

GEN PROBE INC
Form 424B3
September 10, 2003

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PROSPECTUS

This filing is made pursuant to Rule 424(b)(3) under the Securities
Act of 1933 in connection with Registration No. 333-108410

\$150,000,000

Gen-Probe Incorporated

Common Stock

Preferred Stock

Debt Securities

Warrants

From time to time, we may sell any of the securities listed above.

We will provide the specific terms of these securities in one or more supplements to this prospectus. You should read this prospectus, the information incorporated by reference in this prospectus and any prospectus supplement carefully before you invest.

Our common stock is traded on the Nasdaq National Market under the symbol GPRO. The applicable prospectus supplement will contain information, where applicable, as to any other listing on the Nasdaq National Market or any securities market or other exchange of the securities covered by the prospectus supplement.

**INVESTING IN OUR SECURITIES INVOLVES RISKS. SEE RISK FACTORS BEGINNING ON
PAGE 4.**

**THIS PROSPECTUS MAY NOT BE USED TO OFFER OR SELL ANY SECURITIES UNLESS ACCOMPANIED BY A
PROSPECTUS SUPPLEMENT.**

The securities may be sold by us to or through underwriters or dealers, directly to purchasers or through agents designated from time to time. For additional information on the methods of sale, you should refer to the section entitled Plan of Distribution in this prospectus. If any underwriters are involved in the sale of any securities with respect to which this prospectus is being delivered, the names of such underwriters and any applicable discounts or commissions and over-allotment options will be set forth in a prospectus supplement. The price to the public of such securities and the net proceeds we expect to receive from such sale will also be set forth in a prospectus supplement.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or determined if this prospectus is truthful or complete. Any representation to the contrary is a criminal offense.

The date of this prospectus is September 10, 2003

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You should rely only on the information contained or incorporated by reference into this prospectus or any applicable prospectus supplement. We have not authorized anyone to provide you with different information. We are not making an offer of the securities to be sold under this prospectus in any jurisdiction where the offer or sale is not permitted. You should not assume that the information contained in this prospectus or any applicable prospectus supplement is accurate as of any date other than the date on the front cover of this prospectus or the prospectus supplement, or that the information contained in any document incorporated by reference is accurate as of any date other than the date of the document incorporated by reference, regardless of the time of delivery of this prospectus or any sale of a security.

ABOUT THIS PROSPECTUS

This prospectus is part of a registration statement that we filed with the Securities and Exchange Commission, or SEC, using a shelf registration process. Under this shelf registration process, we may sell common stock, preferred stock, debt securities and warrants, in one or more offerings up to a total dollar amount of \$150,000,000. This prospectus provides you with a general description of the securities we may offer. Each time we sell any securities under this prospectus, we will provide a prospectus supplement that will contain more specific information about the terms of those securities. We may also add, update or change in a prospectus supplement any of the information contained in this prospectus or in documents we have incorporated by reference into this prospectus. This prospectus, together with the applicable prospectus supplements and the documents incorporated by reference into this prospectus, includes all material information relating to this offering. You should carefully read both this prospectus and the applicable prospectus supplement together with the additional information described under **Where You Can Find More Information** before buying securities in this offering.

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SUMMARY

Gen-Probe

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 20 years of nucleic acid detection research and product development experience, and our products, which are based on our patented nucleic acid testing, or NAT, technologies, are used daily in clinical laboratories and blood collection centers in major countries throughout the world.

Our principal executive offices are located at 10210 Genetic Center Drive, San Diego, California 92121, and our telephone number is (858) 410-8000. We maintain a worldwide website at www.gen-probe.com. The reference to our worldwide web address does not constitute incorporation by reference of the information contained at this site. On December 10, 2001, Chugai Pharmaceutical Co., Ltd., our former indirect parent, announced its intention to spin us off as a separate, stand alone company by distributing all of its shares of our common stock to its shareholders. On September 15, 2002, Chugai Pharmaceutical completed the distribution, and our common stock began trading on the Nasdaq National Market on September 16, 2002. Our Annual Report on Form 10-K, our Quarterly Reports on Form 10-Q, our Current Reports on Form 8-K and all amendments to those reports that we file with the SEC are currently available free of charge to the general public through our website at www.gen-probe.com. These reports are accessible on our website at a reasonably practicable time after being filed with the SEC.

The Securities We May Offer

We may offer shares of our common stock and preferred stock, various series of debt securities and warrants to purchase any of such securities, with a total value of up to \$150 million from time to time under this prospectus at prices and on terms to be determined by market conditions at the time of offering. This prospectus provides you with a general description of the securities we may offer. Each time we offer a type or series of securities, we will provide a prospectus supplement that will describe the specific amounts, prices and other important terms of the securities, including, to the extent applicable:

designation or classification;

aggregate principal amount or aggregate offering price;

maturity;

original issue discount, if any;

rates and times of payment of interest, dividends or other payments, if any;

redemption, conversion, exchange, settlement or sinking fund terms, if any;

conversion, exchange or settlement prices or rates, if any, and, if applicable, any provisions for changes to or adjustments in the conversion, exchange or settlement prices or rates and in the securities or other property receivable upon conversion, exchange or settlement;

ranking;

restrictive covenants, if any;

voting or other rights, if any; and

important federal income tax considerations.

The prospectus supplement also may add, update or change information contained in this prospectus or in documents we have incorporated by reference into this prospectus.

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This prospectus may not be used to offer or sell any securities unless accompanied by a prospectus supplement.

We may sell the securities directly to or through underwriters, dealers or agents. We, and our underwriters or agents, reserve the right to accept or reject all or part of any proposed purchase of securities. If we do offer securities through underwriters or agents, we will include in the applicable prospectus supplement:

the names of those underwriters or agents;

applicable fees, discounts and commissions to be paid to them;

details regarding over-allotment options, if any; and

the net proceeds to us.

Common Stock. We may issue shares of our common stock from time to time. Holders of our common stock are entitled to one vote per share for the election of directors and on all other matters that require stockholder approval. Subject to any preferential rights of any outstanding preferred stock, in the event of our liquidation, dissolution or winding up, holders of our common stock are entitled to share ratably in the assets remaining after payment of liabilities and the liquidation preferences of any outstanding preferred stock. Our common stock does not carry any preemptive rights enabling a holder to subscribe for, or receive shares of, any class of our common stock or any other securities convertible into shares of any class of our common stock, or any redemption rights.

Preferred Stock. We may issue shares of our preferred stock from time to time, in one or more series. Under our certificate of incorporation, our board of directors has the authority, without further action by stockholders, to designate up to 20,000,000 shares of preferred stock in one or more series and to fix the rights, preferences, privileges, qualifications and restrictions granted to or imposed upon the preferred stock, including dividend rights, conversion rights, voting rights, rights and terms of redemption, liquidation preference and sinking fund terms, any or all of which may be greater than the rights of the common stock. To date, our board of directors has designated 1,000,000 of the 20,000,000 authorized shares of preferred stock as Series A Junior Participating Preferred Stock, which series is described in greater detail in this prospectus under Description of Capital Stock Preferred Stock Stockholder Rights Plan.

We will fix the rights, preferences, privileges, qualifications and restrictions of the preferred stock of each series that we sell under this prospectus and applicable prospectus supplements in the certificate of designation relating to that series. We will incorporate by reference into the registration statement of which this prospectus is a part the form of any certificate of designation that describes the terms of the series of preferred stock we are offering before the issuance of the related series of preferred stock. We urge you to read the prospectus supplements related to the series of preferred stock being offered, as well as the complete certificate of designation that contains the terms of the applicable series of preferred stock.

Debt Securities. We may issue debt securities from time to time, in one or more series, as either senior or subordinated debt or as senior or subordinated convertible debt. The senior debt securities will rank equally with any other unsubordinated debt that we may have and may be secured or unsecured. The subordinated debt securities will be subordinate and junior in right of payment, to the extent and in the manner described in the instrument governing the debt, to all or some portion of our indebtedness. Any convertible debt securities that we issue will be convertible into or exchangeable for our common stock or other securities of ours. Conversion may be mandatory or at your option and would be at prescribed conversion rates.

The debt securities will be issued under one or more documents called indentures, which are contracts between us and a trustee for the holders of the debt securities. In this prospectus, we have summarized certain general features of the debt securities. We urge you, however, to read the prospectus supplements related to the series of debt securities being offered, as well as the complete indentures that contain the terms of the debt securities. Indentures have been filed as exhibits to the registration statement of which

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this prospectus is a part, and supplemental indentures and forms of debt securities containing the terms of debt securities being offered will be incorporated by reference into the registration statement of which this prospectus is a part from reports we file with the SEC.

Warrants. We may issue warrants for the purchase of common stock, preferred stock and/or debt securities in one or more series, from time to time. We may issue warrants independently or together with common stock, preferred stock and/or debt securities, and the warrants may be attached to or separate from those securities.

The warrants will be evidenced by warrant certificates issued under one or more warrant agreements, which are contracts between us and an agent for the holders of the warrants. In this prospectus, we have summarized certain general features of the warrants. We urge you, however, to read the prospectus supplements related to the series of warrants being offered, as well as the complete warrant agreements and warrant certificates that contain the terms of the warrants. Forms of warrant agreements and warrant certificates relating to warrants for the purchase of common stock, preferred stock and debt securities have been filed as exhibits to the registration statement of which this prospectus is a part, and complete warrant agreements and warrant certificates containing the terms of the warrants being offered will be incorporated by reference into the registration statement of which this prospectus is a part from reports we file with the SEC.

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RISK FACTORS

An investment in our securities is risky. Prior to making a decision about investing in our securities, you should carefully consider the specific risks discussed under Risk Factors in both the prospectus and the applicable prospectus supplement, together with all of the other information contained in this prospectus and the prospectus supplement or incorporated by reference in this prospectus. The risks and uncertainties described below are not the only ones facing us. Additional risks and uncertainties not presently known to us, or that we currently see as immaterial, may also harm our business. If any of the risks or uncertainties described below or any such additional risks and uncertainties actually occur, our business, results of operations and financial condition could be materially and adversely affected. In that case, the trading price of the securities being offered by this prospectus and the applicable prospectus supplements could decline, and you might lose all or part of your investment.

