we expect some of our newer products and products under development to share production attributes with our existing products, production of these newer products may require the development of new manufacturing technologies and expertise.

In addition, the amplified NAT tests that we are producing are significantly more expensive to manufacture than our non-amplified products. As we continue to develop new amplified NAT tests in response to market demands for greater sensitivity, our product costs will increase significantly. We sell our products in a number of cost-sensitive market segments, and we may not be able to manufacture these more complex amplified tests at costs that would allow us to maintain our historical gross margins. In addition, new products that detect more than one target organism will contain significantly more complex reagents, which will increase the cost of our manufacturing processes and quality control testing. We or other parties we engage to help us may not be able to manufacture these products at a cost or in quantities that would make these products commercially viable. If we are unable to develop or contract for manufacturing capabilities on acceptable terms for our products under development, we will not be able to conduct pre-clinical and clinical testing on these product candidates, which will prevent or delay regulatory clearance or approval of these product candidates and the initiation of new development programs.

Our blood screening products must be manufactured in compliance with guidelines set forth by the FDA' s Center for Biologics Evaluation and Research, and our clinical diagnostic products must be manufactured in compliance with the guidelines set forth by the FDA' s Center for Devices and Radiological Health. Maintaining compliance with more than one division of the FDA adds complexity and cost to our overall manufacturing processes. In addition, our manufacturing facilities and those of our contract manufacturers are subject to periodic regulatory inspections by the FDA and other federal and state regulatory agencies, and these facilities are subject to Quality System Regulations requirements of the FDA. We or our contractors may fail to satisfy these regulatory requirements in the future, and any failure to do so may prevent us from selling our products.

We distribute instrument systems to be used by our customers in performing our diagnostic assays. These instrument systems have a limited life and may become obsolete over time. For example, our MultiProbe instruments that we have placed with our customers are no longer supported by the manufacturer, and new MultiProbe instruments, while available, are not suitable for our customers. In the future, we intend to develop an instrument to replace the MultiProbe for our lower volume customers. We continue to support our current MultiProbe instruments through our own inventories of parts and used instruments. If we are unable to develop or acquire new instrument systems to replace our existing systems as they become obsolete, we may lose assay product sale revenues and our business may suffer.

Our products are subject to recalls even after receiving FDA approval or clearance.

The FDA and similar governmental authorities in other countries have the authority to require the recall of our products if we fail to comply with relevant regulations pertaining to laboratory practices, product manufacturing, labeling, advertising, or promotional activities, or if new information is obtained concerning the safety of a product. A government-mandated recall, or a voluntary recall by us, could divert managerial and financial resources and harm our reputation with customers.

In the past, we have had four voluntary recalls. The first product recall occurred in September 1999, when we responded to customer complaints about an increase in the number of our Mycobacterium Tuberculosis Direct, or MTD, assays demonstrating inhibition by test specimens. The formulation problem was identified and corrected. The second recall occurred in February 2000 when we recalled our MTD product due to decreased stability of a reagent in certain kit lots. The problem was identified and rectified. The third recall occurred in July 2002 following the discovery of an error in the Chiron Procleix System software used with the Procleix HIV-1/HCV blood screening assay and instruments. A review of prior test results determined that the defect did not cause any inaccurate results. The problem was rectified in a subsequent software update, which was submitted to and approved by the FDA. The fourth voluntary recall occurred in June 2004 for our MTD product. This customer notification by us was due to decreased stability of a reagent in certain kit lots. The problem was identified and rectified through updated raw material specifications. Our products may be subject to additional recalls in the future and we may not be able to identify and correct the problems leading to recalls in all circumstances.

Our sales to international markets are subject to additional risks.

Sales of our products outside the United States accounted for 14% of our total revenues for the six months ended June 30, 2004 and 13% of our total revenues for all of 2003. Sales by Chiron outside of the United States accounted for 44% of our international revenues for the six months ended June 30, 2004 and 58% of our international revenues for all of 2003. Chiron has responsibility for the international distribution of our blood screening products, which includes sales in France, Australia, Singapore, New Zealand, Italy and other countries. Our sales in France and Japan that were not made through Chiron accounted for 12% and 7%, respectively, of our international sales for the six months ended June 30, 2004 and 16% and 10%, respectively, for all of 2003.

We expect a significant portion of our sales growth, especially with respect to our blood screening products, to come from expansion

in international markets. Accordingly, we encounter risks inherent in international operations. Other than Canada, our sales are currently denominated in United States dollars, if the value of the United States dollar increases relative to foreign currencies, our products could become less competitive in international markets. Our international sales also may be limited or disrupted by:

the imposition of government controls,

export license requirements,

economic and political instability,

price controls,

trade restrictions and tariffs,

differing local product preferences and product requirements, and

changes in foreign medical reimbursement and coverage policies and programs.

In addition, we may have difficulty introducing new products in international markets. For example, we do not believe our blood screening products will be widely adopted in Germany until we are able to offer an assay that screens for HBV, HAV, and parvo B19, as well as HIV-1 and HCV, or in Japan until we are able to offer an assay that screens for HBV, HIV-1 and HCV. Whenever we seek to enter a new international market, we will be dependent on the marketing and sales efforts of our international distributors.

We believe that the international markets for our products are important, and therefore we seek patent protection for our products in foreign countries where we feel such protection is needed. Because of the differences in foreign patent and other laws concerning proprietary rights, our products may not receive the same degree of protection in foreign countries as they would in the United States.

If third-party payors do not reimburse our customers for the use of our products or reduce reimbursement levels, our ability to sell our products profitably will be harmed.

We sell our products primarily to large reference laboratories, public health laboratories and hospitals. Large reference laboratories and hospitals receive reimbursement for the health care services they provide to their patients from third-party payors, such as Medicare, Medicaid and other domestic and international government programs, standard state funding, private insurance plans and managed care programs. Most of these third-party payors may deny reimbursement if they determine that a medical product was not used in accordance with cost-effective treatment methods, as determined by the third-party payor, or was used for an unapproved indication. Third-party payors also may refuse to reimburse for experimental procedures and devices.

Third-party payors' reimbursement policies also may affect sales of our products that screen for more than one pathogen at the same time, such as our APTIMA Combo 2 product for screening for the causative agents of chlamydial infections and gonorrhea in the same sample. Third-party payors may choose to reimburse our customers on a per test basis, rather than on the basis of the number of results given by the test. This may result in laboratories and hospitals electing to use separate tests to screen for each disease so that they can receive reimbursement for each test they conduct. In that event, laboratories and hospitals likely would purchase separate tests for each disease, rather than our products that test for more than one microorganism.

In addition, third-party payors are increasingly attempting to contain health care costs by limiting both coverage and the level of reimbursement for medical products and services. Levels of reimbursement may decrease in the future, and future legislation, regulation or reimbursement policies of third-party payors may adversely affect the demand for and price levels of our products. If our customers are not reimbursed for our products, they may reduce or discontinue purchases of our products, which would cause our revenues to decline.

Disruptions in the supply of raw materials from our single source suppliers, including the Roche Molecular Biochemicals division of Roche Diagnostics GmbH, which is an affiliate of one of our primary competitors, could result in a significant disruption in sales and profitability.

We purchase some key raw materials used in the manufacture of our products from single-source suppliers. We may not be able to

obtain supplies from replacement suppliers on a timely or cost-effective basis. For example, our current supplier of key raw materials for our amplified NAT assays, pursuant to a fixed-price contract, is the Roche Molecular Biochemicals division of Roche Diagnostics GmbH, an affiliate of Roche Molecular Systems, which is one of our primary competitors and the purchaser of Boehringer-Mannheim GmbH, with whom we had originally contracted for supplies. A reduction or stoppage in supply while we seek a replacement supplier would limit our ability to manufacture our products, which could result in a significant reduction in sales and profitability. In addition, an impurity or variation in a raw material, either unknown to us or incompatible with our products, could significantly reduce our ability to manufacture products. Our inventories may not be adequate to meet our production needs during any prolonged interruption of supply. We have products under development which, if developed, may require us to enter into additional supplier arrangements. Failure to obtain a supplier for our future products, if any, on commercially reasonable terms, would prevent us from manufacturing our future products and limit our growth.

We are dependent on technologies we license, and if we fail to license new technologies and rights to particular nucleic acid sequences for targeted diseases in the future, we may be limited in our ability to develop new products.

We are dependent on licenses from third parties for some of our key technologies. For example, our patented Transcription-Mediated Amplification technology is based on technology we have licensed from Stanford University and the chemiluminescence technology we use in our products is based on technology licensed by us and our consolidated subsidiary, Molecular Light Technology Limited, from the University of Wales College of Medicine. If our license with respect to any of these technologies is terminated for any reason, we will not be able to sell products that incorporate the technology. In addition, although our research staff seeks to discover particular nucleic acid sequences for targeted diseases, our ability to develop additional diagnostic tests for diseases may depend on the ability of third parties to discover particular sequences or markers and correlate them with disease, as well as the rate at which such discoveries are made. Likewise, our ability to design products that target these diseases may be based on our ability to obtain the necessary rights from third parties who make any of these discoveries. In addition, there are a finite number of diseases and conditions for which our NAT assays may be economically viable. If we are unable to obtain access to new technologies or the rights to particular sequences or markers necessary for additional diagnostic products on commercially reasonable terms, we may be limited in our ability to develop new diagnostic products.

If we fail to attract, hire and retain qualified personnel, we may not be able to design, develop, market or sell our products or successfully manage our business.

Competition for top management personnel is intense and we may not be able to recruit and retain the personnel we need. The loss of any one of our management personnel, particularly Henry L. Nordhoff, our Chairman, President and Chief Executive Officer, or our inability to identify, attract, retain and integrate additional qualified management personnel, could make it difficult for us to manage our business successfully, attract new customers, retain existing customers and pursue our strategic objectives. Although we have employment agreements with our executive officers, we may be unable to retain our existing management. We do not maintain key person life insurance for any of our executive officers.

Similarly, competition for skilled sales, marketing, research, product development, engineering, and technical personnel is intense and we may not be able to recruit and retain the personnel we need. The loss of the services of any key sales, marketing, research, product development, engineering, and technical personnel, or our inability to hire new personnel with the requisite skills, could restrict our ability to develop new products or enhance existing products in a timely manner, sell products to our customers or manage our business effectively.

We may not be able to hire or retain qualified personnel if we are unable to offer competitive salaries and benefits, or if our stock does not perform well.

We may acquire other businesses or form joint ventures that could decrease our profitability, dilute your ownership of us, increase our debt or cause us to incur significant expense.

As part of our business strategy, we intend to pursue acquisitions of other complementary businesses and technology licensing arrangements. We also intend to pursue strategic alliances that leverage our core technology and industry experience to expand our product offerings and geographic presence. We have limited experience with respect to acquiring other companies and with respect to the formation of collaborations, strategic alliances and joint ventures. If we make future acquisitions, we may not be able to integrate these acquisitions successfully into our existing business and we could assume unknown or contingent liabilities. Any future acquisitions by us also could result in large and immediate write-offs or the incurrence of debt and contingent liabilities, any of which could harm our operating results. Integration of an acquired company also may require management resources that otherwise would be available for

ongoing development of our existing business. We may not identify or complete these transactions in a timely manner, on a cost-effective basis, or at all, and we may not realize the anticipated benefits of any acquisition, technology license or strategic alliance.

To finance any acquisitions, we may choose to issue shares of our common stock as consideration, which would dilute your interest in us. If the price of our equity is low or volatile, we may not be able to acquire other companies. Alternatively, it may be necessary for us to raise additional funds through public or private financings. Additional funds may not be available on terms that are favorable to us and, in the case of equity financings, may result in dilution to our stockholders.

We and our customers are subject to various governmental regulations, and we may incur significant expenses to comply with these regulations and develop products compatible with these regulations.

The clinical diagnostic and blood screening products we design, develop, manufacture and market are subject to rigorous regulation by the FDA and numerous other federal, state and foreign governmental authorities. The process of obtaining regulatory approvals, particularly from the FDA and some foreign governmental authorities, to market our products can be costly and time consuming, and approvals might not be granted for future products on a timely basis, if at all. For example, we were prohibited from commercially marketing our blood screening products in the United States until we obtained approval of our Biologics License Application from the FDA' s Center for Biologic Evaluation and Research. We generally are prohibited from marketing our clinical diagnostic products in the United States unless we obtain either 510(k) clearance or premarket approval from the FDA. Delays in receipt of, or failure to obtain, clearances or approvals for future products could result in delayed, or no, realization of product revenues from new products or in substantial additional costs which could decrease our profitability.

In addition, we are required to continue to comply with applicable FDA and other material regulatory requirements once we have obtained clearance or approval for a product. These requirements include, among other things, the Quality System Regulation, labeling requirements, the FDA' s general prohibition against promoting products for unapproved or "off-label" uses and adverse event reporting regulations. Failure to comply with applicable FDA product regulatory requirements could result in, among other things, warning letters, fines, injunctions, civil penalties, repairs, replacements, refunds, recalls or seizures of products, total or partial suspension of production, the FDA' s refusal to grant future premarket clearances or approvals, withdrawals or suspensions of current product applications and criminal prosecution. Any of these actions, in combination or alone, could prevent us from selling our products.

Outside the United States, our ability to market our products is contingent upon receiving marketing authorization from the appropriate regulatory authorities. The requirements governing the conduct of clinical trials, marketing authorization, pricing and reimbursement vary widely from country to country. At present, we apply for foreign marketing authorizations at a national level, although within the European Union, registration procedures are available to companies wishing to market a product in more than one European union member state. We are currently taking action to have our products registered for sale into the European Economic Community following a new requirement that becomes effective in December 2004. Failure to receive, or delays in the receipt of, relevant foreign qualifications could prevent us from selling our products in foreign countries.

As both the FDA and foreign government regulators have become increasingly stringent, we may be subject to more rigorous regulation by governmental authorities in the future. Our products and operations also are often subject to the rules of industrial standards bodies, such as the International Standards Organization. Complying with these rules and regulations could cause us to incur significant additional expenses, which would harm our operating results.

The use of our diagnostic products is also affected by the Clinical Laboratory Improvement Amendments of 1988, or CLIA, and related federal and state regulations which provide for regulation of laboratory testing. CLIA is intended to ensure the quality and reliability of clinical laboratories in the United States by mandating specific standards in the areas of personnel qualifications, administration, participation in proficiency testing, patient test management, quality and inspections. Current or future CLIA requirements or the promulgation of additional regulations affecting laboratory testing may prevent some clinical laboratories from using any or all of our diagnostic products.

If a natural or man-made disaster strikes our manufacturing facilities, we will be unable to manufacture our products for a substantial amount of time and our sales will decline.

We manufacture all of our products in our two manufacturing facilities located in San Diego, California. These facilities and the manufacturing equipment we use to produce our products would be costly to replace and could require substantial lead time to repair or replace. The facilities may be harmed by natural or man-made disasters, including, without limitation, earthquakes and fires, and in the event they were affected by a disaster, we would be forced to rely on third-party manufacturers. In the event of a disaster, we may lose

customers and we may be unable to regain those customers thereafter. Although we possess insurance for damage to our property and the disruption of our business from casualties, this insurance may not be sufficient to cover all of our potential losses and may not continue to be available to us on acceptable terms, or at all.

If we use biological and hazardous materials in a manner that causes injury or violates laws, we may be liable for damages.

Our research and development activities and our manufacturing activities involve the controlled use of potentially harmful biological materials as well as hazardous materials, chemicals and various radioactive compounds. We cannot completely eliminate the risk of accidental contamination or injury, and we could be held liable for damages that result from such contamination or injury. In addition, we are subject to federal, state and local laws and regulations governing the use, storage, handling and disposal of these materials and specified waste products. The damages resulting from any accidental contamination and the cost of compliance with environmental laws and regulations could be significant.

The anti-takeover provisions of our certificate of incorporation and by-laws, provisions of Delaware law and our rights plan could delay or prevent a change of control that you may favor.

Provisions of our amended and restated certificate of incorporation and amended and restated bylaws may discourage, delay or prevent a merger or other change of control that stockholders may consider favorable or may impede the ability of the holders of our common stock to change our management. The provisions of our amended and restated certificate of incorporation and amended and restated bylaws, among other things:

divide our board of directors into three classes, with members of each class to be elected for staggered three-year terms,

limit the right of stockholders to remove directors,

regulate how stockholders may present proposals or nominate directors for election at annual meetings of stockholders, and

authorize our board of directors to issue preferred stock in one or more series, without stockholder approval.

In addition, because we have not chosen to be exempt from Section 203 of the Delaware General Corporation Law, this provision could also delay or prevent a change of control that you may favor. Section 203 provides that, subject to limited exceptions, persons that acquire, or are affiliated with a person that acquires, more than 15% of the outstanding voting stock of a Delaware corporation shall not engage in any business combination with that corporation, including by merger, consolidation or acquisitions of additional shares, for a three-year period following the date on which that person or its affiliate crosses the 15% stock ownership threshold.

