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VALLEY FORGE SCIENTIFIC CORP

Form 10-Q

February 14, 2005

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 December 31, 2004

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

VALLEY FORGE SCIENTIFIC CORP.  
(Exact name of registrant as specified in its charter)

PENNSYLVANIA  
(State or other jurisdiction of  
incorporation or organization)

23-2131580  
(I.R.S. employer  
identification no.)

136 Green Tree Road, Oaks, Pennsylvania 19456  
(Address of principal executive offices and zip code)  
Telephone: (610) 666-7500

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  No

Indicate by check mark whether the registrant is an accelerated filer (as defined in Rule 12b-2 of the Exchange Act).

Yes  No

At February 8, 2005 there were 7,913,712 shares outstanding of the Registrant's no par value Common Stock.

VALLEY FORGE SCIENTIFIC CORP.

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(i)

VALLEY FORGE SCIENTIFIC CORP. AND SUBSIDIARY  
CONSOLIDATED BALANCE SHEETS

	December 31, 2004 (Unaudited)	September 30, 2004 (Audited)
	-----	-----
<b>ASSETS</b>		
-----		
Current Assets:		
Cash and cash equivalents	\$ 2,714,918	\$ 2,322,559
Accounts receivable - net	441,813	646,224
Inventory	669,329	781,604
Prepaid items and other current assets	246,790	146,411
Deferred tax assets	74,655	79,752
	-----	-----
Total Current Assets	4,147,505	3,976,550
Property, plant and equipment - net	170,435	147,967
Goodwill	153,616	153,616
Intangible assets - net	208,224	218,398
Other assets	7,894	26,707
	-----	-----
Total Assets	\$ 4,687,674	\$ 4,523,238
	=====	=====
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
-----		
Current Liabilities:		
Accounts payable and accrued expenses	\$ 341,576	\$ 245,828
Deferred revenue	12,940	5,750
Income taxes payable	-	6,491
	-----	-----

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Total Current Liabilities	354,516	258,069
Deferred Tax Liability	15,311	15,743
Total Liabilities	369,827	273,812
Contingency		
Stockholders' Equity:		
Preferred stock	-	-
Common stock (no par, 20,000,000 shares authorized, shares issued and outstanding at December 31, 2004 and September 30, 2004 - 7,913,712)	3,528,530	3,528,530
Retained earnings	789,317	720,896
Total Stockholders' Equity	4,317,847	4,249,426
Total Liabilities and Stockholders' Equity	\$ 4,687,674	\$ 4,523,238

See accompanying notes to consolidated financial statements.

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VALLEY FORGE SCIENTIFIC CORP. AND SUBSIDIARY  
CONSOLIDATED STATEMENTS OF INCOME  
(UNAUDITED)

	For the Three Months Ended December 31,	
	2004	2003
Net Sales	\$ 1,412,376	\$ 1,199,469
Cost of Sales	648,121	555,304
Gross Profit	764,255	644,165
Other Costs:		
Selling, general and administrative	440,704	398,337
Research and development	207,695	113,895
Amortization	10,174	10,075
Total Other Costs	658,573	522,307
Income from Operations	105,682	121,858
Other Income - Net	8,106	5,669

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Income before Income Taxes	113,788	127,527
Provision for Income Taxes	45,367	54,548
	-----	-----
Net Income	\$ 68,421	\$ 72,979
	=====	=====
Income per Share:		
Basic income per common share	\$ 0.01	\$ 0.01
	=====	=====
Diluted income per common share	\$ 0.01	\$ 0.01
	=====	=====
Basic weighted average common shares outstanding	7,913,712	7,913,712
Diluted weighted average common shares outstanding	7,975,552	7,965,977

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See accompanying notes to consolidated financial statements.

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VALLEY FORGE SCIENTIFIC CORP. AND SUBSIDIARY  
CONSOLIDATED STATEMENTS OF CASH FLOWS  
(UNAUDITED)

	For the Three Months Ended December 31,	
	2004	2003
	-----	-----
Cash Flows from Operating Activities:		
Net income	\$ 68,421	\$ 72,979
Adjustments to reconcile net income to net cash provided by operating activities:		
Depreciation and amortization	17,666	17,732
Interest accrued on loans and advances to employees and related parties	(566)	(616)
Deferred income taxes	4,665	(2,252)
Changes in assets and liabilities:		
(Increase) decrease in:		
Accounts receivable	204,411	(89,420)
Inventory	112,275	83,667
Prepaid items and other current assets	(99,741)	(14,743)
Other assets	4,413	4,414
Increase (decrease) in:		
Accounts payable and accrued expenses and income taxes payable	89,257	28,904
Deferred revenue	7,190	22,310
	-----	-----
Net cash provided by operating activities	407,991	122,975
	-----	-----

