

SURMODICS INC
Form 424B3
July 20, 2005

Table of Contents

Filed pursuant to Rule 424(b)(3)
Registration No. 333-123524

PROSPECTUS

SURMODICS, INC.

1,200,128 Shares of Common Stock

In connection with our January 2005 acquisition of substantially all of the assets of InnoRx, Inc. through the merger of InnoRx with and into SurModics, we agreed to issue up to 1,200,128 shares of our common stock primarily to the selling security holders named in this prospectus. In January 2005, we issued 600,064 shares of common stock, and agreed to issue up to an additional 600,064 shares of common stock (the Milestone Shares) in the future upon the occurrence of certain events. The Milestone Shares might be issued at various times upon the successful completion of certain development and commercial milestones involving InnoRx technology acquired by SurModics. As of July 1, 2005, we issued 60,002 Milestone Shares. This prospectus covers the offer and sale by the selling security holders of all 1,200,128 shares referred to above. The exact aggregate number of Milestone Shares that may be sold under this prospectus will be determined in the future based upon whether each milestone is satisfied. Any Milestone Shares covered by this prospectus that we do not actually issue will be deregistered.

These securities may be offered and sold from time to time by the selling security holders or by pledgees, donees, transferees, or other successors in interest identified in a prospectus supplement, if required, that receive such securities as a gift, distribution, or other non-sale related transfer. The selling security holders may offer their securities from time to time through or to brokers or dealers in the over-the-counter market at market prices prevailing at the time of sale or in one or more negotiated transactions at prices acceptable to the selling security holders. We will not receive any proceeds from the sale of the securities by the selling security holders. See Plan of Distribution.

Our common stock is traded on the Nasdaq National Market under the symbol SRDX. The closing sale price on July 8, 2005 as reflected on the Nasdaq National Market, was \$44.90 per share.

**For information concerning certain risks relating
to an investment in SurModics common stock
see Risk Factors beginning on page 4.**

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

The date of this prospectus is July 11, 2005

TABLE OF CONTENTS

	Page
Table of Contents	2

<u>ABOUT SURMODICS</u>	1
<u>CAUTIONS REGARDING FORWARD-LOOKING STATEMENTS</u>	2
<u>RISK FACTORS</u>	4
<u>USE OF PROCEEDS</u>	10
<u>SELLING SECURITY HOLDERS</u>	10
<u>PLAN OF DISTRIBUTION</u>	12
<u>LEGAL MATTERS</u>	14
<u>EXPERTS</u>	14
<u>WHERE YOU CAN FIND MORE INFORMATION</u>	14

Table of Contents

ABOUT SURMODICS

We are a leading provider of surface modification and drug delivery technologies to the healthcare industry. Our technologies modify and enhance the surface characteristics of medical devices and biomedical applications, improving performance and, in some cases, enabling development of new products. Our strategy is to create strong relationships and coating technology license agreements with the world's leading medical device manufacturers as well as emerging companies with promising technology. By doing so, we leverage our core technologies into high growth, high value opportunities, including drug delivery coatings, genomics and tissue engineering.

Our surface modification and drug delivery coatings are based upon versatile underlying technology platforms: our patented drug delivery matrix technology and our patented PhotoLink® coating technology. Coatings developed from our drug delivery matrix technology allow for the controlled, site specific release of drugs from the surface of medical devices. Therapeutic drugs can be entrapped within the polymer matrix coating to provide controlled, site-specific release of the drug into the surrounding tissue.

PhotoLink® coating technology is a versatile, easily applied, light-activated coating technology that modifies medical device surfaces. PhotoLink® coatings can impart many performance-enhancing characteristics, such as lubricity and hemocompatibility, by becoming bound onto the surface of a medical device without materially changing the dimensions or physical properties of the device.

We commercialize our drug delivery and PhotoLink® coating technologies through licensing and royalty arrangements with medical device manufacturers who apply coatings to their own products. We believe this approach allows us to focus our resources on further development of our technology and expansion of our licensing activities into new markets, while leveraging the established manufacturing, sales and marketing capabilities of our customers. Revenue from these arrangements include license fees, development revenue, minimum royalties, and royalties based on a percentage of licensees' product sales. In addition, we manufacture and sell the chemical reagents used in the coating process. We also manufacture and sell coated glass slides to the genomics market and offers a line of stabilization products used to extend the shelf life of immunoassay diagnostic tests.

We were organized as a Minnesota corporation in June 1979 and became a public company, with shares of its common stock becoming listed for trading on the Nasdaq National Market under the trading symbol SRDX, in 1998. Our principal executive offices are located at 9924 West 74th Street, Eden Prairie, Minnesota 55344. Our telephone number is (952) 829-2700.