We also adopted a rights plan that could discourage, delay or prevent an acquisition of us under certain circumstances. The rights plan provides for preferred stock purchase rights attached to each share of our common stock, which will cause substantial dilution to a person or group acquiring 15% or more of our stock if the acquisition is not approved by our Board of Directors.

On May 28, 2004, our stockholders approved an amendment to our Amended and Restated Certificate of Incorporation to increase our authorized number of shares of common stock from 100,000,000 shares to 200,000,000 shares. The additional shares of common stock may be used for various purposes without further stockholder approval. These purposes may include: effecting additional stock dividends; raising capital; providing equity incentives to employees, officers or directors; establishing strategic relationships with other companies; expanding the company' s business or product lines through the acquisition of other businesses or products; and other purposes. Although the increase in the authorized common stock was prompted by business and financial consideration and not by the threat of any hostile takeover attempt (nor is the Board currently aware of any such attempts directed as us), nevertheless, the availability of these shares could facilitate future efforts by us to deter or prevent changes in control, including transactions in which our stockholders might otherwise receive a premium for their shares over then current market prices.

We may not successfully integrate acquired businesses.

In August 2003, we acquired a majority of the outstanding shares of Molecular Light Technology Limited and its subsidiaries and in the future, we may acquire additional businesses or technologies, or enter into strategic transactions. Managing these acquisitions and any future acquisitions will entail numerous operational and financial risks, including:

the inability to retain key employees of any acquired businesses or hire enough qualified personnel to staff any new or

expanded operations;

the impairment of relationships with key customers of acquired businesses due to changes in management and ownership of the acquired businesses;

the exposure to federal, state, local and foreign tax liabilities in connection with any acquisition or the integration of any acquired businesses;

the exposure to unknown liabilities;

higher than expected acquisition and integration costs that would cause our quarterly and annual operating results to fluctuate;

increased amortization expenses if an acquisition results in significant goodwill or other intangible assets;

combining the operations and personnel of acquired businesses with our own, which would be difficult and costly; and

integrating or completing the development and application of any acquired technologies, which would disrupt our business and divert our management' s time and attention.

If we do not effectively manage our growth, it could affect our ability to pursue opportunities and expand our business.

Growth in our business has placed and may continue to place a significant strain on our personnel, facilities, management systems and resources. We will need to continue to improve our operational and financial systems and managerial controls and procedures and train and manage our workforce. We will have to maintain close coordination among our various departments. If we fail to effectively manage our growth and address the foregoing concerns, it could adversely affect our ability to pursue business opportunities and expand our business.

Future changes in financial accounting standards or practices or existing taxation rules or practices may cause adverse unexpected financial reporting fluctuations and affect our reported results of operations.

A change in accounting standards or practices or a change in existing taxation rules or practices can have a significant effect on our reported results and may even affect our reporting of transactions completed before the change is effective. New accounting pronouncements and taxation rules and varying interpretations of accounting pronouncements and taxation practice have occurred and may occur in the future. Changes to existing rules or the questioning of current practices may adversely affect our reported financial results or the way we conduct our business. For example, any changes requiring that we record compensation expense in the statement of operations for employee stock options using the fair value method or changes in existing taxation rules related to stock options could have a significant negative effect on our reported results. Several agencies and entities are considering, and the Financial Accounting Standards Board has announced, proposals to change generally accepted accounting principles in the United States that, if implemented, would require us to record charges to earnings for employee stock option grants. This pending requirement would negatively impact our earnings. For example, recording a charge for employee stock options under SFAS No. 123, "Accounting for Stock-Based Compensation," would have reduced our net income by $2.4 million and $0.2 million for the three months ended June 30, 2004 and 2003, and $4.3 million and $0.4 million for the six months ended June 30, 2004 and 2003, respectively.

Systems implementation issues could disrupt our internal operations and adversely affect our financial results.

Portions of our information technology infrastructure may experience interruptions, delays or cessations of service or produce errors in connection with ongoing systems implementation work. In particular, we plan to implement a new general ledger information system and data warehouse to replace our current systems over the next two years. As a part of this effort, we are rationalizing various legacy systems and upgrading existing hardware and software applications and implementing new data management applications to administer our business information. We may not be successful in implementing the new system, and transitioning data and other aspects of the process could be more expensive, time consuming and resource intensive than planned. Any disruptions that may occur in the implementation of this new system or any future systems could increase our expenses and adversely affect our ability to report in an accurate and timely manner the results of our consolidated operations, our financial position and cash flow and to otherwise operate our business, which could adversely affect our financial results, stock price and reputation.

Compliance with changing corporate governance and public disclosure regulations may result in additional expenses.

Changing laws, regulations and standards relating to corporate governance and public disclosure, including the Sarbanes-Oxley Act of 2002, new SEC regulations and Nasdaq Stock Market rules, are creating uncertainty for companies such as ours. To maintain high standards of corporate governance and public disclosure, we intend to invest all reasonably necessary resources to comply with evolving standards. These investments may result in increased general and administrative expenses and a diversion of management time and attention from revenue-generating activities.

Available Information

Copies of our public filings are available on our Internet website at http://www.gen-probe.com as soon as reasonably practicable after we electronically file such material with, or furnish them to, the SEC.

Item 3. Quantitative and Qualitative Disclosures about Market Risk

Our exposure to market risk for changes in interest rates relates primarily to the increase or decrease in the amount of interest income we can earn on our investment portfolio. Our risk associated with fluctuating interest income is limited to our investments in interest rate sensitive financial instruments. Under our current policies, we do not use interest rate derivative instruments to manage this exposure to interest rate changes. We seek to ensure the safety and preservation of our invested principal by limiting default risk, market risk, and reinvestment risk. We mitigate default risk by investing in short-term investment grade securities. A hypothetical 100 basis point adverse move in interest rates along the entire interest rate yield curve would not materially affect the fair value of our financial instruments that are exposed to changes in interest rates.

We are exposed to foreign exchange risk for expenditures in certain foreign countries, but the total receivables and payables denominated in foreign currencies at June 30, 2004 were not material. We believe that our business operations are not exposed to market risk relating to commodity price risk.

Item 4. Controls and Procedures

As of the end of the period covered by this Quarterly Report on Form 10-Q, we carried out an evaluation, under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, of the effectiveness of the design and operation of our disclosure controls and procedures, as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended. Based on this evaluation, our Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures were effective as of the end of the quarter ended June 30, 2004.

An evaluation was also performed under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, of any change in our internal control over financial reporting that occurred during our last fiscal quarter and that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting. That evaluation did not identify any change in our internal control over financial reporting that occurred during our latest fiscal quarter and that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

We maintain disclosure controls and procedures that are designed to ensure that information required to be disclosed in our Exchange Act reports is recorded, processed, summarized and reported within the time periods specified in the SEC' s rules and forms, and that such information is accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, as appropriate, to allow timely decisions regarding required disclosure. In designing and evaluating the disclosure controls and procedures, management recognized that any controls and procedures, no matter how well designed and operated, can provide only reasonable and not absolute assurance of achieving the desired control objectives. In reaching a reasonable level of assurance, management necessarily was required to apply its judgment in evaluating the cost-benefit relationship of possible controls and procedures. In addition, the design of any system of controls also is based in part upon certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions; over time, control may become inadequate because of changes in conditions, or the degree of compliance with policies or procedures may deteriorate. Because of the inherent limitations in a cost-effective control system, misstatements due to error or fraud may occur and not be detected.

PART II – OTHER INFORMATION

Item 1. Legal Proceedings

A description of our material pending legal proceedings is disclosed in Note 9 ("Litigation") of the Notes to Condensed Consolidated Financial Statements included in Item 1 of Part I of this report and is incorporated by reference herein. See "Notes to Condensed Consolidated Financial Statement – Note 9 – Litigation." We are also engaged in other legal actions arising in the ordinary course of our business and believe that the ultimate outcome of these actions will not have a material adverse effect on our business, financial condition or results of operations. However, due to the uncertainties inherent in litigation, no assurance can be given as to the outcome of these proceedings. If any of these matters were resolved in a manner unfavorable to us, our business, financial condition and results of operations would be harmed.

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

On May 28, 2004, our Annual Meeting of Stockholders was held in San Diego, California for the following purposes:

(1) To elect three (3) directors to hold office until the 2007 Annual Meeting of Stockholders.

For Mae C. Jemison, M.D., the number of votes were as follows:
For: 39,666,939
Withheld: 1,369,492

For Brian A. McNamee, M.B.B.S., the number of votes were as follows:
For: 39,683,312
Withheld: 1,353,119

For Armin M. Kessler, the number of votes were as follows:
For: 39,679,987
Withheld: 1,356,444

(2) To approve an amendment to our Amended and Restated Certificate of Incorporation to increase the authorized number of shares of common stock from 100,000,000 to 200,000,000 shares. The number of votes were as follows:

For: 34,650,773
Against: 6,352,917
Abstaining: 17,813
Broker Non-votes: 14,928

(3) To ratify the selection by the Audit Committee of our Board of Directors of Ernst &Young LLP as our independent auditors for the fiscal year ending December 31, 2004. The number of votes were as follows:

For: 40,354,192
Against: 646,485
Abstaining: 20,826
Broker Non-Votes: 14,928

Item 6. Exhibits and Report on Form 8-K

(a) Exhibits

Exhibit Number	Description
3.1(1)	Amended and Restated Certificate of Incorporation of Gen-Probe Incorporated.
3.2(1)	Amended and Restated Bylaws of Gen-Probe Incorporated.
3.3†	Certificate of Amendment of Amended and Restated Certificate of Incorporation of Gen-Probe Incorporated.
3.4†	Certificate of Designations of the Series A Junior Participating Preferred Stock of Gen-Probe Incorporated.
4.1(1)	Specimen common stock certificate.
4.2(2)	Rights Agreement, dated as of September 16, 2002, between Gen-Probe Incorporated and Mellon Investor Services LLC, which includes the form of Certificate of Designations of the Series A Junior Participating Preferred Stock of Gen-Probe Incorporated as Exhibit A, the form of Right Certificate as Exhibit B and the Summary of Rights to Purchase Preferred Shares as Exhibit C.
4.4(3)	First Amendment to Rights Agreement, dated October 9, 2002, between Gen-Probe Incorporated and Mellon Investor Services LLC.
4.5(4)	Second Amendment to Rights Agreement, dated November 20, 2003.
10.71†	Employee Stock Purchase Plan.
10.72†	2003 Amendment to the Renewed Distribution Agreement and the Distributorship Arrangements Agreement dated May 2, 1997, entered into May 2, 2003 by and between Gen-Probe Incorporated and bioMerieux, S.A.*
10.73†	Supply Agreement entered into January 1, 2002 by and between Gen-Probe Incorporated and MGM Instruments, Inc.*
10.74†	Supply Agreement Amendment Number One entered into June 4, 2004 by and between Gen-Probe Incorporated and MGM Instruments, Inc.*
31.1†	Certification dated August 9, 2004, of Principal Executive Officer required pursuant to 18 USC. Section 1350, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2†	Certification dated August 9, 2004, of Principal Financial Officer required pursuant to 18 USC. Section 1350, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1†	Certification dated August 9, 2004, of Principal Executive Officer required pursuant to 18 USC. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2†	Certification dated August 9, 2004, of Principal Financial Officer required pursuant to 18 USC. Section 1350, as adopted pursuant to section 906 of the Sarbanes-Oxley Act of 2002.

† Filed herewith.

(1) Incorporated by reference to Gen-Probe' s Amendment No. 2 to Registration Statement on Form 10 filed with the SEC on August 14, 2002.

(2) Incorporated by reference to Gen-Probe' s Report on Form 8-K filed with the SEC on September 17, 2002.

(3) Incorporated by reference to Gen-Probe' s Quarterly Report on Form 10-Q filed with the SEC on November 14, 2002.

(4) Incorporated by reference to Gen-Probe' s Report on Form 8-K filed with the SEC on November 21, 2003.

* Gen-Probe has requested confidential treatment with respect to certain portions of this exhibit. The confidential portions of this exhibit are marked by an asterisk and have been omitted and filed separately with the SEC pursuant to Gen-Probe' s request for confidential treatment.

Reports on Form 8-K

(b) On May 3, 2004, we filed a report on Form 8-K dated May 3, 2004 relating to the results of our fiscal quarter ended March 31, 2004. Under the Form 8-K, we furnished (not filed) pursuant to Item 12 under Item 7 the press release entitled "*Gen-Probe Reports Strong Financial Results for First Quarter 2004, Raises Full-Year Guidance*" relating to the results of our fiscal quarter ended March 31, 2004.

SIGNATURES

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

DATE: August 9, 2004

By: /s/ Henry L. Nordhoff
Henry L. Nordhoff
Chairman, President and Chief Executive Officer
(Principal Executive Officer)

DATE: August 9, 2004

By: /s/ Herm Rosenman
Herm Rosenman
Vice President - Finance and Chief Financial Officer (Principal Financial Officer and Principal Accounting Officer)

Exhibit 3.3

CERTIFICATE OF AMENDMENT OF
AMENDED AND RESTATED
CERTIFICATE OF INCORPORATION OF
GEN-PROBE INCORPORATED

GEN-PROBE INCORPORATED, a Delaware corporation (the "CORPORATION"), does hereby certify that:

FIRST: The name of the Corporation is GEN-PROBE INCORPORATED.

SECOND: The date on which the original Certificate of Incorporation of the Corporation was filed with the Secretary of State of the State of Delaware is July 27, 1987.

THIRD: The Board of Directors of the Corporation, acting in accordance with the provisions of Sections 141 and 242 of the General Corporation Law of the State of Delaware (the "DGCL"), adopted resolutions providing that it was advisable and in the best interests of the Corporation that the first paragraph of Article Fourth of the Corporation's Amended and Restated Certificate of Incorporation be amended in its entirety to read as follows:

> "FOURTH: The Corporation is authorized to issue two classes of stock to be designated, respectively, Common Stock, par value $0.0001 per share ("Common Stock"), and Preferred Stock, par value $0.0001 per share ("Preferred Stock"). The total number of shares the Corporation shall have the authority to issue is 220,000,000 shares, 200,000,000 shares of which shall be Common Stock and 20,000,000 shares of which shall be Preferred Stock."

FOURTH: Thereafter, pursuant to a resolution of the Board of Directors, this Certificate of Amendment was submitted to the stockholders of the Corporation for their approval, and was duly adopted in accordance with the provisions of Section 242 of the DGCL.

IN WITNESS WHEREOF, Gen-Probe Incorporated has caused this Certificate of Amendment to be signed by its Vice President and General Counsel this 28th day of May, 2004.

GEN-PROBE INCORPORATED

By: /s/ R. William Bowen

R. William Bowen
Vice President and General Counsel

State of Delaware

Secretary of State
Division of Corporations
Delivered 11:38 AM 06/01/2004
FILED 09:19 AM 06/01/2004
SRV 040403124 - 2133133 FILE

Exhibit 3.4

STATE OF DELAWARE
SECRETARY OF STATE
DIVISION OF CORPORATIONS
FILED 03:00 PM 09/18/2002
020581984 - 2133133

CERTIFICATE OF DESIGNATIONS
of
SERIES A JUNIOR PARTICIPATING PREFERRED STOCK
of
GEN-PROBE INCORPORATED
(Pursuant to Section 151 of the
Delaware General Corporation Law)

Gen-Probe Incorporated, a corporation organized and existing under the General Corporation Law of the State of Delaware (hereinafter called the "Corporation"), hereby certifies that the following resolution was adopted by the Board of Directors of the Corporation as required by Section 151 of the General Corporation Law at a meeting duly called and held on September 16, 2002.

RESOLVED, that pursuant to the authority granted to and vested in the Board of Directors of this Corporation (hereinafter called the "Board of Directors" or the "Board") in accordance with the provisions of the Certificate of Incorporation of this Corporation, the Board of Directors hereby creates a series of Preferred Stock, par value $.0001 per share (the "Preferred Stock"), of the Corporation and hereby states the designation and number of shares, and fixes the relative rights, powers and preferences, and qualifications, limitations and restrictions thereof as follows:

Section 1. Designation and Amount. The shares of such series shall be designated as "Series A Junior Participating Preferred Stock" (the "Series A Preferred Stock") and the number of shares constituting the Series A Preferred Stock shall be 1,000,000. Such number of shares may be increased or decreased by resolution of the Board of Directors; provided, that no decrease shall reduce the number of shares of Series A Preferred Stock to a number less than the number of shares then outstanding plus the number of shares reserved for issuance upon the exercise of outstanding options, rights or warrants or upon the conversion of any outstanding securities issued by the Corporation convertible into Series A Preferred Stock.

