SYNERGETICS USA INC Form 10-K October 01, 2013

UNITED STATES SECURITIES AND EXCHANGE COMMISSION Washington, D.C. 20549 FORM 10-K

(Mark One)

 $p_{31,\,2013}^{Annual}$ report pursuant to section 13 or 15(d) of the Securities Exchange Act of 1934 for the fiscal year ended July

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 b

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 b

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 b 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 b 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. b

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 b Non-Accelerated Filer o Smaller Reporting Company o

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

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 January 31, 2013, the last business day of the registrant's most recently completed second fiscal quarter, was \$109,256,524.

At September 25, 2013, there were 25,292,960 shares of the registrant's common stock outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's Proxy Statement for its 2013 Annual Meeting of Stockholders, expected to be held on December 12, 2013, are incorporated by reference into Part III of this Form 10-K where indicated.

SYNERGETICS USA, INC.

FORM 10-K

FOR THE FISCAL YEAR ENDED JULY 31, 2013

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PART I

Item 1. Business

Overview

Synergetics USA, Inc. ("Synergetics USA" or "the Company") is a leading supplier of precision surgical devices. The Company's primary focus is on the disciplines of ophthalmology and neurosurgery. Our distribution channels include a combination of direct and independent distributor sales organizations, both domestically and internationally, and important strategic alliances with market leaders. The Company's product lines focus upon precision engineered, disposable and reusable devices, surgical equipment, procedural kits and the delivery of various energy modalities for the performance of surgery, including: (i) laser energy, (ii) ultrasonic energy, (iii) radio frequency energy for electrosurgery and lesion generation and (iv) visible light energy for illumination, and where applicable, simultaneous infusion (irrigation) of fluids into the operative field. Enterprise-wide sales information is included in Note 16 to the audited consolidated 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") and the subsequent reincorporation of Valley Forge (the predecessor to Synergetics USA) in Delaware. Synergetics was founded in 1991. Valley Forge was incorporated in 1980 and became a publicly-held company in November 1989. The Company's securities are listed on The NASDAQ Capital Market under the ticker symbol "SURG."

Recent Developments

We had several developments from fiscal 2011 through fiscal 2013 that we expect will contribute to the growth of our business in the foreseeable future.

On December 9, 2010, the Company announced that it signed a product development and consulting agreement pertaining to ophthalmology with Retinal Solutions, LLC located in Michigan.

On December 14, 2010, the Company announced the introduction of its next generation of the Codman[®] Malis[®] electrosurgical generator, the CMC[®] V. The new electrosurgical generator is a state-of-the-art, digitally controlled system that provides surgeons with significant advancements in controls for intraoperative cutting and coagulating.

On December 22, 2010, Codman & Shurtleff, Inc. ("Codman"), an affiliate of Johnson and Johnson, elected to exercise its option of exclusive distribution with respect to the bipolar generators and related disposables and accessories and to pay a \$600,000 exclusivity fee. The Company recognized \$266,000 and \$334,000 of this revenue during fiscal 2012 and fiscal 2011, respectively.

On February 16, 2011, the Company retired the debt on its O'Fallon, Missouri facility.

On October 27, 2011, the Company announced two new ophthalmic products for the vitrectomy market which were showcased at the 2011 Annual Meeting of the American Academy of Ophthalmology. The Company also announced record sales leads generated from the showcasing of its ophthalmic products.

On November 30, 2011, the Company extended its revolving credit facility and its equipment line of credit through November 30, 2013.

On December 31, 2011, the Company's agreements with Codman expired and were renewed for a period of three years.

On February 9, 2012, Mobius Therapeutics, LLC ("Mobius"), a St. Louis-based ophthalmic pharmaceutical company, announced that the U.S. Food and Drug Administration ("FDA") had approved its orphan drug for glaucoma and that Synergetics would be manufacturing the kit for the administration of the drug.

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On February 13, 2012, Alcon, Inc. ("Alcon") informed the Company that Alcon had decided to cancel the development project, orders and forecasts covering the two products to have been supplied under a Supply Agreement. Accordingly, the Company revised the deferred revenue recognition period to the remaining life of the patents which was 14 years at that time.

On June 27, 2012, the Company announced that it received 510(k) clearance from the FDA for VersaVITTM, a novel vitrectomy system for the retinal surgery market. On July 20, 2012, the VersaVITTM vitrectomy system received clearance for the "CE" mark, allowing access to the European market.

On November 28, 2012, the Company announced the signing of the third amendment to its agreement with Stryker Corporation ("Stryker") for supply and distribution of a multi-channel ablation generator and accessories, used for minimally invasive pain treatment, extending the termination date until June 30, 2015.

On July 9, 2013, the Company announced that it had acquired M.I.S.S. Ophthalmics Limited ("M.I.S.S."), a private ophthalmology distribution company incorporated in England and Wales, for net cash consideration of \$2.8 million. M.I.S.S. was our distributor of ophthalmic products in the United Kingdom, and its wholesale distribution activities contributed approximately \$1.1 million in revenue to the Company in fiscal 2013. M.I.S.S. generated total revenue of approximately \$3.2 million during its fiscal year ended March 31, 2013 and was solidly profitable on an operating basis. The acquisition establishes a direct presence in one of the largest ophthalmic markets outside the U.S. which we believe will drive further operating efficiencies throughout our European operations, enhance sales management capabilities and drive both top and bottom line financial performance in fiscal 2014 and beyond.

On September 30, 2013, the Company extended its revolving credit facility and its equipment line of credit through September 30, 2016.

Summary of Financial Information

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

NET SALES BY CATEGORY

	Fiscal Year Ended July 31,			
	2013	Mix	2012	Mix
Ophthalmic	\$35,446	56.4 %	\$35,240	58.7 %
Original Equipment Manufactured ("OEM")(1	26,469	42.2 %	23,973	40.0 %
Other (2)	881	1.4 %	801	1.3 %
Total	\$62,796	100.0%	\$60,014	100.0%

Net sales from OEM represent sales of electrosurgery generators, disposable bipolar forceps and related accessories and royalties from Codman, multi-channel ablation generators, disposable ultrasonic aspirator tips and related accessories to Stryker, sales of certain disposable products to Mobius along with sales of certain laser

- (1) probes to Iridex Corporation ("Iridex") in the comparable 2012 period. In addition, recognition of deferred revenues of \$1.3 million from Alcon is included in this category for the fiscal year ended July 31, 2013. Recognition of deferred revenues of \$266,000 and \$1.2 million from Codman and Alcon, respectively, are included in this category for the fiscal year ended July 31, 2012.
- (2) Net sales from Other represent direct neurosurgery revenues and other miscellaneous revenues.

The increase in sales during fiscal 2013 compared with fiscal 2012 was primarily due to an increase of \$206,000 in ophthalmic sales, a \$2.5 million increase in OEM sales and an \$80,000 increase in other sales. Currently, disposable product sales account for approximately 80.5 percent of our total product sales. Overall sales of our disposable products grew \$2.2 million, or 4.4 percent, in fiscal 2013 as compared to fiscal 2012. Sales of capital equipment increased by approximately \$839,000, or 8.8 percent, in fiscal 2013 as compared to fiscal 2012.

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Information with respect to the breakdown of revenue for domestic and international sales is included in Note 16 to the consolidated audited financial statements.

RESULTS OF OPERATIONS

(dollars in thousands)

	Fiscal Year Ended July 31,		
	2013	2012	Increase
			(Decrease)
Net Sales	\$62,796	\$60,014	4.6 %
Gross Profit	32,371	34,519	(6.2 %)
Gross Profit Margin %	51.5 %	57.5 %	(10.4 %)
Commercial Expenses			
Research and Development	3,643	3,642	0.0 %
Sales and Marketing	13,805	11,881	16.2 %
General and Administrative	10,932	10,515	4.0 %
Medical Device Tax	289		N/M (1)
Operating Income	3,702	8,481	(56.3 %)
Operating Margin	5.9 %	14.1 %	(58.2 %)
EBITDA(2)	5,501	10,203	(46.1 %)
Income from Continuing Operations	2,559	5,968	(57.1)%
Net Income	2,559	5,586	(54.2 %)
Earnings per share	0.10	0.22	(54.5 %)
Earnings per share from Operations (2)	0.10	0.24	(58.3 %)
Operating Return on average equity (2)	4.4 %	11.1 %	(60.4 %)
Operating Return on average assets (2)	3.2 %	7.5 %	(57.3 %)

(1) Not Meaningful.