Table of Contents

CAUTIONS REGARDING FORWARD-LOOKING STATEMENTS

Certain statements contained in or incorporated by reference into this prospectus and other written and oral statements made from time to time by the Company do not relate strictly to historical or current facts. As such, they are considered forward-looking statements that provide current expectations or forecasts of future events. These forward-looking statements are made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. Such statements can be identified by the use of terminology such as anticipate, believe, could, estimate, expect, forecast, intend, may, plan, possible, project, will and similar words or expressions that is not a historical fact, including estimates, projections, future trends and the outcome of events that have not yet occurred, are forward-looking statements. Our forward-looking statements generally relate to our growth strategy, financial results, product development programs, sales efforts, and the impact of the Cordis agreement and other significant customer agreements. You should carefully consider forward-looking statements and understand that such statements involve a variety of risks and uncertainties, known and unknown, and may be affected by inaccurate assumptions. Consequently, no forward-looking statement can be guaranteed and actual results may vary materially. We undertake no obligation to update any forward-looking statement.

Although it is not possible to create a comprehensive list of all factors that may cause actual results to differ from our forward-looking statements, such factors include, among others:

our significant dependence upon Cordis, which causes our financial results and stock price to be subject to factors affecting Cordis and its Cypher stent program, including among others, the rate of market penetration by Cordis, the timing of market introduction of competing products, product safety or efficacy concerns and intellectual property litigation generally and specifically the damages, settlements and mutual agreements that may result from litigation involving Boston Scientific and Cordis in which a federal jury is reported to have found on June 21, 2005 that certain Boston Scientific stents infringed certain Cordis intellectual property rights, litigation involving Boston Scientific and Cordis in which a federal jury is reported to have found on July 5, 2005 that certain Cordis stents violate certain intellectual property rights of Boston Scientific, and litigation between Cordis Europa, N.V., a subsidiary of Johnson & Johnson, and Boston Scientific in which a Dutch court is reported to have ruled on June 9, 2005 that certain Cordis Europa balloon catheters infringed a Boston Scientific balloon catheter patent;

frequent intellectual property litigation in the medical device industry that may directly or indirectly adversely affect our customers' ability to market their products incorporating our technologies;

our ability to protect our own intellectual property;

healthcare reform efforts and reimbursement rates for medical device products that may adversely affect our customers' ability to cost effectively market and sell devices incorporating our technologies;

our ability to attract new licensees in our current market segments and to enter into agreements for additional product applications with existing licensees, the willingness of potential licensees to sign license agreements under the terms offered by us, and our ability to maintain satisfactory relationships with our licensees;

Table of Contents

our ability to increase the number of market segments and applications that use our coating technologies through our sales and marketing and research and development efforts;

our ability to identify suitable businesses to acquire or with whom to form strategic relationships in order to expand our technology development and commercialization;

our ability to facilitate through strategic investment and research and development support the creation of new medical device market segments and applications that incorporate our coating technologies;

market acceptance of products sold by customers incorporating our technologies and the timing of new product introductions by licensees;

market acceptance of products sold by customers competitors and the timing and pricing of new product introductions by customers competitors;

the difficulties and uncertainties associated with the lengthy and costly new product development and foreign and domestic regulatory approval processes, such as delays, difficulties or failures in achieving acceptable clinical results or obtaining foreign or FDA marketing clearances, which may result in lost market opportunities or postpone or preclude product commercialization by licensees;

efficacy or safety concerns with respect to products marketed by us and our licensees, whether scientifically justified or not, that may lead to product recalls, withdrawals or declining sales;

product liability claims not covered by insurance;

the development of new products or technologies by competitors, technological obsolescence and other changes in competitive factors;

the trend of consolidation in the medical device industry, resulting in more significant, complex and long term contracts than in the past and potentially greater pricing pressures;

economic and other factors over which we have no control, including changes in inflation and consumer confidence;

acts of God or terrorism which impact our personnel or facilities;

the ability to secure raw materials for reagents we sell;

the timing of acquisitions made by us from time to time, our ability to successfully integrate the operations of companies we may acquire and our ability to create synergies from acquisitions and other strategic relationships, including in particular with respect to our January 2005 acquisition of InnoRx's assets; and

other factors described below in Risk Factors.

Many of these factors are outside our control and knowledge and could result in increased volatility in period-to-period results. Investors are advised not to place undue reliance upon our forward-looking statements and to consult any further disclosures by us on this subject in our filings with the

Table of Contents

Securities and Exchange Commission. Many of the factors identified above are discussed in more detail below under Risk Factors.

Market data used or incorporated by reference in this prospectus, including information relating to our relative competitive position, is based on independent industry sources, other publicly available information and the good faith estimates of our management. Although we believe that such sources are reliable, the accuracy and completeness of such information is not guaranteed and may not have been independently verified.

RISK FACTORS

You should consider the following risk factors, as well as other information contained or incorporated by reference in this prospectus before investing in the common stock. If any of these risks occur, our business could suffer. The risks and uncertainties described may not be the only ones we face; additional risks and uncertainties not presently known to us or that we currently deem immaterial may also affect our business operations.

The loss of one or more of our major customers could significantly reduce our revenue and earnings.