Section 2. Dividends and Distributions.

(A) Subject to the prior and superior rights of the holders of any shares of any class or series of stock of this Corporation ranking prior and superior to the Series A Preferred Stock with respect to

dividends, the holders of shares of Series A Preferred Stock, in preference to the holders of Common Stock, par value $.0001 per share (the "Common Stock"), of the Corporation, and of any other stock ranking junior to the Series A Preferred Stock, shall be entitled to receive, when, as and if declared by the Board of Directors out of funds legally available for the purpose, quarterly dividends payable in cash on the first day of March, June, September and December in each year (each such date being referred to herein as a "Quarterly Dividend Payment Date"), commencing on the first Quarterly Dividend Payment Date after the first issuance of a share or fraction of a share of Series A Preferred Stock, in an amount per share (rounded to the nearest cent) equal to the greater of (a) $1.00 or (b) subject to the provision for adjustment hereinafter set forth, 100 times the aggregate per share amount of all cash dividends, and 100 times

the aggregate per share amount (payable in kind) of all non-cash dividends or other distributions, other than a dividend payable in shares of Common Stock or a subdivision of the outstanding shares of Common Stock (by reclassification or otherwise), declared on the Common Stock since the immediately preceding Quarterly Dividend Payment Date or, with respect to the first Quarterly Dividend Payment Date, since the first issuance of any share or fraction of a share of Series A Preferred Stock. In the event the Corporation shall at any time declare or pay any dividend on the Common Stock payable in shares of Common Stock, or effect a subdivision, combination or consolidation of the outstanding shares of Common Stock (by reclassification or otherwise than by payment of a dividend in shares of Common Stock) into a greater or lesser number of shares of Common Stock, then in each such case the amount to which holders of shares of Series A Preferred Stock were entitled immediately prior to such event under clause (b) of the preceding sentence shall be adjusted by multiplying such amount by a fraction, the numerator of which is the number of shares of Common Stock outstanding immediately after such event and the denominator of which is the number of shares of Common Stock that were outstanding immediately prior to such event.

(B) The Corporation shall declare a dividend or distribution on the Series A Preferred Stock as provided in paragraph (A) of this Section 2 immediately after it declares a dividend or distribution on the Common Stock (other than a dividend payable in shares of Common Stock); provided that, in the event no dividend or distribution shall have been declared on the Common Stock during the period between any Quarterly Dividend Payment Date and the next subsequent Quarterly Dividend Payment Date, a dividend of $1.00 per share on the Series A Preferred Stock shall nevertheless be payable on such subsequent Quarterly Dividend Payment Date.

(C) Dividends shall begin to accrue and be cumulative on outstanding shares of Series A Preferred Stock from the Quarterly Dividend Payment Date next preceding the date of issue of such shares, unless the date of issue of such shares is prior to the record date for the first Quarterly Dividend Payment Date, in which case dividends on such shares shall begin to accrue from the date of issue of such shares, or unless the date of issue is a Quarterly Dividend Payment Date or is a date after the record date for the determination of holders of shares of Series A Preferred Stock entitled to receive a quarterly dividend

and before such Quarterly Dividend Payment Date, in either of which events such dividends shall begin to accrue and be cumulative from such Quarterly Dividend Payment Date. Accrued but unpaid dividends shall not bear interest. Dividends paid on the shares of Series A Preferred Stock in an amount less than the total amount of such dividends at the time accrued and payable on such shares shall be allocated pro rata on a share-by-share basis among all such shares at the time outstanding. The Board of Directors may fix a record date for the determination of holders of shares of Series A Preferred Stock entitled to receive payment of a dividend or distribution declared thereon, which record date shall be not more than 60 days prior to the date fixed for the payment thereof.

Section 3. Voting Rights. The holders of shares of Series A Preferred Stock shall have the following voting rights:

(A) Subject to the provision for adjustment hereinafter set forth, each share of Series A Preferred Stock shall entitle the holder thereof to 100 votes on all matters submitted to a vote of the stockholders of the Corporation. In the event the Corporation shall at any time declare or pay any dividend on the Common Stock payable in shares of Common Stock, or effect a subdivision, combination or consolidation of the outstanding shares of Common Stock (by reclassification or otherwise than by payment of a dividend in shares of Common Stock) into a greater or lesser number of shares of Common Stock, then in each such case the number of votes per share to which holders of shares of Series A Preferred Stock were entitled immediately prior to such event shall be adjusted by multiplying such number by a fraction, the numerator of which is the number of shares of Common Stock outstanding immediately after such event and the denominator of which is the number of shares of Common Stock that were outstanding immediately prior to such event.

(B) Except as otherwise provided herein, in any other Certificate of Designations creating a series of Preferred Stock or any similar stock, or by law, the holders of shares of Series A Preferred Stock and the holders of shares of Common Stock and any other capital stock of the Corporation having general voting rights shall vote together as one class on all matters submitted to a vote of stockholders of the Corporation.

(C) Except as set forth herein, or as otherwise provided by law, holders of Series A Preferred Stock shall have no special voting rights and their consent shall not be required (except to the extent they are entitled to vote with holders of Common Stock as set forth herein) for taking any corporate action.

Section 4. Certain Restrictions.

(A) Whenever quarterly dividends or other dividends or distributions payable on the Series A Preferred Stock as provided in Section 2 are in arrears, thereafter and until all accrued and unpaid dividends and

distributions, whether or not declared, on shares of Series A Preferred Stock outstanding shall have been paid in full, the Corporation shall not:

(i) declare or pay dividends, or make any other distributions, on any shares of stock ranking junior (either as to dividends or upon liquidation, dissolution or winding up) to the Series A Preferred Stock;

(ii) declare or pay dividends, or make any other distributions, on any shares of stock ranking on a parity (either as to dividends or upon liquidation, dissolution or winding up) with the Series A Preferred Stock, except dividends paid ratably on the Series A Preferred Stock and all such parity stock on which dividends are payable or in arrears in proportion to the total amounts to which the holders of all such shares are then entitled;

(iii) redeem or purchase or otherwise acquire for consideration shares of any stock ranking junior (either as to dividends or upon liquidation,

dissolution or winding up) to the Series A Preferred Stock, provided that the Corporation may at any time redeem, purchase or otherwise acquire shares of any such junior stock in exchange for shares of any stock of the Corporation ranking junior (both as to dividends and upon dissolution, liquidation or winding up) to the Series A Preferred Stock; or

(iv) redeem or purchase or otherwise acquire for consideration any shares of Series A Preferred Stock, or any shares of stock ranking on a parity with the Series A Preferred Stock, except in accordance with a purchase offer made in writing or by publication (as determined by the Board of Directors) to all holders of such shares upon such terms as the Board of Directors, after consideration of the respective annual dividend rates and other relative rights and preferences of the respective series and classes, shall determine in good faith will result in fair and equitable treatment among the respective series or classes.

(B) The Corporation shall not permit any subsidiary of the Corporation to purchase or otherwise acquire for consideration any shares of stock of the Corporation unless the Corporation could, under paragraph (A) of this Section 4, purchase or otherwise acquire such shares at such time and in such manner.

Section 5. Reacquired Shares. Any shares of Series A Preferred Stock purchased or otherwise acquired by the Corporation in any manner whatsoever shall be retired and canceled promptly after the acquisition thereof. All such shares shall upon their cancellation become authorized but unissued shares of Preferred Stock and may be reissued as part of a new series of Preferred Stock

subject to the conditions and restrictions on issuance set forth herein, in the Certificate of Incorporation, or in any other Certificate of Designations creating a series of Preferred Stock or any similar stock or as otherwise required by law.

Section 6. Liquidation, Dissolution or Winding Up.

(A) Upon any liquidation, dissolution or winding up of the Corporation, voluntary or otherwise, no distribution shall be made (1) to the holders of shares of stock ranking junior (either as to dividends or upon liquidation, dissolution or winding up) to the Series A Preferred Stock unless, prior thereto, the holders of shares of Series A Preferred Stock shall have received an amount per share (the "Series A Liquidation Preference") equal to $100 per share, plus an amount equal to accrued and unpaid dividends and distributions thereon, whether or not declared, to the date of such payment, provided that the holders of shares of Series A Preferred Stock shall be entitled to receive an aggregate amount per share, subject to the provision for adjustment hereinafter set forth, equal to 100 times the aggregate amount to be distributed per share to holders of shares of Common Stock, or (2) to the holders of shares of stock ranking on a parity (either as to dividends or upon liquidation, dissolution or winding up) with the Series A Preferred Stock, except distributions made ratably on the Series A Preferred Stock and all such parity stock in proportion to the total amounts to which the holders of all such shares are entitled upon such liquidation, dissolution or winding up. In the event the Corporation shall at any time declare of pay any dividend on the Common Stock payable in shares of Common Stock, or effect a subdivision, combination or

that any such other series specifically provides that it shall rank on a parity with or junior to the Series A Preferred Stock.

Section 10. Amendment. At any time any shares of Series A Preferred Stock are outstanding, the Certificate of Incorporation of the Corporation shall not be amended in any manner which would materially alter or change the powers, preferences or special rights of the Series A Preferred Stock so as to affect them adversely without the affirmative vote of the holders of at least two-thirds of the outstanding shares of Series A Preferred Stock, voting separately as a single class.

Section 11. Fractional Shares. Series A Preferred Stock may be issued in fractions of a share that shall entitle the holder, in proportion to such holder's fractional shares, to exercise voting rights, receive dividends, participate in distributions and to have the benefit of all other rights of holders of Series A Preferred Stock.

IN WITNESS WHEREOF, this Certificate of Designations is executed on behalf of the Corporation by its Vice President, General Counsel and Assistant Secretary this 17th day of September, 2002.

/s/ R. William Bowen

R. William Bowen
Vice President, General Counsel
and Assistant Secretary

EXHIBIT 10.71

GEN-PROBE INCORPORATED

EMPLOYEE STOCK PURCHASE PLAN
(adopted by Board of Directors on May 3, 2003 and the
Compensation Committee on April 2, 2003)
(amended by the Compensation Committee on August 2, 2004)
(adopted by Stockholders on May 29, 2003)

Gen-Probe Incorporated, a Delaware corporation (the "Company"), hereby adopts the Gen-Probe Incorporated Employee Stock Purchase Plan (the "Plan"), effective as of May 30, 2003.

The purposes of the Plan are as follows:

(1) To assist eligible employees of the Company and its Designated Subsidiary Corporations (as defined below) in acquiring stock ownership in the Company pursuant to a plan which is intended to qualify as an "employee stock purchase plan," within the meaning of Section 423(b) of the Code (as defined below).

(2) To encourage such employees to remain in the employment of the Company and its Subsidiary Corporations.

1. DEFINITIONS. Whenever any of the following terms is used in the Plan with the first letter or letters capitalized, it shall have the following meaning unless context clearly indicates to the contrary (such definitions to be equally applicable to both the singular and the plural forms of the terms defined):

(a) "Account" shall mean the account established for an Eligible Employee under the Plan with respect to an Offering Period.

(b) "Agent" shall mean the brokerage firm, bank or other financial institution, entity or person(s) engaged, retained, appointed or authorized to act as the agent of the Company or an Employee with regard to the Plan.

(c) "Authorization" shall mean an Eligible Employee's payroll deduction authorization with respect to an Offering Period provided by such Eligible Employee in accordance with Section 3(b).

(d) "Base Compensation" shall mean the (i) base salary payable to an Eligible Employee by the Company during such individual's period of participation in one or more Offering Periods under the Plan, plus (ii) all overtime payments, bonuses, commissions, current profit-sharing distributions and other incentive compensation payments. Such Base Compensation shall be calculated before deduction of (A) any income or employment tax withholdings, or

(B) any pre-tax contributions made by the Company to any Code Section 401(k) salary deferral plan or any Code Section 125 cafeteria benefit program now or hereafter established by the Company. However, Base Compensation shall not include any contributions (other than Code Section 401(k) or Code Section 125 contributions) made on the Eligible Employee's behalf by the Company to any employee benefit or welfare plan now or hereafter established.

(e) "Board" means the Board of Directors of the Company.

(f) "Code" means the Internal Revenue Code of 1986, as amended.

(g) "Committee" means the committee of the Board appointed to administer the Plan pursuant to Section 13.

(h) "Company" means Gen-Probe Incorporated, a Delaware corporation.

(i) "Date of Exercise" of any Option means the date on which such Option is exercised, which shall be the last day of the Offering Period with respect to which the Option was granted, in accordance with Section 4(a) (except as provided in Section 9).

(j) "Date of Grant" of any Option means the date on which such Option is granted, which shall be the first day of the Offering Period with respect to which the Option was granted, in accordance with Section 3(a).

(k) "Designated Subsidiary Corporation" means any Subsidiary Corporation designated by the Board in accordance with Section 14.

(l) "Eligible Employee" means an Employee of the Company or any Designated Subsidiary Corporation who does not, immediately after the Option is granted, own (directly or through attribution) stock possessing five percent (5%) or more of the total combined voting power or value of all classes of Stock or other stock of the Company, a Parent Corporation or a Subsidiary Corporation (as determined under Section 423(b)(3) of the Code). The rules of Section 424(d) of the Code with regard to the attribution of stock ownership shall apply in determining the stock ownership of an individual, and stock that an Employee may purchase under outstanding options shall be treated as stock owned by the Employee. During a leave of absence meeting the requirements of Treasury Regulation Section 1.421-7(h)(2), an individual shall be treated as an Employee of the Company or Subsidiary Corporation employing such individual immediately prior to such leave. Notwithstanding the foregoing, an Employee whose customary employment is for 20 hours or less per week or for less than 5 months in any calendar year shall not be Eligible an Employee.

(m) "Employee" shall mean an individual who renders services to the Company or a Subsidiary Corporation in the status of an "employee" within the meaning of Code Section 3401(c). "Employee" shall not include any director of the Company or a Subsidiary Corporation who does not render services to the Company or a Subsidiary Corporation in the status of an "employee" within the meaning of Code Section 3401(c).

(n) "Offering Period" shall mean, effective September 1, 2004, each six-month period commencing on any January 1 and July 1; provided, however, that there shall be an Offering Period under the Plan commencing on September 1, 2004 and ending on the last trading day on or before December 31, 2004. Options shall be granted on the Date of Grant and exercised on the Date of Exercise, as provided in Sections 3(a) and 4(a), respectively.

(o) "Option" means an option to purchase shares of Stock granted under the Plan to an Eligible Employee in accordance with Section 3(a).

(p) "Option Price" means the option price per share of Stock determined in accordance with Section 4(b).

(q) "Parent Corporation" means any corporation, other than the Company, in an unbroken chain of corporations ending with the Company if, at the time of the granting of the Option, each of the corporations other than the Company owns stock possessing 50% or more of the total combined voting power of all classes of stock in one of the other corporations in such chain.

(r) "Payday" means the regular and recurring established day for payment of Base Compensation to an Employee of the Company or any Subsidiary Corporation.

(s) "Plan" means the Gen-Probe Incorporated Employee Stock Purchase Plan.

(t) "Stock" means the shares of the Company's common stock, $0.0001 par value.

(u) "Subsidiary Corporation" means any corporation, other than the Company, in an unbroken chain of corporations beginning with the Company if, at the time of the granting of the Option, each of the corporations other than the last corporation in an unbroken chain owns stock possessing 50% or more of the total combined voting power of all classes of stock in one of the other corporations in such chain.

2. STOCK SUBJECT TO THE PLAN. Subject to the provisions of Section 9 hereof (relating to adjustments upon changes in the Stock) and Section 12 hereof (relating to amendments of the Plan), the

maximum number of shares of Stock which shall be made available for sale under the Plan shall be 1,000,000(1) shares.

3. GRANT OF OPTIONS.

(a) Option Grants. The Company shall grant Options under the Plan to all Eligible Employees in successive Offering Periods until the earlier of: (i) the date on which the number of shares of Stock available under the Plan have been sold or (ii) the date on which the Plan is suspended or terminates. Each

Employee who is an Eligible Employee on the first day of an Offering Period shall be granted an Option with respect to such Offering Period. The Date of Grant of such an Option shall be the first day of the Offering Period with respect to which such Option was granted. Each Option shall expire on the Date of Exercise immediately after the automatic exercise of the Option in accordance with Section 4(a), unless such Option terminates earlier in accordance with Section 5, 6 or 9. The number of shares of Stock subject to an Eligible Employee's Option shall equal the cumulative payroll deductions authorized by such Eligible Employee in accordance with subsection (b) of this Section 3 for the Option Period (if any), divided by the Option Price; provided, however, that the number of shares of Stock subject to such Option shall not exceed 200,000(2) shares; and, provided, further, that the number of shares of Stock subject to such Option shall not exceed the number determined in accordance with subsection (c). The Company shall not grant an Option with respect to an Offering Period to any individual who is not an Eligible Employee on the first day of such Offering Period.

