

SYNERGETICS USA INC

Form 10-Q

December 08, 2006

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

(Mark One)

QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the quarterly period ended October 29, 2006

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 000-51602

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)

(636) 939-5100

(Registrant's Telephone Number, Including Area Code)

Indicate by check mark whether 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 No
Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, or a non-accelerated filer. See definition of "accelerated filer and large accelerated filer" in Rule 12b-2 of the Exchange Act. (Check one):
Large Accelerated Filer Accelerated Filer Non-Accelerated Filer

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

The number of shares outstanding of the issuer's common stock, \$0.001 value per share, as of December 6, 2006 was 24,211,809 shares.

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Synergetics USA, Inc. and Subsidiaries
Unaudited Condensed Consolidated Balance Sheets
As of October 29, 2006 and July 31, 2006
(Dollars in thousands except share data)

	October 29, 2006	July 31, 2006
Assets		
Current Assets		
Cash and cash equivalents	\$ 218	\$ 557
Investment in trading securities		50
Accounts receivable, net of allowance for doubtful accounts of approximately \$180 and \$159, respectively	6,809	6,807
Notes receivable, officer-stockholder	16	20
Income taxes receivable	345	513
Inventories	14,800	13,243
Prepaid expenses	474	422
Deferred income taxes	296	296
Other	16	
Total current assets	22,974	21,908
Property and equipment, net	8,352	8,497
Goodwill	10,660	10,660
Other intangible assets, net	10,361	10,463
Deferred expenses	160	83
Cash value of life insurance	33	32
Total assets	\$ 52,540	\$ 51,643
Liabilities and Stockholders Equity		
Current Liabilities		
Lines-of-credit	\$ 3,649	\$ 3,330
Current maturities of long-term debt	1,185	967
Current maturities of revenue bonds payable	249	249
Accounts payable	2,383	2,255
Accrued expenses	1,903	2,503
Income taxes payable	36	
Deferred revenue	4	6
Total current liabilities	9,409	9,310
Long-Term Liabilities		
Long-term debt, less current maturities	3,676	3,215
Revenue bonds payable, less current maturities	4,077	4,140
Deferred income taxes	2,663	2,663
Deferred compensation		10

Total long-term liabilities	10,416	10,028
Total liabilities	19,825	19,338
Stockholders' Equity		
Common stock at October 29, 2006 and July 31, 2006, \$.001 par value, 50,000,000 shares authorized and \$0.01667 par value; 24,211,809 and 24,206,970 shares issued and outstanding, respectively	24	24
Additional paid-in capital	23,831	23,798
Retained earnings	8,860	8,483
Total stockholders' equity	32,715	32,305
Total liabilities and stockholders' equity	\$ 52,540	\$ 51,643

See Notes to Unaudited Condensed Consolidated Financial Statements.

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Synergetics USA, Inc. and Subsidiaries
Unaudited Condensed Consolidated Statements of Income
Three Months Ended October 29, 2006 and October 27, 2005
(Dollars in thousands, except per share information)

	Three Months Ended October 29, 2006	Three Months Ended October 27, 2005
Sales	\$ 9,906	\$ 7,147
Cost of sales	3,755	2,308
Gross profit	6,151	4,839
Operating expenses		
Research and development	496	277
Selling, general and administrative	4,937	3,802
	5,433	4,079
Operating income	718	760
Other income (expense)		
Interest income		12
Interest expense	(165)	(36)
Miscellaneous	9	
	(156)	(24)
Income before provision for income taxes	562	736
Provision for income taxes	185	250
Net income	\$ 377	\$ 486
Earnings per share:		
Basic	\$ 0.02	\$ 0.04
Diluted	\$ 0.02	\$ 0.04
Basic weighted average common shares outstanding	24,210,680	11,825,344
Diluted weighted average common shares outstanding	24,410,724	11,927,031

See Notes to Unaudited Condensed Consolidated Financial Statements.