EBITDA, earnings per share from operations, operating return on average equity and operating return on average 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. Earnings per share

(2) from operations is net of one-time events. Operating return on average equity is defined as net income (net of one-time events) divided by average equity. Operating return on average assets is defined as net income (net of one-time events) plus interest expense divided by average assets. See disclosure following regarding the use of non-GAAP financial measures.

Fiscal Year	
Ended July 31,	
(dollars in thousands)	
\$2,559	\$5,968
9	43
1,130	2,499
1,123	1,093
680	600
\$5,501	\$10,203
	Ended J (dollars thousand 2013 \$2,559 9 1,130 1,123 680

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	Fiscal Yea July 31, (dollars in thousands)	
	2013	2012
Operating Return on Average Equity Calculation Income from Continuing Operations Average Equity:	\$2,559	\$5,968
July 31, 2013	\$60,152	
July 31, 2012 July 31, 2011	56,478	\$56,478 50,664
Average Equity	\$58,315	\$53,571
Operating Return on Average Equity	4.4 %	11.1 %
Operating Return on Average Assets Calculation Income from Continuing Operations Interest	\$2,559 9	\$5,968 43
Net income from Operations + Interest Expense	\$2,568	\$6,011
Average Assets: July 31, 2013	\$82,693	
July 31, 2012 July 31, 2011	78,763	\$78,763 81,310
Average Assets	\$80,728	\$80,037
Operating Return on Average Assets	3.2 %	

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, earnings per share from operations, operating return on average equity and operating return on average 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 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.

These non-GAAP measures are not in accordance with, or an alternative to, measures prepared in accordance with GAAP and may be different from non-GAAP measures used by other companies. In addition, these non-GAAP measures are not based on any comprehensive set of accounting rules or principles. Non-GAAP measures have limitations in that they do not reflect all of the amounts associated with the Company's results of operations as determined in accordance with GAAP. These measures should only be used to evaluate our results of operations in conjunction with the corresponding GAAP measures.

Our Business Strategy

The Company's strategy is to enhance shareholder value through profitable revenue growth in targeted segments of the ophthalmology and neurosurgery markets. This is accomplished through the identification and development of reusable and disposable devices in collaboration with leading surgeons and OEM partners. We are committed to

establishing a strong operational infrastructure and financial foundation within which growth opportunities can be prudently evaluated, financed and pursued. We will remain vigilant and sensitive to new challenges which may arise from changes in the definition and delivery of appropriate healthcare in our fields of interest. In fiscal 2014 and beyond, our strategic priorities are to drive accelerating growth in the ophthalmology business, deliver improved profitability through our enterprise-wide lean initiatives, manage our neurosurgery and other OEM businesses for stable growth and strong cash flows and demonstrate consistent, solid financial performance.

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Drive Accelerating Growth in our Ophthalmology Business

We are focused on expanding our product platform into larger and faster-growing segments of the vitreoretinal device market. Thus, we have focused our internal research and development efforts on developing innovative technologies that will enable the Company to enhance its value to the vitreoretinal community. We are implementing several focused initiatives to capitalize on our recent new product introduction, the VersaVITTM, and other new products and capitalize on the current macroeconomic environment. In addition, we are also seeking business development opportunities to augment and complement our existing ophthalmic franchise. Finally, we are improving our sales force productivity. For example, in the U.S., we are focused on enhancing our compensation programs to target the appropriate mix of product and rigorous development of our sales force capabilities through enhanced training and customer relationship management. In the international markets, we are working to optimize our sales capabilities and distribution infrastructure. Our recent acquisition of M.I.S.S. demonstrates our commitment to enhancing our international distribution infrastructure.

Deliver Improved Profitability through our Enterprise-Wide Lean Initiatives

We have been developing comprehensive enterprise-wide initiatives aimed at creating a more efficient operating platform. The lean mindset has permeated our corporate culture. We believe we have taken over \$2.5 million out of our cost basis since we implemented our lean efforts. In addition, we implemented our Enterprise Resource Planning ("ERP") system in August 2011. Continued improvements throughout the organization are expected to emerge as we optimize the ERP system.

Manage our Neurosurgery and OEM Businesses for Stable Growth and Strong Cash Flows

We have multi-year contracts established with our two largest OEM partners, Codman and Stryker. These relationships provide high visibility within the neurosurgery and pain control markets. We provide best-in-class technologies with our electrosurgical generators and disposable bipolar forceps being distributed by Codman and our multi-channel ablation generator and ultrasonic aspirator disposables being distributed by Stryker. We are working with both of these OEM partners to provide product line iterations to maintain their technological advantages. We also work to develop relationships with a select number of other potential OEM customers to develop relationships which would continue to enhance our OEM platform growth and profitability to complement our strategic focus.

Demonstrate Consistent, Solid Financial Performance

In the short and long-term, we expect to continue to deliver a growing revenue stream and meet increasing earnings objectives. We also will enhance our working capital usages by employing both our new lean philosophy and our ERP system to derive more free cash flow from the business. We will prudently manage our capital structure to allow for additional growth opportunities and optimal cash deployment.

Research and Development ("R&D") Strategy

Our R&D strategy primarily focuses on developing new products in collaboration with leading retinal surgeons and our OEM partners utilizing our proprietary technology and our expertise in vitreoretinal surgery and neurosurgery. We are continually engineering new products, systems and instrumentation, as well as enhancements to existing products, to meet the needs of surgeons in the ophthalmology and neurosurgery disciplines. We have entered into consultation arrangements with leading ophthalmic surgeons, all of whom specialize in vitreoretinal procedures. In neurosurgery, we have worked closely with our OEM partners to develop ultrasonic aspirator tips and other handheld devices.

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The Company has historically invested in specific R&D projects. In fiscal 2013, we spent approximately 80 percent of our R&D expenditures on ophthalmic opportunities and 20 percent on neurosurgery and other OEM opportunities.

We anticipate ongoing R&D costs in connection with the development of our products. The Company's R&D resources include: an advanced technology group that works on longer-term, highly complex R&D initiatives, a device development group that works on strategically targeted products and an engineering team at the King of Prussia, Pennsylvania, location that develops new electrosurgery and pain control products. The alignment of our R&D resources into these groups allows us greater flexibility to meet the ever-changing needs of our customers as well as allow the Company to focus on those products and technologies that fit within our strategic plan.

At July 31, 2013, the Company's development pipeline included 29 active projects in various stages of completion. The Company completed two of its most recent top priority ophthalmology R&D projects when it introduced the VersaPACKTM vitrectomy packsand our novel VersaVITTM vitrectomy machine for use in vitreoretinal procedures. The launch of these two products allows the Company to compete in the estimated \$336 million and \$215 million segments of the annual vitreoretinal market, respectively, in which we previously did not compete. We have begun development work on several of the larger active projects which are a subset of the 29 and we believe will drive future growth in both our ophthalmic and neurosurgery businesses. In fiscal 2014, our key objective is to continue to commercialize VersaVITTM globally.

The Company expects to invest in R&D at a rate of approximately 6 to 8 percent of net sales each fiscal year. Substantially all of our R&D is conducted internally. In fiscal 2014, we expect to fund all of our R&D projects with current assets and cash flows from operations. We continuously review our R&D initiatives to ensure they remain consistent with and supportive of our strategic growth initiatives.

Marketing

Ophthalmic/Vitreoretinal

Markets

Vitreoretinal surgery refers to any surgical procedures involving the posterior portion of the eye, also commonly referred to as "the back of the eye." Conditions associated with vitreoretinal surgery often require surgical treatment to prevent vision loss. These conditions include proliferative diabetic retinopathy, retinal detachments and tears, macular holes, macular puckers, vitreous hemorrhages and traumatic eye injuries as well as other diseases. The retinal surgeon requires a variety of devices and equipment to perform the surgery, such as a vitrectomy machine and vitrectomy cutter to remove the vitreous from the eye, a light source and endoilluminator to illuminate the eye and a laser and endolaser probe, which provides focused photocoagulation for the treatment of diabetic retinopathy and related conditions.

Based upon a study performed by Market Scope LLC ("Market Scope"), dated March 2012, there are approximately 2,000 practicing retinal specialists in the United States and an additional 7,600 throughout the rest of the world. It is estimated that approximately 324,000 vitrectomies will be performed in the United States and 1.26 million total vitrectomies will be performed throughout the world in 2013. Market Scope estimates that these procedures are growing 2.4 percent annually.

Our business continues to grow and evolve as market conditions change. Due to the changing needs of the retina community, the Company designed the VersaVITTM vitrectomy machine and Core EssentialsTM vitrectomy pack to provide surgeons with a vitrectomy platform that is portable, versatile, space-saving and cost efficient. The Company will continue to focus on market needs and market changes to provide surgeons with products that meet their needs.

