SURMODICS INC
Form 10-K
December 14, 2006

# SECURITIES AND EXCHANGE COMMISSION
**WASHINGTON, DC 20549**

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# FORM 10-K

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**Annual report pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934**
**For the fiscal year ended September 30, 2006**

**Commission file number 0-23837**

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# SURMODICS, INC.
(Exact Name of Registrant as Specified in Its Charter)

| **Minnesota** | **41-1356149** |
|---|---|
| (State or other jurisdiction of incorporation or organization) | (IRS Employer Identification No.) |
| **9924 West 74th Street Eden Prairie, Minnesota** | **55344** |
| (Address of Principal Executive Offices) | (Zip Code) |

(Registrant s Telephone Number, Including Area Code)
**(952) 829-2700**

Securities registered pursuant to Section 12(b) of the Act:
**Common Stock, $.05 par value**

Securities registered pursuant to Section 12(g) of the Act:
**None**

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes o No x

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes o No x

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

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of registrant s knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form

10-K. o

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, or a non-accelerated filer. See definition of accelerated filer and large accelerated filer in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer o Accelerated filer x Non-accelerated filer o

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes o No x

The aggregate market value of the Common Stock held by shareholders other than officers, directors or holders of more than 5% of the outstanding stock of the registrant as of March 31, 2006 was approximately $560 million (based upon the closing sale price of the registrant s Common Stock on such date).

The number of shares of the registrant s Common Stock outstanding as of December 8, 2006 was 18,393,019.

**DOCUMENTS INCORPORATED BY REFERENCE**

Portions of the Registrant s definitive Proxy Statement for the Registrant s 2007 Annual Meeting of Shareholders are incorporated by reference into Part III.

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We make available, free of charge, copies of our annual report on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K and amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Securities Exchange Act on our web site, www.surmodics.com, as soon as reasonably practicable after filing such material electronically or otherwise furnishing it to the SEC. We are not including the information on our web site as a part of, or incorporating it by reference into, our Form 10-K.



## PART I

### ITEM 1. BUSINESS.

**Overview**

SurModics, Inc. (referred to as SurModics, the Company, we, us, our and other like terms) is a lead provider of surface modification and drug delivery technologies to the healthcare industry. Our technologies include, among others, our PhotoLink® surface modification coatings, our drug delivery polymer matrices, and our ophthalmic drug delivery platforms and systems. These technologies are employed in the development of new medical devices and other biomedical products or in the improvement of existing ones. We collaborate with our customers, who include the world s foremost medical device, pharmaceutical and life science companies as well as smaller, development stage companies attempting to develop new technologies, to bring innovation together to improve patient outcomes. Some of the innovations we have developed for the benefit of our customers include polymer coatings for drug-eluting stents, lubricious (slippery) coatings, ophthalmic drug delivery platforms and systems, in vitro diagnostic products, and cell encapsulation technology for islet cell implantation. Our strategy is to continue to demonstrate technical leadership in the field of surface modification and drug delivery technologies and products, such that we are viewed as a leading edge product development partner to the healthcare industry.

Our surface modification and drug delivery technologies are utilized by our customers to either alter the characteristics of the surfaces of devices and biological materials (e.g., lubricity or hemocompatibility), create new functions for the surfaces of the devices (e.g., drug delivery or promotion of healing) or to enable drug delivery from our device platforms. For example, our patented PhotoLink® technology enhances the maneuverability of dilatation catheters or guidewires by improving the lubricity of the device surface. Similarly, our patented drug delivery technologies can create new device capabilities by enabling site specific, controlled release drug delivery in cases where devices are themselves necessary to treat a problem (e.g., stents) and in cases where devices serve only as a vehicle to deliver a drug (e.g., ophthalmology implants).

We believe that site specific drug delivery has the potential to change the landscape of the current medical device industry. Drug-eluting stents are one of the first manifestations of how drugs and devices can be combined to dramatically improve patient outcomes. We also believe that significant opportunities exist for site specific drug delivery from a wide range of other medical devices. Working with both pharmaceutical and medical device companies, we believe we are poised to exploit this growing market opportunity as drugs and devices converge to create improved products and therapies.

We commercialize our surface modification and drug delivery technologies primarily through licensing and royalty arrangements with medical device manufacturers who typically apply the coatings to their products in their own manufacturing facilities. Additionally, we now have the capability to partner with pharmaceutical and ophthalmology companies to integrate their proprietary ophthalmic drugs with our unique drug delivery platform technologies (e.g., our I-vation implant) and delivery systems. We believe this approach allows us to focus our resources on the further development of our core technologies and enables us to expand our licensing activities into new markets.

Revenues from our licensing arrangements typically include research and development revenue, license fees and milestone payments, 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 offer a line of stabilization products used to extend the shelf life of immunoassay diagnostic tests. We also license a format for in vitro diagnostics tests, which has found broad application in the area of rapid point-of-care diagnostic testing, such as pregnancy, strep and flu tests.

In January 2005, we extended our drug delivery technologies beyond the cardiovascular market, where our drug delivery polymer expertise first gained prominence, into the ophthalmology market by acquiring all of the assets of InnoRx, Inc., including its innovative sustained drug delivery platform technologies used to treat a variety of serious eye diseases. (For more information on the InnoRx acquisition, see Liquidity and Capital Resources in Item 7 of this report.) A Phase I clinical trial to demonstrate safety of the I-vation intravitreal implant in patients with diabetic macular edema was initiated during fiscal 2005. The study was fully enrolled and all patients completed their first six-month follow-up during fiscal 2006. The initial data suggest that the I-vation intravitreal



implant is safe and well tolerated in patients with DME. If this and other future clinical trials demonstrate longer term safety and efficacy of this product, I-vation TA (triamcinolone acetonide) may represent a viable commercial prospect. Such positive results can also provide the Company with the ability to partner with pharmaceutical and ophthalmology companies to integrate their proprietary ophthalmic drugs with our unique sustained drug delivery platforms and systems. We plan to continue to invest in our technologies and products to expand our core capabilities for ophthalmic drug delivery implants. We also anticipate entering into one or more strategic relationships to further advance these ophthalmic technologies and products, and eventually commercialize such technologies if they lead to viable, approved treatment solutions.