Revenue from Cordis Corporation represented approximately 52% of our total revenue for the year ended September 30, 2004. There can be no assurance that revenue from any customer will continue at its historical levels. Loss of one or more of our current customers, particularly Cordis or other large customers, could have a material adverse effect on our business, financial condition and results of operations. If we cannot broaden our customer base, we will continue to depend on a few customers for the majority of our revenue.

We rely on third parties to market, distribute and sell the products incorporating our coating technologies and those third parties may not perform or agreements with those parties could be terminated.

The principal element of our business strategy is to enter into licensing arrangements with medical device companies that manufacture products incorporating our technologies. For the fiscal years ended September 30, 2004, 2003 and 2002, we derived approximately 70%, 57% and 40% of our revenue, respectively, from royalties and license fees. We do not currently manufacture, market or sell our own medical devices nor do we intend to do so in the foreseeable future. Thus, our prospects are substantially dependent on the receipt of royalties from licensees of our technologies. The amount and timing of such royalties are, in turn, dependent on the ability of our licensees to successfully gain regulatory approval for, market and sell products incorporating our technologies. Failure of certain licensees to gain regulatory approval or market acceptance for such products could have a material adverse effect on our business, financial condition and results of operations.

Our customers manufacture, market and sell the products incorporating our licensed technologies. If one or more of our licensees fails to pursue the development or marketing of these products as planned, our revenue and profits may not reach our expectations, or may decline. We do not control the timing and other aspects of the development or commercialization of products incorporating our licensed technologies because our customers may have priorities that differ from ours or their development or marketing efforts may be unsuccessful, resulting in delayed or discontinued products. Hence, the amount

Table of Contents

and timing of royalty payments received by us will fluctuate, and such fluctuations could have a material adverse effect on our business, financial condition and results of operations.

Under our standard license agreements, licensees can terminate the license for any reason upon 90 days prior written notice. Existing and potential licensees have no obligation to deal exclusively with the Company in obtaining surface modification technologies and may pursue parallel development or licensing of competing surface modification solutions on their own or with third parties. A decision by a licensee to terminate its relationship with us could materially adversely affect our business, financial condition and results of operations.

We need to expand our licensing base to reduce our reliance upon several major customers.

A significant portion of our revenue is derived from a relatively small number of customer products. We intend to continue pursuing a strategy of licensing our technologies to a diversified base of medical device manufacturers and other customers, thereby expanding the licensing base for our coating technologies. Success will depend, in part, on our ability to attract new licensees, to enter into agreements for additional applications with existing licensees and to develop and market new applications. There can be no assurance that we will be able to identify, develop and adapt our technologies for new applications in a timely and cost effective manner; that new license agreements will be executed on terms favorable to us; that new applications will be accepted by manufacturers in our target markets; or that products incorporating newly licensed technology, including new applications, will gain regulatory approval, be commercialized or gain market acceptance. Delays or failures in these efforts could have an adverse effect on our business, financial condition and results of operations.

Surface modification is a competitive market and carries the risk of technological obsolescence.

We operate in a competitive and evolving field, and new developments are expected to continue at a rapid pace. Our success depends, in part, upon our ability to maintain a competitive position in the development of technologies and products in the field of surface modification and drug delivery. Our technologies compete with technologies developed by AST, Biocompatibles International plc, Carmeda, Hydromer, Specialty Coatings Systems, and STS Biopolymers Inc. (recently acquired by Angiotech Pharmaceuticals, Inc.), among others. In addition, many medical device manufacturers have developed or are engaged in efforts to develop surface modification technologies for use on their own devices. Some of our existing and potential competitors (especially medical device manufacturers pursuing coating solutions through their own research and development efforts) have greater financial and technical resources and production and marketing capabilities than us. Competitors may succeed in developing competing technologies or obtaining governmental approval for products before us. Products incorporating our competitors technologies may gain market acceptance more rapidly than products using ours. Developments by competitors may render our current and potential products noncompetitive or obsolete. Furthermore, there can be no assurance that new products or technologies developed by others, or the emergence of new industry standards, will not render our products or technologies or licensees products incorporating our technologies noncompetitive or obsolete. Any new technologies which make our coating technologies less competitive or obsolete would have a material adverse effect on our business, financial condition and results of operations.

If we cannot adequately protect our technologies and proprietary information, we may be unable to sustain a competitive advantage.

Our success depends, in large part, on our ability to obtain and maintain patents, maintain trade secret protection, operate without infringing on the proprietary rights of third parties and protect our proprietary rights against infringement by third parties. We have been granted U.S. and foreign patents

Table of Contents

and have U.S. and foreign patent applications pending related to our coating technologies. There can be no assurance that any pending patent application will be approved; that we will develop additional proprietary technologies that are patentable, that any patents issued will provide us with competitive advantages or will not be challenged or invalidated by third parties, or that the patents of others will not prevent the commercialization of products incorporating our technologies. Furthermore, there can be no assurance that others will not independently develop similar technologies, duplicate any of our technologies or design around our patents. There can be no assurance that our trade secrets or confidentiality agreements with employees, potential licensees or other parties will provide meaningful protection for our unpatented proprietary information.