<u>Table of Contents</u> Marketing and Sales Force

In the United States, we have assembled a direct, dedicated sales organization, consisting of 23 sales representatives, six field sales management/support persons and seven marketing professionals. In fiscal 2014, we are expanding our application specialists by three and our marketing professionals by one to fully implement our VersaVITTM launch and we are also working on additional devices and accessories to complement our VersaVITTM Vitrectomy Systems. Our team sells our vitreoretinal surgical products directly to end-users at hospitals, ambulatory surgery centers and surgeon offices throughout the country. We offer 650 separate catalogue items in the vitreoretinal surgical market. Our vitreoretinal products include a vitrectomy system under the VersaVITTM brand, procedural packs under VersaPACKTM and Core EssentialsTM brands, fiberoptic endoilluminators and endolaser probes, a variety of disposable and reusable devices designed for intraocular manipulation of tissues, illumination equipment under the PhotonTM brand, laser equipment for the United States market under Ellex's Solitaire brand and Quantel's Supra and Vitra brands, Volk's line of ophthalmic lenses, Labtician's scleral buckles 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 surgical products. On July 8, 2013, we acquired our United Kingdom distributor, M.I.S.S. which added four international employees. At July 31, 2013, we had 16 international direct sales and distribution employees and were represented by over 50 non-U.S. distributors and independent sales representatives. Our vitreoretinal surgical products are offered for sale in approximately 65 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 those to our domestic end-user customers. Selling prices are established based upon each country's competitive pricing environment.

Competition

Competition in the vitreoretinal market is intense and is expected to increase. This market is characterized by technology innovation and change. We compete by providing products and services that are valued by our customers such as: sales relationships, product innovations, and responses to changing market/business needs. See Item 1A, Risk Factors.

Our ophthalmic surgical devices and equipment compete against manufacturers of similar products, including those sold by our major competitors, Alcon, a subsidiary of Novartis Corporation, a Bausch & Lomb, Inc., a subsidiary of Valeant Pharmaceuticals International, Inc., Dutch Ophthalmic Research Center and Iridex. In addition, our products compete with smaller and larger specialized companies that do not otherwise focus on ophthalmic and vitreoretinal surgery.

OEM Partners and OEM Markets

The Company has material OEM relationships with Codman and Stryker.

In the neurosurgical market, the bipolar electrosurgical system manufactured by Valley Forge prior to the merger has been marketed for over 30 years through a series of distribution agreements with Codman. On April 2, 2009, the Company executed a new, three-year distribution agreement (effective January 1, 2009) with Codman for the continued distribution by Codman of the fourth generation electrosurgical generator, certain other electrosurgery generators, related disposables and accessories. In addition, the Company entered into a three-year license agreement, which provides for the continued licensing of the Company's Mali® trademark to Codman for use with certain Codman products, including those covered by the distribution agreement. The initial term of both agreements expired on December 31, 2011, and both agreements were automatically renewed for three years. In December 2010, Codman elected to exercise its option of exclusive distribution with respect to the electrosurgical generators and related disposables and accessories in the fields of neurocranial and neurospinal surgery.

On November 16, 2009, the Company announced the signing of an addendum to its three-year agreement with Codman. Under the terms of the revised agreement, Codman has the exclusive right to market and distribute the Company's Spetzle^{FM}-Malis[®] branded disposable bipolar forceps produced by Synergetics. Codman began distribution of the disposable bipolar forceps in 2009, domestically and in 2010, internationally.

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The Codman relationship has been proceeding well and is meeting the Company's expectations for unit and dollar sales volumes. Sales to Codman in the fiscal year ended July 31, 2013 comprised 22.4 percent of the Company's net sales.

The Company supplies a multi-channel ablation generator used for minimally invasive pain control treatment to Stryker pursuant to a supply and distribution agreement dated as of October 25, 2004, as amended. The agreement expires on June 30, 2015. The agreement covers the manufacture and supply of the multi-channel ablation generator unit together with certain accessories. The pain control generator can be utilized for facet denervation, rhizotomy, percutaneous cordotomy, dorsal root entry zone lesions, peripheral neuralgia, trigeminal neuralgia and ramus communications. Pain relief is achieved by the controlled heating of the area surrounding the electrode tip. A thermosensor in the probe is used to control tissue temperature. Impedance values are displayed for the user to guard against unsafe conditions. The system provides an electrical stimulator for nerve localization and various coagulating outputs that are selectable based on the procedures undertaken. The pain control generator is configured for bipolar output to minimize current spread, as well as monopolar operation. The agreement also provides Stryker the right of first refusal for the distribution of other products for use in the field of pain control or for use in conjunction with a multi-channel ablation generator technically the same as the products distributed under this agreement.

On March 31, 2010, the Company entered into a supply agreement with Stryker pursuant to which the Company agreed to supply Stryker with disposable ultrasonic aspirator instrument tips and certain other consumable products used in conjunction with Stryker's ultrasonic aspirator console and handpieces. The agreement expires on March 31, 2016.

The Stryker relationship has been proceeding well and is meeting the Company's expectations for unit and dollar sales volumes. Sales to Stryker in the fiscal year ended July 31, 2013 comprised 17.2 percent of the Company's net sales.

Markets

Neurosurgical procedures on a global basis continue to rise at an estimated 1 to 3 percent growth rate driven by an aging global population, new technologies, advances in surgical techniques and a growing global market resulting from ongoing improvements in healthcare delivery in emerging markets, among other factors. Based upon this growth in procedures, sales of neurosurgical products worldwide are forecasted to increase by approximately 4 percent.

Competition

In the field of neurosurgery, we develop, design and manufacture precision-engineered, surgical devices and instruments. In addition, we believe we are the premier manufacturer of bipolar electrosurgical systems sold through Codman for use in neurosurgery. Our neurosurgical bipolar electrosurgical systems and accessories compete against the Valleylab division of Covidien Ltd., Kirwan Surgical Products, Inc., Erbe Elektromedizin GmbH and Aesculap, including Aesculap Inc., USA and Aesculap GmbH, divisions of B. Braun Medical Inc. Ultrasonic aspirator and accessory tips sold through Stryker compete against Integra Life Sciences Holdings, Corp., the manufacturer of the CUSATM and the SelectorTM ultrasonic aspirator systems. Additionally, the products we manufacture compete with smaller and larger specialized companies that do not otherwise focus on neurosurgery. Our products also compete with other technologies, such as handheld instruments and a variety of tissue removal systems designed for removing skull-based tumors.

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Manufacturing and Supplies

We design, manufacture and assemble the majority of our ophthalmic, direct neurosurgical and certain of our OEM products in our facility in O'Fallon, Missouri. The bipolar electrosurgical generators (including the neurosurgical, pain control and other generator units) are manufactured in our facility in King of Prussia, Pennsylvania. The SolitaireTM, SupraTM and VitraTM lasers and the Volk lenses are purchased by the Company from their respective manufacturers. Our products are assembled from raw materials and components supplied to us by third parties. Most of the raw materials and components we use in the manufacture of our products are available from more than one supplier. For some components, there are relatively few alternate sources of supply. For a portion of our disposable product line and for several key components of our PhotonTM light sources, our VersaVITTM vitrectomy system and our electrosurgical generators, we rely upon single source suppliers or contract manufacturers.

During the fiscal year ended July 31, 2013, we continued our lean journey and have introduced all of our manufacturing lines to the lean methodology. These manufacturing lines are at varying degrees of maturity with respect to implementing the lean methodology. In fiscal 2014, we expect to continue the maturation process. Throughout the year, we have been able to increase the sales per employee by 10 percent without any increase in the manufacturing footprint.

Government Regulations

Medical devices manufactured by the Company are subject to extensive regulation by governmental authorities, including federal, state and non-U.S. governmental agencies. The principal regulator in the United States is the FDA.

FDA regulations are wide-ranging and govern the development, production and marketing of medical devices, the observance of certain standards with respect to the design, manufacture, testing, labeling and promotion of devices, the maintenance and retention of certain records, the ability to track devices in distribution, the reporting of potential product defects and patient incidents, the export of devices and other matters.

All medical devices introduced into the market since 1976, which include all of our products, are required by the FDA as a condition of sale and marketing to secure either a 510(k) Premarket Notification clearance or an approved Premarket Approval Application ("PMA") unless specifically exempted by regulation. A Premarket Notification clearance indicates FDA agreement with an applicant's determination that the product for which clearance has been sought is substantially equivalent to another medical device that was on the market before 1976 or that has received 510(k) Premarket Notification clearance since that time. The process of obtaining a Premarket Notification clearance can take several months or potentially years and may require the submission of limited clinical data and supporting information. The PMA process typically requires the submission of significant quantities of clinical data and manufacturing information and involves significant review costs. The Company does not anticipate any of our new devices in development at this time will require a PMA.

