SYNERGETICS USA INC
Form 10-K
October 28, 2009

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**UNITED STATES SECURITIES AND EXCHANGE COMMISSION**
**Washington, D.C. 20549**

# Form 10-K

(Mark One)

**þ** **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
**For the fiscal year ended July 31, 2009**

**or**

**o** **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
**For the transition period from to**

**Commission file number 001-10382**

**SYNERGETICS USA, INC.**
*(Exact name of registrant as specified in its charter)*

| **Delaware** | **20-5715943** |
|---|---|
| *(State or other jurisdiction of incorporation or organization)* | *(I.R.S. Employer Identification No.)* |
| **3845 Corporate Centre Drive O Fallon, Missouri** | **63368** |
| *(Address of principal executive offices)* | *(Zip Code)* |

**Registrant s telephone number, including area code**
**(636) 939-5100**

**Securities registered pursuant to Section 12(b) of the Act:**

| **Title of Each Class** | **Name of Each Exchange on Which Registered** |
|---|---|
| Common stock | The Nasdaq Capital Market |

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

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 þ

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 þ

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 þ No o

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes o 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, a non-accelerated filer, or a smaller reporting company. See the definitions of large accelerated filer, accelerated filer, and smaller reporting company in Rule 12b-2 of the Exchange Act.

| Large Accelerated Filer o | Accelerated Filer o | Non-Accelerated Filer o (Do not check if a smaller reporting company) | Smaller Reporting Company þ |
|---|---|---|---|

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

The aggregate market value of voting stock held by non-affiliates of the registrant, computed by reference to the closing sales price as reported by The Nasdaq Stock Market as of February 3, 2009, the last business day of the registrant s most recently completed second fiscal quarter, was $20,668,751.

At October 23, 2009, there were 24,454,256 shares of the registrant s common stock outstanding.

**DOCUMENTS INCORPORATED BY REFERENCE**

Portions of the registrant s Proxy Statement for its 2009 Annual Meeting of Stockholders, expected to be held on December 17, 2009, are incorporated by reference into Part III of this Form 10-K where indicated.

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**SYNERGETICS USA, INC.**
**FORM 10-K**
**FOR THE FISCAL YEAR ENDED JULY 31, 2009**

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**SYNERGETICS USA, INC.**

**STATEMENT REGARDING FORWARD-LOOKING INFORMATION**

*The Private Securities Litigation Reform Act of 1995 and Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities and Exchange Act of 1934, as amended, provide a safe harbor for forward-looking statements made by or on behalf of the Company. The Company and its representatives may from time to time make written or oral statements that are forward-looking, including statements contained in this report and other filings with the Securities and Exchange Commission ( SEC ) and in our reports to stockholders. In some cases forward-looking statements can be identified by words such as believe, expect, anticipate, plan, potential, cont similar expressions. Such forward-looking statements include risks and uncertainties and there are important factors that could cause actual results to differ materially from those expressed or implied by such forward-looking statements. These factors, risks and uncertainties can be found in Part I, Item 1A, Risk Factors.*

*Although we believe the expectations reflected in our forward-looking statements are based upon reasonable assumptions, it is not possible to foresee or identify all factors that could have a material effect on the future financial performance of the Company. The forward-looking statements in this report are made on the basis of management s assumptions and analyses, as of the time the statements are made, in light of their experience and perception of historical conditions, expected future developments and other factors believed to be appropriate under the circumstances.*

*In addition, certain market data and other statistical information used throughout this report are based on independent industry publications. Although we believe these sources to be reliable, we have not independently verified the information and cannot guarantee the accuracy and completeness of such sources.*

*Except as otherwise required by the federal securities laws, we disclaim any obligation or undertaking to publicly release any updates or revisions to any forward-looking statement contained in this annual report on Form 10-K and the information incorporated by reference in this report to reflect any change in our expectations with regard thereto or any change in events, conditions or circumstances on which any statement is based.*

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# PART I

## Item 1. *Business*

### Mission

Through continuous improvement and development of our people, our **mission** is to design, manufacture and market innovative microsurgical instruments and consumables of the highest quality in order to assist and enable surgeons who perform microsurgery around the world to provide a better quality of life for their patients.