(b) Election to Participate; Payroll Deduction Authorization. Except as provided in subsection (d), an Eligible Employee shall participate in the Plan only by means of payroll deduction. Each Eligible Employee who elects to participate in the Plan with respect to an Offering Period shall deliver to the Company, not later than ten (10) days before the first day of the Offering Period, a completed and executed written payroll deduction authorization in a form prepared by the Committee (the "Authorization"). An Eligible Employee's Authorization shall give notice of such Eligible Employee's election to participate in the Plan for the next following Offering Period (and subsequent Offering Periods) and shall designate a whole percentage of such Eligible Employee's Base Compensation to be withheld by the Company or the Designated Subsidiary Corporation employing such Eligible Employee on each Payday during the Offering Period. An Eligible Employee may designate any whole percentage of Base Compensation which is not to be less than one percent (1%) and not more than fifteen percent (15%). An Eligible Employee's Base Compensation payable during an Offering Period shall be reduced each Payday through payroll deduction in an amount equal to the percentage specified in the Authorization, and such amount shall be credited to such Eligible Employee's Account under the Plan. An Eligible Employee may change the percentage of Base Compensation designated in the Authorization, subject to the limits of this subsection (b), or may suspend the Authorization, at any time during the Offering Period, provided, that any such change or suspension shall become effective not later than ten (10) days after receipt by the Company. Any Authorization shall remain in effect for each subsequent Offering Period, unless the Eligible Employee submits a new Authorization pursuant to this subsection (b), withdraws from the Plan pursuant to Section 5, ceases to be an Eligible Employee as defined in Section 1(l) or terminates employment as provided in Section 6.

(c) $25,000 Limitation. No Eligible Employee shall be granted an Option under the Plan which permits his or her rights to purchase shares of Stock under the Plan, together with other options to purchase shares of Stock or other stock under all other employee stock purchase plans of the Company, any Parent Corporation or any Subsidiary Corporation subject to Section 423 of the Code, to accrue at a rate which exceeds $25,000 of fair market value of such

shares of Stock or other stock (determined at the time the Option or other option is granted) for each calendar year in which the Option is outstanding at any time. For purpose of the limitation imposed by this subsection, (i) the right to purchase shares of Stock or other stock under an Option or other option accrues when the Option or other option (or any portion thereof) first becomes exercisable during the calendar year, (ii) the right to purchase shares of

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(1) Adjusted from 500,000 to 1,000,000 to reflect the two-for-one stock split implemented as a 100% stock dividend, effective September 2003.

(2) Adjusted from 100,000 to 200,000 to reflect the two-for-one stock split implemented as a 100% stock dividend, effective September 2003.

Stock or other stock under an Option or other option accrues at the rate provided in the Option or other option, but in no case may such rate exceed $25,000 of the fair market value of such Stock or other stock (determined at the time such Option or other option is granted) for any one calendar year, and (iii) a right to purchase Stock or other stock which has accrued under an Option or other option may not be carried over to any Option or other option. This limitation shall be applied in accordance with Section 423(b)(8) of the Code and the Treasury Regulations thereunder.

(d) Leaves of Absence. During a leave of absence meeting the requirements of Treasury Regulation Section 1.421-7(h)(2), an Employee may continue to participate in the Plan by making cash payments to the Company on each Payday equal to the amount of the Employee's payroll deduction under the Plan for the Payday immediately preceding the first day of such Employee's leave of absence.

4. EXERCISE OF OPTIONS; OPTION PRICE.

(a) Option Exercise. Each Employee automatically and without any act on such Employee's part shall be deemed to have exercised such Employee's Option on the Date of Exercise to the extent that the balance then in the Employee's Account is sufficient to purchase, at the Option Price, shares of the Stock subject to the Option. No fractional shares may be purchased upon exercise of the Option. The balance of the amount credited to the Account of each Employee that has not been applied to the purchase of shares of Stock on the Date of Exercise as a result of the prohibition on the purchase of fractional shares under the Plan shall remain in such Account and shall be applied to subsequent Option exercises, subject to the terms of Sections 4(d) and 5(a). If any additional amount remains credited to the Account of an Employee following the exercise of the Option, the Company or Subsidiary Corporation employing the Employee shall immediately pay to the Employee the amount credited to the Employee's Account in one lump sum payment in cash, without any interest thereon.

(b) Option Price Defined. The option price per share of Stock (the

"Option Price") to be paid by an Employee upon the exercise of the Employee's Option shall be equal to 85% of the lesser of: (i) the Fair Market Value of a share of Stock on the Date of Exercise and (ii) the Fair Market Value of a share of Stock on the Date of Grant. The "Fair Market Value" of a share of Stock as of a given date shall be (a) the closing price of a share of Stock on the principal stock exchange or the Nasdaq National Market or Nasdaq SmallCap Market on which shares of Stock are then outstanding, if any (or as reported on any composite index which includes such principal stock exchange or Nasdaq Market), on the trading day previous to such date, or if shares were not traded on the trading day previous to such date, then on the immediately preceding date on which a trade occurred, (b) if Stock is not traded on an exchange or Nasdaq but is quoted on a quotation system other than Nasdaq, the mean between the closing representative bid and asked prices for the Stock on the trading day previous to such date as reported by such quotation system, or (c) if Stock is not publicly traded on an exchange or Nasdaq and not quoted on a quotation system other than Nasdaq, the Fair Market Value of a share of Stock as established by the Committee acting in good faith.

(c) Book Entry/Share Certificates. As soon as reasonably practicable after the purchase of whole shares of Stock upon the exercise of an Option by an Employee, the Company shall issue the shares of Stock to such Employee and such shares shall be held in the custody of the Agent for the benefit of the Employee. The Company or the Agent shall make an entry on its books and records indicating that the shares of Stock purchased in connection with such exercise have been duly issued as of that date to such Employee. An Employee shall have the right at any time to request in writing a certificate or certificates for all or a portion of the whole shares of Stock purchased hereunder. Upon receipt of an Employee's written request for any such certificate, the Company shall (or shall cause the Agent to), within ten (10) days or, if later, as soon as reasonably practicable after the date of such receipt, deliver any such certificate to the Employee. Nothing in this subsection (c) shall prohibit the sale or other disposition by an Employee of shares of Stock purchased hereunder. In the event the Company is required to obtain authority from any commission or agency to issue any certificate or certificates for all or a portion of the whole shares of Stock purchased hereunder, the Company shall seek to obtain such authority as soon as reasonably practicable.

(d) Pro Rata Allocations. If the total number of shares of Stock for which Options are to be exercised on any date exceeds the number of shares of Stock remaining unsold under the Plan (after deduction for all shares of Stock for which Options have theretofore been exercised), the Committee shall

make a pro rata allocation of the available remaining shares of Stock in as nearly a uniform manner as shall be practicable and the balance of the amount credited to the Account of each Employee which has not been applied to the purchase of shares of Stock shall be paid to such Employee in one lump sum in cash within thirty (30) days after the Date of Exercise, without any interest thereon.

(e) Information Statement. The Company shall provide each Employee whose Option is exercised with an information statement in accordance with Section 6039(a) of the Code and the Treasury Regulations thereunder. The Company shall maintain a procedure for identifying certificates of shares of Stock sold upon the exercise of Options in accordance with Section 6039(b) of the Code.

5. WITHDRAWAL FROM THE PLAN.

(a) Withdrawal Election. An Employee may withdraw from participation under the Plan at any time, except that an Employee may not withdraw during the last ten (10) days of any Option Period. An Employee electing to withdraw from the Plan must deliver to the Company a notice of withdrawal in a form prepared by the Committee (the "Withdrawal Election") not later than ten (10) days prior to the Date of Exercise for such Option Period. Upon receipt of an Employee's Withdrawal Election, the Company or Subsidiary Corporation employing the Employee shall pay to the Employee the amount credited to the Employee's Account in one lump sum payment in cash, without any interest thereon, and subject to Section 4(c), at the Employee's request the Company shall (or shall cause the Agent to) deliver to the Employee certificates for any whole shares of Stock previously purchased by the Employee (the value of any fractional share to be returned to such Employee by check), in either case within thirty (30) days of receipt of the Employee's Withdrawal Election. Upon receipt of an Employee's Withdrawal Election by the Company, the Employee shall cease to participate in the Plan and the Employee's Option for such Option Period shall terminate.

(b) Eligibility following Withdrawal. An Employee who withdraws from the Plan with respect to an Option Period, and who is still an Eligible Employee, may elect to participate again in the Plan for any subsequent Offering Period by delivering to the Company an Authorization not later than ten (10) days before the first day of the Offering Period pursuant to Section 3(b).

6. TERMINATION OF EMPLOYMENT.

(a) Termination of Employment Other than by Death. If the employment of an Employee with the Company and the Subsidiary Corporation terminates other than by death, the Employee's participation in the Plan automatically and without any act on the Employee's part shall terminate as of the date of the termination of the Employee's employment. As soon as practicable after such a termination of employment, the Company or Subsidiary Corporation employing the Employee shall pay to the Employee the amount credited to the Employee's Account in one lump sum payment in cash, without any interest thereon, and subject to Section 4(c), at the Employee's request the Company shall (or shall cause the Agent to) deliver to the Employee certificates for any whole shares of Stock previously purchased by the Employee (the value of any fractional share to be returned to such Employee by check). Upon an Employee's termination of employment covered by this subsection, the Employee's Authorization and Option under the Plan shall terminate.

(b) Termination by Death. If the employment of an Employee is terminated by the Employee's death, the executor of the Employee's will or the administrator of the Employee's estate, by written notice to the Company, may

request payment of the balance in the Employee's Account, in which event the Company or Subsidiary Corporation employing the Employee shall pay the amount credited to the Employee's Account in one lump sum payment in cash, without any interest thereon, and subject to Section 4(c), at the Employee's request the Company shall (or shall cause the Agent to) deliver to the Employee certificates for any whole shares of Stock previously purchased by the Employee (the value of any fractional share to be returned to such Employee by check) as soon as practicable after receiving such notice. Upon receipt of such notice, the Employee's Authorization and Option under the Plan shall terminate. If the Company does not receive such notice prior to the next Date of Exercise, the Employee's Option shall be deemed to have been exercised on such Date of Exercise.

7. RESTRICTION UPON ASSIGNMENT. An Option granted under the Plan shall not be transferable other than by will or the laws of descent and distribution, and is exercisable during the Employee's lifetime only by the Employee. Except as provided in Section 6(b) hereof, an Option may not be exercised to any extent except by the Employee. The Company shall not recognize and shall be under no duty to recognize any assignment or alienation of the Employee's interest in the Plan, the Employee's Option or any rights under the Employee's Option.

8. NO RIGHTS OF STOCKHOLDERS UNTIL SHARES ISSUED. With respect to shares of Stock subject to an Option, an Employee shall not be deemed to be a stockholder of the Company, and the Employee shall not have any of the rights or privileges of a stockholder, until such shares have been issued to the Employee or his or her nominee following exercise of the Employee's Option. No adjustments shall be made for dividends (ordinary or extraordinary, whether in cash securities, or other property) or distribution or other rights for which the record date occurs prior to the date of such issuance, except as otherwise expressly provided herein.

9. CHANGES IN THE STOCK AND CORPORATE EVENTS; ADJUSTMENT OF OPTIONS.

(a) Subject to Section 9(c), in the event that the Committee, in its sole discretion, determines that any dividend or other distribution (whether in the form of cash, Stock, other securities, or other property), recapitalization, reclassification, stock split, reverse stock split, reorganization, merger, consolidation, split-up, spin-off, combination, repurchase, liquidation, dissolution, or sale, transfer, exchange or other disposition of all or substantially all of the assets of the Company, or exchange of Stock or other securities of the Company, issuance of warrants or other rights to purchase Stock or other securities of the Company, or other similar corporate transaction or event, affects the Stock such that an adjustment is appropriate in order to prevent dilution or enlargement of the benefits or potential benefits intended to be made available under the Plan or with respect to an Option, then the Committee shall, in such manner as it may deem equitable, adjust any or all of:

(i) the number and kind of shares of Stock (or other securities or property) with respect to which Options may be granted

(including, but not limited to, adjustments of the limitation in Section 3(a) on the maximum number of shares of Stock which may be purchased),

(ii) the number and kind of shares of Stock (or other securities or property) subject to outstanding Options, and

(iii) the exercise price with respect to any Option.

(b) Subject to Section 9(c), in the event of any transaction or event described in Section 9(a) or any unusual or nonrecurring transactions or events affecting the Company, any affiliate of the Company, or the financial statements of the Company or any affiliate, or of changes in applicable laws, regulations, or accounting principles, the Committee, in its sole discretion, and on such terms and conditions as it deems appropriate, either by the terms of the Option or by action taken prior to the occurrence of such transaction or event and either automatically or upon the Employee's request, is hereby authorized to take any one or more of the following actions whenever the Committee determines that such action is appropriate in order to prevent dilution or enlargement of the benefits or potential benefits intended to be made available under the Plan or with respect to any Option under the Plan, to facilitate such transactions or events or to give effect to such changes in laws, regulations or principles:

(i) To provide that all Options outstanding shall terminate without being exercised on such date as the Committee determines in its sole discretion;

(ii) To provide that all Options outstanding shall be exercised prior to the Date of Exercise of such Options on such date as the Committee determines in its sole discretion and such Options shall terminate immediately after such exercises.

(iii) To provide for either the purchase of any Option outstanding for an amount of cash equal to the amount that could have been obtained upon the exercise of such Option

had such Option been currently exercisable, or the replacement of such Option with other rights or property selected by the Committee in its sole discretion;

(iv) To provide that such Option be assumed by the successor or survivor corporation, or a parent or subsidiary thereof, or shall be substituted for by similar options, covering the stock of the successor or survivor corporation, or a parent or subsidiary thereof, with appropriate adjustments as to the number and kind of shares and prices; and

(v) To make adjustments in the number and type of shares of Stock (or other securities or property) subject to outstanding Options, or in the terms and conditions of outstanding Options, or Options which may

be granted in the future.

(c) No adjustment or action described in this Section 9 or in any other provision of the Plan shall be authorized to the extent that such adjustment or action would cause the Plan to fail to satisfy the requirements of Section 423 of the Code. Furthermore, no such adjustment or action shall be authorized to the extent such adjustment or action would result in short-swing profits liability under Section 16 of the Securities and Exchange Act of 1934, as amended, or violate the exemptive conditions of Rule 16b-3 unless the Committee determines that the Option is not to comply with such exemptive conditions. The number of shares of Stock subject to any Option shall always be rounded to the next whole number.

(d) The existence of the Plan and the Options granted hereunder shall not affect or restrict in any way the right or power of the Company or the stockholders of the Company to make or authorize any adjustment, recapitalization, reorganization or other change in the Company's capital structure or its business, any merger or consolidation of the Company, any issue of stock or of options, warrants or rights to purchase stock or of bonds, debentures, preferred or prior preference stocks whose rights are superior to or affect the Stock or the rights thereof of which are convertible into or exchangeable for Stock, or the dissolution or liquidation of the company, or any sale or transfer of all or any part of its assets or business, or any other corporate act or proceeding, whether of a similar character or otherwise.

10. USE OF FUNDS; NO INTEREST PAID. All funds received or held by the Company under the Plan shall be included in the general funds of the Company free of any trust or other restriction and may be used for any corporate purpose. No interest will be paid to any Employee or credited to any Employee's Account with respect to such funds.

11. DIVIDENDS.

(a) Cash dividends and other cash distributions received by the Agent with respect to Stock held in its custody hereunder will be credited to each Employee's Account in accordance with such Employee's interests in such Stock, and shall be applied, as soon as practicable after the receipt thereof by the Agent, to the purchase in the open market at prevailing market prices of the number of whole shares of Stock that may be purchased with such funds (after deductions of any bank service fees, brokerage charges, transfer taxes, and any other transaction fee, expense or cost payable in connection with the purchase of such shares of Stock and not otherwise paid by the Employer.)

(b) All purchases of shares of Stock made pursuant to this Section 11 will be made in the name of the Agent or its nominee, and shall be transferred and credited to the Account(s) of the Employees to which such dividends or other distributions were credited. Dividends paid in the form of shares of Stock will be allocated by the Agent, as and when received, with respect to Stock held in its custody hereunder to the Account of each Employee in accordance with such Employee's interests in such Stock. Property, other than Stock or cash, received by the Agent as a distribution on Stock held in its

custody hereunder, shall be sold by the Agent for the accounts of Employees, and the Agent shall treat the proceeds of such sale in the same manner as cash dividends received by the Agent on Stock held in its custody hereunder.