Our commercial success also will depend, in part, on our ability to avoid infringing patent or other intellectual property rights of third parties. There has been substantial litigation regarding patent and other intellectual property rights in the medical device industry, and intellectual property litigation may be used against us as a means of gaining a competitive advantage. Intellectual property litigation is complex, time consuming and expensive, and the outcome of such litigation is difficult to predict. If we were found to be infringing any third party patent or other intellectual property right, we could be required to pay significant damages, alter our products or processes, obtain licenses from others, which we may not be able to do on commercially reasonable terms, if at all, or cease commercialization of our products and processes. Any of these outcomes could have a material adverse effect on our business, financial condition and results of operations.

Patent litigation or U.S. Patent and Trademark Office interference proceedings may also be necessary to enforce any patents issued or licensed to us or to determine the scope and validity of third party proprietary rights. These activities could result in substantial cost to us, even if the eventual outcome is favorable to us. An adverse outcome of any such litigation or interference proceeding could subject us to significant liabilities to third parties, require disputed rights to be licensed from third parties or require us to cease using its technology. Any action to defend or prosecute intellectual property would be costly and result in significant diversion of the efforts of our management and technical personnel, regardless of outcome, and could have a material adverse effect on our business, financial condition and results of operations.

We may face product liability claims related to participation in clinical trials or the use or misuse of our products.

The development and sale of medical devices and component products involves an inherent risk of product liability claims. Although we expect that devices incorporating our technologies will be manufactured by others and sold under their own labels, and in most cases our customer agreements provide indemnification against such claims, there can be no assurance that product liability claims will not be filed against us for such devices or that such manufacturers will not seek indemnification or other relief from us for any such claims. In addition, there can be no assurance that product liability claims will not be filed directly against us with respect to our own products. There can be no assurance that our current product liability insurance will continue to be available to us on acceptable terms, if at all, or that, if available, the coverages will be adequate to protect us against any future product liability claims. Furthermore, we do not expect to be able to obtain insurance covering our costs and losses as a result of any recall of products or devices incorporating our technologies due to alleged defects, whether such recall is instituted by a device manufacturer or us or required by a regulatory agency. A product liability claim, recall or other claim with respect to uninsured liabilities or for amounts in excess of insured liabilities could have a material adverse effect on our business, financial condition and results of operations.

Table of Contents

We have a single manufacturing facility and we may lose revenue and be unable to maintain our customer relationships if we lose our production capacity.

We manufacture all of the products we sell in our existing production labs in our Eden Prairie, Minnesota facility. If our existing production facility becomes incapable of manufacturing products for any reason, we may be unable to meet production requirements, we may lose revenue and we may not be able to maintain our relationships with our licensees. Without our existing production facility, we would have no other means of manufacturing products incorporating our coating technologies until we were able to restore the manufacturing capability at our facility or develop an alternative manufacturing facility. Although we carry business interruption insurance to cover lost revenue and profits in an amount we consider adequate, this insurance does not cover all possible situations. In addition, our business interruption insurance would not compensate us for the loss of opportunity and potential adverse impact on relations with our existing licensees resulting from our inability to produce products for them.

Our January 2005 acquisition of InnoRx, Inc. will significantly decrease our net income for the foreseeable future.

We expect to record significant one-time charges following our acquisition of InnoRx as a result of transaction costs for the acquisition and to write-off purchased in-process research and development. A substantial majority of the purchase price in this acquisition is allocated to in-process research and development. The cumulative amount of these one-time charges may exceed the market value of the consideration that we paid to InnoRx's stockholders. These one-time charges are expected to materially decrease our net earnings in our 2005 fiscal year and may also result in charges in each period thereafter in which milestone payments in shares of SurModics stock are made depending on the value of such shares at such time.

We may increasingly perform certain important activities that in the past have been performed by third parties or our customers.

Because of our historical strategy, SurModics has not maintained significant manufacturing operations, managed significant marketing, sales or product branding efforts or developed significant expertise with respect to applying for and receiving governmental and regulatory clearances for marketing products. We may increasingly internally perform certain product development activities and governmental and regulatory compliance activities with respect to technology acquired from InnoRx and with respect to technology acquired from time to time in other acquisitions, but there can be no assurance that our efforts will be effective in these areas.

We are dependent upon key personnel and may not be able to attract qualified personnel in the future.

Our success is dependent upon our ability to retain and attract highly qualified management and technical personnel. We face intense competition for such qualified personnel. We do not maintain key person insurance nor do we have employment agreements with any of our employees. Although we have non-compete agreements with most employees, there can be no assurance that such agreements will be enforceable. The loss of the services of one or more key employees or the failure to attract and retain additional qualified personnel could have a material adverse effect on our business, financial condition and results of operations.

Table of Contents

Our products are subject to continuing regulations and we may be subject to adverse consequences if we fail to comply with applicable regulations.