Risks Relating to Us and Our Industry

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 system. 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 periods, we may not be able to generate revenues and may not maintain profitability in the future. Our failure to maintain profitability in the future could cause the market price of our common stock to decline.

We could incur significant liability if we are acquired or engage in a transaction involving our stock and Chugai Pharmaceutical's Japanese tax liabilities are greater than the amount specified in the separation and distribution agreement.

In connection with the distribution of all of the outstanding shares of our common stock held by Chugai Pharmaceutical Co., Ltd. to holders of its common stock, Chugai Pharmaceutical will be subject to Japanese tax liabilities, the amount of which is dependent upon the fair market value of our stock. While Chugai Pharmaceutical has used its reasonable efforts to estimate the total amount of such Japanese tax liability, the process and methodology by which the Japanese taxing authority will make its determination of the value of our stock and the amount of tax for which Chugai Pharmaceutical is liable with respect to the distribution is uncertain, and Chugai Pharmaceutical's actual tax liability may exceed such estimated amount. As a result, in the separation and distribution agreement between Chugai Pharmaceutical and us, we have agreed to indemnify Chugai Pharmaceutical in the event that, prior to December 16, 2003, we sell all or substantially all of our assets, a person or group acquires beneficial ownership of 50% or more of our voting stock, we are a party to a merger, or we issue common stock or other equity securities other than issuances of equity securities for cash consideration at a price not in excess of the market price of our common stock immediately prior to such issuance or pursuant to an employee benefit or incentive plan and Chugai Pharmaceutical's Japanese tax liabilities are greater than the amount specified in the separation and distribution agreement. This potential obligation to indemnify Chugai Pharmaceutical could discourage, delay or prevent a change of control that would otherwise provide an above market premium to our stockholders.

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.

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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 expect the costs of manufacturing these lots to increase during the remainder of 2003 and in 2004 in connection with the initiation of clinical trials of the TIGRIS instrument for a blood screening application. 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 limited sales history, which limits our ability to project future sales accurately. Our share of revenue from our blood screening collaboration with Chiron, which was 47.5% as of June 30, 2003, may decrease and can vary from 37% to 47.5% based on a number of circumstances. In addition, we base our internal projections of our international sales on projections prepared by our distributors of these products. Because 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.

If we are unable to complete development of our TIGRIS instrument in a timely manner, we may be unable to retain our existing customers and attract new customers.

Our ability to meet demand for increased automation in the blood screening and diagnostic markets depends on our ability to develop our TIGRIS instrument system. This product, which incorporates sophisticated hardware and software, may not perform as anticipated, and there may be unforeseen delays in its final release. The release of this product already has taken longer and has been costlier than we initially anticipated. During 2001, we terminated our relationship with RELA, Inc., the original outside contractor for the design and development of this product and entered into a relationship with KMC Systems, Inc. for its completion. Further delays in the development of the TIGRIS system could erode any time-to-market advantage for the product.

We successfully completed beta trials, which are customer evaluations, of the TIGRIS system for clinical diagnostic applications at the University of Alabama (Birmingham) in August 2002 and for blood screening applications with The American Red Cross in November 2002. Clinical trials have been completed for clinical diagnostics and premarket notification was filed with the FDA on July 18, 2003. The current development schedule calls for instruments to be installed at clinical trial sites by the end of 2003 for blood screening applications. Products as complicated as the TIGRIS system frequently require operating enhancements following their initial introduction. Delivery of products with defects, or reliability or quality problems, could require significant expenditures of capital and other resources and significantly delay or hinder market acceptance of this product. Any such capital expenditures or delays could harm our operating results, materially damage our reputation and prevent us from retaining our existing customers and attracting new customers.

The adoption of the Financial Accounting Standards Board Statement of Financial Accounting Standard 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 Statement of Financial Accounting Standard 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, 2003, we had goodwill and intangible assets valued at approximately \$46.5 million, including \$23.8 million of capitalized software relating to the TIGRIS system currently under development and \$4.1 million of capitalized patents and purchased intangibles that have been included in Other assets on the face of the balance sheet. We performed the first of the required impairment tests of goodwill and indefinite lived intangible assets to determine if a transition impairment charge should be recognized under SFAS 142 and determined that there had been no impairments. In the future, we will test for impairment at least annually. These tests may result in a determination that the assets have been impaired. If at any time we

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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 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 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, but Chiron sells our 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 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.

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 existing products and to develop and introduce new products. 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 system we are developing.

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 these 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 Food and Drug Administration, or FDA, or foreign regulatory authorities on a timely basis, or at all, and the new products may not be successfully commercialized.

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

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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 us. We believe that Roche Molecular Systems, Abbott Laboratories and Becton Dickinson also are developing automated systems similar to our TIGRIS instrument.

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 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. Chiron has granted a license to Roche Molecular Systems in the blood screening field and has granted licenses to other companies in the clinical diagnostic field. To the extent that Chiron grants additional licenses, further competition will be created for sales of HCV and HIV assays and these licenses may affect the prices that can be charged for our products.

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 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.

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If we raise funds through the issuance of debt or equity, any debt securities or preferred stock issued will have rights, and 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 may 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. Also, regardless of the volatility of the price of our equity, we may be limited in our ability to issue shares of our stock because of our obligation in the separation and distribution agreement between Chugai Pharmaceutical and us to indemnify Chugai Pharmaceutical for any increase in its Japanese tax liability in the event that, prior to December 16, 2003, we sell all or substantially all of our assets, a person or group acquires beneficial ownership of 50% or more of our voting stock, we are a party to a merger, or we issue common stock or other equity securities other than issuances of equity securities for cash consideration at a price not in excess of the market price of our common stock immediately prior to such issuance or pursuant to an employee benefit or incentive plan.

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 36.2% of our total revenues for the six months ended June 30, 2003 and 24.5% of our total revenues for 2002. Product sales by Bayer accounted for 1.2% of our total revenues for the six months ended June 30, 2003 and 1.4% of our total revenues for 2002. 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, so that 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.

On February 26, 2001, we commenced an arbitration proceeding against Chiron in connection with the 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 HIV-1/HCV blood screening assay. Other disputed items included the parties' respective obligations in connection with clinical trials of the 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. During the fourth quarter of 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. Although we do not currently anticipate further disputes with Chiron, we or Chiron may commence arbitration against each other under the collaboration agreement in the future. Any such proceedings could delay 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. Bayer has not yet responded to the

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arbitration demand, but has stated that it intends to file a counterclaim for money damages based on alleged delays in the development of the TIGRIS instrument system. 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. Sales by bioMérieux and Rebio Gen, Inc. comprised 2.3% and 1.2%, respectively, of our total revenues for the six months ended June 30, 2003. Our distribution agreements with bioMérieux terminated on May 1, 2003. Our distribution agreement with Chugai Diagnostics Science, which was acquired by Fujirebio Inc. in September 2002, terminates on December 31, 2005. In March 2003, bioMérieux verbally informed us that it was terminating work on probe assays for the semi-automated probe instrument, although we have not received formal notification that bioMérieux has elected to terminate the applicable license agreement. bioMérieux may terminate the agreement after December 30, 2004 without obligation for minimum royalties following termination.

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 new products directly, we would have to invest in additional sales and marketing resources, including additional field sales personnel, which would significantly increase future selling, 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. Both the Chiron and Bayer agreements can be 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.

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 40.1% of our total revenues for the six months ended June 30, 2003 and 29.7% of our total revenues for 2002.

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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, but we did not receive any revenues directly from these entities. Chiron was our only customer that accounted for greater than 10% of our total revenues for the six months ended June 30, 2003. In addition, Quest Diagnostics Incorporated, Laboratory Corporation of America Holdings and various state and city public health agencies accounted for an aggregate of 22.7% of our total revenues for the six months ended June 30, 2003 and 26.0% of our total revenues for 2002. 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.

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 in compliance with regulatory requirements, in sufficient quantities, on a timely basis and at acceptable costs, 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 such 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 products may require the development of new manufacturing technologies and expertise.

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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, or will be, 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.

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 three 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 through a voluntary field correction. The third recall occurred in July 2002 following the discovery of an error in the Chiron Procleix System software used with the 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. Our products may be subject to additional recalls in the future.

Our sales to international markets are subject to additional risks.

Sales of our products outside the United States accounted for 13% of our total revenues for the six months ended June 30, 2003 and 14% of our total revenues for 2002. Sales by Chiron outside of the United States accounted for 55% of our international revenues for the six months ended June 30, 2003 and 41% of our international revenues for 2002. Chiron has responsibility for the international distribution of our blood screening product, 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 17% and 10%, respectively, of our international sales for the three months ended June 30, 2003 and 19% and 14%, respectively, for 2002.

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

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international operations. Because all of our sales are currently denominated in U.S. dollars, if the value of the U.S. 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 or Japan until we are able to offer an assay that screens for HBV, as well as 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 market for our products is 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 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, substantially all of which 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, 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 gonorrhea and chlamydial infections 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.

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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, or TMATM, 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 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 any 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 such 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.

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 more than 171 United States patents and more than 162 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.

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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 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.

Recently, we have been involved in a number of patent disputes with third parties, a number of which remain unresolved. For example, 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.