### Overview

Synergetics USA, Inc. ( Synergetics USA or the Company ) is a leading supplier of precision microsurgery instrumentation. The Company s primary focus is on the microsurgical disciplines of ophthalmology and neurosurgery. Our distribution channels include a combination of direct and independent sales organizations and important strategic alliances with market leaders. The Company s product lines focus upon precision engineered, microsurgical, hand-held instruments and the delivery of various energy modalities for the performance of less invasive microsurgery including: (i) laser energy, (ii) ultrasonic energy, (iii) radio frequency for electrosurgery and oblation and (iv) visible light energy for illumination, and where applicable, simultaneous infusion (irrigation) of fluids into the operative field. Enterprise-wide information is included in Note 16 to the consolidated audited financial statements.

The Company is a Delaware corporation incorporated on June 2, 2005 in connection with the reverse merger of Synergetics, Inc. ( Synergetics ) and Valley Forge Scientific Corp. ( Valley Forge ). Synergetics was founded in 1991. Valley Forge was incorporated in 1980 and became a publicly-held company in November 1989. Prior to the merger of Synergetics and Valley Forge, Valley Forge s common stock was listed on The NASDAQ Small Cap Market (now known as The NASDAQ Capital Market) and the Boston Stock Exchange under the ticker symbol VLFG. On September 21, 2005, Synergetics Acquisition Corporation, a wholly-owned Missouri subsidiary of Valley Forge, merged with and into Synergetics, and Synergetics thereby became a wholly-owned subsidiary of Valley Forge. On September 22, 2005, Valley Forge reincorporated from a Pennsylvania corporation to a Delaware corporation and changed its name to Synergetics USA, Inc. Upon consummation of the merger, the Company s securities began trading on The NASDAQ Capital Market under the ticker symbol SURG, and its shares were voluntarily delisted from the Boston Stock Exchange.

### Summary of Financial Information

The following tables present net sales by category and our results of operations (dollars in thousands):

**NET SALES BY CATEGORY**

| | Year Ended July 31, | | | |
|---|---|---|---|---|
| | **2009** | **Mix** | **2008** | **Mix** |
| Ophthalmic | **$ 29,981** | **56.6%** | $ 28,019 | 56.0% |
| Neurosurgery | **13,968** | **26.4%** | 12,925 | 25.8% |
| OEM Marketing Partners(1) | **8,538** | **16.1%** | 8,347 | 16.7% |
| Other | **478** | **0.9%** | 772 | 1.5% |

| | | |
|---|---|---|
| Total | **$ 52,965** | $ 50,063 |

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## RESULTS OF OPERATIONS

| | Year Ended July 31, 2009 | 2008 | Increase (Decrease) |
|---|---|---|---|
| Net Sales | **$ 52,965** | $ 50,063 | 5.8% |
| Gross Profit(2) | **29,415** | 29,962 | (1.8)% |
| Gross Profit Margin% | **55.5%** | 59.8% | (7.2)% |
| Commercial Expenses | | | |
| Selling | **14,262** | 12,601 | 13.2% |
| G&A | **9,030** | 9,499 | (4.9)% |
| R&D | **2,998** | 2,654 | 13.0% |
| Operating Income | **3,125** | 5,208 | (40.0)% |
| Operating Margin | **5.9%** | 10.4% | (43.3)% |
| EBITDA(3) | **5,093** | 7,221 | (29.5)% |
| Net Income | **$ 1,595** | $ 2,663 | (40.1)% |
| Earnings per share | **0.07** | 0.11 | (36.4)% |
| Return on equity(4) | **4.3%** | 7.6% | (43.4)% |
| Return on assets(5) | **4.0%** | 6.5% | (35.5%) |

(1) Sales from our marketing partners are primarily neurosurgery and pain control revenues.