We manage our business through the following six technology- and market-focused business units:

- ***Drug Delivery***, creating and supporting site specific drug delivery polymers and coating technologies for use in drug/device combination products in our chosen markets, such as drug-eluting stents for the treatment of vascular disease, ophthalmic implants, orthopedics, urology, oncology, and wound treatment, among others.

- ***Ophthalmology***, developing drug delivery systems intended to enhance performance, safety, patient convenience and patient compliance for a variety of drugs and other bioactive agents that are being developed by pharmaceutical and ophthalmology companies for the treatment of serious eye diseases.

- ***Hydrophilic Technologies***, specializing in advanced lubricity (slippery) coatings that can enhance the function of medical devices, facilitating and easing their placement and maneuverability in the body.

- ***Regenerative Technologies***, developing platforms intended to augment or replace tissue/organ function (e.g., cell encapsulation applications), or to modify medical devices to facilitate tissue/organ recovery through natural repair mechanisms (e.g., hemo/biocompatible and prohealing coatings).

- ***Orthopedics***, developing innovative solutions for the treatment of structural defects in patients using proven SurModics technologies, and creating new technology solutions for existing patient care needs in the orthopedics field.

- ***In Vitro Technologies*** *(formerly Diagnostics and Drug Discovery),* specializing in surface modification products and technologies for healthcare applications focused in vitro (outside the body). These products and technologies include protein stabilization reagents, recombinant autoimmune antigens, surface chemistry technologies for nucleic acid and protein immobilization, synthetic extracellular matrix (ECM) cell culture products, and diagnostic format intellectual property.

We believe we have sufficient financial resources available to continue developing and growing our business. We intend to continue investing in research and development to advance our surface modification and drug delivery technologies and to expand uses for our technology bases. In addition, we continue to pursue access to products and technologies developed outside the Company as appropriate to complement our internal research and development efforts.

The Company was organized as a Minnesota corporation in June 1979 and became a public company, with shares of our common stock becoming listed for trading on the Nasdaq market in 1998.

**Medical Device Industry**

Advances in medical device technology have helped drive improved medical device efficacy and patient outcomes. Pacemakers and defibrillators have dramatically reduced deaths from cardiac arrhythmias. Stents, particularly drug-eluting stents, have significantly reduced the need for repeat intravascular procedures, and they have diminished the need for more invasive cardiac bypass surgery. Hip, knee and spine implants have relieved pain and increased mobility. Acceptance of these and other similar innovations by patients, physicians and insurance companies has helped the U.S. medical device industry grow at a faster pace than the economy as a whole. The attractiveness of the industry has drawn intense competition among the companies participating in this area. In an effort to improve their existing products or develop entirely new devices, a growing number of medical device manufacturers are exploring or using surface modification and drug delivery technologies as product differentiators



or device enablers. In addition, the continuing trend toward minimally invasive surgical procedures, which often employ catheter-based delivery technologies, has increased the demand for hydrophilic, lubricious coatings and other technologies.

The convergence of the pharmaceutical, biologics and medical device industries, often made possible by surface modification and drug delivery technologies, presents a powerful opportunity for major advancements in the healthcare industry. The dramatic success of drug-eluting stents in interventional cardiology has captured the attention of the pharmaceutical and medical device industries. We believe the benefits of combining drugs and biologics with implantable devices are becoming increasingly valuable.

**SurModics Coating Technologies  Overview**

We believe SurModics is uniquely positioned to exploit the continuing trend of incorporating surface modification and drug delivery technologies into medical device design, leading to more efficient and effective medical devices as well as creating entirely new applications for medical devices. We have a growing portfolio of proprietary technologies, market expertise and insight, and unique collaborative research and development capabilities  all key ingredients to bring innovation together for the benefit of the Company and the healthcare industry.

Our PhotoLink coating technology is a versatile, easily applied, coating technology that modifies medical device surfaces by creating covalent bonds between device surfaces and a variety of chemical agents. PhotoLink coatings can impart many performance enhancing characteristics, such as advanced lubricity (slippery) and hemocompatibility (preventing clot formation), by becoming bound onto surfaces of medical devices or other biological materials without materially changing the dimensions or other physical properties of devices. Our PhotoLink technology utilizes proprietary, light activated (photochemical) reagents, which include advanced polymers or active biomolecules having desired surface characteristics and an attached light reactive chemical compound (photogroup). When the reagent is exposed to a direct light source, typically ultraviolet light, a photochemical reaction creates a covalent bond between the photogroup and the surface of the medical device,

thereby imparting the desired property to the surface. A covalent bond is a very strong chemical bond that results from the sharing of electrons between carbon atoms of the substrate and the applied coating making the coating very durable and resilient.

Our proprietary PhotoLink reagents can be applied to a variety of substrates. Our reagents are easily applied to the material surface by dipping, spraying, roll coating, ink jetting or brushing. We continue to expand our portfolio of proprietary reagents for use by our customers. These reagents enable our customers to develop novel surface features for their devices, satisfying the expanding requirements of the healthcare industry. We are also continually working to expand the list of materials that are compatible with our surface modification and drug delivery reagents. Additionally, we develop coating processes and coating equipment to meet the device quality, manufacturing throughput and cost requirements of our customers.

Our drug delivery technologies differ from PhotoLink in that they involve non-photochemical reagents Therapeutic drugs are incorporated within our proprietary polymer matrices to provide controlled, site specific release of the drug into the surrounding environment. The release of the drug can be tuned to elute quickly (in a few days) or slowly (ranging from several months to over a year), illustrating the wide range of release profiles that can be achieved with our coating systems. On a wide range of devices, drug-eluting coatings can help improve device performance, increase patient safety and enable innovative new treatments. We work with companies in the pharmaceutical, biotechnology and medical device industries to develop specialized coatings that allow for the controlled release of drugs from device surfaces. We see at least three primary areas with strong future potential: (1) improving the function of a device which itself is necessary to treat the problem; (2) enabling drug delivery in cases where the device serves only as a vehicle to deliver a drug to a specific site in the body; and (3) enhancing the biocompatibility of a medical device to ensure that it continues to function over a long period of time.