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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 no experience with respect to acquiring other companies and limited experience with respect to the formation of collaborations, strategic alliances and joint ventures. If we make any 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 may be limited in our ability to issue shares of our stock as consideration for an acquisition or in a public offering or private placement to raise funds for an acquisition because of our agreement in the separation and distribution agreement between Chugai Pharmaceutical and us to indemnify Chugai Pharmaceutical for any increase in its Japanese tax liability in the event that, prior to December 16, 2003, we sell all or substantially all of our assets, a person or group acquires beneficial ownership of 50% or more of our voting stock, we are a party to a merger, or we issue common stock or other equity securities other than issuances of equity securities for cash consideration at a price not in excess of the market price of our common stock immediately prior to such issuance or pursuant to an employee benefit or incentive plan.

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

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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 and in nearby Rancho Bernardo, 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 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

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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.

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.

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 terms of our separation from Chugai Pharmaceutical, 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.

The terms of our separation from Chugai Pharmaceutical, anti-takeover provisions of our certificate of incorporation and by-laws and provisions of Delaware law could delay or prevent a change of control that you may favor. The separation and distribution agreement requires us to indemnify Chugai Pharmaceutical for any increase in its Japanese tax liability in the event that, prior to December 16, 2003, we sell all or substantially all of our assets, a person or group acquires beneficial ownership of 50% or more of our voting stock, we are a party to a merger, or we issue common stock or other equity securities other than issuances of equity securities for cash consideration at a price not in excess of the market price of our common stock immediately prior to such issuance or pursuant to an employee benefit or incentive plan. These indemnity obligations might discourage, delay or prevent a change of control that you may consider favorable and that would otherwise provide an above market premium to stockholders.

Provisions of our amended and restated certificate of incorporation and amended and restated bylaws also 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,

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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 percent 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 percent 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.

We may not successfully integrate acquired businesses.

In August 2003, we acquired a majority of the outstanding shares of Molecular Light Technologies 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.

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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.

Risks Relating to the Offered Securities

Our stock price may continue to experience fluctuations, which may significantly affect the market price of our common stock and securities convertible into or exchangeable for our common stock.

The market price of our common stock fluctuates over a range and is expected to continue to be volatile in the future. These price fluctuations may be rapid and severe and may leave investors little time to react. Factors that may affect the market price of our common stock include the risks and uncertainties described above in this prospectus and described in the applicable prospectus supplement, as well as changes in securities analysts' earnings projections or securities analysts' recommendations. These factors could lead to a significant decrease in the market price of our common stock and securities convertible into or exchangeable for our common stock.

The securities we are offering may not develop an active public market, which could depress the resale price of the securities.

The securities we are offering, other than our common stock, will be new issues of securities for which there is currently no trading market. We cannot predict whether an active trading market for the securities will develop or be sustained. If an active trading market were to develop, the securities could trade at prices that may be lower than the initial offering price of the securities.

FORWARD-LOOKING INFORMATION

This prospectus contains or incorporates by reference, and the applicable prospectus supplement may contain, forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, or the Securities Act, and Section 21E of the Securities Exchange Act of 1934, as amended, or the Exchange Act. These forward-looking statements can generally be identified as such because the context of the statement will include words such as may, will, intends, plans, believes, anticipates, expects, estimates, predicts, potential, opportunity, the negative of these words or words of similar import. Similarly, statements that describe our reserves and our future plans, strategies, intentions, expectations, objectives, goals or prospects are also forward-looking statements. Discussions containing these forward-looking statements may be found, among other places, in Business and Management's Discussion and Analysis of Financial Condition and Results of Operations incorporated by reference from our most recent Annual Report on Form 10-K and our Quarterly Reports on Form 10-Q for the quarters ended subsequent to our filing of such Annual Report on Form 10-K with the SEC, as well as any amendments thereto reflected in subsequent filings with the SEC. These forward-looking statements are or will be, as applicable, based largely on our expectations and projections about future events and future trends affecting our business, and so are or will be, as applicable, subject to risks and uncertainties that could cause actual results to differ materially from those anticipated in the forward-looking statements.

Our actual results of operations and execution of our business strategy could differ materially from those expressed in, or implied by, the forward-looking statements. In addition, past financial and/or operating performance is not necessarily a reliable indicator of future performance and you should not use our historical performance to anticipate results or future period trends. We can give no assurances that any

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of the events anticipated by the forward-looking statements will occur or, if any of them do, what impact they will have on our results of operations and financial condition. In evaluating our forward-looking statements, you should specifically consider the risks and uncertainties discussed under **Risk Factors** in this prospectus and the applicable prospectus supplement. Except as required by law, we undertake no obligation to publicly revise our forward-looking statements to reflect events or circumstances that arise after the date of this prospectus or the prospectus supplement or the date of documents incorporated by reference in this prospectus that include forward-looking statements.

FINANCIAL RATIOS

The following table sets forth our ratio of earnings to fixed charges and the ratio of our combined fixed charges and preference dividends to earnings for each of the periods presented:

	Years Ended December 31,					Six Months Ended
	1998	1999	2000	2001	2002	June 30, 2003
Ratio of earnings to fixed charges	5.03	8.56	(0.55)	3.55	17.09	89.76
Ratio of combined fixed charges and preference dividends to earnings	0.20	0.12	(1.82)	0.28	0.06	0.01

For purposes of computing the ratio of earnings to fixed charges and the ratio of our combined fixed charges and preference dividends to earnings, earnings consist of income before income taxes before impairment, disposition, restructuring and other charges (credits), and the cumulative effect of a change in accounting principle, plus fixed charges. Fixed charges represent interest expense, including capitalized interest, on all debt, amortized premiums, discounts and capitalized expenses related to indebtedness, and the estimated interest factor attributable to rental expenses. Excluded from the 2002 fixed charges is \$1,200,000 related to the prepayment premium associated with the retirement of \$10,000,000 in outstanding notes payable. In 2003 the Company had no debt outstanding.

USE OF PROCEEDS

Except as described in any prospectus supplement, we currently intend to use the net proceeds from the sale of our securities under this prospectus for general corporate purposes. We may also use a portion of the net proceeds to acquire or invest in businesses, products and technologies that are complementary to our own, although we currently are not planning or negotiating any such transactions.

DESCRIPTION OF CAPITAL STOCK

As of the date of this prospectus, our certificate of incorporation authorizes us to issue 100,000,000 shares of common stock, par value \$0.0001 per share and 20,000,000 shares of preferred stock, par value \$0.0001 per share. As of August 25, 2003, 24,009,551 shares of our common stock were outstanding and no shares of preferred stock were outstanding. To date, our board of directors has designated 1,000,000 of the 20,000,000 authorized shares of preferred stock as Series A Junior Participating Preferred Stock, which series is described in greater detail below under **Preferred Stock** **Stockholder Rights Plan**.

The following summary describes the material terms of our capital stock and stockholder rights plan. The description of capital stock and stockholder rights plan is qualified by reference to our amended and restated certificate of incorporation, as amended, our bylaws, as amended, the certificate of designation for our Series A Junior Participating Preferred Stock, and our stockholder rights plan, which are incorporated by reference as exhibits into the registration statement of which this prospectus is a part.

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Common Stock

Voting. Common stockholders are entitled to one vote per share for the election of directors and on all other matters that require stockholder approval. There is no cumulative voting.

Dividends and Other Distributions. Holders of our common stock are entitled to share in an equal amount per share in any dividends declared by our board of directors on the common stock and paid out of legally available assets.

Distribution on Dissolution. Subject to any preferential rights of any outstanding preferred stock, in the event of our liquidation, dissolution or winding up, holders of our common stock are entitled to share ratably in the assets remaining after payment of liabilities and the liquidation preferences of any outstanding preferred stock.

Other Rights. Our common stock does not carry any preemptive rights enabling a holder to subscribe for, or receive shares of, any class of our common stock or any other securities convertible into shares of any class of our common stock, or any redemption rights.

Preferred Stock

Under our certificate of incorporation, our board of directors has the authority, without further action by stockholders, to designate up to 20,000,000 shares of preferred stock in one or more series and to fix the rights, preferences, privileges, qualifications and restrictions granted to or imposed upon the preferred stock, including dividend rights, conversion rights, voting rights, rights and terms of redemption, and liquidation preference, any or all of which may be greater than the rights of the common stock. To date, our board of directors has designated 1,000,000 of the 20,000,000 authorized shares of preferred stock as Series A Junior Participating Preferred Stock, which series is described in greater detail below under Stockholder Rights Plan.

The issuance of preferred stock could adversely affect the voting power of holders of common stock and reduce the likelihood that common stockholders will receive dividend payments and payments upon liquidation. The issuance could have the effect of decreasing the market price of our common stock. The issuance of preferred stock also could have the effect of delaying, deterring or preventing a change in control of us.

Our board of directors will fix the rights, preferences, privileges, qualifications and restrictions of the preferred stock of each series that we sell under this prospectus and applicable prospectus supplements in the certificate of designation relating to that series. We will incorporate by reference into the registration statement of which this prospectus is a part the form of any certificate of designation that describes the terms of the series of preferred stock we are offering before the issuance of the related series of preferred stock. This description will include:

the title and stated value;

the number of shares we are offering;

the liquidation preference per share;

the purchase price per share;

the dividend rate per share, dividend period and payment dates and method of calculation for dividends;

whether dividends will be cumulative or non-cumulative and, if cumulative, the date from which dividends will accumulate;

our right, if any, to defer payment of dividends and the maximum length of any such deferral period;

the procedures for any auction and remarketing, if any;

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the provisions for a sinking fund, if any;

the provisions for redemption or repurchase, if applicable, and any restrictions on our ability to exercise those redemption and repurchase rights;

any listing of the preferred stock on any securities exchange or market;

whether the preferred stock will be convertible into our common stock or other securities of ours, including warrants, and, if applicable, the conversion period, the conversion price, or how it will be calculated, and under what circumstances it may be adjusted;

whether the preferred stock will be exchangeable into debt securities, and, if applicable, the exchange period, the exchange price, or how it will be calculated, and under what circumstances it may be adjusted;

voting rights, if any, of the preferred stock;

preemption rights, if any;

restrictions on transfer, sale or other assignment, if any;

a discussion of any material or special United States federal income tax considerations applicable to the preferred stock;

the relative ranking and preferences of the preferred stock as to dividend rights and rights if we liquidate, dissolve or wind up our affairs;

any limitations on issuances of any class or series of preferred stock ranking senior to or on a parity with the series of preferred stock being issued as to dividend rights and rights if we liquidate, dissolve or wind up our affairs; and

any other specific terms, rights, preferences, privileges, qualifications or restrictions of the preferred stock.