Although coating technologies themselves are not directly regulated by the FDA, the medical devices incorporating the technologies are subject to FDA regulation. The burden of securing FDA approval for these medical devices rests with our licensees (the medical device manufacturers). In the case of products from the technologies acquired by us from InnoRx, the burden of securing approvals for such products rests with us unless we are able to successfully contract with others to take on such responsibility. We have prepared Device Master Files which may be accessed by the FDA to assist it in its review of the applications filed by our licensees. Historically, most medical devices incorporating a coating have been subject to the FDA's 510(k) marketing approval process, which typically lasts from six to nine months. Supplemental or full pre-market approval (PMA) reviews require a significantly longer period, delaying commercialization. Furthermore, sales of medical devices outside the U.S. are subject to international regulatory requirements that vary from country to country. The time required to obtain approval for sale internationally may be longer or shorter than that required for FDA approval. There can be no assurance that our licensees will be able to obtain regulatory approval for their coated medical devices or we will be able to obtain such approval for our InnoRx products on a timely basis, or at all. Regulatory approvals, if granted, may include significant limitations on the indicated uses for which the product may be marketed. In addition, product approval could be withdrawn for failure to comply with regulatory standards or the occurrence of unforeseen problems following initial marketing. Changes in existing regulations or adoption of new governmental regulations or policies could prevent or delay regulatory approval of products incorporating our technologies or subject us to additional regulation. Failure or delay by our licensees or us in obtaining FDA and other necessary regulatory approval or clearance or the loss of previously obtained approvals could have a material adverse effect on our business, financial condition and results of operations.

Certain of our activities are regulated by federal and state agencies in addition to the FDA. For example, activities in connection with waste disposal are subject to regulation by the U.S. Environmental Protection Agency. Some of our reagent chemicals must be registered with the agency with basic information filed related to toxicity during the manufacturing process as well as the toxicity of the final product. Failure to comply with existing or future regulatory requirements could have a material adverse effect on our business, financial condition and results of operations.

We use hazardous materials in some of our research, development and manufacturing processes.

Our research activities sometimes involve the controlled use of various hazardous materials. Although we believe that our safety procedures for handling and disposing of such materials comply with the standards prescribed by state and federal regulations, the risk of accidental contamination or injury from these materials cannot be completely eliminated. While we currently maintain insurance in amounts which we believe are appropriate in light of the risk of accident, we could be held liable for any damages that might result from any such event. Any such liability could exceed our insurance and available resources and could have a material adverse effect on our business, financial condition and results of operations.

Failure to identify acquisition opportunities and integrate acquired businesses into our operations successfully may limit our growth.

An important part of our growth in the future may involve the acquisition of complementary businesses or technologies. Our identification of suitable acquisition candidates involves risks inherent in

Table of Contents

assessing the technology, value, strengths, weaknesses, overall risks and profitability, if any, of acquisition candidates. We may be unable to identify suitable acquisition candidates. If we do not make suitable acquisitions, we may find it more difficult to realize our growth objectives.

The process of integrating new businesses into our operations poses numerous risks, including:

an inability to assimilate acquired operations, personnel, technology, information systems, and internal control systems and products;

diversion of management's attention;

difficulties and uncertainties in transitioning the business relationships from the acquired entity to us; and

the loss of key employees of acquired companies.

In addition, future acquisitions by us may be dilutive to our shareholders, and cause large one-time expenses or create goodwill or other intangible assets that could result in significant asset impairment charges in the future. In addition, if we acquire entities that have not yet commercialized products but rather are developing technologies for future commercialization, our earnings per share may fluctuate as we expend significant funds for continued research and development efforts for acquired technology necessary to commercialize such technology. We cannot guarantee that we will be able to successfully complete any acquisitions or that we will realize any anticipated benefits from acquisitions that we complete.

Our revenue will be harmed if we cannot purchase sufficient reagent components we use in our manufacture of reagents.

We currently purchase some of the components we use to manufacture coating reagents from sole suppliers. If any of our sole suppliers becomes unwilling to supply components to us, incurs an interruption in its production or is otherwise unable to provide us with sufficient material to manufacture our reagents, we will experience production interruptions. If we lose our sole supplier of any particular reagent component or are otherwise unable to procure all components required for our reagent manufacturing for an extended period of time, we may lose the ability to manufacture the reagents our customers require to commercialize our coating technology. This could result in lost royalties and product sales, which would harm our financial results. Adding suppliers to our approved vendor list may require significant time and resources since we typically thoroughly review a supplier's business and operations to become comfortable with the quality and integrity of the materials we purchase for use with our technology, including reviewing a supplier's manufacturing processes and evaluating the suitability of materials and packaging procedures the supplier uses. We routinely attempt to maintain multiple suppliers of each of our significant materials, so we have alternative suppliers if necessary. However, if the number of suppliers of a material is reduced, or if we are otherwise unable to obtain our material requirements on a timely basis and on favorable terms, our operations may be harmed.

If we are required to disclose any material weaknesses in our disclosure controls and internal controls, our stock price may be harmed and we may incur substantial costs to correct any such deficiencies.