12. AMENDMENT, SUSPENSION OR TERMINATION OF THE PLAN. Each of the Board and the Committee may amend, suspend, or terminate the Plan at any time and from time to time, including with

respect to the duration or frequency of Offering Periods under the Plan, provided that approval by a vote of the holders of the outstanding shares of the Company's capital stock entitled to vote shall be required to amend the Plan to: (a) change the number of shares of Stock that may be sold pursuant to Options under the Plan, (b) alter the requirements for eligibility to participate in the Plan, or (c) in any manner that would cause the Plan to no longer be an "employee stock purchase plan" within the meaning of Section 423(b) of the Code.

13. ADMINISTRATION BY COMMITTEE; RULES AND REGULATIONS.

(a) Appointment of Committee. The Committee shall consist of two or more members, and may be comprised of members of the Board or Employees. Appointment of Committee members shall be made by the Board and shall be effective upon acceptance of appointment. Committee members may resign at any time by delivering written notice to the Board. Vacancies in the Committee may be filled by the Board.

(b) Duties and Powers of Committee. It shall be the duty of the Committee to conduct the general administration of the Plan in accordance with its provisions. The Committee shall have the power to interpret the Plan and the terms of the Options, and to adopt such rules for the administration, interpretation and application of the Plan as are consistent therewith and to interpret, amend or revoke any such rules. In its absolute discretion, the Board may at any time and from time to time exercise any and all rights and duties of the Committee under the Plan.

(c) Majority Rule; Unanimous Written Consent. The Committee shall act by a majority of its members in attendance at a meeting at which a quorum is present or by a memorandum or other written instrument signed by all members of the Committee.

(d) Compensation; Professional Assistance; Good Faith Actions. Members of the Committee shall receive such compensation, if any, for their services as members as may be determined by the Board. All expenses and liabilities that members of the Committee incur in connection with the administration of the Plan shall be borne by the Company. The Committee may, with the approval of the Board, employ attorneys, consultants, accountants, appraisers, brokers or other persons. The Committee, the Company and the Company's officers and Directors shall be entitled to rely upon the advice, opinions or valuations of any such persons. All actions taken and all interpretations and determinations made by the Committee or the Board in good

faith shall be final and binding upon all Option holders, the Company and all other interested persons. No members of the Committee or Board shall be personally liable for any action, determination or interpretation made in good faith with respect to the Plan or Options, and all members of the Committee and the Board shall be fully protected by the Company to the maximum extent permitted under applicable law and the charter documents of the Company in respect of any such action, determination or interpretation.

14. DESIGNATION OF SUBSIDIARY CORPORATIONS. The Board shall designate from among the Subsidiary Corporations, as determined from time to time, the Subsidiary Corporation or Subsidiary Corporations whose Employees shall be eligible to be granted Options under the Plan. The Board may designate a Subsidiary Corporation, or terminate the designation of a Subsidiary Corporation, without the approval of the stockholders of the Company.

15. NO RIGHTS AS AN EMPLOYEE. Nothing in the Plan shall be construed to give any person (including any Eligible Employee) the right to remain in the employ of the Company, a Parent Corporation or a Subsidiary Corporation or to affect the right of the Company, any Parent Corporation or any Subsidiary Corporation to terminate the employment of any person (including any Eligible Employee) at any time, with or without cause.

16. TERM; APPROVAL BY STOCKHOLDERS. Subject to approval by the stockholders of the Company in accordance with this Section, the Plan shall remain in effect until terminated in accordance with Section 12. No Option may be granted during any period of suspension of the Plan or after termination of the Plan. The Plan shall be submitted for the approval of the Company's stockholders within twelve (12) months after the date of the adoption of the Plan by the Board. Options may be granted prior to such stockholder approval; provided, however, that such Options shall not be exercisable

prior to the time when the Plan is approved by the Company's stockholders; and, provided, further, that if such approval has not been obtained by the end of said 12-month period, all Options previously granted under the Plan shall thereupon terminate without being exercised.

17. EFFECT UPON OTHER PLANS. The adoption of the Plan shall not affect any other compensation or incentive plans in effect for the Company, any Parent Corporation or any Subsidiary Corporation. Nothing in this Plan shall be construed to limit the right of the Company, any Parent Corporation or any Subsidiary Corporation to: (a) establish any other forms of incentives or compensation for employees of the Company, any Parent Corporation or any Subsidiary Corporation, or (b) grant or assume options otherwise than under the Plan in connection with any proper corporate purpose, including, but not by way of limitation, the grant or assumption of options in connection with the acquisition, by purchase, lease, merger, consolidation or otherwise, of the business, stock or assets of any corporation, firm or association.

18. CONDITIONS TO ISSUANCE OF STOCK CERTIFICATES. The Company shall not be

required to issue or deliver any certificate or certificates for shares of Stock purchased upon the exercise of Options prior to fulfillment of all the following conditions:

(a) The admission of such shares to listing on all stock exchanges, if any, on which is then listed;

(b) The completion of any registration or other qualification of such shares under any state or federal law or under the rulings or regulations of the Securities and Exchange Commission or any other governmental regulatory body, which the Committee shall, in its absolute discretion, deem necessary or advisable;

(c) The obtaining of any approval or other clearance from any state or federal governmental agency which the Committee shall, in its absolute discretion, determine to be necessary or advisable;

(d) The payment to the Company of all amounts which it is required to withhold under federal, state or local law upon exercise of the Option; and

(e) The lapse of such reasonable period of time following the exercise of the Option as the Committee may from time to time establish for reasons of administrative convenience.

19. NOTIFICATION OF DISPOSITION. Each Employee shall give prompt notice to the Company of any disposition or other transfer of any shares of Stock purchased upon exercise of an Option if such disposition or transfer is made: (a) within two (2) years from the Date of Grant of the Option, or (b) within one (1) year after the transfer of such shares of Stock to such Employee upon exercise of such Option. Such notice shall specify the date of such disposition or other transfer and the amount realized, in cash, other property, assumption of indebtedness or other consideration, by the Employee in such disposition or other transfer.

20. NOTICES. Any notice to be given under the terms of the Plan to the Company shall be addressed to the Company in care of its Secretary and any notice to be given to any Employee shall be addressed to such Employee at such Employee's last address as reflected in the Company's records. By a notice given pursuant to this Section, either party may designate a different address for notices to be given to it, him or her. Any notice which is required to be given to an Employee shall, if the Employee is then deceased, be given to the Employee's personal representative if such representative has previously informed the Company of his status and address by written notice under this Section. Any notice shall have been deemed duly given if enclosed in a properly sealed envelope or wrapper addressed as aforesaid at the time it is deposited (with postage prepaid) in a post office or branch post office regularly maintained by the United States Postal Service.

21. HEADINGS. Headings are provided herein for convenience only and are not to serve as a basis for interpretation or construction of the Plan. -

I hereby certify that the Gen-Probe Incorporated Employee Stock Purchase Plan was adopted by the Board of Directors of Gen-Probe Incorporated on March 3, 2003 and by the Compensation Committee of the Board of Directors on April 2, 2003.

Executed on this 2nd day of April, 2003.

/s/ R. William Bowen

R. William Bowen
Secretary

* * * * * * *

I hereby certify that the Gen-Probe Incorporated Employee Stock Purchase Plan was approved by the stockholders of Gen-Probe Incorporated on May 29, 2003.

Executed on this 29th day of May, 2003.

/s/ R. William Bowen

R. William Bowen
Secretary

Exhibit 10.72

***TEXT OMITTED AND FILED SEPARATELY
CONFIDENTIAL TREATMENT REQUESTED
UNDER 17 C.F.R. SECTIONS 200.80(b)(4)
AND 240.24B-2

2003 AMENDMENT TO THE RENEWED DISTRIBUTORSHIP AGREEMENT AND THE DISTRIBUTORSHIP ARRANGEMENTS AGREEMENT DATED MAY 2ND, 1997

This amendment is entered into as of the 2nd day of May 2003 by and between Gen-Probe Incorporated, a Delaware corporation, with its principal place of business located at 10210 Genetic Center Drive, San Diego, California 92121 ("GEN-PROBE) and bioMerieux S.A., a French corporation, having its principal place of business at Chemin de l'Orme, 69280 Marcy L'Etoile, France ("BIOMERIEUX").

RECITALS

A. GEN-PROBE and BIOMERIEUX have entered into a Distribution Agreement and a Distributorship Arrangements Agreement ("the Agreements") both dated May 2nd, 1997, under which GEN-PROBE has appointed BIOMERIEUX as its exclusive distributor for the sales of certain products in certain specified countries.

B. The Distributorship Arrangements Agreement has been modified twice from its date of conclusion, by way of amendments, in order to (i) delete Singapore from the list of countries identified as Phase II Countries, and (ii) to include Poland, a Phase III Country, into the definition of the Territory pursuant to Section 1.5 of the Distributorship Arrangement Agreement.

C. The Distribution Agreement has been modified once from its date of conclusion, by way of amendment dated February 2, 1998, in order to (i) modify the wording of Section 3.3 of the Distribution Agreement, and (ii) to delete Exhibit C to the Distribution Agreement.

D. The Distribution Agreement and the Distribution Arrangements Agreement are sometimes collectively referred to in this Amendment as "the Distribution Agreements."

E. The original term of the Distribution Agreements has been extended by a Renewal Amendment signed by the parties as of November 23, 1999.

F. Gen-Probe and BIOMERIEUX have entered into a Authorized Representative Appointment Agreement dated July 15, 1998 in order to comply with the requirements of the Council Directive 93/42/EEC of June 14, 1993 concerning medical devices and the sale of the Gen-Probe Collection Kits in Europe.

G. GEN-PROBE and BIOMERIEUX have expressed their mutual interest in extending the Distribution Agreements and have therefore decided to enter into this 2003 Amendment to the renewed Distribution Agreements.

AMENDMENT

Now, therefore, in consideration of the mutual commitments set forth below, the parties hereto as follows:

1. Definitions. Capitalized terms not otherwise defined herein shall have the meaning ascribed to them in the Agreements.

2. The parties hereto mutually agree to renew the Term of the Agreements for a further period of three (3) years, starting from May 2nd, 2003 (the "Renewed Term"), unless earlier terminated according to the provisions of the Agreements. No less than one year prior to the scheduled expiration of the Renewed Term, the parties shall commence good faith negotiations regarding another possible extension of the Renewed Term on mutually acceptable terms, provided that, unless the parties shall have reached mutual agreement on the terms and conditions of such an extension within six (6) months of the scheduled expiration of the Renewed Term, the

Renewed Term shall automatically expire on the date set forth in the first section of this Section 2.

3. Notwithstanding the provisions of the foregoing Paragraph 2, during the Renewed Term, either party may terminate the Agreements as of their anniversary date in any year by giving notice to the other party at least 120 days prior to the anniversary date of an intention to terminate or seek amendment of the Agreements. Furthermore, during the Renewed Term of the Agreements, GEN-PROBE shall have the additional right and option to terminate the Agreements, by giving 90-days notice, if BIOMERIEUX's purchases of GEN-PROBE products under the Distribution Agreement during any period of not less than [...***...] fall [...***...] or more below purchases for the corresponding period of the prior year. The calculation of the amount of decrease in BIOMERIEUX's purchases from GEN-PROBE for purposes of the preceding sentence shall exclude any decline in BIOMERIEUX's purchases from GP due to (i) sales of APTIMA Products by GEN-PROBE from former customers for GP products and/or (ii) any recalls of product by GEN-PROBE.

4. The Parties mutually agree to amend the Distribution Agreement with the updated Product list and Parts list Pricing which is attached to this Amendment as Attachment A.

5. The Parties mutually agree to amend the Distribution Arrangements Agreement to define the Territories as those countries listed on Attachment B to this Amendment.

6. As the manufacturer and as outlined in the 93/42/EEC Directive and 98/79/EC Directive (collectively the "Directives"), Gen-Probe is aware of the terms of the Directives and acknowledges its obligations as the manufacturer for the compliance of Products which are provided to bioMerieux for distribution into the EEC. In conjunction with the Directives, Gen-Probe also warrants to provide bioMerieux the following:

   A. Gen-Probe will provide a 6-language standard Product. Additional languages will be mutually discussed in the future.

   B. Gen-Probe will provide bioMerieux with the following materials:

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   - The declaration of conformity for the Products covered by the Directives and any relevant updates thereof, and

   - A copy of the safety data sheet written in English for Products considered to contain a dangerous substance as defined in directives 67/548/EEC and 1999/45/EC and any relevant updates thereof.

   C. Both Parties agree to authorize and conduct audits in the premises involved in the manufacturing, packaging, storage and shipment of the Products as required by the Directives.

   D. Gen-Probe agrees to implement appropriate corrective and / or preventative actions for complaints relating to the Products.

7. For the MTC-NI Product, sold into the Industrial Marketplace (Non Clinical sites) the Distribution rights of this Product will change from Exclusive to Co-Exclusive.

8. Except as expressly modified hereby, all terms and conditions of the original Distribution Agreements (as previously amended) shall remain unchanged and in full force and effect.

AGREED TO AND ACCEPTED BY:

GEN-PROBE INCORPORATED	BIOMERIEUX S.A.
By: /s/ Henry L. Nordhoff	By: /s/ Benoit Adelus
Name: Henry L. Nordhoff	Name: Benoit Adelus
Title: President & CEO	Title: Chief Executive Officer

ATTACHMENT A
PRODUCT LIST WITH PRICING

<TABLE>
<CAPTION>

CAT #	DESCRIPTION	U.O.M.	NEW PRICE
<S>	<C>	<C>	<C>
1791F	DETECTION REAGENT KIT	Kit	$ [...***...]
1792F	PACE 2 CHLAMYDIA TRACHOMATIS	Kit	$ [...***...]
1793F	PACE 2 NEISSERIA GONORRHOEAE	Kit	$ [...***...]
2325F	STD PROFICIENCY PANEL, 3 VIALS/BOX	Kit	$ [...***...]
2930F	FAST EXPRESS REAGENT KIT	Kit	$ [...***...]
3275F	MALE COLLECTION KITS	Kit	$ [...***...]
3300F	FEMALE COLLECTION KITS	Kit	$ [...***...]
3548F	PACE 2 C. TRACHOMATIS PROBE COMPETITION ASSAY	Kit	$ [...***...]
3549F	PACE 2 N. GONORRHOEAE PROBE COMPETITION ASSAY	Kit	$ [...***...]
3905F	PACE 2C FOR C. TRACHOMATIS & N. GONORRHOEAE	Kit	$ [...***...]
1001F	AMPLIFIED M. TUBERCULOSIS DIRECT	Kit	$ [...***...]
1043F	MTD CONTROLS	Kit	$ [...***...]
LR0019F	MTD NEG. CONTROL	Each	$ [...***...]
LR0030F	MTD POS. CONTROL	Each	$ [...***...]
3890F	GROUP A STREPTOCOCCUS DIRECT	Kit	$ [...***...]
4573F	MYCOPLASMA T.C. NON-ISOTOPIC (MTC-NI)	Kit	$ [...***...]
301012F	AMPLIFIED CHLAMYDIA TRACHOMATIS	Kit	$ [...***...]
301015F	SWAB PROCESS, AMPLIFIED CT	Kit	$ [...***...]
301016F	URINE PROCESS, AMPLIFIED CT	Kit	$ [...***...]
2810F	ACCUPROBE CAMPYLOBACTER	Kit	$ [...***...]
2815F	ACCUPROBE ENTEROCOCCUS	Kit	$ [...***...]
2820F	ACCUPROBE GROUP B STREPTOCOCCUS	Kit	$ [...***...]
2825F	ACCUPROBE HAEMOPHILUS INFLUENZAE	Kit	$ [...***...]
2830F	ACCUPROBE NEISSERIA GONORRHOEAE	Kit	$ [...***...]
2865F	ACCUPROBE STREPTOCOCCUS PNEUMONIAE	Kit	$ [...***...]
2875F	ACCUPROBE STAPHYLOCOCCUS AUREUS	Kit	$ [...***...]
2920F	ACCUPROBE LISTERIA MONOCYTOGENES	Kit	$ [...***...]
2925F	ACCUPROBE GROUP A STREPTOCOCCUS	Kit	$ [...***...]
2800F	ACCUPROBE GENERIC REAGENT KIT	Kit	$ [...***...]
2890F	ACCUPROBE BLASTOMYCES DERMATITIDIS	Kit	$ [...***...]
2895F	ACCUPROBE COCCIDIOIDES IMMITIS	Kit	$ [...***...]
2910F	ACCUPROBE HISTOPLASMA CAPSULATUM	Kit	$ [...***...]
2835F	ACCUPROBE MYCOBACTERIUM AVIUM	Kit	$ [...***...]
2840F	ACCUPROBE M. INTRACELLULARE	Kit	$ [...***...]
2845F	ACCUPROBE M. AVIUM COMPLEX	Kit	$ [...***...]
2850F	ACCUPROBE MYCOBACTERIUM GORDONAE	Kit	$ [...***...]
2855F	ACCUPROBE MYCOBACTERIUM KANSASII	Kit	$ [...***...]
2860F	ACCUPROBE M TUBERCULOSIS COMPLEX	Kit	$ [...***...]
2775F	GEN-PROBE HEAT BATH (20 tube capacity)	Each	$ [...***...]
3100i	LEADER(R) 50i	Each	$ [...***...]
4006	GEN-PROBE HEAT BATH (50 tube capacity)	Each	$ [...***...]
1639F	PACE(R) MAGNETIC SEPARATION UNIT (80 tube capacity)	Each	$ [...***...]
1714	BOTTLE TOP DISPENSER (2mL)	Each	$ [...***...]
1847F	LEADER(R) PRINTER PAPER (1 roll/pack)	Package	$ [...***...]