(2) In the fourth quarter of fiscal 2009, the Company recorded an adjustment of approximately $975,000 (or approximately $.03 earnings per share, net of tax) primarily due to excess and discontinued inventory which was either contributed to a charitable organization or was discarded.

(3) EBITDA, return on equity and return on assets are not financial measures recognized by U.S. generally accepted accounting principles ( GAAP ). EBITDA is defined as net income before interest expense, income taxes, depreciation and amortization. Return on equity is defined as net income divided by average equity. Return on assets is defined as net income plus interest expense divided by average assets. See disclosure following regarding the use of non-GAAP financial measures.

| | July 31, 2009 | July 31, 2008 |
|---|---|---|
| Net income | **$ 1,595** | $ 2,663 |
| Interest | **763** | 1,129 |
| Income taxes | **775** | 1,439 |
| Depreciation | **1,052** | 1,013 |
| Amortization | **908** | 977 |
| EBITDA | **$ 5,093** | $ 7,221 |
| Net income | **$ 1,595** | $ 2,663 |
| Average Equity: | | |
| July 31, 2009 | **$ 38,130** | |

| | | |
|---|---|---|
| July 31, 2008 | **36,357** | $ 36,357 |
| July 31, 2007 | | 33,435 |
| Average Equity | **$ 37,243** | $ 34,896 |
| Return on Equity | **4.3%** | 7.6% |
| Net income | **$ 1,595** | $ 2,663 |
| Interest | **763** | 1,129 |
| Net income + interest expense | **2,358** | 3,792 |

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| | **July 31, 2009** | July 31, 2008 |
|---|---|---|
| Average Assets: | | |
| July 31, 2009 | **$ 58,080** | |
| July 31, 2008 | **58,396** | $ 58,396 |
| July 31, 2007 | | 58,616 |
| Average Assets | **$ 58,238** | $ 58,506 |
| Return on Assets | **4.0%** | 6.5% |

**Non-GAAP Financial Measures**

We measure our performance primarily through our operating profit. In addition to our audited consolidated financial statements presented in accordance with GAAP, management uses certain non-GAAP measures, including EBITDA, return on equity and return on assets, to measure our operating performance. We provide a definition of the components of these measurements and reconciliation to the most directly comparable GAAP financial measure.

These non-GAAP measures are considered by our Board of Directors and management as a basis for measuring and evaluating our overall operating performance. They are presented to enhance an understanding of our operating results and are not intended to represent cash flow or results of operations. The use of these non-GAAP measures provides an indication of our ability to service debt and measure operating performance. We believe these non-GAAP measures are useful in evaluating our operating performance compared to other companies in our industry, and are beneficial to investors, potential investors and other key stakeholders, including creditors who use this measure in their evaluation of performance.

EBITDA, however, does have certain material limitations primarily due to the exclusion of certain amounts that are material to our results of operations, such as interest expense, income tax expense, depreciation and amortization. Because of this limitation, EBITDA should not be considered a measure of discretionary cash available to us to invest in our business and should be utilized in conjunction with other information contained in our consolidated financial statements prepared in accordance with GAAP.

Information with respect to the breakdown of revenue for the geographical areas is included in Note 16 to the consolidated audited financial statements.

**Other Recent Events**

On September 24, 2009, the Company announced that the lawsuit filed by Alcon Research, Ltd. ( Alcon Research ) against the Company and Synergetics in the Northern District of Texas, Case No. 4-08CV-609-Y has been stayed in its entirety until both of the patents at issue have completed re-examination at the United States Patent and Trademark Office ( PTO ). This lawsuit alleges infringement of United States Patents No. 5,603,710 and 5,318,560 and infringement of and unfair competition with respect to three Alcon-owned trademarks, namely Alcon®, Accurus® and Greishaber®. The Court found that the stay would not prejudice or be a tactical disadvantage for Alcon Research and that the stay may allow the re-examination to simplify or eliminate the issues in question. The PTO has stated in its Ex Parte Re-examination Filing Data as of June 30, 2009, that an average re-examination by the PTO takes approximately 25 months to complete and 75 percent of the time the patent s original claims are either canceled or changed. On October 2, 2009, Alcon Research filed a Motion for Reconsideration of the ordered stay, requesting the Court to vacate its order and restart the proceedings. The Company has contested this Motion. The Company is currently awaiting the PTO re-examination results and the Court s ruling on the Motion for Reconsideration.