Prior to filing our annual report on Form 10-K for our 2005 fiscal year, we will be required to perform a comprehensive review of our internal controls in accordance with Section 404 of the Sarbanes-Oxley

Table of Contents

Act, and our independent auditors will be required to audit the completeness and accuracy of our evaluation. If we discover any material deficiencies in our internal controls, we will be required to disclose such deficiencies to the public. Effective disclosure controls and internal controls are important to the production of reliable financial reports and in helping to prevent financial fraud. If, as a result of the discovery of any material deficiencies in our disclosure controls or internal controls, we determine we have not provided reliable financial reports or prevented fraud, our business and operating results could be harmed, investors could lose confidence in our reported financial information and the trading price of our common stock could drop significantly.

Beginning with our 2006 first fiscal quarter, we will be required to account for equity incentive grants under our stock plans as a compensation expense which will harm our financial performance.

Beginning in our 2006 first fiscal quarter, we will be required to comply with the Financial Accounting Standard Board's Statement 123R, Share-Based Payment. Currently we record compensation expense only in connection with option grants that have an exercise price below fair market value. For option grants that have an exercise price at fair market value we calculate compensation expense and disclose the impact on net (loss) income and net (loss) income per share in a footnote to the consolidated financial statements. FASB 123R will require us to begin estimating and recording the fair value of all equity incentive grants under our stock plans as compensation expense in our consolidated statement of operations in a manner substantially similar to the approach now disclosed in the footnote to our consolidated financial statements. As a result of being required to record compensation expense for equity incentives under FASB 123R, our operating margins may decrease, we are likely to experience increased expenses (including R&D expenses) and our tax rates may be affected.

Our stock price has been volatile and may continue to be volatile.

The trading price of our common stock has been, and is likely to continue to be, highly volatile, in large part attributable to developments and circumstances related to factors identified in Forward-looking Statements and Risk Factors. The market value of your investment in our common stock may rise or fall sharply at any time because of this volatility, and also because of significant short positions taken by investors from time to time in our stock. In our fiscal year ended September 30, 2004, the closing sale price for our common stock ranged from \$18.60 to \$28.30 per share. As of July 8, 2005, the last reported sale price of our stock was \$44.90 per share. The market prices for securities of medical technology, drug delivery and biotechnology companies historically have been highly volatile, and the market has experienced significant price and volume fluctuations that are unrelated to the operating performance of particular companies.

USE OF PROCEEDS

We will not receive any proceeds from the sale by the selling security holders of any of the securities offered hereby.

SELLING SECURITY HOLDERS

We are registering the resale of 1,200,128 shares of common stock that may be offered and sold pursuant to this prospectus by or on behalf of the selling security holders. We issued, and may hereafter issue, the common stock as a result of our acquisition of all of the assets of InnoRx, Inc. through the merger of InnoRx with and into SurModics in January 2005. Effective with the closing of our acquisition of InnoRx, we issued 600,064 shares of common stock to the selling security holders, all of which are

Table of Contents

covered by this prospectus. As of July 1, 2005, we issued an additional 60,002 shares of common stock in connection with the achievement of a development and regulatory milestone with respect to the InnoRx technology we acquired. After the date of this prospectus, we may become obligated to issue up to an additional 540,062 shares of common stock upon the achievement of certain additional development and regulatory milestones with respect to InnoRx technology we acquired. The exact number of shares that may be issued after the date of this prospectus will be determined in accordance with the terms of the milestones. All 540,062 shares of common stock that we may issue in the future are covered by this prospectus. Any shares of common stock covered by this prospectus that we do not actually issue will be deregistered.

Set forth below are the names of the selling security holders, the number of shares of our common stock beneficially owned by each selling security holder as of the date of this prospectus and the number of shares that may be offered or sold hereby. To our knowledge, except as indicated in the footnotes to this table, each person named in the table has sole voting and investment power with respect to all shares of common stock shown in the table to be beneficially owned by such person. Because the selling security holders may offer all or some portion of the shares, we have assumed for purposes of the table below that all securities covered by this prospectus will be sold. The common stock covered by this prospectus shall be deemed to include shares offered by any pledgee, donee, transferee or other successor in interest of any of the selling security holders listed below, provided that this prospectus is amended or supplemented if required by applicable law. To our knowledge, based upon information provided to us by selling security holders, no selling security holders are registered broker-dealers or affiliates of registered broker-dealers. None of the selling stockholders has had any position, office or other material relationship with us within the past three years, except that Dr. Eugene de Juan, Jr. has entered into a 2-year consulting agreement with us in connection with our acquisition of InnoRx.