</TABLE>

*CONFIDENTIAL TREATMENT REQUESTED

<TABLE>
<CAPTION>

CAT #	DESCRIPTION	U.O.M.	NEW PRICE
<S>	<C>	<C>	<C>
2065F	PACE(R) REACTION TUBES (120 tubes/box)	Box	$ [...***...]
2085F	PACE(R) SEALING CARDS (35/pack)	Package	$ [...***...]
2113	EPPENDORF REPEAT PIPETTOR	Each	$ [...***...]
2168F	TRITIUM STANDARD	Each	$ [...***...]
2440F	POLYPROPYLENE TUBES (250 tubes/pack)	Package	$ [...***...]
2775A	HEATING BLOCK INSERT (20 tube capacity)	Each	$ [...***...]
3078	BOTTLE TOP DISPENSER (5mL)	Each	$ [...***...]
3919	WASH BOTTLE & CAP ASSEMBLY (200 ml capacity)	Each	$ [...***...]
3994F	50-WELL STRIP RACK SYSTEM (50 tubes)	Each	$ [...***...]
4008	BLUE SNAP CAPS (150/package)	Package	$ [...***...]
4027F	SONICATOR RACK (50 hole)	Each	$ [...***...]
4085F	PLUGGED PIPETTE TIPS (175 mL - 1 case, 6 boxes/case, 120/box)	Case	$ [...***...]
4224F	PLUGGED PIPET TIPS, EXT. LENGTH 250 mL (6 boxes/case)	Case	$ [...***...]
4316F	PLUGGED PIPET TIPS, 1250 mL (6 boxes/case)	Case	$ [...***...]
1042F	LDR CHECK-D	Each	$ [...***...]

</TABLE>

ATTACHMENT B
TERRITORIES COVERED BY BIOMERIEUX

EUROPE :

France (Oct 97)
Germany (Jan 98)
Italy (Feb 98)
Spain (Jan 98)
UK (Jan 98)
Ireland (sales made through UK) (Jan 99)
Portugal (Jan 98)
Greece (June 98)
Switzerland (Jan 98)
Belgium (Jan 98)
Luxembourg (sales made through Belgium) (Jan 98)
The Netherlands (Jan 98)

Austria (Jan 98)
Czech Republic (Sales made through Austria) (Jan 98)
Hungary (Sales made through Austria) (Jan 98)
Slovakia (Sales made through Austria) (Jan 98)
Romania
Tunisia
Croatia (Sales made through A&B) (Jan 98)
Macedonia (Sales made through Avicena) (April 00)
Slovenia (Sales made through Mikro-polo) (Jan 98)
Poland (Oct 98) Liechtenstein (Sales made through Switzerland)
Malta (Jan 98)
Iceland

LATIN AMERICA :

Argentina (June 99)
Columbia
Mexico (Jan 00)

ASIA & PACIFIC :

Australia (Jan 98)
New Zealand (sales made through Australia) (Jan 99)
China (Jan 01)
Taiwan (March 03)
India (May 00)

Exhibit 10.73

***TEXT OMITTED AND FILED SEPARATELY
CONFIDENTIAL TREATMENT REQUESTED
UNDER 17 C.F.R. SECTIONS 200.80(b)(4)
AND 240.24B-2

SUPPLY AGREEMENT

This Supply Agreement ("Agreement") is entered into this 1st day of January, 2002 ("Effective Date") by and between:

GEN-PROBE INCORPORATED, a Delaware corporation, with its principal place of business at 10210 Genetic Center Drive, San Diego, California 92121-4362 ("Gen-Probe") and

MGM INSTRUMENTS, INC., a Nevada corporation, with its principal place of business at 925 Sherman Avenue, Hamden, Connecticut 06514 ("MGM").

RECITALS

WHEREAS, Gen-Probe is in the business of developing, marketing, and selling medical diagnostic products;

WHEREAS, MGM is in the business of manufacturing and selling medical diagnostics instrumentation devices;

WHEREAS, Gen-Probe desires to have MGM manufacture and supply certain medical diagnostics instrumentation devices to Gen-Probe for sale or lease to Gen-Probe's customers; and

WHEREAS, MGM is willing to manufacture and supply such medical diagnostics instrumentation devices to Gen-Probe according to the terms and conditions hereinafter set forth;

NOW THEREFORE, in consideration of the mutual covenants contained herein, Gen-Probe and MGM agree as follows:

1. DEFINITIONS

1.1 "ATP" shall mean the final Acceptance Test Procedures for the commercial production of the Instruments, referenced in Exhibit A, attached hereto and incorporated by reference herein, as they may be modified from time to time in accordance with Article 3 of this Agreement.

1.2 "Decontamination Procedures" shall mean the cleaning procedures to be used prior to the return of an instrument to MGM, attached hereto as Exhibit F and incorporated by reference herein.

1.3 "Instrument" or "Instruments" shall mean those items identified in Exhibit C, which is attached hereto and incorporated by reference herein.

1.4 "Specifications" shall mean the specifications and drawings of the Instruments provided by Gen-Probe as they may be modified from time to time in accordance with Article 3 of this Agreement.

1.5 "Supply Term" shall have the meaning set forth in Section 4.1.

1.6 "Warranty Period" shall have the meaning set forth in Section 10.3(a).

2. SCOPE OF WORK TO BE PERFORMED BY MGM AND GEN-PROBE

2.1 MGM shall manufacture, supply, and deliver the Instruments and Parts, as defined below, in accordance with the terms of this Agreement and in accordance with the Specifications.

2.2 Gen-Probe may purchase spare parts listed on Exhibit E, attached hereto and incorporated by reference herein (collectively, "Parts"), and Instruments from MGM under this Agreement and then resell, rent, lease, or otherwise dispose of such Instruments and Parts to users and distributors.

3. MODIFICATIONS TO SPECIFICATIONS AND TESTING PROCEDURES

3.1 During the term of this Agreement, either party can propose changes to the Specifications and ATP which may enhance the Instrument's performance or reliability, or may make it easier or more economical to manufacture, handle or repair, or which otherwise may be an improvement thereof. Such proposals shall be made in writing describing the change in detail and effect on the technical specifications, spare parts, the compatibility of any part, component or performance. Such proposals shall also include an estimate of the change in the price, if any, for the Instrument.

3.2 MGM may not modify any component or part of the Instrument that may affect form, fit, function, or appearance of the Instrument without obtaining the prior written approval of Gen-Probe. Gen-Probe may at any time require reasonable modifications which are directed to achieve compliance with the Specifications or regulatory requirements. MGM will make any other modifications to the Instrument reasonably requested by Gen-Probe. If the proposed modifications will materially increase or decrease MGM's costs, the parties agree that such changes will be implemented only after the parties have agreed to a revised pricing schedule, reflecting such increased or decreased costs.

3.3 All engineering changes shall be accomplished by Gen-Probe's written acceptance of an Engineering Change Notice ("ECN"). Engineering changes that result in an alteration of the form, fit, function, or appearance of a part, assembly, Instrument or the device performance specifications shall be subject to Sections 3.1 and 3.2, above.

3.4 Modifications pursuant to this Article 3 does not require an amendment to this Agreement, and all agreed upon modifications will automatically be incorporated herein.

4. SUPPLY OF INSTRUMENT AND PARTS

4.1 The Instrument Supply Term shall commence on the Effective Date and shall continue through December 31, 2005 ("Term"). Prior to the end of the Term, the parties may agree to renew this Agreement for either one-, two-, or three-year periods on the same terms and conditions by executing a Renewal

Agreement, an example of which is attached hereto as Exhibit G and incorporated by reference herein.

4.2 Gen-Probe shall submit purchase orders to MGM for its [...***...] requirements of Instruments [...***...] in advance of the start of each [...***...]. Gen-Probe shall further provide MGM a nonbinding [...***...] rolling forecast as available.

4.3 MGM shall, during the Term (including renewal periods) and for a period of five (5) years after delivery of the last Instrument purchased hereunder by Gen-Probe or its customers, supply or arrange to supply to Gen-Probe or its customers all Parts for service and repair of the Instruments. All Parts shall be identified and coded by MGM in the following categories: "A" are items manufactured by MGM; "B" are items manufactured for MGM; and "C" are items supplied only through a commercial source other than MGM. MGM will be required to supply all Parts categorized as A and B or notify Gen-Probe of alternate sources for category B. If MGM is not capable of supplying category A Parts, it will provide Gen-Probe with detailed documentation including, but not limited to, parts drawings, specifications, assembly instructions, and quality specifications which will allow Gen-Probe to source these items from other suppliers.

4.4 MGM will manufacture all Instruments with packaging, labels, colors, and markings as specified by Gen-Probe.

5. PRICING

5.1 The prices payable by Gen-Probe to MGM for each Instrument for the current calendar year are set forth in Exhibit C. MGM warrants that said prices are [...***...] prior to the start of a [...***...], MGM will provide a new price list for the [...***...], based upon [...***...] forecast provided by Gen-Probe. The prices shall be [...***...].

5.2 Additional discounts/repayments for each calendar year may be agreed upon by Gen-Probe and MGM, and any such additional discount/repayments will be set forth in and made a part of Exhibit D, which is attached hereto, without the necessity of amending this Agreement.

5.3 Parts and materials shall be priced as shown on Exhibit E. These items will be appropriately wrapped, packaged, and identified with Gen-Probe's and MGM's part numbers, revision and description.

5.4 All payments hereunder shall be in United States dollars. Terms of payment for all invoices, [...***...], are [...***...].

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5.5 Gen-Probe shall pay MGM a [...***...] on Instruments within [...***...] days of each order placed as set out in Section 4.2. Terms of payment for [...***...] will be [...***...];[...***...] will be given on [...***...].

6. RELIABILITY TESTING, SHIPMENT AND ACCEPTANCE

6.1 MGM shall test all Instruments in accordance with the ATP and shall deliver to Gen-Probe the Final Acceptance Test Data Sheet with the ATP. MGM will

pack all Instruments ordered hereunder suitably for shipment in accordance with the accepted industry standards.

6.2 MGM shall deliver Instruments in accordance with the schedule of purchase orders placed by Gen-Probe. Title and risk of loss shall pass to Gen-Probe at the MGM manufacturing facility. Freight will be collect with carrier assigned by Gen-Probe.

6.3 Upon delivery of any Instrument, Gen-Probe and/or its designee shall have the right to inspect and test such item for defects and will notify MGM of its acceptance or rejection thereof. Instrument shall be deemed accepted if not rejected within [...***...] working days of receipt. Any Instrument rejected shall be returned to MGM at MGM's cost with a written explanation specifying the reason for such return; and MGM, at its sole cost, shall repair such defects or replace such defective parts and reship such item or replacement to its original destination within [...***...] of The Instrument's receipt by MGM.

6.4 Gen-Probe will provide metrics of the incoming quality of Instruments and spare parts as well as the quality of Instruments delivered to customers; frequency to be at least quarterly. A continuous improvement process will be established between the parties, with a minimum of one (1) meeting each quarter.

7. SERVICE, MANUALS AND REPLACEMENT PARTS

7.1 It is understood that upon delivery and acceptance of an Instrument by Gen-Probe or its designee, all field service and maintenance shall be the responsibility of Gen-Probe, except as otherwise required or provided in Article 10.

7.2 MGM shall prepare and provide, at its cost, appropriate Operator's and Service Manuals relating to each Instrument. The Operator's Manual shall instruct the user of the Instrument regarding the proper usage and operation of the unit, including all safety precautions and warnings necessary to adequately inform the user of the potential for injury or harm from the use or operation of the Instrument. The Service Manual shall instruct the service technician regarding the proper diagnostics, testing, repair, maintenance, and other required service of the Instrument, as well as all safety precautions and warnings needed to adequately inform the service technician of the potential for injury or harm from the service or use of the Instrument.

7.3 MGM shall prepare in English the appropriate Service Manuals and Operator's Manuals for the Instruments, including all schematics required for the proper

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operation or service of the Instruments. MGM shall provide one copy of the Operator's Manual with each lnstrument delivered at no additional cost over the Instrument price. Gen-Probe shall have the right to make copies of the Operator's Manual and Service Manual, including all schematics required to service the Instruments and to provide such Operator's Manuals, Service Manuals and schematics to its customers and any independent service organization which it may designate to service Instruments.

8. TERMINATION

8.1 Either party may terminate this Agreement upon written notice to the other party if the other party commits a material breach of this Agreement and fails to cure such material breach within [...***...] after said written notice identifying the breach.

8.2 In addition to other provisions herein which survive termination or expiration, termination or expiration of this Agreement shall not relieve MGM of its obligations or warranties outlined in Section 10.3 and to supply Parts as outlined in Section 4.3.

8.3 Either party may terminate this Agreement for its convenience after providing the other party a [...***...] prior written notice.

9. FORCE MAJEURE

9.1 Each party shall be excused from the performance of its obligations hereunder in the event performance of this Agreement is prevented by a force majeure and such excuse shall continue as long as the condition constituting such force majeure continues, plus thirty (30) days after the termination of such condition.

9.2 For purposes of this Agreement, force majeure is defined as follows: Causes beyond the control of MGM or Gen-Probe, including acts of God, war, any regulations, acts, rules, orders, proclamations, requirements or laws of any government, civil commotion, strike, lockout or other industrial dispute, destruction of production facilities or material by fire, water, earthquake or storm, plant breakdown or failure of equipment, inability to obtain equipment and/or supplies, epidemics and failure of public utilities or common carriers or by any circumstances whatsoever beyond a party's reasonable control.

10. REPRESENTATIONS AND WARRANTIES

10.1 MGM represents and warrants to Gen-Probe that it has full corporate authority to enter into this Agreement, to consummate the transactions, and to fulfill its obligations set forth herein.

10.2 Gen-Probe represents and warrants to MGM that (i) it has full corporate authority to enter into this Agreement, (ii) it will sell MGM products with usage guidelines recommended by MGM, and (iii) it will not alter and sell lnstruments in a manner not approved by MGM.

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10.3 MGM will provide the following product warranty to Gen-Probe and its customers/clients:

10.3.1 The Instruments and Parts delivered will (i) perform in accordance with the requirements of the Specifications, the ATP, and Article 12 of this Agreement; and (ii) be free from defects in material, design, and workmanship for a period of twelve (12) months beginning from the date of delivery of the lnstrument to Gen-Probe's customer, or eighteen (18) months beginning from the date of delivery to Gen-Probe, whichever is longer (the "Warranty Period"). As to any such lnstrument defect, MGM shall be relieved of all obligations of liability under this Section 10.3.1 if the Instrument is operated with any accessory or part not manufactured in accordance with the approved Specifications, or is operated with any fluid or material not jointly

approved by MGM and Gen-Probe, or is not operated or maintained in accordance with the Operator's and/or Service Manuals.

10.3.2 Should any of the Instruments or Parts fail to conform with the foregoing warranty under normal and proper use and maintenance, MGM shall, upon receipt of prompt notice thereof, at MGM's option (i) replace without charge any Instrument or Part manufactured by it which is found to be defective; or (ii) repair such Instrument or Part at MGM's sole expense upon return to MGM's facility in a decontaminated condition pursuant to Decontamination Procedures as outlined in Exhibit F; or (iii) pay Gen-Probe to repair such Instrument or Part. In all cases, MGM shall pay all shipping costs.

10.3.3 After acceptance of an Instrument by Gen-Probe and delivery to a customer, all non-warranty field service and maintenance of the Instrument conducted at the customer site shall be the responsibility of Gen-Probe or its designee.

11. CONFIDENTIALITY OBLIGATIONS

All proprietary and confidential information in connection with the activities contemplated herein (including, without limitation, technical information, marketing information, and vendor information) exchanged between MGM and Gen-Probe during the Term and for a period of seven years following termination or expiration shall be treated as confidential information of the disclosing party, and the receiving party shall never use such information for any purpose other than furtherance of this Agreement, or disclose such information to any third party without the prior written approval of the other party unless such information (a) has become public knowledge through no fault of the party receiving such information, (b) lawfully comes to such party from a third party under no obligation of confidentiality with respect to such information, (c) was in the possession of such party as evidenced by its written records prior to the date of disclosure, (d) was independently developed by receiving party as evidenced by its written records or (e) is required by law or regulation to be disclosed, provided that the party so required to disclose confidential information shall give the disclosing party sufficient notice (in no case less than four (4) days) of the proposed disclosure to oppose or limit disclosure or to seek a protective order for such information. Both parties shall use the same precautions to prevent the unauthorized disclosure of

confidential information to third parties that they take to prevent the unauthorized disclosure of their own confidential information.