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Synergetics USA, Inc. and Subsidiaries
Unaudited Condensed Consolidated Statements of Cash Flows
Three months Ended October 29, 2006 and October 27, 2005
(Dollars in thousands)

	Three Months Ended October 29, 2006	Three Months Ended October 27, 2005
Cash Flows from Operating Activities		
Net income	\$ 377	\$ 486
Adjustments to reconcile net income to net cash used in operating activities		
Depreciation and amortization	356	243
Provision for doubtful accounts receivable	21	3
Stock-based compensation	33	201
Change in assets and liabilities, net of fiscal year 2006 acquisition of Valley Forge:		
(Increase) decrease in:		
Receivables, net	(23)	(114)
Inventories	(1,557)	(1,378)
Prepaid expenses	(52)	(221)
Other current assets	152	(7)
(Decrease) increase in:		
Accounts payable	128	(66)
Accrued expenses and other liabilities	(612)	270
Income taxes payable	36	(43)
Net cash used in operating activities	(1,141)	(626)
Cash Flows from Investing Activities		
Net decrease in notes receivable, officer-stockholder	4	3
Purchase of property and equipment	(75)	(1,451)
Acquisition of patents and other intangibles	(112)	(8)
Cash paid for reverse merger costs		(498)
Cash acquired through reverse merger		2,024
Sales of trading securities	50	
Net cash provided by (used in) investing activities	(133)	70
Cash Flows from Financing Activities		
Net borrowings on lines-of-credit	319	1
Principal payments on revenue bonds payable	(63)	(62)
Proceeds from long-term debt	919	115
Principal payments on long-term debt	(125)	(69)
Payments on debt incurred for acquisition of trademark	(115)	(160)
Proceeds from the exercise of stock options		7
Net cash provided by (used in) financing activities	935	(168)

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Net decrease in cash and cash equivalents	(339)	(724)
Cash and cash equivalents		
Beginning	557	1,817
Ending	\$ 218	\$ 1,093

See Notes to Unaudited Condensed Consolidated Financial Statements.

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Synergetics USA, Inc. and Subsidiaries
Notes to Unaudited Condensed Consolidated Financial Statements
(Dollars in thousands, except per share information)

Note 1. General

Nature of business: Synergetics USA, Inc. (Synergetics USA or the Company) is a Delaware corporation incorporated on June 2, 2005 in connection with the 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. The Company is located in O Fallon, Missouri and King of Prussia, Pennsylvania and is engaged in the manufacture and worldwide sale of microsurgical instruments, capital equipment and devices primarily for use in vitreoretinal surgery and neurosurgical applications. During the ordinary course of its business, the Company grants unsecured credit to its domestic and international customers.

Reporting period: The Company s year end is July 31 of each calendar year. For interim periods, the Company uses a 21 business day per month reporting cycle. As such, the information presented in the Form 10-Q is for the three month periods August 1, 2006 through October 29, 2006 and August 1, 2005 through October 27, 2005, respectively. As such, the three month period contains 63 business days.

Basis of presentation: The unaudited condensed consolidated financial statements include the accounts of Synergetics USA, Inc., and its wholly owned subsidiaries: Synergetics, Synergetics Development Company, LLC and Synergetics IP, Inc. All significant intercompany accounts and transactions have been eliminated. The accompanying unaudited condensed consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States for interim financial information and with the instructions to Form 10-Q and Article 10 of Regulation S-X. Accordingly, they do not include all of the information and notes required by generally accepted accounting principles for complete financial statements. In the opinion of management, all adjustments (consisting of normal recurring items) considered necessary for a fair presentation have been included. Operating results for the three months ended October 29, 2006 are not necessarily indicative of the results that may be expected for the year ending July 31, 2007. These unaudited condensed consolidated financial statements should be read in conjunction with the audited consolidated financial statements of the Company for the year ended July 31, 2006, and notes thereto filed with the Company s Annual Report on Form 10-K filed with the Securities and Exchange Commission on October 16, 2006 (the Annual Report).

Note 2. Summary of Significant Accounting Policies

The Company s significant accounting policies are disclosed in the Annual Report. In the first three months of fiscal 2007, no significant accounting policies were changed.

Reclassifications: Certain reclassifications have been made to prior year financial statements to conform with the current year presentation. Total assets, total liabilities and net income were not affected.