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Cash Flows from Investing Activities:		
Purchases of property, plant and equipment	(15,632)	(1,802)
	-----	-----
Net cash (used in) investing activities	(15,632)	(1,802)
	-----	-----
Net Change in Cash and Cash Equivalents	392,359	121,173
Cash and Cash Equivalents - Beginning of Period	2,322,559	2,305,556
	-----	-----
Cash and Cash Equivalents - End of Period	\$ 2,714,918	\$ 2,426,729
	=====	=====
Schedule of non-cash operating and investing activities:		
Use of deposit for acquisition of property, plant and equipment	\$ 14,400	\$ -
	=====	=====
Supplemental Disclosures of Cash Flow Information:		
Cash paid during the period for:		
Interest	\$ -	\$ -
Income taxes	42,588	-

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See accompanying notes to consolidated financial statements.

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VALLEY FORGE SCIENTIFIC CORP. AND SUBSIDIARY  
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (UNAUDITED)  
DECEMBER 31, 2004

NOTE 1 - DESCRIPTION OF BUSINESS:

Valley Forge Scientific Corp. ("VFSC") was incorporated on March 27, 1980, in the Commonwealth of Pennsylvania and is engaged in the business of developing, manufacturing, and selling medical devices and products. On August 18, 1994, VFSC formed a wholly-owned subsidiary, Diversified Electronics Company, Inc. ("DEC"), a Pennsylvania corporation, in order to continue the operations of Diversified Electronic Corporation, a company which was merged with and into VFSC on August 31, 1994. Collectively, VFSC and DEC are referred to herein as the "Company".

NOTE 2 - SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES:

Principles of Consolidation and Basis of Presentation

-----  
The accompanying financial statements consolidate the accounts of VFSC and its wholly-owned subsidiary. All significant intercompany accounts and transactions have been eliminated in consolidation

The accompanying unaudited consolidated financial statements have been prepared pursuant to rules and regulations of the Securities and Exchange Commission and, therefore, do not include all information and footnote disclosures normally

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included in audited financial statements. However, in the opinion of management, all adjustments that are of a normal and recurring nature, necessary to present fairly the results of operations, financial position, and cash flows have been made. It is suggested that these statements be read in conjunction with the financial statements included in the Company's Annual Report on Form 10-K for the year ended September 30, 2004.

The statements of operations for the three months ended December 31, 2004, are not necessarily indicative of results for the full year.

### Earnings per Share

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The Company computes earnings per share in accordance with Statement of Financial Accounting Standards No. 128, "Earnings Per Share" (SFAS 128). Basic earnings per share are computed by dividing income available to common stockholders by the weighted average number of common shares outstanding. Diluted earnings per share reflect the potential dilution that could occur if securities or other agreements to issue common stock were exercised or converted into common stock. Diluted earnings per share is computed based upon the weighted average number of common shares and dilutive common equivalent shares outstanding, which include convertible debentures, stock options, and warrants.

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### VALLEY FORGE SCIENTIFIC CORP. AND SUBSIDIARY NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (UNAUDITED) DECEMBER 31, 2004

#### NOTE 2 - SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (CONTINUED):

##### Recently Issued Accounting Standards

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In December, 2003, the Financial Accounting Standards Board ("FASB") issued a revised Interpretation No. 46, "Consolidation of Variable Interest Entities - An Interpretation of ARB No. 51," which provides guidance on the identification of and reporting for variable interest entities for consideration in determining whether a variable interest entity should be consolidated. Interpretation No. 46, as revised, is effective for the Company in the third quarter of fiscal 2004. The adoption of Interpretation No. 46 had no impact on the Company's results of operations for the quarter ended December 31, 2004, or its financial condition at that date, nor is it expected to have a significant impact in the future.

In December 2004, the FASB issued SFAS No. 123(R), "Share-Based Payment," which replaces SFAS 123, "Accounting for Stock-Based Compensation" ("SFAS No. 123"), and supersedes Accounting Principles Board Opinion No. 25, "Accounting for Stock Issued to Employees" ("APB No. 25"). SFAS 123(R) requires companies to recognize in their income statement the grant-date fair value of stock options and other equity-based compensation issued to employees. This SFAS is effective for most public companies for interim and annual reporting periods beginning after June 15, 2005. Grant-date fair value will be determined using one of two acceptable valuation models. This Standard requires that compensation expense for most equity-based awards be recognized over the requisite service period, usually the vesting period; while compensation expense for liability-based awards (those usually settled in cash rather than stock) be re-measured to fair-value at each balance sheet date until the award is settled. The Standard also provides guidance as to the accounting treatment for income taxes related to such compensation costs, as well as transition issues related to adopting the new

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Standard. The Company has been using the intrinsic value method as set forth under APB No. 25 with no stock-based compensation cost reflected in net earnings while complying with footnote disclosure requirements of SFAS No. 123 setting forth the pro forma effect on net earnings of applying fair value recognition to stock based awards. The Company is currently evaluating the requirements of SFAS 123(R).