When we issue shares of preferred stock under this prospectus, the shares will be fully paid and nonassessable and will not have, or be subject to, any preemptive or similar rights.

Delaware law provides that the holders of preferred stock will have the right to vote separately as a class on any proposal involving fundamental changes in the rights of holders of that preferred stock. This right is in addition to any voting rights that may be provided for in the applicable certificate of designation.

Stockholder Rights Plan. Each outstanding share of our common stock has attached to it one preferred share purchase right, which we refer to as a right. Each right entitles the registered holder of our common stock at the close of business on September 26, 2002 to purchase from us one one-hundredth of a share of Series A Junior Participating Preferred Stock, which we refer to as participating preferred shares, at a price of \$100 per one one-hundredth of a participating preferred share, subject to adjustment. Each one one-hundredth of a share of participating preferred shares has designations and powers, preferences and rights, and the qualifications, limitations and restrictions which make its value approximately equal to the value of a share of our common stock. The description and terms of the rights are set forth in a Rights Agreement, dated as of September 16, 2002, and amended on October 9, 2002, between us and U.S. Bank National Association, as rights agent, which is incorporated by reference as an exhibit into the registration statement of which this prospectus is a part.

Until the distribution date described below, we will not issue separate certificates evidencing the rights. Until that date, the rights will be evidenced, with respect to any common stock certificate, by that common stock certificate. The rights will detach from the common stock and a distribution date will occur upon the earlier of the following dates:

the tenth business day following the public announcement that an acquiring person, which may include an entity or group of affiliated or associated persons, has acquired, or obtained the right to acquire, beneficial ownership of 15% or more of our outstanding common stock, or

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the tenth business day following the commencement of, or the first public announcement by any person or group of an intention to commence, a tender offer that would result in any person or entity, including a group of affiliated or associated persons, acquiring beneficial ownership of 15% or more of our outstanding common stock.

Our board of directors may postpone the distribution date by determining a later distribution date before the time any person or group becomes an acquiring person.

The term "acquiring person" does not include us, any of our subsidiaries, any of our or our subsidiaries' employee benefit plans, any entity holding our common stock for or under any of our or our subsidiaries' employee benefit plans or an existing holder of 15% of our common stock at the time we adopted the Rights Plan, unless the existing holder acquires an additional 2% or more of new common stock. In addition, a person who would otherwise be an acquiring person will not be considered an acquiring person if our board of directors determines in good faith that such person inadvertently became the beneficial owner of 15% or more of our common stock and such person divests itself, as promptly as practicable, of beneficial ownership of a sufficient number of shares of our common stock so that it would no longer otherwise qualify as an acquiring person.

In addition, except under limited circumstances, no person or entity shall become an acquiring person as the result of the acquisition by us of our common stock which, by reducing the number of shares outstanding, increases the proportionate number of shares beneficially owned by such person or entity to 15% or more of our outstanding common stock.

The rights agreement provides that, until the distribution date, or earlier redemption or expiration of the rights, the rights will be transferred only with our common stock. The rights are evidenced, with respect to any common stock certificate that was outstanding at the close of business on September 26, 2002, by that common stock certificate with a summary of the rights attached to it. Until the distribution date, or earlier redemption or expiration of the rights, new common stock certificates issued after September 26, 2002, upon transfer or new issuances of common stock contain or will contain a notation incorporating the rights agreement by reference. Until the distribution date, the surrender for transfer of any certificates for common stock, even without a summary of the rights attached to it, also will constitute the transfer of the rights associated with the common stock represented by that certificate. As soon as practicable after the distribution date, separate certificates evidencing the rights will be mailed to holders of record of our common stock as of the close of business on the distribution date, and the separate right certificates alone will evidence the rights. Only our common stock issued before the distribution date will be issued with rights.

The rights are not exercisable until the distribution date. The rights will expire on September 26, 2012, unless the rights are earlier redeemed or exchanged by us, in each case, as described below.

The purchase price payable for the participating preferred shares, and the number of participating preferred shares or other securities or property issuable, upon exercise of the rights, as well as the number of rights outstanding, are subject to adjustment from time to time to prevent dilution in the following circumstances:

in the event of a stock dividend on, or a subdivision, combination or reclassification of the participating preferred shares,

upon the grant to holders of the participating preferred shares of rights or warrants to subscribe for or purchase participating preferred shares at a price, or securities convertible into participating preferred shares with a conversion price less than the current market price of the participating preferred shares, or

upon the distribution to holders of the participating preferred shares of evidences of indebtedness, cash, securities or assets, excluding regular periodic cash dividends at a rate not in excess of 125% of the rate of the last regular cash dividend previously paid or, in case regular periodic cash dividends have not previously been paid, at a rate not in excess of 50% of the average net income

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per share of the Company for the four quarters ended immediately prior to the payment of such dividend, or dividends payable in participating preferred shares or of subscription rights or warrants, other than those referred to above.

The number of outstanding rights and the number of one one-hundredths of a participating preferred share issuable upon exercise of each right are also subject to adjustment in the event of a dividend or other distribution on the common stock payable in common stock or subdivisions, consolidations or combinations of our common stock occurring, in any of those cases, before the distribution date.

Participating preferred shares purchasable upon exercise of the rights will not be redeemable. Each participating preferred share will be entitled to a minimum preferential quarterly dividend payment of \$1.00 per share, but will be entitled to an aggregate dividend of 100 times the dividend declared per share of our common stock. If there is a liquidation, the holders of the participating preferred shares will be entitled to a minimum preferential liquidation payment of \$100 per share, but will be entitled to an aggregate payment of 100 times the payment made per share of our common stock. Each participating preferred share will have 100 votes, voting together with our common stock. If there is a merger, consolidation or other transaction in which our common stock is exchanged, each participating preferred share will be entitled to receive 100 times the amount received per share of our common stock. These rights are protected by customary antidilution provisions.

Because of the nature of the dividend, liquidation and voting rights of the participating preferred shares, the value of the one one-hundredth interest in a participating preferred share purchasable upon exercise of each right should approximate the value of one share of our common stock.

If any person or group becomes an acquiring person, or if we are the surviving corporation in a merger with an acquiring person or any affiliate or associate of an acquiring person and our common stock is not changed or exchanged, proper provision will be made so that each holder of a right, other than rights beneficially owned by the acquiring person, which will become null and void, will have the right to receive upon exercise of the right at the then-current market price, instead of participating preferred shares, that number of shares of our common stock having a market value of two times the exercise price of the right. If we do not have sufficient common stock issued but not outstanding, or authorized but unissued, to permit the exercise in full of the rights, we will be required to take all action necessary to authorize additional common stock for issuance upon exercise of the rights.

If, after a person or group has become an acquiring person, we are acquired in a merger or other business combination transaction or 50% or more of our consolidated assets or earning power are sold, proper provision will be made so that each holder of a right, other than rights beneficially owned by the acquiring person, which will become null and void, will have the right to receive, upon the exercise of the right at its then-current exercise price and instead of participating preferred shares, that number of shares of common stock of the acquiring company, or its parent, which at the time of the transaction will have a market value of two times the exercise price of the right.

At any time after any person or group becomes an acquiring person and before the acquisition by that person or group of 50% or more of our outstanding common stock, our board of directors may exchange the rights, in whole or in part, for a number of shares of our common stock, per right, having an aggregate value equal to the excess of the value of the shares of our common stock issuable upon exercise of a right after a person or group becomes an acquiring person over the purchase price, subject to adjustment. Our board of directors will not exchange the rights owned by the acquiring person or group, which will have become null and void.

With specified exceptions, no adjustments in the purchase price for the preferred shares will be required until cumulative adjustments require an adjustment of at least 1% of that purchase price. No fractional participating preferred shares will be issued, other than fractions which are integral multiples of one one-hundredth of a participating preferred share, which may, at our election, be evidenced by depositary receipts. Instead of issuing fractional participating preferred shares, we will make an adjustment

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in cash based on the market price of the participating preferred shares on the last trading day before the date of exercise.

Upon approval by our board of directors, we may redeem the rights, in whole, but not in part, at a price of \$.01 per right at any time until the earlier of:

at any time prior to the time that an acquiring person has become such, or

September 26, 2012.

Until a right is exercised, the holder of the right, in the capacity of a holder, will have no rights as a stockholder of ours, including, without limitation, the right to vote or to receive dividends. Although the distribution of the rights will not be taxable to stockholders or to us, stockholders may, depending upon the circumstances, recognize taxable income in the event that the rights become exercisable for our common stock or other consideration, or for common stock of the acquiring company or its parent as set forth above.

Any of the provisions of the rights agreement may be amended or supplemented by our board of directors before the distribution date. From and after the distribution date, we and the rights agent may amend or supplement the rights agreement from time to time without the approval of any holders of rights:

to cure any ambiguity, to correct or supplement any defective or inconsistent provisions,

to make any other provisions with respect to the rights which we and the rights agent may deem necessary or desirable.

Notwithstanding this right to amend or supplement, from and after the distribution date, the rights agreement may not be amended in any manner which would adversely affect the interest of the holders of rights.

The rights have certain anti-takeover effects. The rights will cause substantial dilution to a person or group that attempts to acquire us on terms not approved by our board of directors. The rights should not interfere with any merger or other business combination approved by the board of directors, since the rights may be amended to permit such an acquisition or they can be redeemed by us at \$.01 per right prior to the earliest of the time that a person or group has acquired beneficial ownership of 15% or more of our common stock or the final expiration date of the rights.