The Company had one 510(k) issued during fiscal 2013 for bipolar forceps. 11

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Under FDA regulations, after a device receives 510(k) clearance, any modification that could significantly affect its safety or effectiveness, or that would constitute a major change in the intended use of the device, technology, materials or packaging, requires a new 510(k) clearance. The FDA requires a manufacturer to make this determination in the first instance, but the FDA can review any such decision. If the FDA disagrees, it can require a manufacturer to obtain a new 510(k) clearance or it can seek enforcement action against the manufacturer.

We are also required to register with the FDA as a device manufacturer and to maintain compliance with the FDA's Quality System Regulations ("QSR"). The QSR incorporates the requirements of Good Manufacturing Practice as well as other regulatory requirements of the FDA, which mandate detailed quality assurance and record-keeping procedures and subject manufacturers to unscheduled periodic quality system inspections. We conduct internal quality assurance audits to ensure compliance throughout the manufacturing process.

We may not promote or advertise our products for uses not within the scope of our clearances or approvals or make unsupported safety or effectiveness claims. Further, we are required to comply with various FDA regulations for labeling and promotion. The Medical Device Reporting regulations require that we provide information to the FDA whenever there is evidence to reasonably suggest that one of our devices may have caused or contributed to a death or serious injury. In addition, the FDA prohibits us from promoting a medical device before marketing clearance has been received or promoting a cleared device for unapproved indications. Noncompliance with applicable regulatory requirements can result in enforcement action, which is more fully described in Part 1, Item 1A, "Risk Factors" section of this Annual Report on Form 10-K.

Medical device regulations also are in effect in many of the countries outside the United States in which our products are sold. These laws range from comprehensive device approval and quality system requirements for some or all of our medical device products to simpler requests for product data or certifications. The number and scope of these requirements are increasing. In June 1998, the European Union Medical Device Directives became effective, and all medical devices sold in the European common market must meet the Medical Device Directives standards. The Company sells its products in the European medical device market; as such, we have voluntarily chosen to participate in audits established by the European Union through which we have obtained "CE marking" for many of our products. The Company is subjected to annual audits at both of our manufacturing facilities for compliance to the quality system standards established by the International Standards Organization ("ISO") and Medical Device Directives established by European law. The Company is certified to ISO 13485:2003, the international standard for quality systems as applied to medical devices. Failure to correct deficiencies discovered during an audit could result in the removal of the CE mark on our products, which would effectively bar the sale of the Company's products in the European market. Such a result would have a significant and material negative impact on the Company and its business. In addition, there are several other countries that require additional regulatory clearances.

Management believes that we are in material compliance with the government regulations governing our business in the countries where we market our products.

Safety Approvals

The majority of our capital equipment products also require electrical safety testing, and in some cases electromagnetic compatibility testing, either as a product registration requirement and/or to gain market acceptance. Testing to internationally recognized standards is provided by third party vendors, who certify our products' compliance to these standards. The primary standard to which our capital equipment must comply requires that we provide detailed risk management documentation to support the electrical safety testing.

<u>Table of Contents</u> Intellectual Property

Our continuing technological innovations and superior engineering designs, as well as the goodwill associated with our products, provide us with competitive advantages, many of which are proprietary to the Company. We protect our proprietary advantages, in large part, by obtaining legal rights in issued patents, the filing of patent applications, maintaining trade secrets and confidential know how, and through the use of trademarks.

Patented and/or patent pending technology is used in most of our product lines, from our most recently released surgical equipment, the VersaVITTM vitrectomy system and its associated disposables, to our line of Directional Laser ProbeTM devices, our DDMSTM membrane scrapers, our PhotonTM line of illumination technology with complimentary accessories, and further, to the products we make for our OEM partners, such as our Malis[®] line of bipolar electrosurgical generators, forceps and other accessories, as well as certain surgical ultrasonic aspiration tips. When deemed appropriate for our business success, we have chosen to and will continue to choose to enforce and defend these patent rights.

We generally seek patent protection on those technological advancements that are believed to be patentable and are planned or likely to be used in our products or product improvements. Currently, the Company owns 97 unexpired patents around the world, 37 of which have been issued in the United States. Our oldest, unexpired patent was issued in the United States almost 15 years ago, in 1998. Given the range of ages of the patents in our portfolio, we expect that patent expiration will be a routine event going forward for some time. We do not believe that the expiration of any one patent, or the expiration over time of each of our currently unexpired patents, will have a material, adverse effect on our business. Furthermore, we manage our patent portfolio such that we will delete a patent application or an issued patent from our portfolio when we determine that the offensive and defensive value of such patent or application is outweighed by its costs of maintenance.

Through our research and development efforts, we are continually creating new intellectual property, and continue to file patent applications around the world to protect our rights in these developments. The Company has numerous, pending patent applications in the United States and in other countries. We believe that these patent applications will mature into issued patents in due course; however, we also know that other legal rights, whether of other inventors or of the public, ultimately may prevent our applications from issuing as patents.

We do not rely exclusively on our patents to provide us with intellectual property protections, but also rely on trade secrets, know-how, and trademarks. In an effort to protect our trade secrets and know-how, we generally require our employees, consultants, and advisors to enter into confidentiality agreements with us upon the commencement of their respective relationships with us. These confidentiality agreements typically provide that all confidential information developed or disclosed by us during the course of the relationship must be kept confidential and cannot be used except to further the purposes of the relationship. To the extent that such confidential information is likely to include inventions, our agreements with our employees, consultants, and advisors may also contain provisions requiring these individuals to assign to us any inventions conceived or reduced to practice in the course of the relationship.

Regarding our trademarks, the Company relies on protections from both formal registrations and common law rights. The Synergetics brand name is a registered trademark of the Company. Other trademarks used in association with the Company's products include the diamond logo, Vision for Life, VersaVIT, VersaPACK, Core Essentials, Bullseye, Corona, Diamond Black, DDMS, Directional Laser Probe, Extendable Directional Laser Probe, Inverted Directional Laser Probe, FullView, I-Pack, Kryoptonite, Maxillum, Microfiber, Microserrated, One-Step, Photon, Photon I, Photon II, P1, P2, Pinnacle, Syntrifugal, Apex, Synerport, TruCurve and Vivid. Other trademark registrations owned by the Company include Malis, the Malis waveform logo, Bident, and Finest Energy Source Available for Surgery. Other trademarks owned by us and for which use inures to the benefit of the Company include Burst, Barracuda, Gentle Gel, Lumen, Lumenator and TruMicro. All other trademarks appearing in this Annual Report on Form 10-K are the property of their respective owners.

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Backlog

As of July 31, 2013, our backlog was approximately \$1.9 million.

Employees

On July 31, 2013, we had approximately 336 employees, of which 335 were full-time employees. As part of our lean manufacturing philosophy, we currently utilize temporary staffing agencies to provide us with approximately 15% of our manufacturing staff in order to remain flexible. Including the temporary staff and planned replacements, our head count would be approximately 387 employees. From time to time, we retain temporary employees, part-time employees, engineering consultants, scientists and other consultants. All full-time employees are eligible to participate in our health benefit plan. None of our employees are represented by a union or covered by a collective bargaining agreement. We consider our relationship with our employees to be satisfactory.

Executive Officers of the Registrant

The following table sets forth certain information, as of the date of this Annual Report on Form 10-K, with respect to the executive officers of the Company.

Name Age Position(s) with the Company

David M. Hable 58 President, Chief Executive Officer & Director

Pamela G. Boone 50 Executive Vice President, Chief Financial Officer, Treasurer & Secretary

Jerry L. Malis 81 Executive Vice President & Chief Scientific Officer

Jason J. Stroisch 38 Vice President of Marketing and Technology

Michael R. Fanning 47 Vice President of Domestic Sales

David M. Hable joined the Company as its President, Chief Executive Officer ("CEO") and director in January 2009. Prior to joining the Company, Mr. Hable served as President and Chief Executive Officer 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 20 years with Codman, 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. Mr. Hable has overall responsibility for the management of the Company.

Pamela G. Boone joined the Company as its Chief Financial Officer in May 2005. Prior to this, Ms. Boone served as Vice President and Chief Financial Officer of Maverick Tube Corporation ("Maverick") from 2001 until January 2005 and as Vice President, Treasurer and acting Chief Financial Officer until May 2005. Maverick, a Missouri-based company, was a leading North American producer of welded tubular steel products used in energy and industrial applications. From 1997 to 2001, Ms. Boone served as Maverick's Corporate Controller. Ms. Boone coordinates and supervises the finance, treasury, budgeting, investor relations, accounting and information technology functions of the Company.