In December 2004, the FASB issued SFAS No. 153, "Exchange of Non-monetary Assets an amendment of APB Opinion No. 29." This Statement precludes companies from using the "similar productive assets" criteria to account for non-monetary exchanges at book value with no gain or loss being recognized. Effective for fiscal periods beginning after June 15, 2005, all companies will be required to use fair value for most non-monetary exchanges, recognizing gain or loss, if the transaction meets commercial, substance criteria. The Company does not expect this Standard to have a significant impact on its current consolidated financial statements.

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### VALLEY FORGE SCIENTIFIC CORP. AND SUBSIDIARY NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (UNAUDITED) DECEMBER 31, 2004

#### NOTE 2 - SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (CONTINUED):

##### Recently Issued Accounting Standards (Continued)

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In November 2004, the FASB issued Statement No. 151, "Inventory Costs, an amendment of ARB 43, Chapter 4" ("SFAS 151"), to clarify the accounting for abnormal amounts of idle facility expense, freight, handling costs, and wasted materials (spoilage). ARB 43 allowed some of these "abnormal costs" to be carried as inventory, whereas the new Standard requires that these costs be expensed as incurred. This Statement is effective for fiscal years beginning after June 15, 2005. The Company is currently evaluating what effect, if any, this standard will have on its current consolidated financial statements.

In December 2004, the FASB issued FSP FAS 109-1, "Application of FASB Statement No. 109, "Accounting for Income Taxes," to the "Tax Deduction on Qualified Production Activities Provided by the American Jobs Creation Act of 2004" to provide accounting guidance on the appropriate treatment of tax benefits generated by the enactment of the Act. The FSP requires that the manufacturer's deduction be treated as a special deduction in accordance with SFAS 109 and not as a tax rate reduction. The Company is awaiting final tax regulations from the IRS before completing its assessment of the impact of adopting FSP FAS 109-1 on its current consolidated financial statements.

##### Stock-Based Compensation

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In December 2002, the FASB issued Statement of Financial Accounting Standards ("SFAS") No. 148, "Accounting for Stock-Based Compensation - Transition and Disclosure - an amendment of FASB Statement No. 123." SFAS No. 148 amended SFAS No. 123, "Accounting for Stock-Based Compensation," to provide alternative methods of transition for a voluntary change to the fair value based method of accounting for stock-based employee compensation. In addition, SFAS No. 148 amended the disclosure requirements of SFAS No. 123 to require prominent disclosures in both annual and interim financial statements about the method of accounting for stock-based employee compensation and the effect of the method used on reported results. SFAS No. 148 is effective for the Company as of

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January 1, 2003. The Company has not elected a voluntary change in accounting to the fair value based method. Accordingly, the adoption of SFAS No. 148 did not have a significant impact on the Company's results of operations or financial position.

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VALLEY FORGE SCIENTIFIC CORP. AND SUBSIDIARY  
 NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (UNAUDITED)  
 DECEMBER 31, 2004

NOTE 2 - SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (CONTINUED):

Stock-Based Compensation (Continued)  
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The Black-Scholes option valuation model was developed for use in estimating the fair value of traded options which have no vesting restrictions and are fully transferable. In addition, option valuation models require the input of highly subjective assumptions including the expected stock price volatility. Because the Company's stock options have characteristics significantly different from those of traded options, and because changes in subjective input assumptions can materially affect the fair value estimated, in management's opinion, the existing models do not necessarily provide a reliable single measure of the fair value of its stock options. In addition, option pricing models require the input of highly subjective assumptions, including expected stock price volatility.

For purposes of pro forma disclosures, the estimated fair value of the options is amortized to expense over the options' vesting period. In accordance with SFAS 123 and 148, only stock options granted after September 30, 1995, have been included for the Company's pro forma information as follows:

	Three Months Ended December 31,	
	2004	2003
Net income - as reported	\$ 68,421	\$ 72,979
Less: total compensation expense determined under fair value based method - net of tax effect	-	-
Pro Forma Net Income	\$ 68,421	\$ 72,979
Pro Forma Income Per Share:		
Basic	\$ 0.01	\$ 0.01
Diluted	\$ 0.01	\$ 0.01

Revenue Recognition  
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Product revenue is recognized when the product has been shipped, which is when title and risk of loss has been transferred to the customer.