Name	Number of Shares Beneficially Owned	Number of Shares Offered Hereby	Common Stock Owned After Offering ⁽²⁾	
			Number of Shares	Percentage
Ana Carmen Chambers 1996 Irrevocable Trust(1)(3)	11,874	11,874		
K.W. Michael Chambers(1)	163,284	163,284		
Rosemary de Juan Chambers(1)	17,812	17,812		
Eugene de Juan, Jr.(1)	123,706	123,706		
Elizabeth Robison de Juan(1)	123,706	123,706		
Elena Vaughan de Juan 2000 Irrevocable Trust(1)(4)	123,700	123,700		
Elizabeth Anna de Juan 2000 Irrevocable Trust(1)(4)	123,700	123,700		
Emily Rose de Juan 2000 Irrevocable Trust(1)(4)	123,700	123,700		
Eugene de Juan, III 2000 Irrevocable Trust(1)(4)	123,700	123,700		
James Harris Oppenheimer 2000 Irrevocable Trust(1)(5)	20,782	20,782		
Johns Hopkins University(1)(6)	86,816	86,816		
Nancy Carmen Oppenheimer 2000 Irrevocable Trust(1)(5)	20,782	20,782		
Richard Candler de Juan 2000 Irrevocable Trust(1)(7)	35,626	35,626		
Sarah Camille Chambers 1996 Irrevocable Trust(1)(3)	11,874	11,874		
Otto J. Semrow Declaration of Trust(8)(9)	40,080	89,066		
Eileen T. Nash	9,797	9,797		
Odetta L. Zebell	9,797	9,797		
Mary C. Bulger	9,797	9,797		
Jeanne S. McKiernan Revocable Trust of 2004(10)	9,797	9,797		

Carol S. McCarthy Revocable Trust(11)	9,798	9,798
---------------------------------------	-------	-------

- (1) Forty five percent (45%) of the shares listed are the shares of common stock that may be issued to such holder upon achievement of certain development and regulatory milestones with respect to InnoRx technology acquired by SurModics.
- (2) Assumes the sale of all shares being offered hereby.

Table of Contents

- (3) Rosemary de Juan Chambers, as trustee, has sole voting and dispositive power over the shares.
- (4) Elizabeth Robison de Juan, as trustee, has sole voting and dispositive power over the shares.
- (5) Nancy Carmen de Juan Oppenheimer, as trustee, has sole voting and dispositive power over the shares.
- (6) William E. Snow, Jr., is the Treasurer of this selling shareholder and has voting and dispositive power over the shares.
- (7) M. Richard de Juan, as trustee, has sole voting and dispositive power over the shares.
- (8) One hundred percent (100%) of the shares listed are shares of common stock that may be issued to such holder upon achievement of certain development and regulatory milestones with respect to InnoRx technology acquired by SurModics.
- (9) The co-trustees of the Trust have voting and dispositive power over the shares. The persons exercising these powers on behalf of the Trust as co-trustees are Sherwin H. Leff, Carol S. McCarthy and Eileen Nash.
- (10) Jeanne E. McKiernan, as trustee, has sole voting and dispositive power over the shares.
- (11) Carol S. McCarthy, as trustee, has sole voting and dispositive power over the shares.

PLAN OF DISTRIBUTION

The selling security holders may sell the shares of common stock on the Nasdaq National Market or otherwise at prices and on terms then prevailing or at prices related to the then current market price, or in negotiated transactions. When used in this prospectus, selling security holder includes donees, pledges, transferees or other successors-in-interest selling shares received from the named selling security holders after the date of this prospectus as a gift, pledge, partnership distribution or other non-sale related transfer. We will pay all expenses we incur associated with registering the selling security holders' shares. The selling security holders will pay any brokerage commissions and similar expenses attributable to the sale of the shares and their own legal fees. The common stock may be sold in:

- a block trade, where a broker or dealer will try to sell the common stock as agent but may position and resell a portion of the block as principal to facilitate the transaction;
- transactions where a broker or dealer acts as principal and resells the common stock for its account pursuant to this prospectus;
- an exchange distribution in accordance with the rules of such exchange;
- ordinary brokerage transactions and transactions in which the broker solicits purchases; and
- in privately negotiated transactions.

The common stock may also be sold through short sales of shares, put or call option transactions, loans or pledges of the shares, hedging or similar transactions, or a combination of such methods. The selling security holders may or may not involve brokers or dealers in any of these transactions. In effecting sales, brokers or dealers engaged by the selling security holders may arrange for other brokers or dealers to participate. The selling security holders may, from time to time, authorize underwriters acting as their agents to offer and sell the common stock upon such terms and conditions as shall be set forth in a prospectus supplement. Underwriters, brokers or dealers will receive

commissions or discounts from the selling security holders in amounts to be negotiated immediately prior to sale. Offers and sales may also be made directly by the selling security holders, or other bona fide owners of the common stock, so long as an applicable exemption from state broker-dealer registration requirements is available in the jurisdiction of sale. The selling security holders, underwriters, brokers or dealers and any other participating brokers or dealers may be deemed to be underwriters within the meaning of the Securities Act in connection with these sales, and any discounts and commissions received by them and any profit

Table of Contents

realized by them on the resale of the common stock may be deemed to be underwriting discounts and commissions under the Securities Act. The selling security holders may agree to indemnify any agent, dealer or broker-dealer that participates in transactions involving sales of the common stock against liabilities, including liabilities arising under the Securities Act. We have agreed to indemnify each of the selling security holders and each selling security holder has agreed, severally and not jointly, to indemnify us against some liabilities in connection with the offering of the shares, including liabilities arising under the Securities Act. The selling security holders have advised us that they have not entered into any agreements, understandings or arrangements with any underwriters or broker-dealers regarding the sale of their securities.