Jerry L. Malis is the Company's Executive Vice President and Chief Scientific Officer and has served in these positions and as director since 2005. Immediately prior to the consummation of the merger with Valley Forge, Dr. Malis served as Valley Forge's Chief Executive Officer, President and Chairman of the Board. He has published over 50 articles in the biological science, electronics and engineering fields, and has been issued ten United States patents. Dr. Malis coordinates and supervises the scientific developments of the Company's electrosurgery products.

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Jason J. Stroisch joined the Company in the Engineering division in September 1995. In his 18 years with the Company, Mr. Stroisch has had increasing levels of responsibility within the organization, including International Product Manager, International Sales Manager and Vice President of Ophthalmic Sales. In April 2009, he was promoted to Vice President of International Sales and Marketing. In August 2012, oversight of our R&D efforts was added to his responsibilities. Mr. Stroisch coordinates and supervises the marketing efforts of the Company and the scientific development of the Company's ophthalmic and OEM products.

Michael R. Fanning joined the Company as a territory manager in June 2003. He was promoted to National Sales Manager in May 2006 and became Vice President of Domestic Sales in April 2009. Prior to this, Mr. Fanning worked for GE Capital for over ten years. Mr. Fanning coordinates and supervises the domestic sales and customer service operations of the Company.

Available Information

We make available free of charge our annual reports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K and amendments to those reports filed or furnished as required by Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), through our internet website at www.synergeticsusa.com as soon as reasonably practicable after we electronically file such material with, or furnish it to, the Securities and Exchange Commission ("SEC").

Special Note 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 Exchange Act, 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 SEC and in our reports and presentations to stockholders or potential stockholders. In some cases forward-looking statements can be identified by words such as "believe," "expect," "anticipate," "plan," "potential," "continue" or 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.

Item 1A. Risk Factors

In addition to the other information contained in this Annual Report on Form 10-K, we have identified the following risks and uncertainties that may have a material adverse effect on our business, financial condition or results of operations. You should carefully consider the risks described below before making an investment decision.

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Risks related to Our Business

The medical device industry is highly competitive and subject to technological change. If our competitors are better able to develop and market products that are safer, more effective, less costly, easier to use, or are otherwise more attractive, we may be unable to compete effectively with other companies.

The medical technology industry is characterized by intense competition and technology change. We compete with established medical technology companies and early stage companies that have alternative solutions for the markets we serve or intend to serve. Many of our competitors have several advantages over us; including:

- ·access to greater financial and human resources for product development, sales and marketing and patent litigation;
- · greater name recognition;
- ·long established relationships with physicians and customers;
- ·additional lines of products and the ability to offer rebates or bundle products to offer greater discounts or incentives;
- ·more established sales and marketing programs, and distribution networks; and
- greater experience in conducting research and development, manufacturing, preparing regulatory submissions and obtaining regulatory clearance or approval for products and marketing approved products.

Our competitive position depends on multiple, complex factors, including our ability to achieve market acceptance for our products, develop new products, implement production and marketing plans, secure regulatory approvals for products under development and protect our intellectual property. We may need to develop new applications for our products to remain competitive. Technological advances outside of our field, such as in pharmacology, by one or more of our current or future competitors could render our present or future products obsolete or uneconomical. Our future success depends, among other things, upon our ability to compete effectively against current technology, as well as to respond effectively to technological advances, and upon our ability to successfully implement our marketing strategies and execute our R&D plan.

Our products may not be accepted in the market.

We cannot be certain that our current products or any other products we have or may develop or market will achieve or maintain market acceptance. We cannot be certain that our devices and the procedures they perform will be able to replace established treatments or that physicians or the medical community in general will accept and utilize our devices or any other medical products that we may develop.

Market acceptance of our products depends on many factors, including our ability to:

convince key opinion leaders to provide recommendations regarding our products;

convince distributors and customers that our technology is an attractive alternative to other technologies;

price our products competitively in light of the current macroeconomic environment where healthcare systems and healthcare operators are becoming increasingly price sensitive;

manufacture products in sufficient quantities; and

supply and service sufficient quantities of our products directly or through marketing alliances.

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If we do not introduce new commercially successful products in a timely manner, our products may become obsolete over time, thereby decreasing our revenue and profitability.

Demand for our products may change as a result of evolving customer needs, the introduction of new products and technologies, the discovery of cures for certain medical problems, including pharmacology technologies and discoveries, evolving surgical practices and evolving industry standards. Without the timely introduction of new commercially successful products and enhancements, our products may become obsolete over time causing our sales and operating results to suffer. The success of our new products will depend on several factors, including our ability to:

properly identify and anticipate customer needs;

obtain regulatory approval for new products;

achieve positive clinical outcomes;

commercialize new products in a cost-effective and timely manner;

manufacture and deliver products in sufficient volumes on time;

differentiate our products from those of our competitors;

satisfy the increased demands by health care payers, providers and patients for lower-cost procedures and shorter hospital stays and recovery times;

innovate and develop product designs and surgical techniques; and

provide adequate medical and/or customer education relating to new products and attract key surgeons to advocate these new products.

New products and enhancements usually require a substantial investment in R&D before we can determine the viability of the product. We spent 5.8 percent of our sales on R&D during the fiscal year ended July 31, 2013 and we expect to spend 6 to 8 percent of our sales for this purpose in future periods. Our R&D process entails considerable uncertainty. Moreover, new products and enhancements may not produce revenues in excess of the R&D costs, and they may become obsolete by changing customer preferences or the introduction by our competitors of new technologies or features. Failure to develop our manufacturing capability may mean that even if we develop promising new products, we may not be able to produce them profitably, as a result of delays and additional capital investment costs.

A significant part of our product sales comes from two customers, which makes us vulnerable to the loss of those customers.

During the fiscal year ended July 31, 2013, revenue from sales of our bipolar electrosurgical generators, disposable bipolar forceps, cord tubing sets and royalty payments from Codman represented approximately 22.4 percent of the Company's total net sales. Under our existing agreement with Codman, it distributes all contract products on an exclusive basis and has exclusive rights to distribute all monopolar and bipolar generators for use in neurocranial and neurospinal surgery. The initial term of our existing agreement with Codman expired on December 31, 2011, after which the agreement entered into a single, automatic, three-year renewal term. We continue to enhance the contract products and to develop new generators and additions to the disposable bipolar forceps line for Codman which we expect will expand their reach to additional markets.

In addition, revenue from the sales of our pain control generators, the ultrasonic aspirator tips and accessories by Stryker accounted for 17.2 percent of the Company's total net sales for fiscal 2013. Under our existing agreements with Stryker, it distributes the pain control generator and ultrasonic aspirator tips on an exclusive basis. The pain control generator agreement expires on June 30, 2015, and the ultrasonic aspirator tip agreement expires on March 31, 2016. We continue to develop new ultrasonic aspirator tips for Stryker which will expand their reach to additional markets.

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Our international operations subject us to certain operating risks, which could adversely impact our net sales, results of operations and financial condition.

Sales of our products outside the U.S. represent approximately 26 percent of our revenue in 2013. As of July 31, 2013, we sell our products outside the U.S. through five direct sales organizations in Australia, France, Germany, Italy and the United Kingdom, after our acquisition of M.I.S.S. on July 8, 2013. The results of operations and the financial position of certain of our foreign operations are reported in the relevant local currencies and then translated into U.S. dollars at the applicable exchange rates for inclusion in our consolidated financial statements, exposing us to translation risk. Our most significant currency exposure is to the euro. The exchange rates between the euro and the U.S. dollar may fluctuate substantially. We have not attempted to offset our exposure to these risks by investing in derivatives or engaging in hedging activities.

In addition to our direct sales outside the U.S., we have over 50 independent distributors selling our products in over 65 countries. The sales of our products across international borders subject us to extensive U.S. and foreign government trade, import, export and custom regulations and laws. Compliance with these regulations is costly and may expose us to penalties for non-compliance. Other laws and regulations that can significantly impact us are various anti-bribery laws including the U.S. Foreign Corrupt Practices Act, the U.K. Bribery Act and anti-boycott laws. Any failure to comply with applicable legal and regulatory obligations could impact us in a variety of ways that include, but are not limited to, significant criminal, civil and administrative penalties, including imprisonment of individuals, fines and penalties, denial of export privileges, seizure of shipments, restrictions of certain business activities and exclusion or debarment from government contracting. Also, the failure to comply with applicable legal and regulatory obligations could result in delays and other disruptions of our shipping and sales activities.