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VALLEY FORGE SCIENTIFIC CORP. AND SUBSIDIARY  
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (UNAUDITED)  
DECEMBER 31, 2004

NOTE 3 - DISTRIBUTION AGREEMENTS:

The Company sells its products to U.S. based national and international distributors and dealers including those as described below:

Codman and Shurtleff, Inc. ("Codman")  
-----

A significant part of the Company's sales were made pursuant to a distribution agreement with Codman, an affiliate of a major medical company and the Company's largest customer. The agreement provided for worldwide exclusive distribution rights of neurosurgery products during the term. This distribution agreement included minimum purchase obligations which were adjusted annually during the term of the agreement. It also included a price list for the specified products, which was fixed for a period of time, after which those prices were subject to adjustment by the Company due to changes in manufacturing cost or technological improvements to the products. On October 15, 2004, the Company executed a new agreement with Codman for the period October 1, 2004 through December 31, 2005. The agreement provides for exclusive worldwide distribution rights of the Company'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. The agreement also includes a price list for the specified products, and a minimum purchase obligation of \$1,000,000 per calendar quarter, through March 31, 2005. There is no minimum purchase obligation for the period April 1, 2005 through December 31, 2005. The agreement also provides that the above-indicated periods of exclusive and nonexclusive distribution rights can each be extended by mutual consent of the parties.

During the quarter ended December 31, 2004, Codman did not meet its minimum purchase obligation under the agreement for the quarter by approximately \$113,000 and is proposing increasing its minimum purchase obligation by such amount for the quarter ended March 31, 2005.

Stryker Corporation ("Stryker")  
-----

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

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VALLEY FORGE SCIENTIFIC CORP. AND SUBSIDIARY  
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (UNAUDITED)  
DECEMBER 31, 2004

NOTE 3 - DISTRIBUTION AGREEMENTS (CONTINUED):

Stryker Corporation ("Stryker") (Continued)

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There is a minimum purchase obligation that is specified by "Agreement Year." The first Agreement Year commenced on the date of the first acceptance by Stryker of a generator product delivered by the Company as ready for commercial sale, which was November 11, 2004, and ends on the last day of the calendar quarter in which the first anniversary date of such inception date occurs. In the first Agreement Year, Stryker is required to make minimum purchases of \$900,000 comprised of demonstration and commercial sales units. In the second and third Agreement Years, Stryker is required to make minimum purchases in each year of \$500,000 of commercial sales 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 provides Stryker certain rights for other new product concepts developed by the Company in both pain control and expanded market areas. The Agreement contains various terms related to the provision of repair services for the product by the Company and maintenance of spare parts, the distributor's obligation to market the product, to provide training to sales personnel, and other provisions.

NOTE 4 - OPTION AGREEMENT:

On October 22, 2004, the Company entered into an Option Agreement with Dr. Leonard I. Malis, a director and stockholder of the Company, giving the Company the right to purchase from Dr. Malis his "Malis" trademark at any time over a period of five years. The Company paid Dr. Malis \$35,000 for the option and is required to pay an annual fee before each anniversary of the option agreement \$20,000 for each of the first two anniversaries and increasing to \$60,000 before the fourth anniversary in order to keep the option in effect from year to year. The exercise price of the option is \$4,157,504 and would be paid with an initial payment of \$159,904 and the execution of a note payable to Dr. Malis for \$3,997,600, including interest. This note would be secured by a security interest in the Company's rights to the "Malis" trademark and certain of the Company's patents.

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VALLEY FORGE SCIENTIFIC CORP. AND SUBSIDIARY  
 NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (UNAUDITED)  
 DECEMBER 31, 2004

NOTE 5 - SUPPLEMENTAL BALANCE SHEET INFORMATION:

Accounts Receivable - Net  
 -----

	December 31, 2004	September 30, 2004
	-----	-----
Accounts receivable	\$ 457,293	\$ 661,704
Less: Allowances	15,480	15,480
	-----	-----
Accounts receivable - net	\$ 441,813	\$ 646,224
	=====	=====

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Inventory

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	December 31, 2004	September 30, 2004
	-----	-----
Finished goods	\$ 163,376	\$ 94,405
Work-in-process	239,006	396,810
Materials and parts	409,449	424,052
	-----	-----
	811,831	915,267
Less: Allowances for slow moving and obsolete inventory	142,502	133,663
	-----	-----
	\$ 669,329	\$ 781,604
	=====	=====

Property, Plant and Equipment - Net

-----

	Useful Life (Years)	December 31, 2004	September 30, 2004
		-----	-----
Land	-	\$ 11,953	\$ 11,953
Buildings and improvements	15 - 39	103,467	103,467
Furniture and fixtures	5 - 7	17,953	17,953
Laboratory equipment	5 - 10	406,959	378,159
Office equipment	5	186,762	185,530
Leasehold improvements	3 - 5	9,413	9,413
		-----	-----
		736,507	706,475
Less: Accumulated depreciation and amortization		566,072	558,508
		-----	-----
		\$ 170,435	\$ 147,967
		=====	=====

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VALLEY FORGE SCIENTIFIC CORP. AND SUBSIDIARY  
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (UNAUDITED)  
DECEMBER 31, 2004

NOTE 5 - SUPPLEMENTAL BALANCE SHEET INFORMATION (CONTINUED):

Property, Plant and Equipment - Net (Continued)

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Depreciation amounted to \$7,492 and \$7,657 for the three months ended December 31, 2004 and 2003, respectively.