All or any portion of the shares of common stock covered by this prospectus that qualify for sale under Rule 144 under the Securities Act may be sold under Rule 144 rather than pursuant to this prospectus.

Upon being notified by a selling security holder that a material arrangement has been entered into with a broker-dealer for the sale of shares through a block trade, special offering, exchange distribution or secondary distribution or a purchase by a broker or dealer, we will file a supplement to this prospectus, if required pursuant to Rule 424(b) under the Securities Act, disclosing:

the name of each such selling security holder and of the participating broker-dealer(s);

the number of shares involved;

the initial price at which the shares were sold;

the commissions paid or discounts or concessions allowed to the broker-dealer(s), where applicable;

that such broker-dealer(s) did not conduct any investigation to verify the information set out or incorporated by reference in this prospectus; and

other facts material to the transactions.

In addition, if required under applicable law or the rules or regulations of the Securities and Exchange Commission, we will file a supplement to this prospectus when a selling security holder notifies us that a donee, pledge, transferee or other successor-in-interest intends to sell more than 500 shares of common stock.

In connection with the InnoRx merger in January 2005, pursuant to which the selling security holders acquired their shares of common stock covered by this prospectus, each selling security holder agreed that the holder would not sell or otherwise transfer, directly or indirectly, whether pursuant to this prospectus or otherwise, any of such shares until after July 17, 2005 (180 days after the effectiveness of the InnoRx merger). Thereafter, until approximately the one year anniversary of the effectiveness of the InnoRx merger, each selling security holder has agreed that the holder will not sell pursuant to this prospectus during any single calendar month a number of shares of common stock that exceeds in the aggregate one third (1/3) of the maximum aggregate number of shares of common stock issued to such selling security holder by SurModics pursuant to the InnoRx merger. We currently do not anticipate maintaining the registration covered by this prospectus past the one-year anniversary of the effectiveness of the InnoRx merger. Accordingly, after such time, any offers and sales by a selling security holder will not be done pursuant to this prospectus but will be done pursuant to Rule 144 or other exemptions that may be available to the selling security holder.

Table of Contents

There is no assurance that the selling security holders will offer for sale or sell any or all of the shares of common stock covered by this prospectus.

LEGAL MATTERS

The validity of the common stock offered in this prospectus will be passed upon for us by Fredrikson & Byron, P.A., Minneapolis, Minnesota.

EXPERTS

The financial statements incorporated in this prospectus by reference from SurModics Annual Report on Form 10-K for the year ended September 30, 2004 have been audited by Deloitte & Touche LLP, an independent registered public accounting firm, as stated in their report, which is incorporated herein by reference, and has been so incorporated in reliance upon the report of such firm given upon 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 under the Exchange Act. You may read and copy this information at the SEC's Public Reference Room, 450 Fifth Street, N.W., Room 1024, Washington, D.C. 20549. You may also obtain copies of this information by mail from the Public Reference Section of the SEC at prescribed rates. Please call the SEC at 1-800-SEC-0330 for additional information about the Public Reference Room.

The SEC also maintains a website that contains reports, proxy statements and other information about issuers, including SurModics, Inc., that file electronically with the SEC. The address of that site is www.sec.gov. You can also inspect reports and other information about us at the office of the Nasdaq National Market, 1735 K Street, N.W., Washington, D.C. 20006-1005.

The SEC allows us to incorporate by reference the information we file with it, which means that we can disclose important information to you by referring you to those documents. The information incorporated by reference is considered to be part of this prospectus, and information that we file later with the SEC will automatically update and supersede this information. We incorporate by reference the documents listed below and any future filings (File No. 000-23837) we will make with the SEC under Sections 13(a), 13(c), 14 or 15(d) of the Securities Exchange Act of 1934:

1. Annual Report on Form 10-K for fiscal year ended September 30, 2004, filed December 14, 2004;
2. Proxy Statement for the 2005 Annual Meeting of Shareholders filed December 15, 2004;
3. Quarterly Reports on Form 10-Q for three-month period ended December 31, 2004, filed February 9, 2005, and for the three- and six-month periods ended March 31, 2005, filed May 10, 2005.
4. Current Reports on Form 8-K filed March 25, 2005, February 4, 2005, January 24, 2005, November 19, 2004 and November 17, 2004.

Table of Contents

5. The description of our common stock which is contained in our Registration Statement on Form SB-2 filed December 24, 1997.

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

Philip D. Ankeny, CFO
SurModics, Inc.
9924 West 74th Street
Eden Prairie, MN 55344
(952) 829-2700

This prospectus is part of a registration statement we filed with the SEC. You should rely only on the information or representations provided in this prospectus. We have authorized no one to provide information other than that provided in this prospectus. We have authorized no one to provide you with different information. You should not assume that the information in this prospectus is accurate as of any date other than the date on the front of the document.