In addition, many countries in which we sell our products are, to some degree, subject to political, economic or social instability. Our international operations expose us and our distributors to risks inherent in operating in foreign jurisdictions. These risks include:

changes in foreign medical reimbursement and coverage policies and programs;

cultural differences;

shortage of high-quality sales personnel and distributors;

the ability and motivation of our independent distributors to sell our products;

pricing pressure from local and regional competitors;

foreign certification requirements, including the ability to use the "CE" mark in Europe, and other local regulatory requirements;

difficulties in enforcing or defending our intellectual property rights;

fluctuations in currency exchange rates and foreign currency translation adjustments;

unexpected changes in international or local market regulatory requirements, including imposition of currency exchange controls;

longer accounts receivable collection cycles;

import or export licensing requirements;

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potentially adverse tax consequences;

political and economic instability;

obtaining regulatory approvals for our products;

end-market and/or regional competition that may have competitive advantages; and

subjectivity of foreign laws.

Continuing worldwide macroeconomic instability, including challenges faced by the European Union and Emerging Markets, could adversely affect our revenues, financial condition or results of operations.

Since fiscal 2008, the global economy has been impacted by the sequential effects of an ongoing global financial crisis which has caused extreme disruption in the financial markets, including severely diminished liquidity and credit availability. There can be no assurance that further deterioration will not occur. Our customers may experience financial difficulties or be unable to borrow money to fund their operations which may adversely impact their ability to purchase our products or to pay for them on a timely basis, if at all. A significant portion of our trade receivables are with many countries significantly impacted by the financial crises (including, but not limited to, France, Greece, Italy, Spain and Turkey). Payment by our customers of our receivables is dependent upon the financial stability of the economies of those countries. In light of the current economic state of many countries outside of the U.S., we continue to monitor the creditworthiness of our customers. Failure to receive payment of all or a significant portion of our receivables could adversely affect our results of operations. Further, there are concerns for the overall stability and suitability of the euro as a single currency, given the economic and political challenges facing the European Union. Continuing deterioration in the creditworthiness of the eurozone countries, the withdrawal of one or more member countries from the European Union or the failure of the euro as the common European currency could adversely affect our net sales, financial condition or results of operations.

We may face manufacturing and quality control challenges which could impact our competitive advantage.

The manufacturing of our surgical equipment and disposable accessories is a highly complex and precise process. We assemble critical components and sub-assemblies and substantially all our final products at our facilities in O'Fallon, Missouri and King of Prussia, Pennsylvania. We may experience manufacturing difficulties, quality control issues or manufacturing constraints particularly with regards to new products and increased production demands. If our sales increase substantially, we may need to increase our production and quality control capacity and may not be able to do so in a timely, effective or cost efficient manner. We may not be able to manufacture sufficient quantities of our products which may require us to qualify other manufacturers of our products. Furthermore, we may experience delays, disruptions, capacity constraints or quality control problems in our manufacturing operations and as a result, product shipments to our customers could be delayed, which would negatively impact our net sales.

If any of our single source or limited source suppliers were to cease providing components, we may not be able to produce certain products.

Our products are assembled from raw materials and components supplied to us by third parties. Most of the raw materials and components used in the manufacturing of our products are available from more than one supplier. For some components, there are relatively few alternate sources of supply. However, we rely upon single source suppliers or contract manufacturers for a portion of our disposable product line and for several key components of our PhotonTM light sources, our VersaVITTM vitrectomy system and our electrosurgical generators. Our profit margins and our ability to develop and deliver products on a timely basis may be adversely affected by the lack of alternative supply in the required timeframe.

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There are risks associated with the use of independent manufacturers including unavailability, shortage or limitations on the ability to obtain supplies of components in the quantities we require, delays in delivery or failure of suppliers to deliver critical components on the dates we require, failure of suppliers to manufacture our components to our specifications and potentially reduced quality and inability to obtain components at acceptable prices. In addition, these suppliers must also adhere to the FDA's rigorous manufacturing standards.

Pursuant to the conflict minerals requirements promulgated by the SEC as part of Dodd-Frank Act, we are required to report on the source on any conflict minerals used in our products, as well as the process we use to determine the source of such materials. We may incur expenses as we work with our suppliers to evaluate the source of any conflict minerals in our products.

The loss of key personnel or failure to integrate replacement personnel could harm our business.

Our future success depends upon the continued service of key management, technical sales and other critical personnel, including Messrs. Hable, Malis, Fanning and Stroisch and Mmes. Boone and Kraus, our Chief Executive Officer, our Chief Scientific Officer, our Vice President of Domestic Sales, our Vice President of Marketing and Technology, our Chief Financial Officer and our Vice President of Regulatory/Quality Assurance, respectively. We maintain key person life insurance for Mr. Hable and Ms. Boone. Our officers and other key personnel are employees-at-will, and we cannot assure you that we will be able to retain them. The loss of any key employee could result in a disruption to our operations and could materially harm our business. In addition, the integration of replacement personnel could be time consuming, may cause additional disruptions to our operations, and may be unsuccessful.

Our operating results may fluctuate.

Our operating results have fluctuated in the past and can be expected to fluctuate from time to time in the future. Some of the factors that may cause these fluctuations include, but are not limited to:

general economic uncertainties and political concerns;

changes in demand for our base ophthalmology and neurosurgery products;

changes in customer capital availability and customer budgets as a result of, among other things, reimbursement policies of government programs and private insurers for treatments that use our products;

receipt of necessary regulatory approvals;

the introduction of new products or product lines;

product modifications;

the level of market acceptance of new products;

the timing of R&D and other expenditures;

timing of the receipt of orders from, and product shipments to, distributors and customers;

changes in the distribution arrangements for our products;

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manufacturing or supply delays including the ability of our sole or limited source suppliers to timely deliver components at the times and prices that we have planned;

the time needed to educate and train additional sales and manufacturing personnel;

increased costs associated with product introductions;

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costs associated with defending our intellectual property; and

product returns.

In addition to these factors, current expenditures are based, in part, on expected future sales. If sales levels in a particular quarter do not meet expectations, we may be unable to adjust operating expenses quickly enough to compensate for the shortfall of sales, and our results of operations may be adversely affected. We have historically made a significant portion of each quarter's product shipments near the end of such quarter.

We may have product liability claims, and our insurance may not cover all claims.

The development, manufacture, sale and use of medical products entail significant risk of product liability claims. We maintain product liability coverage at levels we have determined are reasonable. We cannot assure you that such coverage limits are adequate to protect us from any liabilities we might incur in connection with the development, manufacture, sale or use of our products. In addition, we may require increased product liability coverage as our sales increase in their current product applications and new applications, and with respect to new products. Product liability insurance is expensive and in the future may not be available on acceptable terms, if at all. A successful product liability claim or series of claims brought against us in excess of our insurance coverage could adversely affect our business.

Efforts to acquire additional companies or product lines may consume managerial resources and we may incur or assume additional liabilities or experience integration problems.

We seek to acquire additional businesses or product lines for strategic reasons, including adding new products, new customers and increasing penetration with existing customers, adding new manufacturing capabilities or expanding into new geographic markets. Our recent acquisition of M.I.S.S. establishes a direct presence in one of the largest ophthalmic markets outside the U.S. Our ability to successfully grow through the M.I.S.S. acquisition and through additional acquisitions depends upon our ability to identify, negotiate, complete and integrate suitable acquisitions and to obtain any necessary financing. Upon completion of any acquisition, including the M.I.S.S. acquisition, we may also experience:

- difficulties integrating any acquired products into our existing business;
- delays in realizing the benefits of the acquired products;
- difficulties integration acquired systems or processes;
- difficulties integrating business cultures; or
 - diversion of our management's time and attention from ongoing business.

If our facilities were to experience catastrophic loss, our operations would be seriously harmed.

Our facilities could be subject to catastrophic loss such as fire, flood, tornados or earthquake. A substantial portion of our R&D and manufacturing activities, our corporate headquarters and other critical business operations are located in O'Fallon, Missouri near a major fault line which could result in an earthquake. We maintain property and business interruption insurance coverage at levels we have determined are reasonable. Any such loss at any of our facilities could disrupt our operations, delay production, shipments and revenue and result in large expenses to repair and replace our facilities.

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Risks related to Our Financial Condition

We are subject to credit risk from our accounts receivable related to our product sales, which include sales within European and Emerging Market countries that are currently experiencing economic turmoil.