Goodwill and Intangible Assets

-----

In accordance with SFAS 142, Goodwill has been reflected on the balance sheet separate from other intangible assets which continue to be amortized. No change in the carrying amount of goodwill was made for the quarter ended December 31, 2004. The Company completed its annual impairment test during the quarter ended March 31, 2004, and no impairment was identified.

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

	December 31, 2004			September 30,	
	Gross Carrying Value	Accumulated Amortization	Net	Gross Carrying Value	Accumulate Amortizati
Patents, trademarks and licensing agreements	\$ 573,804	\$ 506,312	\$ 67,492	\$ 573,804	\$ 503,6
Proprietary know-how	452,354	311,622	140,732	452,354	304,0
Acquisition costs	55,969	55,969	-	55,969	55,9
	\$ 1,082,127	\$ 873,903	\$ 208,224	\$ 1,082,127	\$ 863,7
	\$ 1,082,127	\$ 873,903	\$ 208,224	\$ 1,082,127	\$ 863,7

Amortization expense of intangible assets amounted to \$10,174 and \$10,075 for the three months ended December 31, 2004 and 2003, respectively.

Annual amortization expense for intangible assets held as of December 31, 2004, is estimated to be \$40,800 for 2005, \$40,800 for 2006, \$40,700 for 2007, \$40,100 for 2008, \$34,900 for 2009 and \$21,100 thereafter.

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VALLEY FORGE SCIENTIFIC CORP. AND SUBSIDIARY  
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (UNAUDITED)  
DECEMBER 31, 2004

NOTE 7 - CONTINGENCY:

On September 19, 2002, the Company was served with a complaint that was filed in the Superior Court of the State of Arizona, County of Maricopa, entitled Jeffrey Turner and Cathryn Turner et al v. Phoenix Children's Hospital, Inc., et al, (CV 2002-010791) in which the Company was named as one of the defendants. The plaintiffs seek damages from all defendants for permanent brain damage suffered by a four year old girl during a surgery that took place in June 2000. The alleged damages sought by the plaintiffs against all parties are in excess of the Company's product liability insurance policy limit of \$1,000,000, and the Company's net worth. The claim against the Company is a products liability claim. The Company's product liability insurance carrier is providing the Company's defense in this matter. This insurance coverage has a \$10,000 deductible that applies to attorney fees and damages, which has been provided for in other costs under selling, general and administrative expense for the year ended September 30, 2002. In an answer that was filed on November 26, 2002, the Company denied any wrongdoing. The Company believes the claim is without merit and is vigorously defending itself in this action. This case is currently in the discovery process.

NOTE 8 - EARNINGS PER SHARE:

Three Months Ended December 31,	
2004	2003
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Income available to common stockholders	\$ 68,421	\$ 72,979
	=====	=====
Weighted average common shares outstanding - basic	7,913,712	7,913,712
Net effect of dilutive shares issuable in connection with stock plans	61,840	52,265
	-----	-----
Weighted average common shares outstanding - diluted	\$ 7,975,552	\$ 7,965,977
	=====	=====
Earnings Per Share:		
Basic	\$ 0.01	\$ 0.01
Diluted	\$ 0.01	\$ 0.01

Options to purchase 507,250 and 477,350 shares of common stock were outstanding on December 31, 2004 and 2003, respectively. Of these shares, 445,410 and 425,085 shares were not included in the computation of diluted earnings per share for the three months ended December 31, 2004 and 2003, respectively, in accordance with SFAS 128, as the issuance prices were in excess of the average market price for the period.

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### Item 2. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

The following is a discussion and analysis of Valley Forge Scientific Corp.'s financial condition and results of operations for the quarterly periods ended December 31, 2004 and 2003. This section should be read in conjunction with the financial statements and related notes in Item 1 of this report and Valley Forge Scientific Corp.'s annual report on Form 10-K for the year ended September 30, 2004, which has been filed with the Securities and Exchange Commission. This discussion and analysis contains forward-looking statements that involve risks, uncertainties and assumptions. Our actual results may differ materially from those anticipated in these forward looking statements as a result of many factors including but not limited to those under the headings "Special Note Regarding Forward Looking Statements" and "Factors That Might Affect Future Results". Unless the context requires otherwise, references to "we", "us", "our" and "Valley Forge Scientific" refer to Valley Forge Scientific Corp.

#### Overview

Valley Forge is a medical device company that develops, manufactures and sells medical devices for use in surgery and other healthcare applications. Our core business involves the sale of bipolar electrosurgical generators and other bipolar generators, based on our DualWave(TM) technology, and complementary instrumentation and disposable products.