Anti-Takeover Provisions

Delaware Law. We are governed by the provisions of Section 203 of the Delaware General Corporation Law. In general, Section 203 prohibits a publicly held Delaware corporation from engaging in a business combination with an interested stockholder for a period of three years after the date of the transaction in which the person became an interested stockholder, unless before the date that the person became an interested stockholder, the board of directors approved either the business combination or the transaction which makes the person an interested stockholder, or after the date that the person became an interested stockholder, the business combination is approved by our board of directors and the vote of at least 66 2/3% of our outstanding voting stock that is not owned by the interested stockholder. Generally, a business combination includes a merger, asset sale or other transaction resulting in a financial benefit to the stockholder. An interested stockholder is a person who either owns 15% or more of our outstanding voting stock or, together with affiliates and associates, owns or, within three prior years, did own, 15% or more of our outstanding voting stock. The statute could have the effect of delaying, deferring or preventing a change in our control.

Bylaw and Certificate of Incorporation Provisions. Our bylaws provide that special meetings of our stockholders may be called only by the Chairman of the board of directors or by written request of a majority of the members of the board of directors. Our bylaws also specifies that the authorized number of directors may be changed only by resolution of the board of directors. Our certificate does not include a

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provision for cumulative voting for directors. Under cumulative voting, a minority stockholder holding a sufficient percentage of a class of shares may be able to ensure the election of one or more directors. These and other provisions contained in our certificate of incorporation and bylaws could delay or discourage transactions involving an actual or potential change in control of us or our management, including transactions in which stockholders might otherwise receive a premium for their shares over then current prices. These provisions could also limit the ability of stockholders to remove current management or approve transactions that stockholders may deem to be in their best interests and could adversely affect the price of our common stock.

Transfer Agent And Registrar

The transfer agent and registrar for our common stock is Mellon Investor Services LLC.

Listing on the Nasdaq National Market

Our common stock is listed on the Nasdaq National Market under the symbol GPRO.

DESCRIPTION OF DEBT SECURITIES

The following description, together with the additional information we include in any applicable prospectus supplements, summarizes the material terms and provisions of the debt securities that we may offer under this prospectus. While the terms we have summarized below will generally apply to any future debt securities we may offer under this prospectus, we will describe the particular terms of any debt securities that we may offer in more detail in the applicable prospectus supplement. The terms of any debt securities we offer under a prospectus supplement may differ from the terms we describe below.

We will issue the senior notes under the senior indenture which we will enter into with the trustee named in the senior indenture. We will issue the subordinated notes under the subordinated indenture which we will enter into with the trustee named in the subordinated indenture. We have filed forms of these documents as exhibits to the registration statement of which this prospectus is a part. We use the term indentures to refer to both the senior indenture and the subordinated indenture.

The indentures will be qualified under the Trust Indenture Act of 1939. We use the term debenture trustee to refer to either the senior trustee or the subordinated trustee, as applicable.

The following summaries of material provisions of the senior notes, the subordinated notes and the indentures are subject to, and qualified in their entirety by reference to, all the provisions of the indenture applicable to a particular series of debt securities. We urge you to read the applicable prospectus supplements related to the debt securities that we sell under this prospectus, as well as the complete indentures that contain the terms of the debt securities. Except as we may otherwise indicate, the terms of the senior indenture and the subordinated indenture are identical.

General

We will describe in the applicable prospectus supplement the terms relating to a series of debt securities, including:

the title;

the principal amount being offered, and, if a series, the total amount authorized and the total amount outstanding;

any limit on the amount that may be issued;

whether or not we will issue the series of debt securities in global form and, if so, the terms and who the depositary will be;

the maturity date;

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the principal amount due at maturity, and whether the debt securities will be issued with any original issue discount;

whether and under what circumstances, if any, we will pay additional amounts on any debt securities held by a person who is not a United States person for tax purposes, and whether we can redeem the debt securities if we have to pay such additional amounts;

the annual interest rate, which may be fixed or variable, or the method for determining the rate, the date interest will begin to accrue, the dates interest will be payable and the regular record dates for interest payment dates or the method for determining such dates;

whether or not the debt securities will be secured or unsecured, and the terms of any secured debt;

the terms of the subordination of any series of subordinated debt;

the place where payments will be payable;

restrictions on transfer, sale or other assignment, if any;

our right, if any, to defer payment of interest and the maximum length of any such deferral period;

the date, if any, after which, the conditions upon which, and the price at which we may, at our option, redeem the series of debt securities pursuant to any optional or provisional redemption provisions, and any other applicable terms of those redemption provisions;

provisions for a sinking fund, purchase or other analogous fund, if any;

the date, if any, on which, and the price at which we are obligated, pursuant to any mandatory sinking fund or analogous fund provisions or otherwise, to redeem, or at the holder's option to purchase, the series of debt securities;

whether the indenture will restrict our ability and/or the ability of our subsidiaries to:

- incur additional indebtedness;
- issue additional securities;
- create liens;
- pay dividends and make distributions in respect of our capital stock and the capital stock of our subsidiaries;
- redeem capital stock;
- place restrictions on our subsidiaries' ability to pay dividends, make distributions or transfer assets;
- make investments or other restricted payments;
- sell or otherwise dispose of assets;
- enter into sale-leaseback transactions;
- engage in transactions with stockholders and affiliates;
- issue or sell stock of our subsidiaries; or

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effect a consolidation or merger;

whether the indenture will require us to maintain any interest coverage, fixed charge, cash flow-based, asset-based or other financial ratios;

a discussion of any material or special United States federal income tax considerations applicable to the debt securities;

information describing any book-entry features;

the procedures for any auction and remarketing, if any;

the denominations in which we will issue the series of debt securities, if other than denominations of \$1,000 and any integral multiple thereof;

if other than dollars, the currency in which the series of debt securities will be denominated; and

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any other specific terms, preferences, rights or limitations of, or restrictions on, the debt securities, including any events of default that are in addition to those described in this prospectus or any covenants provided with respect to the debt securities that are in addition to those described above, and any terms which may be required by us or advisable under applicable laws or regulations or advisable in connection with the marketing of the debt securities.

Conversion or Exchange Rights

We will set forth in the prospectus supplement the terms on which a series of debt securities may be convertible into or exchangeable for common stock or other securities of ours or a third party, including the conversion or exchange rate, as applicable, or how it will be calculated, and the applicable conversion or exchange period. We will include provisions as to whether conversion or exchange is mandatory, at the option of the holder or at our option. We may include provisions pursuant to which the number of our securities or the securities of a third party that the holders of the series of debt securities receive upon conversion or exchange would, under the circumstances described in those provisions, be subject to adjustment, or pursuant to which those holders would, under those circumstances, receive other property upon conversion or exchange, for example in the event of our merger or consolidation with another entity.

Consolidation, Merger or Sale

The indentures in the forms initially filed as exhibits to the registration statement of which this prospectus is a part do not contain any covenant which restricts our ability to merge or consolidate, or sell, convey, transfer or otherwise dispose of all or substantially all of our assets. However, any successor of ours or acquiror of such assets must assume all of our obligations under the indentures and the debt securities.

If the debt securities are convertible for our other securities, the person with whom we consolidate or merge or to whom we sell all of our property must make provisions for the conversion of the debt securities into securities which the holders of the debt securities would have received if they had converted the debt securities before the consolidation, merger or sale.

Events of Default Under the Indenture

The following are events of default under the indentures with respect to any series of debt securities that we may issue:

if we fail to pay interest when due and payable and our failure continues for 90 days and the time for payment has not been extended or deferred;

if we fail to pay the principal, or premium, if any, when due and payable and the time for payment has not been extended or delayed;

if we fail to observe or perform any other covenant contained in the debt securities or the indentures, other than a covenant specifically relating to another series of debt securities, and our failure continues for 90 days after we receive notice from the debenture trustee or holders of at least 25% in aggregate principal amount of the outstanding debt securities of the applicable series; and

if specified events of bankruptcy, insolvency or reorganization occur.

If an event of default with respect to debt securities of any series occurs and is continuing, other than an event of default specified in the last bullet point above, the debenture trustee or the holders of at least 25% in aggregate principal amount of the outstanding debt securities of that series, by notice to us in writing, and to the debenture trustee if notice is given by such holders, may declare the unpaid principal of, premium, if any, and accrued interest, if any, due and payable immediately. If an event of default specified in the last bullet point above occurs with respect to us, the principal amount of and accrued interest, if any, of each issue of debt securities then outstanding shall be due and payable without any notice or other action on the part of the debenture trustee or any holder.

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The holders of a majority in principal amount of the outstanding debt securities of an affected series may waive any default or event of default with respect to the series and its consequences, except defaults or events of default regarding payment of principal, premium, if any, or interest, unless we have cured the default or event of default in accordance with the indenture.

Subject to the terms of the indentures, if an event of default under an indenture shall occur and be continuing, the debenture trustee will be under no obligation to exercise any of its rights or powers under such indenture at the request or direction of any of the holders of the applicable series of debt securities, unless such holders have offered the debenture trustee reasonable indemnity. The holders of a majority in principal amount of the outstanding debt securities of any series will have the right to direct the time, method and place of conducting any proceeding for any remedy available to the debenture trustee, or exercising any trust or power conferred on the debenture trustee, with respect to the debt securities of that series, provided that:

the direction so given by the holder is not in conflict with any law or the applicable indenture; and

subject to its duties under the Trust Indenture Act of 1939, the debenture trustee need not take any action that might involve it in personal liability or might be unduly prejudicial to the holders not involved in the proceeding.