12. COMPLIANCE WITH LAW: QUALITY ASSURANCE POLICY

12.1 With respect to all instruments and Parts sold to Gen-Probe hereunder, MGM agrees to manufacture and furnish same in compliance with all applicable federal, state, and local laws and regulations including, but not limited to: (a) the Federal Food, Drug and Cosmetics Act, as amended, including, without limitation, then current Good Manufacturing Practices as established by the United States Food and Drug Administration, (b) Canadian CSA Standards, (c) European Community Council Directive 89/336/EEC, the EMC Directive and Directive 73/23/EEC, the Low Voltage Directive, and (d) the Japanese Ministry of Health and Welfare Koseisho guidelines, including, but not limited to, all Japanese electrical requirements.

12.2 Gen-Probe may, at its expense, inspect and audit lnstrument

manufacture and handling at MGM's facilities to confirm compliance with Section 12.1 above. The date and time of such inspections shall be mutually agreed upon.

13. ASSIGNMENT

Neither party shall have any right or ability to assign, transfer, or sublicense any obligations or benefit under this Agreement without the written consent of the other party except that either party may, without restriction, assign and transfer this Agreement and its rights and obligations hereunder to any affiliate who succeeds to substantially all its business or assets.

14. INDEPENDENT CONTRACTOR

Notwithstanding any provision hereof, for all purposes of this Agreement each party shall act as an independent contractor and not as a partner, joint venturer, franchisee, employee, agent, representative, or participant of or with the other for any purpose whatsoever. MGM agrees that all services hereunder will be rendered by MGM as an independent contractor. Neither party shall have any right or authority whatsoever to assume or to create any obligation or responsibility, express or implied, on behalf of the other party.

15. HEADINGS

The headings in this Agreement are for reference purposes only and shall not affect in any way the meaning or interpretation of this Agreement.

16. ARBITRATION

Any controversy, claim or dispute existing out of or relating to this Agreement, or the breach thereof, shall be resolved by binding arbitration, with any proceedings or hearings to take place in a mutually agreed upon location; and any judgment upon the award rendered by arbitration may be entered in any Court having jurisdiction. If

arbitration is necessary pursuant to this paragraph, the parties shall agree upon a single arbitrator. If the parties are unable to agree on an arbitrator, then they will obtain nominations of three potential arbitrators from JAMS/Endispute and each party will have the right to strike one candidate's name from the list. JAMS/Endispute will then designate the arbitrator. Any arbitration award shall also include, but shall not be limited to, any and all court or arbitration costs, attorney fees and any other costs or charges reasonably necessary to adjudicate the controversy, in addition to any and all damages deemed fair by the Arbitrator(s). Nothing contained herein shall deprive any party of its right to obtain injunctive or other equitable relief.

17. THIRD PARTY LEGAL ACTIONS

17.1 Each party shall be obligated to ensure that the other party is promptly notified concerning any of the legal actions instituted during the term of this Agreement which could effect the other or concern the subject matter of this Agreement.

17.2 Each party shall be responsible for its own defense in any action brought against that party under this Agreement.

17.3 Each party agrees to provide reasonable cooperation and assistance to

the other in connection with any third party suit, without any charge therefor other than reasonable out-of-pocket expenses.

18. NOTICES

Any notices given by one party to the other hereunder shall be in the English language and shall be sent to the address/fax number set forth below (provided that any party may at any time change its address for notice or other such information by giving written notice thereof in accordance with this Section), and shall be deemed to be duly given upon the earliest of (a) hand delivery, (b) the first business day after sending by reputable overnight delivery service for next-day delivery, (c) the third business day after sending by first class United States mail, postage prepaid, (d) the time of successful facsimile transmission (or in the event the time of receipt of the fax in the city where the fax is received is not during regular business hours on a business day, then at the customary hour for the opening of business on the next business day), provided that a complete copy of the notice is also sent by first class United States mail (postage prepaid) on the same day as facsimile transmission or on the next business day, or (e) the date actually received by the other party:

To GEN-PROBE: Gen-Probe Incorporated
Attention: Henry L. Nordhoff
Chairman, President, & Chief Executive Officer
10210 Genetic Center Drive
San Diego, CA 92121
Fax: [...***...]
cc: General Counsel - Fax: [...***...]

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To MGM: MGM Instruments, Inc.
Attention: George Mismas, Chief Executive Officer
925 Sherman Avenue
Hamden CT 06514
Fax: [...***...]

19. GOVERNING LAW

The laws of the State of California shall govern this Agreement without regard to its conflicts of laws principles. All actions arising therefrom shall be brought in the State Court of California located in San Diego, California or, in the case of federal jurisdiction, in the United States District Court for the Southern District of California. The parties hereby submit to the venue and personal jurisdiction of such courts.

20. SURVIVABILITY

The following provisions shall survive the termination or expiration of this Agreement: Articles 1, 10, 11, 12, 13, 15, 16, 17, 18, and 19 and Sections 4.3, 4.4, and 8.2.

21. ENTIRE AGREEMENT

This Agreement constitutes the entire agreement and understanding between the parties with respect to the subject matter hereof and there are no promises,

representations, conditions, warranties, commitments, understandings, provisions or terms related thereto other than those set forth in this Agreement, and this Agreement supersedes all previous understandings, agreements and representations between the parties, written or oral with respect to the subject matter hereof. The provisions of this Agreement may not be waived, changed, modified, or amended except by a writing signed by both parties.

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IN WITNESS WHEREOF, the parties have caused this Agreement to be executed by their duly authorized representatives as of the date first written above.

GEN-PROBE INCORPORATED	MGM INSTRUMENTS, INC.
By:/s/ Henry L. Nordhoff	By:/s/ George Mismas
Henry L. Nordhoff	George Mismas
Chairman, President, & CEO	Chief Executive Officer

EXHIBIT LLST

"A" FINAL ACCEPTANCE TEST PROCEDURES ("ATP")

"B" (INTENTIONALLY OMITTED)

"C" LlST OF INSTRUMENTS/PRICING

"D" ADDITIONAL DISCOUNTS AND REPAYMENTS

"E" SPARE PARTS PRICE LlST

"F" DECONTAMINATION PROCEDURES

"G" RENEWAL AGREEMENT FORM

"H" AGREEMENT AMENDMENT FORM

EXHIBIT A

FINAL ACCEPTANCE TEST PROCEDURES ("ATP")

The appropriate Final Acceptance Test Procedure shall be referenced by MGM in their final inspection documentation per Section 6.1. Final Acceptance Test Procedures are subject to revision per Section 3. Gen-Probe shall update MGM as revisions occur.

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ATP NUMBER	DESCRIPTION

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[...***...] [...***...]
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[...***...] [...***...]
[...***...] [...***...]
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*CONFIDENTIAL TREATMENT REQUESTED

EXHIBIT B

(INTENTIONALLY OMITTED)

EXHIBIT C

LIST OF INSTRUMENTS/PRICING

<TABLE>
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MGM CATALOG #
PART NUMBER GEN-PROBE DESCRIPTION U. S. DOLLAR PRICE

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[...***...] [...***...] [...***...] [...***...]
[...***...] [...***...] [...***...] [...***...]
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*CONFIDENTIAL TREATMENT REQUESTED

EXHIBIT E

SPARE PARTS PRICE LIST

(ATTACHED)

EXHIBIT E

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*CONFIDENTIAL TREATMENT REQUESTED

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*CONFIDENTIAL TREATMENT REQUESTED

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[...***...]			

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*CONFIDENTIAL TREATMENT REQUESTED

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[...***...]			

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*CONFIDENTIAL TREATMENT REQUESTED

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<S>	<C>	<C>	<C>
[...***...]			

</TABLE>

*CONFIDENTIAL TREATMENT REQUESTED

EXHIBIT F

DECONTAMINATION PROCEDURES

1. PURPOSE: To define procedures for the cleaning and disinfecting of instruments returned to Gen-Probe for service and repair.

2. SCOPE: This procedure will be followed when a specific procedure is not included in the QOP for the Instrument. It is intended for lnstruments returned to Gen-Probe from a customer site prior to performing any service or repair work. It does not apply to new lnstruments received from a manufacturer or vendor.

3. REFERENCE DOCUMENTS:

QOP 0011 General Instrumentation Operating Procedure

4. SUPPLIES:

4.1 10% Bleach solution. Prepare by diluting 1 part by volume commercial bleach (containing ca. 5% sodium hypochlorite) with 9 parts by volume Dl or AE water. Label prepared solution with date of preparation. Use within one week of preparation date.

4.2 Paper towels

4.3 Lab coat

4.4 Latex or nitrile gloves

4.5 lnstrument Repair Report

5 PREPARATION PROCEDURE:

5.1 Before proceeding with the cleaning procedure, ensure that you are wearing a lab coat and protective gloves.

5.2 Prepare area by ensuring that there is sufficient quantity of 10% bleach solution prepared and the lab area is clean and there are sufficient supplies such as paper towels, etc.

5.3 Each instrument that is brought into the area designated for cleaning cannot be removed from the area until the cleaning procedure is complete.

5.4 Initiate an lnstrument Repair Report form or Quality Control Form

("QCF"), as appropriate for each instrument. Complete the top portion of the form.

EXHIBIT F

DECONTAMINATION PROCEDURES (Continued)

6 CLEANING PROCEDURE

6.1 Open carton containing the instrument and place it on a bench or cart. Set aside all packing material and the carton. If these items cannot be reused, discard in the appropriate waste container.

6.2 Wipe down the outside of the instrument with the 10% bleach solution. Open lid and inspect interior chamber. lnspect for any solutions returned by the customer and dispose of them properly. If there is any doubt, contact the Biological safety officer. Discard any returned tubes.

6.3 Wipe the inside chamber(s) thoroughly with the 10% bleach solution. Do not use excessive solution or allow any "puddling" of the cleaning solution.

6.4 lnspect for any reagent damage and note this on the lnstrument Repair Report. Record on the lnstrument Repair Report any missing components such as pump assembly, power cord, cassettes, etc. that should have been included with the instrument.

6.5 Thoroughly dry all surfaces with paper towels.

6.6 After cleaning, move instrument into the repair area. Document on the instrument QOP or QCF that the cleaning procedure has been completed.

6.7 Dispose of all used supplies. Do not return unused cleaning solution to the stock bottles.

6.8 Notify your supervisor of any irregularities.

EXHIBIT G

RENEWAL AGREEMENT
RENEWAL NUMBER

THIS RENEWAL AGREEMENT is made and entered into as of _____, by and between:

MGM INSTRUMENTS, INC., with offices at 925 Sherman Avenue, Hamden, Connecticut 06514 ("MGM") and

GEN-PROBE INCORPORATED, with offices at 10210 Genetic Center Drive, San Diego, California 92121-4362 ("Gen-Probe")

RECITALS

WHEREAS, MGM and Gen-Probe entered into a Supply Agreement ("Agreement") having an effective date of ;

WHEREAS, MGM and Gen-Probe wish to amend the Agreement;

NOW, THEREFORE, the parties agree as follows:

TERMS

1. The term of the Agreement shall be extended for the time period commencing and terminating .

2. All other terms and conditions remain unchanged and in full force and effect.

3. This Renewal Agreement shall become effective on .

IN WITNESS WHEREOF, the parties have entered into this Renewal Agreement on the day and year written above.

GEN-PROBE INCORPORATED	MGM INSTRUMENTS, INC.
By: _____	By:_____
Henry L. Nordhoff	George Mismas
President & Chief Executive Officer	Chief Executive Officer

EXHIBIT H

SUPPLY AGREEMENT
AMENDMENT NUMBER

THIS SUPPLY AGREEMENT AMENDMENT is made and entered into as of , by and between:

MGM INSTRUMENTS, INC. ("MGM"), with offices at 925 Sherman Avenue, Hamden, Connecticut 06514 and

GEN-PROBE INCORPORATED ("Gen-Probe"), with offices at 10210 Genetic Center Drive, San Diego, California 92121.

RECITALS

WHEREAS, MGM and Gen-Probe entered into a Supply Agreement having an effective date of ("Agreement");

WHEREAS, MGM and Gen-Probe wish to amend the Agreement;

NOW, THEREFORE, the parties agree as follows:

TERMS

1. The terms of the Agreement shall be amended as follows:

2. All other terms and conditions remain unchanged and in full force and effect.

3. This Agreement Amendment shall become effective on .

IN WITNESS WHEREOF, the parties have entered into this Amendment Agreement by their duly authorized representatives.

GEN-PROBE INCORPORATED	MGM INSTRUMENTS, INC.
By: _____	By: _____
Henry L. Nordhoff	George Mismas
President & Chief Executive Officer	Chief Executive Officer

Exhibit 10.74

***TEXT OMITTED AND FILED SEPARATELY
CONFIDENTIAL TREATMENT REQUESTED
UNDER 17 C.F.R. SECTIONS 200.80(b)(4)
AND 240.24B-2

SUPPLY AGREEMENT
AMENDMENT NUMBER ONE

THIS SUPPLY AGREEMENT AMENDMENT NUMBER ONE ("Amendment") is made and entered into as of June 4, 2004 ("Amendment Effective Date"), by and between GEN-PROBE INCORPORATED, a Delaware corporation, with its principal place of business at 10210 Genetic Center Drive, San Diego, California 92121 ("Gen-Probe") and MGM INSTRUMENTS, INC., a Nevada corporation, with its principal place of business at 925 Sherman Avenue, Hamden, Connecticut 06514 ("MGM"). All capitalized terms used but not defined in this Amendment will have the respective meaning given to them in the Agreement (defined below).

RECITALS

WHEREAS, MGM and Gen-Probe previously entered into a Supply Agreement having an effective date of January 1, 2002 ("Agreement"); and

WHEREAS, MGM has developed a thermoelectric device known as the Shaker/Baker, which Gen-Probe desires to have MGM manufacture and supply to Gen-Probe for sale or lease to Gen-Probe's customers under the terms and conditions set forth herein.

NOW, THEREFORE, for good and valuable consideration, the parties agree to amend the Agreement as follows:

1. DEFINITIONS

1.1. "Affiliate" shall mean, as to any Person, any other Person which directly or indirectly controls, is controlled by, or is under common control with such Person. For purposes of the preceding definition, "control" shall mean beneficial ownership of more than fifty percent (50%) of the outstanding shares or securities or the ability otherwise to elect a majority of the board of directors or other managing authority.

1.2. "[...***...]" shall mean the [...***...].

1.3. "[...***...]" shall mean the [...***...].

1.4. "Instrument" or "Instruments" shall mean those items identified in EXHIBIT C to the Agreement and in EXHIBIT C-1, which is attached hereto and incorporated

by reference herein.

1.5. "MGM Technology" shall mean all techniques, ideas, inventions (including patentable inventions), practices, methods, knowledge, know-how, trade secrets, skill, experience, documents, data or apparatus relating to, and all Patents claiming, any aspect or component of the Shaker/Baker Instrument.

1.6. "Shaker/Baker Instrument" shall mean the instrument described on EXHIBIT C-1 hereto.

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1.7. "Specifications" shall mean with respect to the Shaker/Baker Instrument, the specifications and drawings of the Shaker/Baker Instrument provided by MGM as they may be modified from time to time in accordance with Article 3 of the Agreement.

1.8. "Patent" shall mean any (a) U.S. or foreign patent, re-examination, reissue, renewal, extension or term restoration, or (b) pending application for a U.S. or foreign patent, including, without limitation, any provisional application, continuation, continuation-in-part, divisional or substitute application, or inventors' certificate.

1.9. "Person" shall mean any corporation, natural person, firm, joint venture, partnership, trust, unincorporated organization, government or any department or agency of any government.

1.10. "Repair" shall mean to bring an instrument to working order.

1.11. "Retrofit" shall mean to upgrade an instrument to the latest revision or version of an instrument.

1.12. "Refurbishment" shall mean to bring an instrument to nearly new condition.

1.13. "Parts" for purposes of this Amendment shall have the meaning set forth in Section 2.2.

1.14. "Supply Term" for purposes of this Amendment shall have the meaning set forth in Section 4.1 of this Amendment.

1.15. "Third Party" shall mean any Person other than MGM, Gen-Probe or an Affiliate of MGM or Gen-Probe.

1.16. "Warranty Period" for purposes of this Amendment shall have the meaning set forth in Section 10.3.1 of this Amendment.