Our current line of bipolar electrosurgical products are used in neurosurgery and spine surgery and in dental applications. We also recently commenced selling a lesion generator for the percutaneous treatment of pain. We plan to expand the market for our products with our new multifunctional bipolar electrosurgical generator and new proprietary single-use hand-switching bipolar instruments, new products based on our proprietary lesion generator technology, and other products and product refinements. Our new multifunctional bipolar electrosurgical system, which is expected to be introduced in the market in fiscal 2005, is designed to replace other surgical tools, such as monopolar electrosurgical systems, lasers and ultrasonic aspirators.

We believe our DualWave(TM) technology distinguishes our products from our

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competitors. With appropriate technique, our bipolar electro-surgical systems based on our DualWave(TM) technology allow a surgeon or dentist to cut tissue in a manner that minimizes collateral damage to surrounding healthy tissue and to coagulate blood vessels quickly, safely and efficiently. By substantially reducing damage to surrounding healthy tissue, the surgeon or dentist can work safely in close proximity with nerves, blood vessels and bone. Our bipolar electro-surgical systems can also be used in close proximity with metal implants and irrigated fields.

For over 20 years, we have had worldwide exclusive distribution agreements with Codman & Shurtleff, Inc. ("Codman"), a subsidiary of Johnson & Johnson, Inc., to market our neurosurgery bipolar electro-surgical systems and other products. On October 15, 2004, we entered into a new agreement with Codman defining our business relationship from October 1, 2004 through December 31, 2005. Under that agreement, Codman continues to be the exclusive worldwide distributor of our existing products in the fields of neurocranial and neurospinal surgery through March 31, 2005 and the nonexclusive distributor in

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those fields until December 31, 2005, as those terms may be extended by mutual agreement of the parties. Under the agreement, Codman is also given a limited right of first refusal until March 31, 2005 regarding the marketing of our new multifunctional electro-surgical generator and single use hand switching bipolar instruments in the fields of neurospinal and neurocranial surgery. Historically, we have derived a significant portion of our sales from sales to Codman. For the quarterly period ended December 31, 2004 and the year ended September 30, 2004, 66% and 86%, respectively, of our revenue was derived from sales to Codman.

Our goal is to be the global leader in the development of bipolar medical devices and other products in specialty surgical and healthcare fields. The key elements of our strategy include:

- o Expanding the use of our new multifunctional bipolar electro-surgical system into other surgical markets, such as, spine, maxillofacial, ENT, orthopedic and general surgery.
- o Increasing revenues in the neurosurgery field with our new multifunctional bipolar electro-surgical system.
- o Expanding our product lines with new products and other applications of our bipolar lesion technology.

### Results of Operations

Results of Operations for the Three Months Ended December 31, 2004 compared to the Three Months Ended December 31, 2003.

#### Summary -----

Sales of \$1,412,376, for three months ended December 31, 2004 were 18% greater than sales of \$1,199,469 for the three months ended December 31, 2003. Operating income was \$105,682 for the three months ended December 31, 2004 as compared to \$121,858 for the three months ended December 31, 2003. Net income for the three months ended December 31, 2004 was \$68,421 as compared to net income of \$72,979 for the three months ended December 31, 2003.

### Sales

Total Sales and Gross Margin on Sales:

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	Unaudited	
	Three Months Ended	
	December 31,	
	2004	2003
	----	----
Total sales:	\$1,412,376	\$1,199,469
Cost of sales:	648,121	555,304
Gross profit on sales:	764,255	644,165
Gross profit as a percentage of sales:	54%	54%

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The increase in sales in first quarter of the 2005 fiscal year as compared to the first quarter of the 2004 fiscal year reflects new sales to Stryker Corporation of a lesion generator model we developed for the percutaneous treatment of pain, offset by decreased sales to Codman and a decrease in sales of our dental products.

During the first quarter of fiscal 2005, we had sales to Stryker Corporation of \$375,000 pursuant to a supply and distribution agreement we entered into on October 25, 2004. There were no sales of this product during the three months ended December 31, 2003. The supply and distribution agreement is for a term commencing on November 11, 2004 and ending on December 31, 2009, under which Stryker has agreed to make minimum purchases of approximately \$900,000 in the first agreement year for a combination of sales demonstration units and commercial sale units and minimum purchases of approximately \$500,000 per year for commercial sale units in the each of the second and third agreement years. Minimum purchase requirements for agreement years four and five are to be determined by the parties based on market conditions and other factors. The agreement also provides Stryker certain rights for other new product concepts developed by Valley Forge in both pain control and expanded market areas.