We offer customers several distinct polymer families for site specific drug delivery. Our Bravo™ Drug Delivery Polymer Matrix is utilized on the CYPHER® Sirolimus-eluting Coronary Stent from Cordis Corporation, a Johnson & Johnson company. CYPHER® is a trademark of Cordis Corporation. The Bravo polymer is also used on our I-vation™ Intravitreal Implant within our Ophthalmology division. Our Encore™ Drug Delivery Polymer Matrix delivers a wider variety of therapeutic agents, including Rapamycin analogs, from more types of devices than previously possible. In addition, we offer several biodegradable polymer technologies that can be used for drug delivery applications. Because some biodegradable polymers can deliver proteins and other large molecule therapeutic



agents, they have the potential to expand the breadth of drug delivery applications we can pursue. Biodegradable polymers can be combined with one or more drugs and applied to a medical device, and the drug is then released as the polymer degrades in the body over time.

**SurModics™ Coating Technologies – Product Development Benefits**

We believe that our proprietary coating technologies provide our customers with a number of benefits, including:

- *Flexibility*. Coatings can be applied to many different kinds of surfaces and can immobilize a variety of chemical, pharmaceutical and biological agents, which allow customers to be innovative in the design of their products without significantly changing the dimensions or other physical properties of the device.

- *Multiple Surface Properties*. The surface modification process can be tailored to provide customers with the ability to improve the performance of their devices by choosing the specific coating properties desired for particular applications. Our surface modification technologies also can be combined to deliver multiple surface-enhancing characteristics on the same device.

- *Ease of Use*. Unlike other coating processes, the PhotoLink coating process is relatively simple and is easily integrated into the customer's manufacturing process. In addition, it does not subject the coated products to harsh chemical or temperature conditions, produces no hazardous byproducts, and does not require lengthy processing or curing time. Further, the coatings are compatible with generally accepted

sterilization processes, so the surface attributes are not lost when the medical device is sterilized.

**SurModics Coating Technologies  Clinical Benefits**

- *Lubricity*. Low friction or lubricious coatings reduce the force and time required for insertion, navigation and removal of devices in a variety of minimally invasive applications. Lubricity also reduces tissue irritation and damage caused by products such as catheters, guidewires and endoscopy devices. Based on internal and customer evaluation, when compared with uncoated surfaces, our PhotoLink coatings have reduced the friction on surfaces by more than 90%, depending on the substrate being coated.

- *Drug Delivery*. We provide drug delivery polymer technology to enable controlled, site specific delivery of therapeutic agents. Our proprietary polymer reagents and coating methods do not require light activation (i.e., they are not based on PhotoLink), to create biodurable coatings which serve as reservoirs for therapeutic drugs. The drugs can then be released from the coating on a controlled basis. When a drug-eluting stent is implanted into a patient, the drug releases from the surface of the stent into the blood vessel wall where it can act to inhibit unwanted tissue growth, thereby reducing the occurrence of restenosis. Cordis Corporation, a division of Johnson & Johnson, is currently selling a drug-eluting stent incorporating SurModics technology around the world. In addition to our biodurable polymer technologies, we offer a number of biodegradable polymer technologies allowing us to deliver both large and small molecule drugs and address a wide variety of applications. We also believe that drug-eluting devices have significant potential in the ophthalmology market, where sustained drug delivery implants have the potential to provide a long-term therapy benefit for patients with serious eye diseases.

- *Prohealing*. We are developing biologically based extracellular matrix (ECM) protein coatings for use in various applications that may accelerate blood clotting in a controlled fashion, thereby minimizing thromboembolism (blood clots that detach from the device surface and travel downstream). Moreover, these coatings may improve device-site healing through specific protein-cell interactions. Such surfaces may be useful for endovascular grafts and neuroaneurysm devices where it is important to seal off blood clots before serious life threatening complications can occur. Certain ECM proteins specifically stimulate the migration and proliferation of endothelial cells (cells that line blood vessels). Covalently attaching the appropriate ECM proteins to stent surfaces with PhotoLink coatings may signal endothelial cells to migrate to the surface where they can rapidly form a stable endothelial lining. We believe these prohealing coatings could help prevent late stent thrombosis.



- *Hemo/biocompatibility*. Hemocompatible/biocompatible coatings help reduce adverse reactions that may be created when a device is inserted into the body and comes in contact with blood. Heparin has been used for decades as an injectable drug to reduce blood clotting in patients. PhotoLink reagents can be used to immobilize heparin on the surface of medical devices, thereby inhibiting blood clotting on the device surface, minimizing patient risk and enhancing the performance of the device. We have also developed synthetic, non-biological coatings that provide medical device surfaces with improved blood compatibility without the use of heparin. These coatings prevent undesirable cells and proteins that lead to clot formation from adhering to the device surface. These coatings may also reduce fibrous encapsulation.

- *Tissue Engineering*. Studies have shown that attachment of extracellular matrix proteins and peptides onto surfaces of implantable medical devices improves host cell attachment, growth and subsequent tissue integration. Company studies have shown that biomedical implants (such as vascular grafts) coated with photoreactive collagen and other proteins may improve attachment, cell growth and acceptance by surrounding tissues. We have developed several coating and matrix technologies for tissue engineering applications, such as naturally biodegradable matrix forming polymers to provide scaffolds for cells, proteins, and genes for a variety of applications. For example, biocompatible coatings that form a semipermeable barrier may be used to encapsulate transplant cells, rendering them invisible to a patient s immune system. Accordingly, we have licensed technology to and have made an investment in Novocell, Inc., which is pursuing a treatment for diabetes by implanting encapsulated islet cells.

- *Wettability*. PhotoLink hydrophilic coatings have been shown in internal and customer tests to accelerate liquid flow rates on normally hydrophobic (water repelling) materials by up to 75%. For example, some rapid point-of-care diagnostic tests, such as home monitoring or physician monitoring of glucose levels in diabetics, are currently done by pricking a patient's finger and placing a drop of blood onto a polymer strip which is then inserted into a blood glucose reader. We believe that the time it takes for the blood to flow up the strip to provide a readout can be dramatically reduced and the consistency can be greatly improved with the use of PhotoLink technology.