On January 29, 2009, the Company appointed David M. Hable as President, Chief Executive Officer ( CEO ) and a member of the Board of Directors. Prior to joining Synergetics, Mr. Hable served as President and CEO of Afferent Corporation, a venture capital backed medical device company focused on neuro stimulation therapies. Previously, he was Chairman of the Board of ONI Medical Systems, Inc., a developer and marketer of magnetic resonance imaging equipment for extremity applications in non-hospital settings. Mr. Hable also spent over

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20 years with Codman & Shurtleff, Inc. ( Codman ), a Johnson & Johnson company, which develops and markets a wide range of diagnostic and therapeutic products for the treatment of central nervous system disorders. Mr. Hable was engaged at Codman in several sales and marketing positions. From 1998 to 2003, Mr. Hable served as Codman s Worldwide President leading all functions in the company, both domestically and internationally.

**Strategy**

The Company s key strategy is to enhance shareholder value through profitable revenue growth in ophthalmology and neurosurgery markets through the identification and development of reusable and disposable instrumentation in conjunction with leading surgeons and marketing partners and to build out a strong operational infrastructure and financial foundation within which prudently financed growth opportunities can be realized and implemented. At the same time, we will maintain vigilance and sensitivity to new challenges which may arise from changes in the definition and delivery of appropriate healthcare in our fields of interest.

The strategy can be divided and summarized as follows:

Improve Profitability and Cash Efficiency through:

Manufacturing Efficiencies

*Lean Manufacturing* The Company continues to implement lean manufacturing in its production facilities one product line value stream at a time. During the fiscal year ended July 31, 2009, four product families were converted to the lean manufacturing methodology, with the realization of cost savings. We plan to continue to implement lean manufacturing techniques in all disposable product lines during the fiscal year ending July 31, 2010.

*Plastic Molding* The Company s most recent acquisition, Medimold, is producing plastic components which were previously supplied by outside vendors. In addition to lower costs for certain parts, we continue to convert select high volume plastic parts and metal machined parts to injection molded, plastic parts. Our annual savings from the continued introduction of new parts to this process is projected to be over $200,000 for fiscal year 2010.

*Supply Chain Management* During the fiscal year 2009, the Company implemented Material Requirements Planning ( MRP ) in planning and controlling its production processes. The implementation of MRP helped reduce days in inventory on hand from 218 days for the three month period ended July 31, 2008 (annualized) to 201 days for the three month period ended July 31, 2009. In addition, our service level on our A products (those products which provide over 80 percent of our sales) increased to 1.55 days and our backorder decreased from approximately $750,000 at July 31, 2008 to $40,000 at July 31, 2009.

*Human Resource Rationalization* Starting with a hiring freeze in January 2009, the Company redeployed certain human resources and reduced the number of employees and temporary workers by 10% during fiscal 2009. These changes were made possible by the introduction of manufacturing efficiencies in certain product lines, the implementation of improvements in our enterprise wide information system, the implementation of MRP and supply chain management and related consolidations, and the shift from direct sales of certain neurosurgery products in the U.S. to the sales of these same products through marketing partners.

*Cash Management* The Company is focused on its debt level and intends to continue to monitor and reduce its leverage by focusing on the reduction in days sales in accounts receivable and inventory and where appropriate, the increase in days in accounts payable. During the fiscal year ended July 31, 2009, the Company improved its leverage ratio to 25.7 percent from 26.8 percent at July 31, 2008.