Note 3. Reverse Merger

On September 21, 2005, Synergetics Acquisition Corporation, a wholly owned subsidiary of Valley Forge, merged with and into Synergetics and Synergetics thereby became a wholly owned subsidiary of Valley Forge. Pursuant to the terms of the merger agreement, stockholders of Synergetics common stock received in the aggregate 15,960,648 shares of Valley Forge common stock, or 4.59 Valley Forge shares for each share of Synergetics resulting in Synergetics former private stockholders owning approximately 66 percent of Valley Forge s outstanding common stock upon completion of the reverse merger. The reverse merger was accounted for as a purchase business combination with Synergetics deemed the accounting acquirer and Valley Forge s assets acquired and liabilities assumed recorded at fair value as follows (dollars in thousands):

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Assets:	
Cash, net of merger expenses of \$892	\$ 1,132
Accounts receivable	703
Inventories	926
Prepaid expenses and other current assets	574
Property and equipment	324
Other intangibles	10,183
Goodwill	10,660
Liabilities assumed:	
Accounts payable and accrued expenses	(510)
Income taxes payable	(36)
Note payable issued in connection with Malis® trademark	(3,473)
Deferred income taxes	(2,496)
Net assets acquired	\$ 17,987

The operations of Valley Forge have been consolidated from the acquisition date. The cost to acquire Valley Forge has been allocated to the Valley Forge assets acquired and liabilities assumed according to their estimated fair values. The allocation purchase price of \$18,879,000, including Synergetics' transaction costs, resulted in acquired goodwill of \$10,660,501, which is not deductible for tax purposes.

The unaudited pro forma results, assuming the reverse merger with Valley Forge had occurred at August 1, 2005, would have yielded the following results (dollars in thousands, except per share data):

	Three Months Ended October 27, 2005 (1)
Net sales	\$ 8,019
Net income	321
Basic earnings per share	0.01
Diluted earnings per share	0.01

(1) Prior to the reverse merger, Valley Forge had a fiscal year end of September 30 with quarterly results reported on calendar quarters. Accordingly, the unaudited pro forma condensed combined statement of income for the three months ended October 27, 2005 was derived by adding the results of the three months ended October 27, 2005 for Synergetics, Inc. and the results of the three months ended September 30, 2005 for Valley Forge (which was derived by taking the results of the year ended September 30, 2005 less the results of the nine months ended June 30, 2005).

These pro forma results include adjustments to give effect to interest expense of the trademark-related debt and other purchase price adjustments. The pro forma results are not necessarily indicative of the operating results that would have occurred had the reverse merger been consummated as of August 1, 2005, nor are they necessarily indicative of future operating results.

Note 4. Distribution Agreements

In connection with the reverse merger described in Note 3, the Company became a party to the distribution agreements described below which are in addition to its pre-merger distribution agreements:

Codman and Shurtleff, Inc. (Codman)

In the neurosurgery market, the bipolar electro-surgical system manufactured by Valley Forge prior to the merger has been sold for over 20 years through a series of distribution agreements with Codman, an affiliate of Johnson & Johnson and formerly Valley Forge's largest customer. On October 15, 2004, Valley Forge executed an agreement with Codman for the period October 1, 2004 through December 31, 2005. The agreement provided for exclusive

worldwide distribution rights of Valley Forge's existing neurosurgery products in the fields of neurocranial and neurospinal surgery until March 31, 2005, and non-exclusive rights in these fields from April 1, 2005 through December 31, 2005. On May 6, 2005, in accordance with the terms of the agreement, Valley Forge notified Codman that, effective July 15, 2005, Codman would be the non-exclusive worldwide distributor of its existing products in the fields of neurocranial and neurospinal surgery until December 31, 2005. On January 9, 2006, the Company executed a new, three-year distribution agreement with Codman for the continued distribution by Codman of certain bipolar generators and related disposables and accessories. In addition, the Company entered into a new, three-year license agreement, which provides for the

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continued licensing of Synergetics Malis® trademark to Codman for use with certain Codman products, including those covered by the distribution agreement.

Net sales to Codman amounted to approximately \$1,725,000 for the three month period ended October 29, 2006 and \$380,000 for the period from September 22, 2005 to October 27, 2005, respectively. This represented 17.4 and 5.3 percent of net sales for the three months ended October 29, 2006 and October 27, 2005, respectively.