- *DNA and Protein Immobilization*. Both DNA and protein microarrays are useful tools for the pharmaceutical, diagnostic and research industries. During a DNA gene analysis, typically thousands of different probes need to be placed in a pattern on a surface, called a DNA microarray. These microarrays are used by the pharmaceutical industry to screen for new drugs, by genome mappers to sequence human, animal or plant genomes, or by diagnostic companies to search a patient sample for disease causing bacteria or viruses. However, DNA does not readily adhere to most surfaces. We have developed various surface chemistries for both DNA and protein immobilization. GE Healthcare has licensed our technology in this area and sells genomics slides under the trade name CodeLink®. CodeLink® is a trademark of GE Healthcare. Protein microarrays are used as diagnostic and research tools to determine the presence and/or quantity of proteins in a biological sample. The most common type of protein microarray is the antibody microarray, where antibodies are spotted onto a surface and used as capture molecules for protein detection.



**SurModics' Coating Technologies – Applications**

The table below identifies several market segments where surface modification and drug delivery technologies are desired to improve and enable both existing and new medical devices.

| Market Segment Served | Desired Surface Property and Examples of Applications |
|---|---|
| **Interventional cardiology and vascular access** | *Lubricity:* catheters, guidewires<br>*Hemocompatibility:* vascular stents, catheters, distal protection devices<br>*Site specific drug/biologics delivery:* vascular stents, catheters<br>*Prohealing:* vascular stents, vascular grafts |
| **Cardiac rhythm management** | *Lubricity:* pacemaker and defibrillator leads, electrophysiology devices<br>*Hemocompatibility:* electrophysiology devices |
| **Cardiothoracic surgery** | *Prohealing:* heart valves, septal defect repair devices<br>*Hemocompatibility:* minimally invasive bypass devices, vascular grafts, ventricular assist devices |
| ***In Vitro* Diagnostics** | *Lubricity:* microfluidic devices<br>*Hemocompatibility:* blood/glucose monitoring devices, biosensors<br>*Biomolecule Immobilization:* DNA and protein arrays, protein attachment to synthetic nanofibrillar extracellular matrix for cell culture applications<br>*Cell culture growth and tissue integration*: cell culture products, *in vitro* applications using synthetic nanofibrillar extracellular matrix to provide a more "*in vivo*-like" surface |
| **Interventional neurology and** | *Lubricity:* catheters, guidewires |

| | |
|---|---|
| **neurosurgery** | |
| **Urology and gynecology** | *Lubricity:* urinary catheters, incontinence devices, ureteral stents, fertility devices<br>*Site specific drug/biologics delivery:* prostatic stents |
| **Ophthalmology** | *Site specific drug/biologics delivery:* sustained drug delivery implants |
| **Orthopedics** | *Cell growth and tissue integration:* bone and cartilage growth<br>*Infection resistance:* orthopedic implants<br>*Site specific drug/biologics delivery:* orthopedic implants |

Examples of applications for our coating technologies include guidewires, angiography catheters, IVUS catheters, neuro microcatheters/infusion catheters, PTCA/PTA laser and balloon angioplasty catheters, atherectomy systems, chronic total occlusion catheters, stent delivery catheters, cardiovascular stents, embolic protection devices, vascular closure devices, EP catheters, pacemaker leads, drug infusion catheters, wound drains, ureteral stents, urological catheters and implants, hydrocephalic shunts, ophthalmic implants, among other devices.

**Licensing Arrangements**

We commercialize our surface modification and drug delivery technologies primarily through licensing arrangements with medical device manufacturers, who typically apply the surface modifications to their products in their own facilities. We believe this approach allows us to focus our resources on further developing new technologies and expanding our licensing activities rather than making substantial capital investments in contract coating equipment. Our technologies have been designed to allow manufacturers to easily implement them into their own manufacturing processes so customers can control production and quality internally without the need to send their products to a coating contract manufacturer.

We generate the largest portion of our revenue from commercializing our surface modification and drug delivery technologies for use in connection with medical devices, primarily through licensing and royalty arrangements. Revenue from these licensing and royalty arrangements typically includes research and development revenue, license



fees and milestone payments, minimum royalties, and royalties based on a percentage of licensees product sales. We also generate revenue from sales of chemical reagents to licensees for use in their coating processes, and from licensing our proprietary diagnostic formats for use in point-of-care testing.

The licensing process begins with the customer specifying a desired product feature to be created by surface modification, e.g., lubricity, drug delivery, etc. Because each device is unique, we routinely conduct a feasibility study to qualify each new potential product application, often generating research and development revenue. Once the feasibility has been completed in a manner satisfactory to the customer, the customer funds a development project to optimize the coating formulation to meet the customers specific technical needs. At any time prior to commercialization, a license agreement may be executed granting the licensee rights to use our technology. We also manufacture and sell the chemical reagents used by licensees in the coating process, generating another source of recurring revenue. We often support our customers by providing coating assistance for parts required in animal tests and human clinical trials. However, most customers perform the coating work internally once a product has received regulatory approval and is being actively marketed.

The term of a license agreement is generally for a specified number of years or the life of our patents, whichever is longer, although a license generally may be terminated by the licensee for any reason upon 90 days advance written notice. Our license agreements may include certain license fees and/or milestone payments. The

license can be either exclusive or nonexclusive, but a significant majority of our licensed applications are nonexclusive, allowing us to license technology to multiple customers. The royalty rate on a substantial number of the agreements has traditionally been in the 2% to 3% range, but there are certain contracts with lower or higher rates. Royalty rates in certain more recent agreements have been trending higher, especially where the relevant SurModics technology is an enabling component of the customer's device (i.e., the device could not perform as desired without our technology). The amount of the license fees, milestone payments, and the royalty rate are based on various factors including whether the arrangement is exclusive or nonexclusive, the perceived expected value of the coating application to the device, the size of the potential market, and customer preferences. Most of our agreements also incorporate a minimum royalty to be paid by the licensee. Royalties are generally paid on a quarter-lag basis, and are based on the customer's actual sales of coated products in the prior quarter.