The majority of our accounts receivable arise from product sales in the U.S. Our accounts receivable in the U.S. are primarily due from OEM partners, public and private hospitals and ambulatory surgery centers. However, we also have receivable balances from customers within the European Union, Turkey, Canada, Japan, Russia and Brazil. Our accounts receivable outside the U.S. are due from independent distributors and, to a lesser extent, public and private hospitals. Our historic write-offs of accounts receivable have not been significant.

We monitor the financial performance and creditworthiness of our customers so that we can properly assess and respond to changes in their credit profile. Our independent distributors operate in Spain, Italy and Greece, among other countries, where economic conditions continue to present challenges to our independent distributors' businesses, and thus, could place at risk the amount due to us from them.

Our cash maintained with a bank may not be fully insured.

We maintain significant amounts of cash and cash equivalents at a financial institution that is in excess of federally insured limits. Given the current instability of financial institutions, we cannot be assured that we will not experience losses on these deposits.

Risks related to the Regulation of our Industry

The recent U.S. healthcare reform legislation and other healthcare regulatory changes could adversely affect our revenue and financial condition.

The Patient Protection and Affordable Care Act and Health Care and Education Affordability Reconciliation Act were enacted into law in March 2010. The Patient Protection and Affordable Care Act imposes an excise tax on domestic sales of class I, II and III medical devices at the rate of 2.3 percent of sales revenue, for which medical device manufacturers became liable beginning in January 2013. Substantially all of our products are class I and II medical devices. The inability to offset this tax could have a material impact on results of operations.

The law also focuses on a number of Medicare provisions aimed at improving quality and decreasing costs, though we are not certain of the impact that these provisions will have on patient access to new technologies and medical procedures.

Changes in government legislation or regulation or in private third-party payers' policies toward reimbursement for procedures employing our products may prohibit adequate reimbursement. There have been a number of legislative and regulatory proposals to change the healthcare system, reduce the cost of healthcare and change medical reimbursement policies. Further proposed legislation or regulation and policy changes affecting third-party reimbursement are likely. We cannot predict what legislation or regulation, if any, relating to the health care industry or third-party coverage and reimbursement may be enacted in the future, or what the effect of such legislation or regulation may have on us. However, any changes that lower reimbursement for our products or reduce medical procedure volumes could adversely affect our business and results of operations.

Our industry is experiencing greater scrutiny and regulation by governmental authorities, which may lead to greater governmental regulation in the future.

Medical device companies are subject to rigorous regulation, including by the FDA and numerous other federal, state and foreign governmental authorities. These authorities and members of the United States Congress have been increasing their scrutiny of our industry. In addition, certain states have recently passed or are considering legislation restricting our interactions with health care providers and requiring disclosure of payments to them. As a result, we are required by law to disclose payments and other transfers of value to health care providers licensed by certain states and, starting with payments or other transfers of value made on or after August 1, 2013, to all U.S. physicians and U.S. teaching hospitals at the federal level. Any failure to comply with these legal and regulatory requirements could impact our business. Also, while recent case law has clarified that the FDA's authority over medical devices preempts state tort laws, legislation has been introduced at the federal level to allow state intervention. We anticipate that the various governments will continue to closely scrutinize our industry, and additional regulations by governmental authorities may increase compliance costs, exposure to litigation and other adverse effects to our operations.

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Delays in the receipt of or our failure to receive regulatory clearances or approvals, the loss of previously received clearances or approvals, or failure to comply with existing or future regulatory requirements could have a material adverse effect on our business, financial condition, results of operations and future growth prospects.

Our R&D activities and the manufacturing, labeling, distribution and marketing of our existing and future products are subject to regulation by governmental agencies in the United States and in other countries. The FDA and comparable agencies in other countries impose mandatory procedures and standards for the conduct of clinical trials and the production and marketing of products for medical diagnostic and therapeutic use.

Products under development are subject to FDA approval or clearance prior to commercial use. The process of obtaining necessary FDA approvals or clearances is not only costly but can potentially take years and the outcome may be uncertain. Our inability to obtain required regulatory approval or clearance in a timely manner could harm our business. Further, approval or clearance may place substantial restrictions on the indications for which the product may be marketed or to whom it may be marketed. Additional studies may be required to gain approval or clearance for the use of a product for clinical indications other than those for which the product was initially approved or cleared or for changes to the product.

Furthermore, an additional risk relates to the regulatory classification of new products or proposed new uses for existing products. With each application, we are required to make a judgment about the appropriate form and content of the application. If the FDA disagrees with our judgment in any particular case and, for example, requires us to file a premarket approval application rather than a Section 510(k) premarket notification or requires clinical data be added to our application, the time and expense required to obtain the approval might be significantly increased and approval may become less likely.

Once approved or cleared for marketing, our products are subject to continuing FDA requirements, such as those relating to quality control and quality assurance, maintenance of records, reporting of adverse events and product recalls, documentation and labeling and restrictions on promotion of medical devices. Failure to precisely follow any of these requirements may lead to unanticipated costs of remediation, a product recall and/or an order to cease production and sales of a product. A recall could divert management's attention, cause us to incur significant expenses, harm our reputation with customers and negatively affect our future net sales.

There can be no assurance that we will be able to obtain necessary clearances or approvals to market any new products, or to market existing products for new intended uses, on a timely basis, if at all. There can be no assurance that we will be able to continue to market existing products without interruption due to regulatory oversight.

Moreover, for the majority of our non-direct, foreign sales, our distributors assist with and control regulatory approval or clearance for product marketing. We cannot be certain that such approvals or clearances are actually effective. Nor can we be assured that approval or clearance for product marketing in any given country would continue to be effective for any distributor other than our current distributor in that same country, if any of our current distributors cease to distribute our products. A change in our distributor in any country could lead to delays in continued sales in that country while regulatory approval or clearances are sought to be renewed. Such a delay could have significant impacts on our net sales outside the U.S.

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We may be subject to penalties and may be precluded from marketing our products if we fail to comply with extensive governmental regulations.

The FDA and non-U.S. regulatory authorities require that our products be manufactured according to rigorous standards. These regulatory requirements may significantly increase our production costs and may even prevent us from making our products in amounts sufficient to meet market demand. If we change our approved manufacturing process, the FDA may need to review the process before it may be used. Failure to comply with applicable regulatory requirements discussed could subject us to enforcement actions, including:

warning letters;

fines, injunctions and civil penalties against us;

recall or seizure of our products;

operating restrictions, partial suspension or total shutdown of our production;

refusing our requests for premarket clearance or approval of new products;

withdrawing product approvals already granted; and

eriminal prosecution.

Federal, state and non-U.S. regulations, regarding the manufacture and sale of medical devices are subject to future changes. The complexity, timeframes and costs associated with obtaining marketing clearances are unknown. Although we cannot predict the impact, if any, these changes might have on our business, the impact could be material.

Changes in tax laws or exposure to additional income tax liabilities could have a material impact on our financial condition and results of operations.

We are subject to income taxes as well as non-income based taxes, in both the U.S. and various jurisdictions outside the U.S. We are subject to ongoing tax audits in various jurisdictions. Tax authorities may disagree with certain positions we have taken and assess additional taxes and penalties. We regularly assess the likely outcomes of these audits in order to determine the appropriateness of our tax provision. However, there can be no assurance that we will accurately predict the outcomes of these audits, and the actual outcomes of these audits could have a material impact on our consolidated earnings and financial condition. Additionally, changes in tax laws or tax rulings could materially impact our effective tax rate. Proposals for fundamental U.S. corporate tax reform, if enacted, could have a material impact on our future results of operations.

Our intellectual property rights may not provide meaningful commercial protection for our products, which could adversely affect our ability to compete in the market.

Our ability to compete effectively depends, in part, on our ability to maintain the proprietary nature of our technologies and manufacturing processes, which includes the ability to obtain, protect and enforce patents on our technology and to protect our trade secrets. We own patents that cover significant aspects of our products. Certain patents of ours have expired and others will expire in the future. Competitors may develop products similar to ours that our patents do not cover. In addition, our current and future patent applications may not result in the issuance of patents in the United States or other countries. Further, there is a substantial backlog of patent applications in the U.S. Patent and Trademark Office and the approval or rejection of patent applications may take several years. In addition,

challenges may be made to our patents in the courts or any of various patent offices around the world, and as a result our patents could be narrowed, invalidated or rendered unenforceable.