Accelerate growth through:

*Research & Development ( R&D )* In order to focus resources on the most important projects, in October 2008, the Company completed a thorough review of its R&D efforts leading to a reduction in the number of active projects in the R&D pipeline to 39 such projects. In addition, we developed a uniform

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policies and procedures manual for our top 10 R&D initiatives. In July 2009, the Company reorganized its R&D resources into an advanced technology group which works on longer-term, highly complex R&D initiatives, an instrument development group which works on strategically targeted products and a manufacturing engineering group which works on product line extensions. These three groups focus on projects in both ophthalmology and neurosurgery. The engineering team at the King of Prussia, Philadelphia location has been strengthened to provide capacity for new electrosurgery products.

*New Business Development* The Company s core assets, including a history of customer driven innovation, quality differentiated products and an extensive distribution network makes it a logical component of value-creating business combinations. We continue to evaluate such potential combinations and opportunities for potential acquisitions that can expand the Company s product offerings.

Assess Distribution Alternatives:

The Company competes in two distinct medical device markets, ophthalmology and neurosurgery. These markets are very different in terms of the number and size of the competitors in each and the size and maturity of their respective distribution networks. The Company is actively engaged in pursuing marketing partner opportunities basis the opportunities afforded by their distribution network.

Improve Sales Force Productivity:

The professionalism of the Company s sales force is one of its true assets. Significant effort was made in the last year in aligning their incentives and promotional direction with those of the Company s interests as a whole. It is anticipated that this will result in enhanced productivity.

**Marketing**

***Ophthalmic and Vitreoretinal***

*Markets*

Various diseases of the eye, including trauma to the eye, can lead to a damaged retina. Conditions associated with retinal detachment often require surgical treatment to prevent vision loss. These conditions include proliferative diabetic retinopathy, macular holes, macular puckers and traumatic eye injuries. Vitreoretinal surgery involves the removal of tissue from the eye necessitated by disease or injury that interferes with normal vision. This surgery is generally performed on the posterior portion of the eye surrounding the retina through incisions made in the front of the eye. The retinal surgeon needs a variety of instruments and capital equipment to perform the surgery, such as a vitreous cutter to remove the vitreous from the eye, a light source and an illuminator to illuminate the eye, a laser and a laser probe which provides focused photocoagulation to reattach the retina or mitigate disease, and other microsurgical instruments including forceps, scissors and picks, many of which are offered by the Company.

Based upon a study performed for the Company by Market Scope LLC, there are approximately 2,200 practicing retinal specialists in the United States and an additional 11,300 throughout the rest of the world. It is estimated that approximately 300,000 vitrectomies are performed each year in the United States and 1.1 million vitrectomies are performed throughout the rest of the world.

The Company initially engineered and produced prototype instruments designed to assist retinal surgeons in treating acute subretinal pathologies such as histoplasmosis and age-related macular degeneration. Synergetics developed a number of specialized lines of finely engineered microsurgical instruments, which today have grown to comprise a

product catalogue of over 1,400 retinal surgical items including scissors, fiberoptics, cannulas, forceps and other reusable and disposable surgical instruments.

We are a leading supplier of 25, 23 and 20 gauge instrumentation to the vitreoretinal surgical market. The larger 20 gauge size remains the industry standard. The 25 and 23 gauge microsurgical instruments enable surgeons to make smaller sutureless incisions. However, the use of these instruments limits the amount of light that can be delivered to the surgical site using traditional light sources. In July 2004, we introduced our Photon$^{tm}$ xenon light source for vitreoretinal illumination to operating rooms across the world which addressed the light limitation issues. In addition, we engineered a system solution using smaller optical fibers that, in combination with other product

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functionality, are capable of efficiently delivering more light to the surgical site than traditional illumination systems. At the same time, the device can deliver concentrated, illuminated laser energy to the site to provide endophotocoagulation. In addition to a high output light, the illuminator is also able to deliver laser energy. The light and laser energy are delivered coaxially to the surgical site through a single, ultra-fine fiberoptic. When used in conjunction with a laser, the ability of the Photon™ to deliver both laser energy and vitreoretinal illumination through the same fiber line is unique, as is the number of accessories which can be attached to the device. These features distinguish the Photon™ from other xenon light sources in the marketplace. We believe the Photon™ will continue to gain acceptance in the ophthalmic surgical market as demand increases for 25, 23 and finer gauge instrumentation used in connection with minimally invasive surgical techniques.