Stryker Corporation (Stryker)

On October 25, 2004, Valley Forge executed a Supply and Distribution Agreement (the Agreement) with Stryker, a Michigan corporation, which provides that the Company will supply to Stryker and Stryker will distribute exclusively, on a world-wide basis, a unique RF generator for the percutaneous treatment of pain. The Agreement is for a term of five years after the first acceptance of the unique RF generator by Stryker, which was on November 11, 2004.

There is a minimum purchase obligation that is specified by Agreement Year. The first Agreement Year commenced on November 11, 2004 and ended on the last day of the calendar quarter in which the first anniversary date of such inception date occurred, which was December 31, 2005. Stryker satisfied the first Agreement Year minimum. In the second and third Agreement Years, Stryker agreed to make minimum purchases of approximately \$500,000 per year for commercial sale units. On or before the beginning of the last calendar quarter of the third Agreement Year, and each Agreement Year thereafter, the Company and Stryker will conduct good faith negotiations regarding the minimum purchase obligation for the next Agreement Year. Also, during the first two months of the last calendar quarter in any Agreement Year, the Company and Stryker will conduct good faith negotiations regarding changes in prices that will take effect on the first day of the ensuing Agreement Year. The Agreement also grants Stryker the right of first refusal for other generator products in pain control and in orthopedic, ENT (ear, nose and throat), craniomaxillofacial and head and neck surgery.

Net sales to Stryker amounted to approximately \$577,000 for the three month period ended October 29, 2006 and \$225,000 for the period from September 22, 2005 to October 27, 2005, respectively. This represented 5.8 and 3.1 percent of net sales for the three months ended October 29, 2006 and October 27, 2005, respectively.

Note 5. Stock-Based Compensation*Stock Option Plans*

The following table provides information about awards outstanding at October 29, 2006:

	Three Months Ended October 29, 2006		
	Shares	Weighted-Average Exercise Price	Weighted-Average Fair Value
Options outstanding, beginning of period	411,750	\$ 1.98	\$ 1.63
For the period from August 1, 2006 through October 29, 2006:			
Granted		\$	\$
Forfeited		\$	\$
Exercised		\$	\$
Options outstanding, end of period	411,750	\$ 1.98	\$ 1.63
Options exercisable, end of period	354,375	\$ 2.12	\$ 1.75

Restricted Stock Plans

Under our 2001 Plan, our common stock may be granted at no cost to certain employees and consultants of the Company. Certain plan participants are entitled to cash dividends and voting rights for their respective shares. Restrictions limit the sale or transfer of these shares during a vesting period whereby the restrictions lapse either pro-ratably over a five year vesting period or at the end of the fifth year. Upon issuance of stock under the 2001 Plan,

unearned compensation equivalent to the market value at the date of the grant is charged to stockholders' equity and subsequently amortized to expense over the applicable restriction period. During the three

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months ended October 29, 2006, shares granted were 4,839 shares. Compensation expense related to these shares was \$8,900. As of October 29, 2006, there was approximately \$56,000 of total unrecognized compensation cost related to nonvested share-based compensation arrangements granted under the Company's 2001 Plan. The cost is expected to be recognized over a weighted average period of five years.

Note 6: Supplemental Balance Sheets Information

Inventories (dollars in thousands)

	October 29, 2006	July 31, 2006
Raw material and component parts	\$ 6,282	\$ 5,614
Work-in-progress	2,652	2,493
Finished goods	5,866	5,136
	\$ 14,800	\$ 13,243

Property and equipment (dollars in thousands)

	October 29, 2006	July 31, 2006
Land	\$ 730	\$ 730
Building and improvements	5,397	5,340
Machinery and equipment	4,170	4,196
Furniture and fixtures	539	546
Software	105	105
Construction in process	65	
	11,006	10,917
Less accumulated depreciation	2,654	2,420
	\$ 8,352	\$ 8,497

Other intangible assets (dollars in thousands)

Information regarding the Company's other intangible assets is as follows:

	Gross Carrying Value	Accumulated Amortization October 29, 2006	Net
Patents	\$ 907	\$ 197	\$ 710
Proprietary know-how	4,047	428	3,619
Licensing agreements	140	67	73
Organizational costs	36		36
Trademark	5,923		5,923
	\$ 11,053	\$ 692	\$ 10,361
		July 31, 2006	
Patents	\$ 915	\$ 184	\$ 731

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Proprietary know-how	4,057	337	3,720
Licensing agreements	140	51	89
Trademark	5,923		5,923
	\$ 11,035	\$ 572	\$ 10,463

Goodwill is a result of the reverse merger transaction as described in Note 3 to the unaudited financial statements.

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Estimated amortization expense on other intangibles for the remaining nine months of fiscal year ending July 31, 2007 and the next four years thereafter is as follows (dollars in thousands):

Years Ending July 31:	Amount
2007	\$402
2008	370
2009	328
2010	318
2011	303

Amortization expense for the three months ended October 29, 2006 was \$136,681.

Pledged assets; short and long-term debt (excluding revenue bonds payable)

Short-term debt as of October 29, 2006 and July 31, 2006 consisted of the following:

Revolving Credit Facilities: Under a revolving credit facility, the Company may borrow up to \$5.5 million with a graduated interest rate starting at LIBOR plus 2.25 percent and adjusting each quarter based upon the Company's leverage ratio. Borrowings under this facility at October 29, 2006 and July 31, 2006 were \$3.6 million and \$2.6 million, respectively. Outstanding amounts are collateralized by Synergetics' receivables and inventory. This credit facility is scheduled to expire on December 1, 2007. The facility has two financial covenants: a maximum leverage ratio of 3.75 times and a minimum fixed charge coverage ratio of 1.1 times. As of October 29, 2006, the Company's leverage ratio was 1.68 times and the minimum fixed charge coverage ratio was 2.4 times. On December 8, 2006, the aggregate amount available under the revolving credit facility was increased to \$7.5 million from \$5.5 million.

Equipment Line of Credit: Under this credit facility, Synergetics may borrow up to \$1.0 million, with interest at the bank's prime lending rate. Outstanding amounts are secured by the purchased equipment. In October 2006, the Company signed a long-term loan agreement under one new bank note in the principal amount of \$918,925. The Company will make principal payments of \$19,173 plus interest, on a monthly basis. The effective interest rate for this note is 8.25 percent. Final payment is due on November 14, 2010. The equipment line of credit facility of \$1.0 million was also renewed as of this date and expires on October 31, 2007.

Long-term debt as of October 29, 2006 and July 31, 2006 consisted of the following (dollars in thousands):

	October 29, 2006	July 31, 2006
Note payable to bank, due in monthly principal installments of \$1,139 plus interest at prime rate plus 1% (an effective rate of 8.25% as of October 29, 2006), remaining balance due September 2007, collateralized by a second deed of trust	\$ 161	\$ 165
Note payable, due in monthly installments of \$509, including interest at 4.9%, remaining balance due May 2008, collateralized by a vehicle	7	9
Note payable to bank, due in monthly principal installments of \$39,642 beginning November 2005 plus interest at a rate of 6.75%, remaining balance due September 30, 2008, collateralized by substantially all assets of the Company	912	1,031
Note payable to bank, due in monthly installments of \$19,173 beginning December 2006 plus interest at a rate of 8.25%, remaining balance due on November 14, 2010, collateralized by substantially all assets of the Company	919	
Note payable to the estate of the late Dr. Leonard I. Malis, due in quarterly installments of \$159,904 which includes interest at an imputed rate of 6.00%, remaining balance of \$3,357,984, including contractual interest payments, due December 2011, collateralized by the Malis® trademark	2,862	2,977
	4,861	4,182

Less current maturities	1,185	967
Long-term portion	\$ 3,676	\$ 3,215

Note 7. Related Party Transactions

Notes receivable, officer-stockholder represents various loans made during and before 2001 to a principal stockholder, director and officer of the Company. The notes bear interest at rates of 4.83 percent to 6.97 percent and are payable in either quarterly installments of \$3,525 or annual installments of \$14,100 until the principal and accrued interest have been repaid. The notes are collateralized by 5,833 shares of the Company's common stock. At October 29, 2006, notes receivable, officer-stockholder totaled \$16,443 and all amounts are current.