A holder of the debt securities of any series will only have the right to institute a proceeding under the indentures or to appoint a receiver or trustee, or to seek other remedies if:

the holder has given written notice to the debenture trustee of a continuing event of default with respect to that series;

the holders of at least 25% in aggregate principal amount of the outstanding debt securities of that series have made written request, and such holders have offered reasonable indemnity to the debenture trustee to institute the proceeding as trustee; and

the debenture trustee does not institute the proceeding, and does not receive from the holders of a majority in aggregate principal amount of the outstanding debt securities of that series other conflicting directions within 90 days after the notice, request and offer.

These limitations do not apply to a suit instituted by a holder of debt securities if we default in the payment of the principal, premium, if any, or interest on, the debt securities.

We will periodically file statements with the debenture trustee regarding our compliance with specified covenants in the indentures.

Modification of Indenture; Waiver

We and the debenture trustee may change an indenture without the consent of any holders with respect to specific matters, including:

to fix any ambiguity, defect or inconsistency in the indenture;

to comply with the provisions described above under Consolidation, Merger or Sale ;

to comply with any requirements of the SEC in connection with the qualification of any indenture under the Trust Indenture Act of 1939;

to evidence and provide for the acceptance of appointment hereunder by a successor trustee;

to provide for uncertificated debt securities and to make all appropriate changes for such purpose;

to add to, delete from, or revise the conditions, limitations and restrictions on the authorized amount, terms or purposes of issuance, authorization and delivery of debt securities of any series;

to add to our covenants such new covenants, restrictions, conditions or provisions for the protection of the holders, to make the occurrence, or the occurrence and the continuance, of a default in any

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such additional covenants, restrictions, conditions or provisions an event of default, or to surrender any of our rights or powers under the indenture; or

to change anything that does not materially adversely affect the interests of any holder of debt securities of any series.

In addition, under the indentures, the rights of holders of a series of debt securities may be changed by us and the debenture trustee with the written consent of the holders of at least a majority in aggregate principal amount of the outstanding debt securities of each series that is affected. However, we and the debenture trustee may only make the following changes with the consent of each holder of any outstanding debt securities affected:

extending the fixed maturity of the series of debt securities;

reducing the principal amount, reducing the rate of or extending the time of payment of interest, or reducing any premium payable upon the redemption of any debt securities; or

reducing the percentage of debt securities, the holders of which are required to consent to any supplemental indenture.

Discharge

Each indenture provides that we can elect to be discharged from our obligations with respect to one or more series of debt securities, except for obligations to:

register the transfer or exchange of debt securities of the series;

replace stolen, lost or mutilated debt securities of the series;

maintain paying agencies;

hold monies for payment in trust;

recover excess money held by the debenture trustee;

compensate and indemnify the debenture trustee; and

appoint any successor trustee.

In order to exercise our rights to be discharged, we must deposit with the debenture trustee money or government obligations sufficient to pay all the principal of, any premium, if any, and interest on, the debt securities of the series on the dates payments are due.

Form, Exchange and Transfer

We will issue the debt securities of each series only in fully registered form without coupons and, unless we otherwise specify in the applicable prospectus supplement, in denominations of \$1,000 and any integral multiple thereof. The indentures provide that we may issue debt securities of a series in temporary or permanent global form and as book-entry securities that will be deposited with, or on behalf of, The Depository Trust Company or another depository named by us and identified in a prospectus supplement with respect to that series. See *Legal Ownership of Securities* for a further description of the terms relating to any book-entry securities.

At the option of the holder, subject to the terms of the indentures and the limitations applicable to global securities described in the applicable prospectus supplement, the holder of the debt securities of any series can exchange the debt securities for other debt securities of the same series, in any authorized denomination and of like tenor and aggregate principal amount.

Subject to the terms of the indentures and the limitations applicable to global securities set forth in the applicable prospectus supplement, holders of the debt securities may present the debt securities for exchange or for registration of transfer, duly endorsed or with the form of transfer endorsed thereon duly

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executed if so required by us or the security registrar, at the office of the security registrar or at the office of any transfer agent designated by us for this purpose. Unless otherwise provided in the debt securities that the holder presents for transfer or exchange, we will make no service charge for any registration of transfer or exchange, but we may require payment of any taxes or other governmental charges.

We will name in the applicable prospectus supplement the security registrar, and any transfer agent in addition to the security registrar, that we initially designate for any debt securities. We may at any time designate additional transfer agents or rescind the designation of any transfer agent or approve a change in the office through which any transfer agent acts, except that we will be required to maintain a transfer agent in each place of payment for the debt securities of each series.

If we elect to redeem the debt securities of any series, we will not be required to:

issue, register the transfer of, or exchange any debt securities of any series being redeemed in part during a period beginning at the opening of business 15 days before the day of mailing of a notice of redemption of any debt securities that may be selected for redemption and ending at the close of business on the day of the mailing; or

register the transfer of or exchange any debt securities so selected for redemption, in whole or in part, except the unredeemed portion of any debt securities we are redeeming in part.

Information Concerning the Debenture Trustee

The debenture trustee, other than during the occurrence and continuance of an event of default under an indenture, undertakes to perform only those duties as are specifically set forth in the applicable indenture. Upon an event of default under an indenture, the debenture trustee must use the same degree of care as a prudent person would exercise or use in the conduct of his or her own affairs. Subject to this provision, the debenture trustee is under no obligation to exercise any of the powers given it by the indentures at the request of any holder of debt securities unless it is offered reasonable security and indemnity against the costs, expenses and liabilities that it might incur.

Payment and Paying Agents

Unless we otherwise indicate in the applicable prospectus supplement, we will make payment of the interest on any debt securities on any interest payment date to the person in whose name the debt securities, or one or more predecessor securities, are registered at the close of business on the regular record date for the interest.

We will pay principal of and any premium and interest on the debt securities of a particular series at the office of the paying agents designated by us, except that, unless we otherwise indicate in the applicable prospectus supplement, we may make interest payments by check which we will mail to the holder or by wire transfer to certain holders. Unless we otherwise indicate in a prospectus supplement, we will designate an office or agency of the debenture trustee in the City of New York as our sole paying agent for payments with respect to debt securities of each series. We will name in the applicable prospectus supplement any other paying agents that we initially designate for the debt securities of a particular series. We will maintain a paying agent in each place of payment for the debt securities of a particular series.

All money we pay to a paying agent or the debenture trustee for the payment of the principal of or any premium or interest on any debt securities which remains unclaimed at the end of two years after such principal, premium or interest has become due and payable will be repaid to us, and the holder of the debt security thereafter may look only to us for payment thereof.

Governing Law

The indentures and the debt securities will be governed by and construed in accordance with the laws of the State of New York, except to the extent that the Trust Indenture Act of 1939 is applicable.

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Subordination of Subordinated Debt Securities

The subordinated debt securities will be subordinate and junior in priority of payment to certain of our other indebtedness to the extent described in a prospectus supplement. The indentures in the forms initially filed as exhibits to the registration statement of which this prospectus is a part do not limit the amount of indebtedness which we may incur, including senior indebtedness or subordinated indebtedness, and do not limit us from issuing any other debt, including secured debt or unsecured debt.

DESCRIPTION OF WARRANTS

The following description, together with the additional information we include in any applicable prospectus supplements, summarizes the material terms and provisions of the warrants that we may offer under this prospectus, which consist of warrants to purchase common stock, preferred stock and/or debt securities in one or more series. Warrants may be offered independently or together with common stock, preferred stock and/or debt securities offered by any prospectus supplement, and may be attached to or separate from those securities. While the terms we have summarized below will generally apply to any future warrants we may offer under this prospectus, we will describe the particular terms of any warrants that we may offer in more detail in the applicable prospectus supplement. The terms of any warrants we offer under a prospectus supplement may differ from the terms we describe below.

We will issue the warrants under a warrant agreement which we will enter into with a warrant agent to be selected by us. We have filed forms of the warrant agreements and the related warrant certificates for each type of warrant we may offer under this prospectus as exhibits to the registration statement of which this prospectus is a part. We use the term **warrant agreement** to refer to any of these warrant agreements. We use the term **warrant agent** to refer to the warrant agent under any of these warrant agreements. The warrant agent will act solely as an agent of ours in connection with the warrants and will not act as an agent for the holders or beneficial owners of the warrants.

The following summaries of material provisions of the warrants and the warrant agreements are subject to, and qualified in their entirety by reference to, all the provisions of the warrant agreement applicable to a particular series of warrants. We urge you to read the applicable prospectus supplements related to the warrants that we sell under this prospectus, as well as the complete warrant agreements that contain the terms of the warrants.

General

We will describe in the applicable prospectus supplement the terms relating to a series of warrants. If warrants for the purchase of debt securities are offered, the prospectus supplement will describe the following terms, to the extent applicable:

the offering price and the aggregate number of warrants offered;

the currencies in which the warrants are being offered;

the designation, aggregate principal amount, currencies, denominations and terms of the series of debt securities that can be purchased if a holder exercises a warrant;

the designation and terms of any series of debt securities with which the warrants are being offered and the number of warrants offered with each such debt security;

the date on and after which the holder of the warrants can transfer them separately from the related series of debt securities;

the principal amount of the series of debt securities that can be purchased if a holder exercises a warrant and the price at which and currencies in which such principal amount may be purchased upon exercise;

the terms of any rights to redeem or call the warrants;

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the date on which the right to exercise the warrants begins and the date on which such right expires;

federal income tax consequences of holding or exercising the warrants; and

any other specific terms, preferences, rights or limitations of, or restrictions on, the warrants.

Warrants for the purchase of debt securities will be in registered form only.