In September 2006, the Company announced that a new version of the Photon™ had been designed, called the Photon™ II, which features an advanced illumination source that offers surgeons increased light output and a light spectrum that more closely matches the light response of the human retina. These additional features offer surgeons up to two times the apparent light levels as compared to the Photon™. However, the Photon™ remains available for ophthalmic surgeons who prefer the xenon light.

In September 2007, we entered into two new distribution agreements with Volk Optical, granting Synergetics the rights over the next three years to sell Volk s products to vitreoretinal surgeons in the United States. These agreements cover Volk s line of ophthalmic lenses, used for detailed examination and treatment of the retina, and grant the Company exclusive rights to sell Volk s new Optiflex™ Surgical Assistant and surgical lenses in the United States. This new vitreoretinal system, compatible with all leading surgical microscopes, enhances the surgeon s visual ability with precision focus and control.

In June 2009, our three-year distribution agreements for certain ophthalmic and vitreoretinal products with Quantel Medical, Inc. expired and a decision was made not to renew immediately; however, all products previously distributed per the agreements, including the Vitra™ and Supra™ lasers, continue to be part of the Company s product offerings. The Vitra™ and Supra™ are portable lasers and are compatible with the Photon™ and Photon™ II light sources.

Our business continues to grow and evolve as new, minimally invasive surgical techniques are pioneered by leading vitreoretinal surgeons. As microsurgical instruments become ever smaller, new endoillumination technology is required to assist surgeons in this field. The Company was an early developer of cutting-edge endoillumination products and continues to be an innovative leader in the marketplace in the design, manufacture and marketing of laser probes and fiberoptic endoilluminators.

*Marketing and Sales Force*

In the United States over a number of years, we have assembled a dedicated sales team. Our team sells our ophthalmic and vitreoretinal surgical products directly to end-users employing a staff of approximately 32 sales and marketing professionals. We offer over 1,400 separate catalogue items in the ophthalmic and vitreoretinal surgical market segments. Our ophthalmic and vitreoretinal products include fiberoptic endoilluminators, laser probes, a variety of disposable and reusable instruments designed for intraocular manipulation of tissues, illumination equipment under the Photon™ brand, laser equipment for the United States market under Quantel s Vitra™ and Supra™ brands, Volk s line of ophthalmic lenses and its Optiflex™ Surgical Assistant and other miscellaneous products.

Internationally, we utilize a hybrid sales network comprised of direct and distributor sales. We have distribution agreements with independent representatives to sell and distribute our ophthalmic and vitreoretinal surgical products. At July 31, 2009, we had 13 international direct sales employees and were represented by approximately 47 non-U.S. distributors and independent sales representatives. Our ophthalmic and vitreoretinal surgical products are offered for sale in approximately 60 countries outside the United States. The terms of sale to our non-U.S. distributors

and our non-U.S. end-user customers do not differ materially from our terms to our domestic end-user customers. Selling prices are established based upon each country s competitive pricing methodology.

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*Competition*

Our ophthalmic and vitreoretinal surgical instruments, lasers and disposables compete against manufacturers of similar products, including those sold by our major competitors, Alcon, Inc., Iridex Corporation ( Iridex ), Bausch & Lomb, Inc. and Dutch Ophthalmic Research Corp ( DORC ). Our Photon™ xenon light source and our new Photon™ II gas-arc light source compete with manufacturers of similar products, including those sold by Alcon, Inc. and DORC. In addition, our products compete with smaller and larger specialized companies that do not otherwise focus on ophthalmic and vitreoretinal surgery. In the future, aggressive pharmaceutical intervention may adversely affect the use of our surgical products.