We currently have 83 licensed products (customer products utilizing SurModics technology) already on the market generating royalties and 84 customer products incorporating our technology pending regulatory approval. These 167 products are being sold or developed by 83 licensed customers. We signed a record 21 new licenses in fiscal 2006.

Licensed customers include AbbeyMoor Medical, Abbott Laboratories, Bausch & Lomb, Boston Scientific Corporation, CardioMind, Inc., Conor Medsystems, Cook, Corning Incorporated, Cordis Corporation (a Johnson & Johnson company), Devax, Edwards, ev3 Inc., FoxHollow Technologies, Inc., GE Healthcare, Medtronic, Inc., Novocell, Inc., Spectranetics Corporation, St. Jude Medical, Inc., ThermopeutiX, X-Cell Medical and Xtent, among others. Under most of our licensing agreements, we are required to keep confidential the identity of our customers unless they approve such disclosure.

**In Vitro Products**

**Genomics Products**

During fiscal 1999, we launched our 3D-Link® Activated Slide to the genomics market. Coated glass slides are used by genomics researchers to prepare microarrays for DNA analysis. General Electric Company, through GE Healthcare, has an exclusive license to our coated glass slide technology. In addition to license fees, we generate revenue under this license from the manufacture and sale of coated glass slides to GE Healthcare, who markets the slides under their CodeLink® brand.

**Stabilization Products**

SurModics offers a full line of stabilization products for the in vitro diagnostics market. These products decrease the variability often associated with storage conditions, thereby producing more consistent assay results. SurModics' stabilization products are ready-to-use, eliminating the preparation time and cost of producing stabilization and blocking reagents in house.



**Recombinant Human Antigens**

SurModics is the exclusive North American distributor (and non-exclusive in Japan) of DIARECT AG's line of recombinant autoimmune antigens. Because of the lack of high-quality antigens from natural sources, DIARECT produces these proteins and other components using biotechnological methods. DIARECT has strong capabilities in the bacilovirus/Sf9 expression system for autoimmune antigens as well as *E. coli* systems for particular expression tasks.

**Ultra-Web™ Synthetic Extracellular Matrix (ECM)**

The Ultra-Web™ Synthetic ECM product line, is the result of a collaboration between the Donaldson Company (providing the nanofiber technology) and SurModics (providing the surface modification technology). Ultra-Web™ is a trademark of Donaldson Company, Inc. In May 2006, SurModics and Donaldson entered into a strategic marketing and distribution agreement with Corning Incorporated, through which Corning Life Sciences, a subsidiary of Corning Incorporated, will provide worldwide marketing and distribution of the nanofiber cell culture products for *in vitro* cell culture research and drug discovery applications.

Ultra-Web Synthetic ECM is a nanofibrillar cell culture surface that provides a biomimetic environment for more consistent and reproducible *in vivo*-like cell phenotypes, leading to more biologically accurate results. The Ultra-Web technology involves electrospinning various polymers to produce a nanofiber material that is a defined and reproducible cell culture surface. Modification of the nanofibers with specific surface chemistries and functional groups can further enhance the desired cell matrix interactions. Extensive laboratory testing of this cell culture surface has substantiated improved performance when compared to conventional plastic and glass surface technology, with observations of more *in vivo*-like cellular morphology, organization, and activity.

**Diagnostic Royalties**

We have also licensed patent rights to Abbott Laboratories involving a format for in vitro diagnostic tests. This format has found broad application in the area of rapid point-of-care diagnostic testing, such as pregnancy, strep and flu tests. At the end of fiscal 2004, we expanded our agreement with Abbott by purchasing the future royalty streams under certain of Abbott's sublicenses until the expiration of our patents in fiscal 2009. Prior to such expansion, we were receiving only a portion of the royalties under such sublicenses.

**Research and Development**

Our research and development personnel work to enhance and expand our technology offerings in the area of surface modification and drug delivery through internal scientific investigation. These scientists and engineers also evaluate external technologies in support of our business development activities. All of these efforts are directed by an assessment of the needs of the markets in which we do business. Additionally, the R&D staff support the sales staff and business units in performing feasibility studies, providing technical assistance to potential customers, optimizing the coating methodologies for specific customer applications, supporting clinical trials, training customers, and integrating our technologies and know-how into customer manufacturing operations.

We work together with our customers to integrate the best possible surface modification and drug delivery technologies with their devices, not only to meet their performance requirements, but also to perform services quickly so that the product may reach the market ahead of the competition. To quickly solve problems that might arise during the development process and optimization of the coating formulation and process, we have developed comprehensive capabilities in analytical chemistry and surface characterization within our R&D organization. Our state-of-the-art instrumentation and extensive experience allow us to test the purity of coating reagents, to monitor the elution rate of drug from coatings, to measure coating thickness and smoothness, and to map the distribution of chemicals at the surface and within the coating. We believe our capabilities far exceed those of our direct competitors, and sometimes even exceed those of our large-company customers.

As medical devices become more sophisticated and complex, we believe the need for surface modification and drug delivery will continue to grow. We intend to continue our development efforts to expand our surface modification and drug delivery technologies to provide additional optimized surface properties to meet these needs across multiple medical markets. In addition, we are expanding our drug delivery and surface modification technology



expertise to capture more of the final product value. We are doing this by, in selected cases, developing or acquiring technologies or devices to develop from feasibility, up to and including animal and human clinical tests. There can be no assurance that we will be successful in developing or acquiring additional technologies or devices.

After thorough consideration of each market opportunity, our technical strategy is to target selected coating characteristics for further development, to facilitate and shorten the license cycle. We continue to perform research into applications for future products both on our own and in conjunction with some of our customers. Some of the research and development projects currently being worked on include additional polymer systems for site specific drug delivery, including biodegradable technologies, as well as technologies to improve endothelialization of implantable devices and to improve long-term blood compatibility, nanofiber cell culture technologies and drug delivery platforms for ophthalmic applications.