Sales of our neurosurgical products to, and repair revenue from, Codman & Shurtleff, Inc. decreased to \$935,770 in the first quarter of fiscal 2005 as compared to sales of \$1,025,965 in the first quarter of 2004. The decrease reflects a difference in the timing of shipments to Codman. On October 15, 2004, we entered into a new agreement with Codman which defines our business relationship from October 1, 2004 to December 31, 2005. Under the new agreement, Codman continues to be the exclusive worldwide distributor of our existing products in the fields of neurocranial and neurospinal surgery through March 31, 2005, and the nonexclusive distributor in those fields until December 31, 2005, as those terms may be extended by mutual agreement of the parties. For the period from October 1, 2004 to March 31, 2005, Codman agreed to make minimum purchases of \$1 million per calendar quarter in order to maintain its exclusivity. Codman did not satisfy its minimum purchase requirements for the three months ended December 31, 2004, and Codman is proposing to increase its minimum purchase obligations by approximately \$113,000 for the quarter ending March 31, 2005 to make up for the shortfall.

For the first quarter of fiscal 2005, sales of the Bident(R) Bipolar Tissue Management System for dental applications decreased to \$72,827, or 5% of sales, as compared to \$170,049, or 14% of sales, for the first quarter of fiscal 2004. We are considering product modifications and other strategies for our dental products.

Sales by Medical Field:

The table below sets forth our sales by medical field of "Generators, Irrigators and Other Products" and "Disposable Products" for the three months

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ended December 31, 2004, and 2003. Sales of "Generators, Irrigators and Other Products" in "Other fields" represent sales to Stryker Corporation and sales of "Disposable Products" in "Other fields" represent sales to Boston Scientific Corporation and direct sales to hospitals.

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	For the Three Months Ended December 31,	
	2004	2003
	----	----
Generators, Irrigators and Other Products		
Neurosurgery field	\$481,025	\$607,391
Dental field	61,509	152,039
Other fields	390,000	
	-----	-----
Total of all fields:	\$932,534	\$759,430
	=====	=====
Disposable Products		
Neurosurgery field	\$411,810	\$371,585
Dental field	11,318	18,010
Other fields	10,520	2,858
	-----	-----
Total of all fields:	\$433,648	\$392,453
	=====	=====

For the first quarter of fiscal 2005, 66% of our sales related to sales of bipolar electrosurgical generators, irrigators and accessories as compared to approximately 59% of our sales for the first quarter of fiscal 2004. Sales of disposable products accounted for approximately 31% of our sales in the first quarter fiscal 2005 as compared to approximately 36% of our sales in the first quarter of fiscal 2004.

### Cost of Sales

Cost of sales was 46% of sales for the three months ended December 31, 2004 and the three months ended December 31, 2003. Gross margin was 54% for the three months ended December 31, 2004 for the three months ended December 31, 2003.

We cannot be sure that gross margins will remain at current levels or show improvement in the future due to the distribution channels used, product mix, and fluctuation in manufacturing production levels and overhead costs as new products are introduced. In addition, inefficiencies in manufacturing new products and the distribution channels utilized to sell those products may adversely impact gross margin.

### Operating Expenses

Selling, general and administrative expenses, as a percentage of sales, decreased from 33% for the three months ended December 31, 2003 to 31% for the three months ended December 31, 2004. Selling, general and administrative expenses increased to \$440,704 for the three months ended December 31, 2004 from \$398,337 for the three months ended December 31, 2003. The increase reflects increases in professional fees partially offset by decreases in sales and marketing expenses.

Research and development expenses were \$207,695, or 15% of sales, for the three months ended December 31, 2004 as compared to \$113,895, or 9% of sales, for the three months ended December 31, 2003. We will continue to invest in



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research and development to expand our technological base for use in both

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existing and additional clinical areas. The increase in research and development expenses in the first quarter of fiscal 2005 was primarily related to the continued development of our new multifunction bipolar electrosurgical generator and instrumentation and also for the completion of the lesion generator model being sold to Styker Corporation.

### Other Income

Other income increased slightly for the three months ended December 31, 2004, to \$8,106 from \$5,669 for the three months ended December 31, 2003 due primarily to interest income. At December 31, 2004, we had \$2,714,918 in cash and cash equivalents as compared to \$2,426,726 at December 31, 2003.

### Income Tax Provision

The provision for income taxes was \$45,367 for the three months ended December 31, 2004 as compared to \$54,548 for the three months ended December 31, 2003. Our effective tax rate for the three months ended December 31, 2004 was approximately 40% as compared to approximately 43% for the three months ended December 31, 2003.

### Net Income

Net income decreased slightly to \$68,421 for the three months ended December 31, 2004, as compared to net income of \$72,979 for the three months ended December 31, 2003. Basic and diluted income per share was \$0.01 for the three months ended December 31, 2004 and the three months ended December 31, 2003.

### Liquidity and Capital Resources

At December 31, 2004, we had \$3,792,989 in working capital compared to \$3,718,481 at September 30, 2004 and \$3,560,999 at December 31, 2003. The primary measures of our liquidity are cash, cash equivalents, accounts receivable and inventory balances. The cash equivalents are highly liquid with original maturities of ninety days or less.