If warrants for the purchase of common stock or preferred stock are offered, the prospectus supplement will describe the following terms, to the extent applicable:

the offering price and the aggregate number of warrants offered;

the total number of shares that can be purchased if a holder of the warrants exercises them and, in the case of warrants for preferred stock, the designation, total number and terms of the series of preferred stock that can be purchased upon exercise;

the designation and terms of any series of preferred stock with which the warrants are being offered and the number of warrants being offered with each share of common stock or preferred stock;

the date on and after which the holder of the warrants can transfer them separately from the related common stock or series of preferred stock;

the number of shares of common stock or preferred stock that can be purchased if a holder exercises the warrant and the price at which such common stock or preferred stock may be purchased upon exercise, including, if applicable, any provisions for changes to or adjustments in the exercise price and in the securities or other property receivable upon exercise;

the terms of any rights to redeem or call, or accelerate the expiration of, the warrants;

the date on which the right to exercise the warrants begins and the date on which that right expires;

federal income tax consequences of holding or exercising the warrants; and

any other specific terms, preferences, rights or limitations of, or restrictions on, the warrants.

Warrants for the purchase of common stock or preferred stock will be in registered form only.

A holder of warrant certificates may exchange them for new certificates of different denominations, present them for registration of transfer and exercise them at the corporate trust office of the warrant agent or any other office indicated in the applicable prospectus supplement. Until any warrants to purchase debt securities are exercised, the holder of the warrants will not have any of the rights of holders of the debt securities that can be purchased upon exercise, including any rights to receive payments of principal, premium or interest on the underlying debt securities or to enforce covenants in the applicable indenture. Until any warrants to purchase common stock or preferred stock are exercised, holders of the warrants will not have any rights of holders of the underlying common stock or preferred stock, including any rights to receive dividends or to exercise any voting rights, except to the extent set forth under **Warrant Adjustments** below.

Exercise of Warrants

Each holder of a warrant is entitled to purchase the principal amount of debt securities or number of shares of common stock or preferred stock, as the case may be, at the exercise price described in the applicable prospectus supplement. After the close of business on the day when the right to exercise terminates (or a later date if we extend the time for exercise), unexercised warrants will become void.

A holder of warrants may exercise them by following the general procedure outlined below:

delivering to the warrant agent the payment required by the applicable prospectus supplement to purchase the underlying security;

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properly completing and signing the reverse side of the warrant certificate representing the warrants; and

delivering the warrant certificate representing the warrants to the warrant agent within five business days of the warrant agent receiving payment of the exercise price.

If you comply with the procedures described above, your warrants will be considered to have been exercised when the warrant agent receives payment of the exercise price, subject to the transfer books for the securities issuable upon exercise of the warrant not being closed on such date. After you have completed those procedures and subject to the foregoing, we will, as soon as practicable, issue and deliver to you the debt securities, common stock or preferred stock that you purchased upon exercise. If you exercise fewer than all of the warrants represented by a warrant certificate, a new warrant certificate will be issued to you for the unexercised amount of warrants. Holders of warrants will be required to pay any tax or governmental charge that may be imposed in connection with transferring the underlying securities in connection with the exercise of the warrants.

Amendments and Supplements to the Warrant Agreements

We may amend or supplement a warrant agreement without the consent of the holders of the applicable warrants to cure ambiguities in the warrant agreement, to cure or correct a defective provision in the warrant agreement, or to provide for other matters under the warrant agreement that we and the warrant agent deem necessary or desirable, so long as, in each case, such amendments or supplements do not materially adversely affect the interests of the holders of the warrants.

Warrant Adjustments

Unless the applicable prospectus supplement states otherwise, the exercise price of, and the number of securities covered by, a common stock warrant or preferred stock warrant will be adjusted proportionately if we subdivide or combine our common stock or preferred stock, as applicable. In addition, unless the prospectus supplement states otherwise, if we, without payment for:

issue capital stock or other securities convertible into or exchangeable for common stock or preferred stock, or any rights to subscribe for, purchase or otherwise acquire any of the foregoing, as a dividend or distribution to holders of our common stock or preferred stock;

pay any cash to holders of our common stock or preferred stock other than a cash dividend paid out of our current or retained earnings or other than in accordance with the terms of the preferred stock;

issue any evidence of our indebtedness or rights to subscribe for or purchase our indebtedness to holders of our common stock or preferred stock; or

issue common stock or preferred stock or additional stock or other securities or property to holders of our common stock or preferred stock by way of spinoff, split-up, reclassification, combination of shares or similar corporate rearrangement, then the holders of common stock warrants and preferred stock warrants, as applicable, will be entitled to receive upon exercise of the warrants, in addition to the securities otherwise receivable upon exercise of the warrants and without paying any additional consideration, the amount of stock and other securities and property such holders would have been entitled to receive had they held the common stock or preferred stock, as applicable, issuable under the warrants on the dates on which holders of those securities received or became entitled to receive such additional stock and other securities and property.

Except as stated above, the exercise price and number of securities covered by a common stock warrant and preferred stock warrant, and the amounts of other securities or property to be received, if any, upon exercise of those warrants, will not be adjusted or provided for if we issue those securities or any securities convertible into or exchangeable for those securities, or securities carrying the right to purchase those securities or securities convertible into or exchangeable for those securities.

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Holders of common stock warrants and preferred stock warrants may have additional rights under the following circumstances:

certain reclassifications, capital reorganizations or changes of the common stock or preferred stock, as applicable;

certain share exchanges, mergers, or similar transactions involving us and which result in changes of the common stock or preferred stock, as applicable; or

certain sales or dispositions to another entity of all or substantially all of our property and assets.

If one of the above transactions occurs and holders of our common stock or preferred stock are entitled to receive stock, securities or other property with respect to or in exchange for their securities, the holders of the common stock warrants and preferred stock warrants then outstanding, as applicable, will be entitled to receive upon exercise of their warrants the kind and amount of shares of stock and other securities or property that they would have received upon the applicable transaction if they had exercised their warrants immediately before the transaction.

LEGAL OWNERSHIP OF SECURITIES

We can issue securities in registered form or in the form of one or more global securities. We describe global securities in greater detail below. We refer to those persons who have securities registered in their own names on the books that we or any applicable trustee or depository or warrant agent maintain for this purpose as the holders of those securities. These persons are the legal holders of the securities. We refer to those persons who, indirectly through others, own beneficial interests in securities that are not registered in their own names, as indirect holders of those securities. As we discuss below, indirect holders are not legal holders, and investors in securities issued in book-entry form or in street name will be indirect holders.

Book-Entry Holders

We may issue securities in book-entry form only, as we will specify in the applicable prospectus supplement. This means securities may be represented by one or more global securities registered in the name of a financial institution that holds them as depository on behalf of other financial institutions that participate in the depository's book-entry system. These participating institutions, which are referred to as participants, in turn, hold beneficial interests in the securities on behalf of themselves or their customers.

Only the person in whose name a security is registered is recognized as the holder of that security. Global securities will be registered in the name of the depository. Consequently, for global securities, we will recognize only the depository as the holder of the securities, and we will make all payments on the securities to the depository. The depository passes along the payments it receives to its participants, which in turn pass the payments along to their customers who are the beneficial owners. The depository and its participants do so under agreements they have made with one another or with their customers; they are not obligated to do so under the terms of the securities.

As a result, investors in a global security will not own securities directly. Instead, they will own beneficial interests in a global security, through a bank, broker or other financial institution that participates in the depository's book-entry system or holds an interest through a participant. As long as the securities are issued in global form, investors will be indirect holders, and not holders, of the securities.

Street Name Holders

We may terminate a global security or issue securities that are not issued in global form. In these cases, investors may choose to hold their securities in their own names or in street name. Securities held by an investor in street name would be registered in the name of a bank, broker or other financial institution that the investor chooses, and the investor would hold only a beneficial interest in those securities through an account he or she maintains at that institution.

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For securities held in street name, we or any applicable trustee or depository will recognize only the intermediary banks, brokers and other financial institutions in whose names the securities are registered as the holders of those securities, and we or any such trustee or depository will make all payments on those securities to them. These institutions pass along the payments they receive to their customers who are the beneficial owners, but only because they agree to do so in their customer agreements or because they are legally required to do so. Investors who hold securities in street name will be indirect holders, not holders, of those securities.

Legal Holders

Our obligations, as well as the obligations of any applicable trustee or third party employed by us or a trustee, run only to the legal holders of the securities. We do not have obligations to investors who hold beneficial interests in global securities, in street name or by any other indirect means. This will be the case whether an investor chooses to be an indirect holder of a security or has no choice because we are issuing the securities only in global form.

For example, once we make a payment or give a notice to the holder, we have no further responsibility for the payment or notice even if that holder is required, under agreements with its participants or customers or by law, to pass it along to the indirect holders but does not do so. Similarly, we may want to obtain the approval of the holders to amend an indenture, to relieve us of the consequences of a default or of our obligation to comply with a particular provision of an indenture, or for other purposes. In such an event, we would seek approval only from the holders, and not the indirect holders, of the securities. Whether and how the holders contact the indirect holders is up to the holders.

Special Considerations for Indirect Holders

If you hold securities through a bank, broker or other financial institution, either in book-entry form because the securities are represented by one or more global securities or in street name, you should check with your own institution to find out:

how it handles securities payments and notices;

whether it imposes fees or charges;

how it would handle a request for the holders' consent, if ever required;

whether and how you can instruct it to send you securities registered in your own name so you can be a holder, if that is permitted in the future;

how it would exercise rights under the securities if there were a default or other event triggering the need for holders to act to protect their interests; and

if the securities are global securities, how the depository's rules and procedures will affect these matters.

Global Securities

A global security is a security which represents one or any other number of individual securities held by a depository. Generally, all securities represented by the same global securities will have the same terms.

Each security issued in book-entry form will be represented by a global security that we issue to, deposit with and register in the name of a financial institution or its nominee that we select. The financial institution that we select for this purpose is called the depository. Unless we specify otherwise in the applicable prospectus supplement, The Depository Trust Company, New York, New York, known as DTC, will be the depository for all global securities issued under this prospectus.