In fiscal years 2006, 2005, and 2004, our research and development expense was $20.4 million, $16.1 million, and $12.6 million, respectively. A portion of this expense is billed to customers for coating optimization and other development work on customer product applications. Research and development revenue in fiscal years 2006, 2005, and 2004 was approximately $5.7 million, $5.4 million, and $4.4 million, respectively. We intend to continue investing in research and development to advance our surface modification and drug delivery technologies and to expand uses for our technology bases. In addition, we continue to pursue access to products and technologies developed outside the Company as appropriate to complement our internal research and development efforts.

**Patents and Proprietary Rights**

Patents and other forms of proprietary rights are an essential part of the SurModics business model. We protect our extensive portfolio of technologies through a number of U.S. patents covering a variety of coating methods, reagents, and formulations, as well as particular clinical device applications. We generally file international patent applications in the locations matching the major markets of our customers (primarily in North America, Europe, and Japan) in parallel with U.S. applications. In fiscal 2006, we filed 56 United States patent applications, expanding the portfolio protection around our current technologies as well as enabling pursuit of new technology concepts, innovations, and directions. At fiscal year end, we had 101 pending United States patent applications, 16 of which were exclusively licensed from others, and 224 foreign patent applications, of which 61 were exclusively licensed from others. We own 79 issued United States patents, and are the exclusive licensee on 18 of those patents. Internationally, we own 147 patents and are exclusively licensed under 29 of those patents. Extensive in-licensing rights of a more limited nature are available to us from other third party patents, enabling efficient use of such intellectual property in various ways favorable to the Company.

We also rely upon trade secrets and other unpatented proprietary technologies. We seek to maintain the confidentiality of such information by requiring employees, consultants and other parties to sign confidentiality agreements and by limiting access by parties outside the Company to such information. There can be no assurance, however, that these measures will prevent the unauthorized disclosure or use of this information or that others will not be able to independently develop such information. Additionally, there can be no assurance that any agreements regarding confidentiality and non-disclosure will not be breached, or, in the event of any breach, that adequate remedies would be available to us.

**Marketing and Sales**

We market our core technologies and products throughout the world using a direct sales force consisting of dedicated sales professionals who focus on specific markets and companies. These sales professionals work in concert with business unit personnel to coordinate customer activities. Business unit general managers are also integrally involved in sales and marketing activities. The specialization of our sales professionals fosters an in-depth knowledge of the issues faced by our customers within these markets such as industry trends, technology changes, biomaterial changes and the regulatory environment. In addition, we are pursuing additional sales and marketing relationships in other geographies around the world.

In general, we license our technologies on a non-exclusive basis to customers for use on specific products. This strategy enables us to license our technologies to multiple customers in the same market. We also target new product applications with existing customers.



To support our marketing and sales activities, we publish technical literature on our various surface modification technologies (e.g., lubricity, hemocompatibility, drug delivery, etc.). In addition, we exhibit at major trade shows and technical meetings, advertise in selected trade journals and through our website, and conduct direct mailings to appropriate target markets.

We also offer ongoing customer service and technical support throughout our licensees relationships with us. This service and support begins with a coating feasibility study, and includes additional services such as assistance in the transfer of the technology to the licensee, further coating optimization, process control and trouble shooting, coating of product for clinical studies, and assistance with regulatory submissions for coated product approval. Most of these services are billable to customers.

**Significant Customers**

We have two customers that each provided more than 10% of our revenue in fiscal 2006. Revenue from Cordis Corporation and Abbott Laboratories represented approximately 47% and 12%, respectively, of our total revenue for the year ended September 30, 2006. The loss of one or more of our largest customers could have a material adverse effect on our business, financial condition, results of operations, and cash flow as discussed in more detail below.

**Competition**

The ability for surface modification and drug delivery technologies to improve the performance of medical devices and to enable new product categories has resulted in increased competition in these markets. Our surface modification and drug delivery technologies compete with technologies developed by Affinergy, AST, Biocompatibles International plc, BioSensors, Hydromer, MediVas, pSivida Limited, Specialty Coatings Systems, STS Biopolymers Inc., a division of Angiotech Pharmaceuticals, Inc., TyRx, and W.L. Gore, among others. Some of these companies offer drug delivery technologies, while others specialize in lubricious or hemocompatible coating technology. Some of these companies target ophthalmology applications, while others target cardiovascular medical device applications. In addition, due to the many product possibilities afforded by surface modification technologies, many of the large medical device manufacturers have developed or are engaged in efforts to develop internal competency in the area of surface modification and drug delivery. Some of our existing and potential competitors (especially medical device manufacturers pursuing coating solutions through their own research and development efforts) have greater financial, technical and marketing resources than we have.

We attempt to differentiate ourselves from our competitors by providing what we believe is a high value added approach to surface modification and drug delivery technology. We believe that the primary factors customers consider in choosing a particular technology include performance (e.g., flexibility, ability to fine tune drug elution profiles, biocompatibility, etc.), ease of manufacturing, time-to-market, intellectual property protection, ability to produce multiple properties from a single process, compliance with manufacturing regulations, customer service and total cost of goods (including manufacturing process labor). We believe our technologies deliver exceptional performance in these areas, allowing us to compete favorably with respect to these factors. We believe that the cost and time required to obtain the necessary regulatory approvals significantly reduces the likelihood of a manufacturer changing the coating process it uses once a device has been approved for sale.

Because a significant portion of our revenue is dependent on the receipt of royalties based on sales of medical devices incorporating our technologies, we are also affected by competition within the markets for such devices. We believe that the intense competition within the medical device market creates opportunities for our technologies as medical device manufacturers seek to differentiate their products through new enhancements or to remain competitive with enhancements offered by other manufacturers. Because we seek to license our technologies on a non-exclusive basis, we may further benefit from competition within the medical device markets by offering our technologies to multiple competing manufacturers of a device. However, competition in the medical device market could also have an adverse effect on us. While we seek to license our products to established manufacturers, in certain cases our licensees may compete directly with larger, dominant manufacturers with extensive product lines and greater sales, marketing and distribution capabilities. We also are unable to control other factors that may impact commercialization of coated devices, such as regulatory approval, marketing and sales efforts of our



licensees or competitive pricing pressures within the particular device market. There can be no assurance that products employing our technologies will be successfully commercialized by our licensees or that such licensees will otherwise be able to compete effectively.