2. SCOPE OF WORK TO BE PERFORMED BY MGM AND GEN-PROBE

2.1 For purposes of this Amendment and only with respect to the Shaker/Baker

Instrument, Section 2 of the Agreement shall be amended and replaced in its entirety as follows:

"2.1 MGM shall manufacture, supply, deliver and service the Shaker/Baker Instrument in accordance with the terms of the Agreement and this Amendment.

2.2 Gen-Probe may purchase spare parts listed on EXHIBIT E-1 ("Spare Parts Price List"), attached hereto and incorporated by reference herein ("Parts") and the Shaker/Baker Instruments from MGM and then distribute, sell, resell, rent, lease or otherwise dispose of such instruments and parts to users and distributors pursuant to Section 4 of this Amendment."

3. SUPPLY OF INSTRUMENT AND PARTS

3.1 For purposes of this Amendment and only with respect to the Shaker/Baker Instrument, Section 4.1 of the Agreement shall be amended as follows:

"4.1 The Shaker/Baker Supply Term shall commence on the Amendment Effective Date and shall continue for six (6) years from the Amendment Effective Date ("Supply Term"). Prior to the end of the Supply Term, the parties may agree to renew this Agreement for additional six (6) year periods on the same terms and conditions by executing a Renewal Agreement, an example of which is attached to the Agreement as EXHIBIT G and incorporated by reference herein."

4. DISTRIBUTION AND EXCLUSIVITY

4.1 MGM grants Gen-Probe the worldwide exclusive right to distribute, sell, rent, lease or otherwise dispose of the Shaker/Baker Instrument [...***...] for six (6) years from the Amendment Effective Date ("Initial Distribution Term"). Gen-Probe may, at its option, extend the Initial Distribution Term for subsequent six (6) year terms (each an "Additional Distribution Term") subject to the terms of Section 5.1 of the Amendment, by providing written notice to MGM prior to the expiration of the Initial Distribution Term or any subsequent term.

4.2 If after the first [...***...] of the Initial Distribution Term, Gen-Probe has failed to distribute, sell, rent, lease or otherwise dispose of any Shaker/Baker Instrument(s) [...***...], then MGM shall also have the right (co-exclusive with Gen-Probe) to distribute, sell, rent, lease or otherwise dispose of the Shaker/Baker Instrument [...***...]. If after the first [...***...] of the Initial Distribution Term, Gen-Probe has failed to distribute, sell, rent, lease or otherwise dispose of any Shaker/Baker Instrument(s) [...***...], then MGM shall also have the right (co-exclusive with Gen-Probe) to distribute, sell, rent, lease or otherwise dispose of the Shaker/Baker Instrument [...***...].

5. FEES AND PRICING

5.1 For purposes of this Amendment and only with respect to the Shaker/Baker Instrument, Section 5 of the Agreement shall be amended as follows:

"5.1 In consideration of the rights granted by MGM to Gen-Probe in Section 4.1 of the Amendment, Gen-Probe shall pay to MGM [...***...], payable upon execution of this Amendment. In the event Gen-Probe elects to extend the Initial Distribution Term or any subsequent term for an Additional Distribution Term, Gen-Probe shall pay MGM [...***...] for each such Additional Distribution Term, payable within [...***...] of Gen-Probe's election to extend such term.

5.2 Gen-Probe shall pay to MGM the purchase price of [...***...] for each Shaker/Baker Instrument ("Shaker/Baker Instrument Purchase Price") purchased by Gen-Probe from MGM during the period following [...***...] from the Amendment Effective Date.

*CONFIDENTIAL TREATMENT REQUESTED

5.3 Following the [...***...] anniversary of the Effective Date, MGM may adjust the Shaker/Baker Instrument Purchase Price, [...***...]. In the event that Gen-Probe elects to extend the Initial Distribution Term or any subsequent term for Additional Distribution Terms pursuant to Section 4.1 of the Amendment, Gen-Probe shall pay to MGM the Adjusted Price for each Shaker/Baker Instrument purchased during such Additional Distribution Term.

5.4 In the event that MGM distributes, sells, rents, leases or otherwise disposes of the Shaker/Baker Instrument to a party other than Gen-Probe (a "Third Party") [...***...] described in Section 5.1 of this Amendment; [...***...].

5.4 Additional discounts/repayments for each calendar year may be agreed upon by Gen-Probe and MGM, and any such additional discounts/repayments will be set forth in and made a part of EXHIBIT D ("Additional Discounts and Repayments") of the Agreement, without the necessity of amendment of the Agreement or this Amendment.

5.5 Parts and materials shall be priced as shown on EXHIBIT E-1 ("Spare Parts Price list"). These items will be appropriately wrapped, packaged, and identified with Gen-Probe's and MGM's part numbers, revision, description and any other markings or designations requested by Gen-Probe.

5.6 All payments hereunder shall be made in United States dollars. Gen-Probe shall pay MGM [...***...] for each Shaker/Baker Instrument [...***...] as set forth in Section 4.2 of the Agreement. The [...***...] shall be paid by Gen-Probe within [...***...] of Gen-PROBe's receipt and acceptance of the Shaker/Baker Instrument."

6. SERVICE, MANUALS AND REPLACEMENT PARTS

6.1 For purposes of this Amendment and only with respect to the Shaker/Baker Instrument, Section 7 shall be amended as follows:

6.2 The following Sections 7.4 and 7.5 shall be added as follows:

"7.4 Within three (3) months of the Amendment Effective Date, MGM will provide Gen-Probe with procedures for on-site Repair of the Shaker/Baker Instrument by Gen-Probe service technicians, including a list and pricing of parts necessary for such on-site Repairs.

7.5 Within [...***...] of the Amendment Effective Date, MGM will:

7.5.1 Establish repair facilities in the United States and the European Union for the Repair, Refurbishment and/or Retrofit of the Shaker/Baker Instruments beyond the Warranty Period.

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7.5.2 Establish a menu and price list for each Repair, Refurbishment and Retrofit and update such price list annually for reasonable cost of living and material increases or decreases only.

7.5.3 Establish a list and prices for replacement parts for preventative maintenance recommended every three (3) years at MGM's repair facilities and update such price list annually for reasonable cost of living and material increases or decreases only."

7. REPRESENTATION AND WARRANTIES

7.1 For purposes of this Amendment and only with respect to the Shaker/Baker Instrument, Section 10.1 and Section 10.3.1 of the Agreement shall be amended as follows:

"10.1 MGM represents and warrants to Gen-Probe that: (i) it has full corporate authority to enter into the Agreement and this Amendment and to consummate the transactions contemplated herein and to fulfill its obligations set forth in the Agreement and this Amendment; and (ii) the MGM Technology and the Shaker/Baker Instrument do not infringe the intellectual property rights of any Third Party."

"10.3.1 The Shaker/Baker Instruments and Parts delivered will (i) perform in accordance with the requirements of the Specifications, the ATP, and Article 12 of the Agreement; and (ii) be free from defects in material, design, and workmanship for a period of twenty-four (24) months beginning from the date of delivery of the Shaker/Baker Instrument to Gen-Probe (the

"Warranty Period"). As to any such Shaker/Baker Instrument defect, MGM shall be relieved of all obligations of liability under Section 10.3.1 of the Agreement if the Shaker/Baker Instrument is operated with any accessory or part not manufactured in accordance with the approved Specifications, or is operated with any fluid or material not jointly approved by MGM and Gen-Probe, or is not operated or maintained in accordance with the Operator's and/or Service Manuals."

8. BACK-UP MANUFACTURING RIGHTS

8.1 If MGM: (i) discontinues or permanently ceases to manufacture the Shaker/Baker Instrument (unless otherwise agreed to in advance by Gen-Probe); or (ii) otherwise breaches its supply obligations hereunder ("Back-up License Event"), then, effective as of the occurrence of such Back-up License Event, Gen-Probe shall have a right to purchase from MGM, at a reasonable purchase price to be negotiated in good faith and to conclusion by the parties pursuant to Section 8.3 below, and MGM shall grant to Gen-Probe a non-exclusive, worldwide, irrevocable and perpetual license under the MGM Technology necessary or useful to the manufacture, use, importation or sale of the Shaker/Baker Instrument ("Back-up License"), solely to enable Gen-Probe to make or have made the Shaker/Baker Instruments for distribution, sale, rental, lease or other disposition of the Shaker/Baker Instrument by Gen-Probe. In the event of a Back-up License Event during the Initial Distribution Term or any Additional Distribution Term, MGM shall refund to Gen-Probe a pro-rata amount of exclusive distribution fee paid by Gen-Probe for any remaining portion of such term following a Back-up License Event.

8.2 If a Back-up License Event has occurred, and Gen-Probe has purchased the Back-up License from MGM pursuant to Section 8.1 above, MGM shall cooperate with Gen-Probe in effecting the disclosure and/or transfer, as appropriate, of such MGM Technology as is reasonably necessary to commence or continue commercial manufacture of Shaker/Baker Instrument, and shall provide such technical assistance as Gen-Probe may reasonably require, at Gen-Probe's cost to the extent of any out-of-pocket expenses incurred by MGM in connection therewith. Such cooperation shall include the prompt assignment to Gen-Probe of any Third Party manufacturing or supply contracts relevant to the manufacture of the Shaker/Baker Instrument, or, where assignment is impractical because such Third Party is performing other services for MGM under the same contract, MGM shall take reasonable steps to facilitate a similar agreement between such Third Party and Gen-Probe directly.

8.3 If Gen-Probe notifies MGM in writing that Gen-Probe believes a Back-up License Event has occurred and that Gen-Probe elects to exercise its right to a Back-up License, the parties shall immediately negotiate the purchase price for the Back-up License pursuant to terms of this Section 8.3. If the parties are unable to agree on the purchase price within 10 days despite their best efforts, then each party shall notify the other in writing of its final purchase price offer. With its notice, Gen-Probe shall deliver to MGM payment in an amount

equal to its final purchase price offer. MGM shall then immediately take the actions required by Section 8.2. The parties shall then submit the purchase price dispute to arbitration pursuant to Section 16 of the Agreement for decision within 45 days. The arbitrator shall determine the purchase price by selecting one party's final purchase price offer made in accordance with this Section 8.3. If the arbitrator finds that a Back-up License Event did not occur, the arbitrator shall award MGM [...***...] of the purchase price determined by the arbitrator, as MGM's sole relief; provided, however, that if the arbitrator determines that Gen-Probe acted with intentional bad faith in declaring a Back-up License Event, then the arbitrator may award MGM not more than [...***...] of the purchase price, as MGM's sole relief. Gen-Probe shall pay any additional amount due MGM as a result of the arbitrator's decision within [...***...] business days of the award.

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9. INDEMNIFICATION AND LIMITATIONS

9.1 MGM will indemnify and hold harmless Gen-Probe, its officers, directors, employees and agents ("Indemnified Parties") from and against any and all losses, damages, liabilities, expenses and costs, including reasonable legal expense and attorneys' fees ("Losses") to which such Indemnified Parties may become subject as a result of any claim, demand, action or other proceeding by any Third Party to the extent such Losses arise directly or indirectly out of (a) a breach by MGM of any warranty, representation, covenant or agreement made by MGM in this Amendment, or (b) personal injury resulting from the manufacture of the Shaker/Baker Instrument by MGM, except in each case, to the extent such Losses result from, the breach of this Agreement by, or the gross negligence or willful misconduct of, any of the Indemnified Parties.

9.2 Notwithstanding Section 9.1 above or any other provision of this Agreement, MGM will have no liability for any claim based on: (i) Gen-Probe's noncompliance with MGM's Specifications, (ii) any modification of or damage to the Shaker/Baker Instrument after shipment by MGM, including any repair of the Shaker/Baker Instrument performed by a party other than MGM or its designated agent(s), or (iii) use of the Shaker/Baker Instrument in combination with materials or instrumentation from third parties not provided or approved by MGM and used in a manner that is materially inconsistent with the Operator's and Service Manuals for the Shaker/Baker Instrument.

10. LIMITATION OF LIABILITY.

Except for liability for breach of Section 11 of the Agreement, neither party shall be entitled to recover from the other party any special, incidental, consequential or punitive damages in connection with the Agreement or this Amendment; provided however, that this Section 10 shall not be construed to limit either Gen-Probe's indemnification rights or obligations under Section 9 of this Amendment.

11. FULL FORCE AND EFFECT

All other terms and conditions of the Agreement remain unchanged and in full force and effect.

12. SIGNATURES

Facsimile signatures are deemed equivalent to original signatures for purposes of this Amendment.

13. ENTIRE AGREEMENT

The Agreement and this Amendment constitute the entire agreement and understanding between the parties with respect to the subject matter hereof and there are no promises, representations, conditions, warranties, commitments, understanding, provisions or terms related thereto other than those set forth in the Agreement and this Amendment, and the Agreement and this Amendment supercede all previous understandings, agreements and representations between

the parties, written or oral with respect to the subject matter hereof. The provisions of this Agreement may not be waived, changed, modified or amended except by a writing signed by both parties.

IN WITNESS WHEREOF, the parties have entered into this Amendment by their duly authorized representatives as of the date first written above.

GEN-PROBE INCORPORATED	MGM INSTRUMENTS, INC.
By: /s/ Henry L. Nordhoff	By: /s/ George Mismas
Henry L. Nordhoff	George Mismas
President & Chief Executive Officer	Chief Executive Officer

LIST OF EXHIBITS

EXHIBIT C-1

LIST OF INSTRUMENTS/PRICING

Shaker/Baker Instrument: Thermoelectric device capable of active heating and cooling as well as mixing.

<TABLE>
<S> <C>
Gen-Probe part number: [...***...]
Description: [...***...]
Price: $ [...***...]
</TABLE>

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EXHIBIT E-1

SPARE PARTS PRICE LIST

[...***...]

[...***...]
[...***...]

[...***...]

[...***...]

[...***...]

[...***...]

[...***...]

*CONFIDENTIAL TREATMENT REQUESTED

Exhibit 31.1

CERTIFICATION OF PRINCIPAL EXECUTIVE OFFICER PURSUANT TO
SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Henry L. Nordhoff, certify that:

1. I have reviewed this Form 10-Q of Gen-Probe Incorporated;

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 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 we 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 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.

DATE: August 9, 2004

By: /s/ Henry L. Nordhoff

Henry L. Nordhoff
Chairman, President and Chief Executive Officer

Exhibit 31.2

CERTIFICATION OF PRINCIPAL FINANCIAL OFFICER PURSUANT TO
SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Herm Rosenman, certify that:

1. I have reviewed this Form 10-Q of Gen-Probe Incorporated;

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 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 we 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 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.

DATE: August 9, 2004

By: /s/ Herm Rosenman

Herm Rosenman
Vice President, Finance and
Chief Financial Officer

Exhibit 32.1

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Quarterly Report of Gen-Probe Incorporated (the "Company") on Form 10-Q for the fiscal quarter ended June 30, 2004 (the "Report"), as filed with the Securities and Exchange Commission on or about the date hereof, I, Henry L. Nordhoff, President and Chief Executive Officer of the Company certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, to the best of my knowledge, that:

(i) the Report fully complies with the requirements of Section 13(a) and Section 15(d) of the Securities Exchange Act of 1934, as amended; and

(ii) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company at the end of the period covered by the Report and results of operations of the Company for the period covered by the Report.

DATE: August 9, 2004

By: /s/ Henry L. Nordhoff

Henry L. Nordhoff
Chairman, President and Chief Executive Officer

This certification shall not be deemed "filed" for purposes of Section 18 of the Securities and Exchange Act of 1934, or the Exchange Act, or otherwise subject to the liability of Section 18 of the Exchange Act. Such certification shall not be deemed to be incorporated by reference into any filing under the Securities Act of 1933 or the Exchange Act, except to the extent that the Company specifically incorporates it by reference.

Exhibit 32.2

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Quarterly Report of Gen-Probe Incorporated (the "Company") on Form 10-Q for the fiscal quarter ended June 30, 2004 (the "Report"), as filed with the Securities and Exchange Commission on or about the date hereof, I, Herm Rosenman, Vice President, Finance and Chief Financial Officer of the Company certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, to the best of my knowledge, that:

(i) the Report fully complies with the requirements of Section 13(a) and Section 15(d) of the Securities Exchange Act of 1934, as amended; and

(ii) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company at the end of the period covered by the Report and results of operations of the Company for the period covered by the Report.

DATE: August 9, 2004

By: /s/ Herm Rosenman

Herm Rosenman
Vice President, Finance and Chief Financial Officer

This certification shall not be deemed "filed" for purposes of Section 18 of the Securities and Exchange Act of 1934, or the Exchange Act, or otherwise subject to the liability of Section 18 of the Exchange Act. Such certification shall not be deemed to be incorporated by reference into any filing under the Securities Act of 1933 or the Exchange Act, except to the extent that the Company specifically incorporates it by reference.