A global security may not be transferred to or registered in the name of anyone other than the depository, its nominee or a successor depository, unless special termination situations arise. We describe

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those situations below under Special Situations When a Global Security Will Be Terminated. As a result of these arrangements, the depositary, or its nominee, will be the sole registered owner and holder of all securities represented by a global security, and investors will be permitted to own only beneficial interests in a global security. Beneficial interests must be held by means of an account with a broker, bank or other financial institution that in turn has an account with the depositary or with another institution that does. Thus, an investor whose security is represented by a global security will not be a holder of the security, but only an indirect holder of a beneficial interest in the global security.

If the prospectus supplement for a particular security indicates that the security will be issued as a global security, then the security will be represented by a global security at all times unless and until the global security is terminated. If termination occurs, we may issue the securities through another book-entry clearing system or decide that the securities may no longer be held through any book-entry clearing system.

Special Considerations for Global Securities

As an indirect holder, an investor's rights relating to a global security will be governed by the account rules of the investor's financial institution and of the depositary, as well as general laws relating to securities transfers. We do not recognize an indirect holder as a holder of securities and instead deal only with the depositary that holds the global security.

If securities are issued only as a global security, an investor should be aware of the following:

An investor cannot cause the securities to be registered in his or her name, and cannot obtain non-global certificates for his or her interest in the securities, except in the special situations we describe below;

An investor will be an indirect holder and must look to his or her own bank or broker for payments on the securities and protection of his or her legal rights relating to the securities, as we describe above;

An investor may not be able to sell interests in the securities to some insurance companies and to other institutions that are required by law to own their securities in non-book-entry form;

An investor may not be able to pledge his or her interest in the global security in circumstances where certificates representing the securities must be delivered to the lender or other beneficiary of the pledge in order for the pledge to be effective;

The depositary's policies, which may change from time to time, will govern payments, transfers, exchanges and other matters relating to an investor's interest in the global security. We and any applicable trustee have no responsibility for any aspect of the depositary's actions or for its records of ownership interests in the global security. We and the trustee also do not supervise the depositary in any way;

The depositary may, and we understand that DTC will, require that those who purchase and sell interests in the global security within its book-entry system use immediately available funds, and your broker or bank may require you to do so as well; and

Financial institutions that participate in the depositary's book-entry system, and through which an investor holds its interest in the global security, may also have their own policies affecting payments, notices and other matters relating to the securities. There may be more than one financial intermediary in the chain of ownership for an investor. We do not monitor and are not responsible for the actions of any of those intermediaries.

Special Situations When a Global Security Will be Terminated

In a few special situations described below, a global security will terminate and interests in it will be exchanged for physical certificates representing those interests. After that exchange, the choice of whether

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to hold securities directly or in street name will be up to the investor. Investors must consult their own banks or brokers to find out how to have their interests in securities transferred to their own name, so that they will be direct holders. We have described the rights of holders and street name investors above.

A global security will terminate when the following special situations occur:

if the depositary notifies us that it is unwilling, unable or no longer qualified to continue as depositary for that global security and we do not appoint another institution to act as depositary within 90 days;

if we notify any applicable trustee that we wish to terminate that global security; or

if an event of default has occurred with regard to securities represented by that global security and has not been cured or waived.

The prospectus supplement may also list additional situations for terminating a global security that would apply only to the particular series of securities covered by the prospectus supplement. When a global security terminates, the depositary, and not we or any applicable trustee, is responsible for deciding the names of the institutions that will be the initial direct holders.

PLAN OF DISTRIBUTION

We may sell the securities covered by this prospectus in any of three ways (or in any combination):

to or through underwriters or dealers;

directly to a limited number of purchasers or to a single purchaser; or

through agents.

The prospectus supplement will set forth the terms of the offering of the securities covered by this prospectus, including:

the name or names of any underwriters, dealers or agents and the amounts of securities underwritten or purchased by each of them;

any over-allotment options under which underwriters may purchase additional securities from us;

any underwriting discounts or commissions or agency fees and other items constituting underwriters' or agents' compensation;

the initial public offering price of the securities and the proceeds to us and any discounts, commissions or concessions allowed or reallocated or paid to dealers; and

any securities exchanges or markets on which the securities may be listed.

Any initial public offering price and any discounts or concessions allowed or reallocated or paid to dealers may be changed from time to time.

Underwriters may offer and sell the offered securities from time to time in one or more transactions, including negotiated transactions, at a fixed public offering price or at varying prices determined at the time of sale. If underwriters are used in the sale of any securities, the securities will be acquired by the underwriters for their own account and may be resold from time to time in one or more transactions described above. The securities may be either offered to the public through underwriting syndicates represented by managing underwriters, or directly by underwriters. Generally, the underwriters' obligations to purchase the securities will be subject to certain conditions precedent. The underwriters will be obligated to purchase all of the securities if they purchase any of the securities. We may use underwriters with whom we have a material relationship. We will describe in the prospectus supplement, naming the underwriter, the nature of any such relationship.

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We may sell the securities through agents from time to time. The prospectus supplement will name any agent involved in the offer or sale of the securities and any commissions we pay to them. Generally, any agent will be acting on a best efforts basis for the period of its appointment.

We may authorize underwriters, dealers or agents to solicit offers by certain purchasers to purchase the securities from us at the public offering price set forth in the prospectus supplement pursuant to delayed delivery contracts providing for payment and delivery on a specified date in the future. The contracts will be subject only to those conditions set forth in the prospectus supplement, and the prospectus supplement will set forth any commissions we pay for solicitation of these contracts.

Agents and underwriters may be entitled to indemnification by us against certain civil liabilities, including liabilities under the Securities Act, or to contribution with respect to payments which the agents or underwriters may be required to make in respect thereof. Agents and underwriters may be customers of, engage in transactions with, or perform services for us in the ordinary course of business.

All securities we offer, other than common stock, will be new issues of securities with no established trading market. Any underwriters may make a market in these securities, but will not be obligated to do so and may discontinue any market making at any time without notice. We cannot guarantee the liquidity of the trading markets for any securities.

Any underwriter may engage in overallotment, stabilizing transactions, short covering transactions and penalty bids in accordance with Regulation M under the Exchange Act. Overallotment involves sales in excess of the offering size, which create a short position. Stabilizing transactions permit bids to purchase the underlying security so long as the stabilizing bids do not exceed a specified maximum. Short covering transactions involve purchases of the securities in the open market after the distribution is completed to cover short positions. Penalty bids permit the underwriters to reclaim a selling concession from a dealer when the securities originally sold by the dealer are purchased in a covering transaction to cover short positions. Those activities may cause the price of the securities to be higher than it would otherwise be. If commenced, the underwriters may discontinue any of the activities at any time.

LEGAL MATTERS

The validity of the securities being offered hereby will be passed upon by Cooley Godward LLP, San Diego, California.

EXPERTS

Ernst & Young LLP, independent auditors, have audited our consolidated financial statements and schedule included in our Annual Report on Form 10-K for the year ended December 31, 2002, as set forth in their report, which is incorporated by reference into this prospectus and elsewhere in the registration statement. Our financial statements and schedule are incorporated by reference in reliance on Ernst & Young LLP's report, given on their authority as experts in accounting and auditing.

WHERE YOU CAN FIND MORE INFORMATION

We file annual, quarterly and special reports, proxy statements and other information with the SEC. Our SEC filings are available to the public over the Internet at the SEC's web site at <http://www.sec.gov>. You may also read and copy any document we file at the SEC's public reference room at 450 Fifth Street, N.W., Washington, D.C. 20549. You may obtain information on the operation of the SEC's public reference room in Washington, D.C. by calling the SEC at 1-800-SEC-0330.

The SEC allows us to incorporate by reference into this prospectus the information in documents we file with it, which means that we can disclose important information to you by referring you to those documents. Any statement contained in any document incorporated or deemed to be incorporated by reference herein shall be deemed to be modified or superseded, for purposes of this prospectus, to the

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extent that a statement contained in or omitted from this prospectus, or in any other subsequently filed document which also is or is deemed to be incorporated by reference herein, modifies or supersedes such statement. Any such statement so modified or superseded shall not be deemed, except as so modified or superseded, to constitute a part of this prospectus. We incorporate by reference the documents listed below and any future filings we make with the SEC under Sections 13(a), 13(c), 14 or 15(d) of the Exchange Act until the offering is completed:

The description of our common stock set forth in the registration statement on Form 10, as amended, which was filed with the SEC on May 24, 2002 (File No. 0-49834).

Our Annual Report on Form 10-K for the fiscal year ended December 31, 2002, which was filed on March 24, 2003;

Our Quarterly Reports on Form 10-Q for the quarters ended March 31, 2003 and June 30, 2003, which were filed on May 9, 2003 and August 14, 2003, respectively; and

Our Current Reports on Form 8-K which were filed on April 29, 2003, July 31, 2003, August 8, 2003 and September 5, 2003.

You may request a copy of these filings at no cost, by writing or telephoning us at the following address:

Gen-Probe Incorporated
10210 Genetic Center Drive
San Diego, CA 92121-4362
(858) 410-8000
Attention: Investor Relations

All documents that we file with the SEC pursuant to Section 13(a), 13(c), 14 or 15(d) of the Exchange Act after the date of this prospectus and before the termination of the offering of the securities offered in this prospectus shall be deemed incorporated by reference into this prospectus and to be a part of this prospectus from the respective date of filing such documents.

We have filed with the SEC a registration statement on Form S-3 under the Securities Act covering the securities described in this prospectus. This prospectus does not contain or incorporate by reference all of the information included in the registration statement, some of which is contained in exhibits included with or incorporated by reference into the registration statement. The registration statement, including the exhibits contained or incorporated by reference therein, can be read at the SEC web site or at the SEC office referred to above. Any statement made or incorporated by reference in this prospectus concerning the contents of any contract, agreement or other document is only a summary of the actual contract, agreement or other document. If we have filed or incorporated by reference any contract, agreement or other document as an exhibit to the registration statement, you should read the exhibit for a more complete understanding of the document or matter involved. Each statement regarding a contract, agreement or other document is qualified in its entirety by reference to the actual document.