**Manufacturing**

In accordance with our licensing strategy, we generally do not coat medical devices to be sold by our customers following regulatory approval. However, we often support our customers by coating products for human clinical trials. We also manufacture most of the reagent chemicals used by our customers in the coating process, allowing us to control the quality of the reagents and maintain their proprietary nature, while providing an additional source of revenue. Reagents are polymer chemicals that are prepared using a proprietary formula

in relatively small batch processes (as contrasted with commodity chemicals prepared by large continuous methods). The reagents are sold in dry form, requiring the licensee, in most cases, to simply add water, a water/isopropyl alcohol mix, or other solvent to put them into solution before application. We have developed proprietary testing and quality assurance standards for manufacturing our reagents and do not disclose the reagent formulas or manufacturing methods.

We also manufacture our proprietary line of activated coated glass slides for sale by GE Healthcare under the CodeLink® brand. Precision glass slides are cleaned and pretreated in a multiple-step process. We apply our proprietary PhotoLink coating in a clean room environment, test the slides to assure they meet quality standards, package slides in specialized containers and seal them in moisture-proof packaging. Marketed and sold as either blank slides or pre-arrayed with up to 40,000 genes, these products are a core technology of GE Healthcare.

We also manufacture stabilization products employing a three-step production process. First, component chemicals are mixed in high purity water; next, these liquids are sterile-filtered into specific container sizes under aseptic conditions; and finally, the resultant finished goods are sealed and labeled.

We attempt to maintain multiple sources of supply for the key raw materials used to manufacture our products. We do, however, purchase some raw materials from single sources, but we believe that additional sources of supply are readily available. Further, to the extent additional sources of supply are not readily available, we believe that we could manufacture such raw materials.

Although not regulated by Good Manufacturing Practices (GMP), we do follow quality management procedures in part to respond to requests of customers to establish compliance with their individual criteria. In an effort to better meet our customers needs in this area, we received ISO 13485:2003 and ISO 9001:2000 certification in fiscal 2004 and have received updated certifications in each subsequent year.

**Government Regulation**

Although our coating technologies themselves are not directly regulated by the U.S. Food and Drug Administration (FDA), the medical devices incorporating our technologies are subject to FDA regulation. New medical products utilizing our coating technologies can only be marketed in the United States after a 510(k) application has been cleared or a pre-market approval application has been approved by the FDA. This process can take anywhere from three months for a 510(k) application, to two or three years or more for a PMA application. The burden of demonstrating to the FDA that a new device is either equivalent to a previously marketed device (510k process), or in the case of implantable devices, safe and effective (PMA process), rests with our customers as the medical device manufacturers. If the primary mode of action for a product is as a drug or biologic, customers are typically required to submit an Investigational New Drug (IND) application to initiate clinical studies that will support their marketing application, which is called a New Drug Application (NDA) or Biologics License Application (BLA). These applications contain the results of design verification and validation testing, biocompatibility testing, and clinical evaluations conducted with the device.

In support of our customers regulatory filings, we maintain confidential Device Master Files at the FDA regarding the nature, chemical structure and biocompatibility of our reagents. Although our licensees do not have direct access to these files, they may, with our permission, reference these files in their medical device submission to the FDA. This approach allows the FDA to understand in confidence the details of the coating technologies without us having to share this highly confidential information with our customers.



U.S. legislation allows device manufacturers, prior to obtaining FDA approval, to manufacture devices in the U.S. and export them for sale in international markets. This generally allows us to realize earned royalties sooner. However, sales of medical devices outside the U.S. are subject to international requirements that vary from country to country. The time required to obtain approval for sale internationally may be longer or shorter than that required by the FDA.

SurModics is currently conducting a Phase I safety trial for our I-vation implant. The study is being conducted at four clinical sites under an IND according to Good Clinical Practices. We completed enrollment of the Phase I trial in fiscal 2006, and we will conduct follow-up monitoring of the patients for three years.

**Employees**

As of December 1, 2006, we had 146 employees, of whom 106 were engaged in product development, quality, and manufacturing positions, with the remainder in sales, marketing, or administrative positions. Post-graduate degrees are held by 32 of our employees, 16 of whom hold Ph.D. degrees. We are not a party to any collective bargaining agreements and we believe that our employee relations are good.

We believe that future success will depend in part on our ability to attract and retain qualified technical, management and marketing personnel. Such experienced personnel are in high demand, and we must compete for their services with other firms that may be able to offer more favorable benefits.

**Forward-Looking Statements**

Certain statements contained in this Form 10-K, in the Company's annual report to shareholders or in other reports of the Company 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," "m "possible," "project," "will" and similar words or expressions. Any statement 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. The Company's forward-looking statements generally relate to its 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. The Company undertakes 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 the Company's forward-looking statements, such factors include, among others:

- the Company's 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 litigation involving Boston Scientific Scimed, Inc. and Cordis in the U.S. District Court for the District of Delaware in which each was reported in June and July 2005 to have infringed the patent rights of the other;
- 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;



- the Company's ability to attract new licensees 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 the Company, and the Company's ability to maintain satisfactory relationships with its licensees;
- the Company's ability to increase the number of market segments and applications that use its coating

technologies through its sales and marketing and research and development efforts;

- the Company's ability to facilitate through strategic investment and research and development support the creation of new medical device market segments and applications that incorporate its 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;
- the ability to secure raw materials for reagents the Company sells;
- the Company's ability to manage successfully clinical trials and related foreign and domestic regulatory processes for the I-vation' intravitreal implant or other acquired products from InnoRx under development by the Company's ophthalmology division, whether delays, difficulties or failures in achieving acceptable clinical results or obtaining foreign or FDA marketing clearances postpone or preclude product commercialization of the intravitreal implant or other acquired products, and whether the intravitreal implant and any other acquired products remain viable commercial prospects;
- 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;
- the Company's ability to identify suitable businesses to acquire or with whom to form strategic relationships to expand its technology development and commercialization, its ability to successfully integrate the operations of companies it may acquire from time to time and its ability to create synergies from acquisitions and other strategic relationships;
- the Company's ability to successfully internally perform certain product development activities and governmental and regulatory compliance activities with respect to acquired technology, including InnoRx technology, which activities the Company has not previously undertaken in any significant manner;
- economic and other factors over which the Company has no control, including changes in inflation and consumer confidence;
- acts of God or terrorism which impact the Company's personnel or facilities; and
- other factors described below in 'Risk Factors.'