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Our competitive position depends, in part, upon unpatented trade secrets, which can be difficult to protect. Others may independently develop substantially equivalent proprietary information and techniques or gain access to our trade secrets. In an effort to protect our trade secrets, we require consultants, advisors and most of our employees to execute confidentiality agreements and certain of them to sign invention assignment agreements upon commencement of employment or a consulting relationship with us. Some jurisdictions limit the enforceability and scope of these agreements, and these agreements may not provide meaningful protection for our trade secrets or other proprietary information in the event of the unauthorized use or disclosure of confidential information.

The intellectual property rights of others may adversely affect our ability to introduce new products or continue to sell existing products.

The medical device industry is characterized by frequent litigation regarding patent and other intellectual property rights. Companies in the medical device industry have employed intellectual property litigation to gain a competitive advantage. Numerous patents are held by others, including academic institutions and our competitors. These patents may be employed to limit our ability to market our products, for example, through patent infringement litigation. Patent applications generally will be published 18 months after the filing date. However, since patent applications continue to be maintained in secrecy for at least some period of time, we cannot assure you that our technology does not infringe any patents, patent applications held by third parties, prior patents, or prior art. We have, from time to time, been notified of, or have otherwise been made aware of, claims that we are infringing upon patents or other proprietary intellectual property owned by others. If it appears necessary or desirable, we may seek licenses under such patents or proprietary intellectual property. Although patent holders may offer such licenses, licenses under such patents or intellectual property may not be offered or the terms of any offered licenses may not be reasonable. Any infringement claims, with or without merit, and regardless of whether we are successful on the merits, could be time-consuming, result in costly litigation and diversion of technical and management personnel, cause shipment delays or require us to develop non-infringing technology or enter into royalty or licensing agreements. An adverse determination could prevent us from manufacturing or selling our products, which could have a material adverse effect on our business, results of operations and financial condition.

Risks related to Ownership of Our Common Stock

The market price of our stock may be highly volatile.

Our stock price has fluctuated widely. It ranged from \$2.93 to \$5.45 per share during the year ended July 31, 2013. Our stock price could continue to experience significant fluctuations in response to certain factors, some of which are beyond our control, such as:

our ability to successfully commercialize our products;

the execution of new agreements and material changes in our relationships with companies with whom we contract;

quarterly fluctuations in results of operations;

announcements regarding technological innovations or new commercial products by us or our competitors or the results of regulatory filings;

market reaction to trends in sales, marketing and R&D and reaction to acquisitions;

sales of common stock by existing shareholders;

changes in key personnel;

economic and political conditions, including worldwide geopolitical events; and

fluctuations in the United States financial markets.

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In addition, our common stock may experience an imbalance between supply and demand resulting from low trading volumes, and therefore broad market fluctuations could have a significant impact on the market price of our common stock regardless of our performance.

Synergetics USA, Inc. has anti-takeover defenses that could delay or prevent an acquisition and could adversely affect the price of its common stock.

Provisions of our certificate of incorporation, bylaws and Delaware law may have the effect of deterring hostile takeovers or delaying or preventing changes in the control of the Company, including transactions in which our shareholders might otherwise receive a premium for their shares over then current market prices. In addition, these provisions may limit the ability of our shareholders to approve transactions that they may deem to be in their best interest. Also, our Board of Directors is divided into three classes, as nearly equal in size as practicable, with three-year staggered terms. This provision may deter a potential acquirer from engaging in a transaction with us because it will be unable to gain control of our Board of Directors until at least two annual meetings have been held in which directors are elected by our shareholders.

Item 1B. Unresolved Staff Comments

None.

Item 2. Properties

Our primary office and manufacturing operations are conducted in a 60,000 square foot building owned by our wholly owned subsidiary, Synergetics Development Company, LLC, a Missouri limited liability company. The facility is located in O'Fallon, Missouri, approximately 25 miles west of St. Louis, Missouri. We also lease 19,200 square feet of additional space adjacent to our headquarters in O'Fallon, Missouri pursuant to a lease that expires on February 29, 2016. The additional space houses the advanced technology R&D Group and the manufacturing of the ophthalmic capital equipment.

We also lease 13,500 square feet of office, assembly and manufacturing space in King of Prussia, Pennsylvania, which serves as office, engineering, and manufacturing space. The lease for this facility expires on October 31, 2015.

In addition, we acquired a 1,703 square foot building owned by M.I.S.S. approximately 90 kilometers outside of London which houses our warehouse for our United Kingdom operations. In fiscal 2014, this facility will be used as our European warehouse.

We believe that these facilities are suitable and adequate for our operations. Given our lean manufacturing initiative, we believe that we have the ability to generate additional production capacity using our existing manufacturing facilities.

Item 3. Legal Proceedings

From time to time we may become subject to litigation claims that may greatly exceed our product liability insurance limits. An adverse outcome of such litigation may adversely impact our financial condition, results of operations or liquidity. We record a liability when a loss is known or considered probable and the amount can be reasonably estimated. If a loss is not probable, a liability is not recorded. As of July 31, 2013, the Company has no litigation reserve recorded.

Item 4. Mine Safety Disclosures

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Item 5. Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities

The Company's common stock is listed on The NASDAQ Capital Market under the ticker symbol "SURG." The table below sets forth the range of high and low sales prices per share of the Company's common stock as reported by The NASDAQ Capital Market for each of the quarterly periods within the fiscal years ended July 31, 2013 and 2012. None of the prices shown reflect retail mark-ups, mark-downs or commissions. For current price information, you are urged to consult publicly available sources.

	High	Low
Year ended July 31, 2012		
Quarter ended October 31, 2011	\$6.97	\$4.61
Quarter ended January 31, 2012	\$7.55	\$5.39
Quarter ended April 30, 2012	\$7.03	\$5.40
Quarter ended July 31, 2012	\$6.62	\$3.30
Year ended July 31, 2013		
Quarter ended October 31, 2012	\$5.13	\$3.92
Quarter ended January 31, 2013	\$5.45	\$4.06
Quarter ended April 30, 2013	\$5.31	\$2.95
Quarter ended July 31, 2013	\$4.37	\$2.93

The number of shareholders of Synergetics USA, Inc. as of September 25, 2013, was approximately 4,598.

The Company has not paid a dividend to holders of its common stock. We currently intend to retain earnings to finance growth and development of our business and do not anticipate paying cash dividends in the near future. Our revolving credit facility restricts the payment of dividends, if, following the distribution, the fixed charge coverage ratio would fall below the required minimum ratio.

STOCK PERFORMANCE GRAPH

The following graph is not "soliciting material," is not deemed filed with the SEC, and is not to be incorporated by reference into any of the Company's filings under the Securities Act of 1933 or the Securities Exchange Act of 1934, as amended, respectively.

The graph below compares the cumulative total stockholder return on an investment in our common stock, and the stocks of The NASDAQ Composite Stock Market and The NASDAQ Medical Devices, Instruments and Supplies Index for the five-year period ended July 31, 2013. The Previous Peer Group is composed of six small companies with sales ranging from approximately \$28 million to \$106 million and whose primary business is medical devices: Bovie Medical Corporation, Endologix, Inc., Iridex Corporation, STAAR Surgical Company, Stereotaxis, Inc. and Vascular Solutions, Inc. The graph assumes the value of an investment of \$100 in the common stock of each group or entity at August 1, 2008 and that all dividends were reinvested.

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Item 6. Selected Financial Data

The selected financial data set forth below should be read in conjunction with Management's Discussion and Analysis of Financial Condition and Results of Operations and the consolidated financial statements and notes thereto appearing elsewhere in this Annual Report on Form 10-K. The statements of income data for the years ended July 31, 2013, 2012 and 2011 and the balance sheet data as of July 31, 2013 and 2012 have been derived from audited consolidated financial statements of the Company included elsewhere in this report. The consolidated statements of income for the year ended July 31, 2010 and 2009 and the balance sheets data as of July 31, 2011, 2010 and 2009 have been derived from audited consolidated financial statements that are not included in this Annual Report on Form 10-K. The historical results are not necessarily indicative of the results of operations to be expected in the future.

	For the Fiscal Years Ended July 31,				
	2013 *	2012 **	2011	2010	2009 ***
	(in thousands, except per share data)				
Statements of Income Data:					
Sales	\$62,796	\$60,014	\$55,657	\$52,010	\$52,965
Cost of sales	30,425	25,495	22,876	22,050	23,550
Gross profit	32,371	34,519	32,781	29,960	29,415
Operating income	3,702	8,481	8,349	6,091	3,125
Income from continuing operations	2,559	5,968	5,669	5,767	1,595
Earnings per common share from income from continuing					
operations – basic	\$0.10	\$0.24	\$0.23	\$0.23	\$0.07
Earnings per common share from income from continuing					
operations – diluted	\$0.10	\$0.24	\$0.23	\$0.23	\$