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Also in conjunction with the reverse merger described in Note 3, the Company entered into three-year employment agreements with its Chief Executive Officer, its Chief Operating Officer and its Chief Scientific Officer. In the event any such executive officer is terminated without cause, or if such executive officer resigns for good reason, such executive officer shall be entitled to his base salary and health care benefits through the end of his employment agreement.

On October 19, 2005, IRIDEX Corporation (IRIDEX) filed suit in the United States District Court, Eastern District of Missouri against the Company for patent infringement. This suit is captioned IRIDEX Corporation v. Synergetics USA, Inc., Case No. 4:05CV1916CDP. On November 2, 2006, IRIDEX amended the complaint to add Synergetics. IRIDEX filed suit against the Company and Synergetics for infringement of the IRIDEX Patent No. 5,085,492 entitled Optical Fiber with Electrical Encoding. IRIDEX alleges that Synergetics Quick Disconnect Laser Probes and adapter infringe its patent. It seeks damages, including treble damages, and injunctive relief. On November 10, 2006, the Defendants answered the amended complaint and asked the court to declare that Synergetics products do not infringe the IRIDEX patent. In addition, Synergetics countersued IRIDEX, alleging that it engaged in false advertising, commercial disparagement, trade libel, injurious falsehood and unfair competition under the Federal Lanham Act and applicable Missouri common law. The counterclaim also includes a count of defamation. These claims primarily relate to alleged false or misleading statements and publications by IRIDEX and its representatives with respect to Synergetics laser adapters and laser probes. Litigation in this matter is ongoing. The Company's core liability defenses include non-infringement of the Quick Disconnect adapter, invalidity of the IRIDEX patent in light of the Laserscope patent which may be considered prior art, estoppel and written description. The Company's damage limiting defenses include laches, the doctrine of repair and reconstruction and reasonable royalty rate. The case is expected to come to trial in April 2007. Although the Company believes it has strong defenses, management is not able at this time to predict the ultimate effect of this litigation, if any, on the Company's financial position, results of operations, or cash flows.

On January 10, 2006, Synergetics filed a suit in the United States District Court, Eastern District of Pennsylvania against Innovatech Surgical, Inc. (Innovatech) and Peregrine Surgical Ltd. (Peregrine) for infringement of U.S. Patent No. 6,984,230, and on April 25, 2006 the Court permitted Synergetics to amend its complaint to add IRIDEX, as well. This suit is captioned Synergetics, Inc. v. Peregrine Surgical, Ltd., *et al.*, Case No. 2:06-cv-00107. The suit arises out of the Defendants' sale, use and manufacture of a laser probe that is alleged to infringe Synergetics' patent. Synergetics seeks damages and injunctive relief in this action. Innovatech and Peregrine have asserted by way of affirmative defenses or counterclaims, *inter alia*, that they do not infringe the patent, that the patent in suit is invalid, and that Synergetics engaged in inequitable conduct rendering the patent unenforceable. Innovatech also counterclaimed for alleged violations of the Lanham Act, 15 U.S.C. § 1125. Moreover, Innovatech has moved to add the Company as a party to the case, and to add a counterclaim for violation of the Sherman Act, 15 U.S.C. § 1 and § 2. Synergetics does not believe the patent is invalid, or that it engaged in inequitable conduct or conduct that violated the Lanham Act or Sherman Act, and intends to vigorously prosecute this litigation.

Various other claims, incidental to the ordinary course of business, are pending against the Company. In the opinion of management, after consulting with legal counsel, resolution of these matters is not expected to have a material adverse effect on the accompanying financial statements.

The Company is subject to regulatory requirements throughout the world. In the normal course of business, these regulatory agencies may require companies in the medical industry to change their products or operating procedures, which could affect the Company. The Company regularly incurs expenses to comply with these regulations and may be required to incur additional expenses. Management is not able to estimate any additional expenditure outside the normal course of operations which will be incurred by the Company in future periods in order to comply with these regulations.

Note 9. Segment Information