Many of these factors are outside the control and knowledge of the Company, and could result in increased volatility in period-to-period results. Investors are advised not to place undue reliance upon the Company's

forward-looking statements and to consult any further disclosures by the Company on this subject in its filings with the Securities and Exchange Commission. Many of the factors identified above are discussed in more detail below under Risk Factors.

**ITEM 1A. RISK FACTORS.**

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

We have two customers that each provided more than 10% of our revenue in fiscal 2006. Revenue from Cordis Corporation and Abbott Laboratories represented approximately 47% and 12%, respectively, of our total revenue for the year ended September 30, 2006. The loss of one or more of our largest customers could have a material adverse effect on our business, financial condition, results of operations, and cash flow. There can be no assurance that revenue from any customer will continue at their historical levels. Loss of one or more of our current customers, particularly Cordis, Abbott, 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 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, 2006, 2005, and 2004, we derived approximately 76%, 76%, and 70% 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 gain successful 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 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 or drug delivery technologies and may pursue parallel development or licensing of competing technological 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 Affinergy, AST, Biocompatibles International plc, BioSensors, Hydromer, MediVas, pSivida Limited, Specialty Coatings Systems, STS Biopolymers Inc., a division of Angiotech Pharmaceuticals, Inc., TyRx, and W.L. Gore, among others. In addition, many medical device manufacturers have developed or are engaged in efforts to develop surface modification or drug delivery 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 existing 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 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 our 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 because of 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.

**Any adverse results in our Phase I trials for our I-vation intravitreal implant could harm our ability to commercialize the implant in a timely, cost-effective manner, if at all.**

We are currently conducting a Phase I safety trial for our I-vation intravitreal implant. Our Phase I trial is intended to help assess the safety and tolerability of the implant in patients with diabetic macular edema (DME), and is being conducted under an investigational new drug application with the U.S. Food and Drug Administration. A total of thirty subjects were enrolled in this Phase I trial, which enrollment was completed in March 2006, and will be subject to follow-up monitoring for three years. Our ability to commercialize this implant in a timely manner will depend upon the success of this Phase I safety trial, as well as future required clinical trials that will further evaluate and document the safety profile and therapeutic benefit in targeted patient populations. Although the early results of the Phase I trial have not presented any significant safety issues, we cannot be certain the implant will perform as expected in additional clinical tests. Problems in connection with our Phase I trials or in any subsequent phases of required clinical trials may prevent or delay us or a partner obtaining necessary regulatory approvals and threaten our ability to timely or cost-effectively commercialize the implant, if at all. Our Phase I trial is being conducted on a statistically insignificant number of human patients and is not intended to evaluate aspects of the effectiveness of the implant. Because the initial number of tests performed in humans has been relatively small, there is no assurance that the Phase I trials will identify problems that may become evident from a larger base of tests or after a longer period of observation of the patients. We will be able to accurately evaluate the performance of the implant in humans only after extensive testing in large numbers of patients over a period of years.

**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 customers resulting from our inability to produce products for them.

**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.

**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.

**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). However, 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 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 of our licensees 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 disposal of certain chemical waste 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, development and manufacturing 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.

**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 the year ended September 30, 2006, the closing sale price for our common stock ranged from $31.92 to $43.37 per share. As of December 8, 2006, the last reported sale price of our stock was $33.21 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.

**Failure to identify strategic investment and 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 strategic investments and the acquisition of complementary businesses or technologies. Our identification of suitable investment opportunities and acquisition candidates involves risks inherent in assessing the technology, value, strengths, weaknesses, overall risks and profitability, if any, of investment and acquisition candidates. We may not be able to identify suitable investment and acquisition candidates. If we do not make suitable investment and 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. Strategic investments may result in impairment charges if the value of any such investment declines significantly. 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 complete successfully any investments or acquisitions or that we will realize any anticipated benefits from investments or acquisitions that we complete.

**ITEM 1B. UNRESOLVED STAFF COMMENTS.**

None.

**ITEM 2. PROPERTIES.**

We conduct our operations in two facilities. In May 1999, we purchased the land and building we currently occupy in Eden Prairie, a suburb of Minneapolis, Minnesota. The building has approximately 64,000 square feet of space. Throughout fiscal 2005 and 2006, we made $6.1 million in capital improvements to enhance the research and development capabilities at the Eden Prairie facility. The purchase and subsequent upgrade of the property was internally funded and it remains unencumbered. We believe that projected capacity of our Eden Prairie facility is adequate to service the needs of our customers for the foreseeable future. Most of our operations take place at the Eden Prairie location, however, we lease approximately 3,000 square feet of office space in Irvine, California for use by our Ophthalmology division.

**ITEM 3. LEGAL PROCEEDINGS.**

We are not a party to nor is any of our property subject to any material pending legal proceedings.

**ITEM 4. SUBMISSION OF MATTERS TO A VOTE OF SECURITY HOLDERS.**

There were no matters submitted to a vote of security holders during the fourth quarter of fiscal 2006.



**EXECUTIVE OFFICERS OF THE REGISTRANT**

The names, ages and positions of the Company□s executive officers are as follows:

| Name | Age | Position |
|---|---|---|
| Bruce J Barclay | 50 | President and Chief Executive Officer |
| Aron B. Anderson, Ph.D | 43 | Vice President and Chief Scientific Officer |
| Philip D. Ankeny | 43 | Senior Vice President and Chief Financial Officer |
| Douglas P. Astry | 54 | General Manager, In Vitro Technologies |
| Lise W. Duran, Ph.D | 51 | Vice President and General Manager, Regenerative Technologies |
| Peter L. Ginsberg | 41 | |