***Neurosurgery***

*Markets*

There are over 120 different types of brain tumors, and more than 190,000 adults and approximately 3,400 children diagnosed with brain tumors each year. In addition to brain tumors, cerebral aneurysms, congenital malformations of the skull and vessels, excess fluid in the brain and other disorders, including those caused by trauma, can lead to neurosurgery. Neurosurgery is a medical specialty dealing with disorders of the brain, skull, spinal column, spinal cord, cranial and spinal nerves, the autonomic nervous system and the pituitary gland. The neurosurgeon needs a variety of different hand-held instruments and energy source devices to perform the surgery, such as operating microscopes, tissue fragmentation and suction devices, electrosurgical generators, and other instruments, many of which are offered by the Company.

The Company estimates that there are approximately 3,400 practicing neurological surgeons in the United States and an additional 3,700 throughout the rest of the world. It is estimated that approximately 200,000 cranial procedures are performed each year in the United States, including over 51,000 craniotomies for tumor removal. In addition, over 1.3 million spine surgery procedures are performed annually in the United States and a total of over one million such procedures are performed worldwide by neurological and orthopedic surgeons.

The Company has an integrated neurosurgical product line which includes the Omni® ultrasonic aspirator, the Malis® electrosurgical generators and precision neurosurgical instruments. Our neurosurgical product catalogue consists of over 300 neurosurgical items including energy source devices, disposable and reusable instruments and other disposable items.

The primary use of the Company s Omni® ultrasonic aspirator in neurosurgery is tumor removal. The Company distributes the Omni® control module, handpieces and accessory tips in the United States, Canada, Australia, New Zealand, a portion of Latin and South Americas and all but two countries in Europe. The control module and handpieces are manufactured by Mutoh America Co., Ltd., a division of Miwatec Co., Ltd. ( Mutoh ). The accessory tips are manufactured by the Company. The Omni® system uses ultrasonic waves to cause vibration of a tip that emulsifies bone and tissue for removal and then utilizes suction to aspirate these bone and tissue fragments. The Omni® system is unique in its ability to cause the handpiece tip to oscillate torsionally allowing the surgeon to remove bone, a feature that is a safer alternative to a rotating drill in removing bone in or near critical anatomical structures in intracranial and spine surgery. The tips and disposable packs are manufactured at the Company s facility in O Fallon, Missouri.

In intracranial neurosurgery, a bipolar electrosurgical system is the modality of choice for tissue coagulation as compared to monopolar products. The popularity of the bipolar system is largely due to the efforts of the late Dr. Leonard I. Malis, who designed and developed the first commercial bipolar coagulator in 1955 and pioneered the use of bipolar electrosurgery for use in the brain.

The foundation of our bipolar electrosurgical system lies in our proprietary DualWave[tm] technology. Using this technology, our bipolar generators are able to deliver two separate waveforms to perform the two separate and distinct functions of cutting and coagulation. With the virtual elimination of heat and electrical current spread, this technology, when used in accordance with the product instructions, can be used in direct contact with nerves, bones, blood vessels and metal implants, and we believe can be used in many areas of surgery. Our generators contain a rigidly stabilized voltage control to provide a controlled cut, using about one-fifth the power of other generators.

In addition, the Company has developed and released a line of bipolar instruments in both disposable and reusable models, some of which will connect to all compatible electrosurgical generators.

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*Marketing and Sales Force*

In July 2009, the Company completed a reduction in personnel of approximately 10 percent of our workforce including most of our direct neurosurgical sales force. We continue to sell this product line through our team of approximately two sales representatives, a marketing professional and four independent representatives. This realignment was designed to increase profitability through the elimination of a substantial portion of our commercial expenses associated with direct distribution. The distribution of our neurosurgical products will continue through a combination of our existing marketing partners and potentially new marketing partners or distribution channels.

*Competi*