Cash provided by operating activities was \$407,991 for the three months ended December 31, 2004 as compared to \$122,975 for the three months ended December 31, 2003. The cash provided by operating activities was mainly attributable to operating profits net of adjustments for non-cash items, a decrease in accounts receivable of \$204,411, a decrease in inventory of \$112,275 and an increase in accounts payable and accrued expenses and income taxes payable of \$89,257, partially offset by an increase in prepaid items and other current assets of \$99,741.

In the first quarter of fiscal 2005, accounts receivable net of allowances decreased by \$204,411 to \$441,813 at December 31, 2004 from \$646,224 at September 30, 2004. The decrease in accounts receivable was principally due to improved collections and the timing of shipments.

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In the first quarter of fiscal 2005, inventories decreased by \$112,275 to \$669,329 at December 31, 2004 from \$781,604 at September 30, 2004. The decrease was primarily due to improved inventory management and increased sales.

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For the three months ended December 31, 2004, we used \$15,632 for the purchase of equipment and building improvements in connection with our manufacturing operations. Net property and equipment increased to \$170,435 at December 31, 2004 as compared to \$147,967 at September 30, 2004.

In August 2002, our Board of Directors terminated our then existing stock repurchase plan and authorized a new repurchase plan to purchase up to 200,000 shares of our common stock. We did not purchase any of our stock in the first quarter of fiscal 2005 pursuant to this plan. To date, we have repurchased 154,100 shares of our common stock under the plan, leaving a balance of 45,900 that is available for repurchase under the plan.

On October 22, 2004, we entered into an option agreement to purchase the Malis(R) trademark from Leonard I. Malis. Under the option agreement, we are granted an option to acquire the Malis(R) trademark at any time over a period of five years. We paid Dr. Leonard I. Malis \$35,000 for the option and are required to pay an annual fee before each anniversary of the option agreement of \$20,000 for each of the first two anniversaries and increasing to \$60,000 before the fourth anniversary in order to continue the option in effect from year to year. In the event that we decide to exercise the option, we will pay Dr. Leonard I. Malis \$4,157,054, which includes interest, in twenty-six equal quarterly installments of \$159,104, and which will be evidenced by a promissory note secured with a security interest in the trademark and certain of our patents.

At December 31, 2004, we had cash and cash equivalents of \$2,714,918. We plan to finance our operating and capital needs principally with cash flows from operations and existing balances of cash and cash equivalents, which we believe will be sufficient to fund our operations in the near future. However, should it be necessary, we believe we could borrow adequate funds at competitive rates and terms. Our future liquidity and capital requirements will depend on numerous factors, including the funds we expend in marketing, selling and distributing our products, the success in commercializing our existing products, development and commercialization of products in other clinical markets, the ability of our suppliers to continue to meet our demands at current prices, the status of regulatory approvals and competition.

We have a line of credit of \$1,000,000 with Wachovia Bank, N.A. which calls for interest to be charged at the bank's national commercial rate. The credit accommodation is unsecured and requires us to have a tangible net worth of no less than \$3,000,000. Our current tangible net worth exceeds \$3,000,000 at December 31, 2004. As of December 31, 2004, there was no outstanding balance on this line.

### USE OF ESTIMATES AND CRITICAL ACCOUNTING POLICIES

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The preparation of financial statements and related disclosures in conformity with accounting principles generally accepted in the United States requires management to make judgments, assumptions, and estimates that affect the amounts reported in the Consolidated Financial Statements and accompanying

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notes. Note 1 to the Consolidated Financial Statements describes the significant accounting policies and methods used in the preparation of the Consolidated Financial Statements. Estimates are used for, but not limited to, the accounting for the allowance for doubtful accounts and sales returns, inventory allowances, warranty costs, contingencies and other special charges, and taxes. Actual results could differ materially from these estimates. The following critical accounting policies are impacted significantly by judgments, assumptions, and

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estimates used in the preparation of the Consolidated Financial Statements.

### Allowances For Doubtful Accounts, Sales Returns and Warranty Costs

We evaluate the collectibility of accounts receivable based on a combination of factors. In circumstances where a specific customer is unable to meet its financial obligations to us, we record an allowance against amounts due to reduce the net recognized receivable to the amount that we reasonably expect to collect. For all other customers, we record allowances for doubtful accounts based on the length of time the receivables are past due, the current business environment and our historical experience. If the financial condition of customers or the length of time that receivables are past due were to change, we may change the recorded amount of allowances for doubtful accounts in the future. We record a provision for estimated sales returns and allowances on product revenues in the same period as the related revenues are recorded. We base these estimates on historical sales returns and other known factors. Actual returns could be different from our estimates and the related provisions for sales returns and allowances, resulting in future changes to the sales returns and allowances provision. Our warranty obligation is affected primarily by product that does not meet specifications within the applicable warranty period and any related costs to repair or replace such products. Should our actual experience of warranty claims differ from our estimates of such obligations, our provision for warranty costs could change.

### Inventories

Inventories, consisting of purchased materials, direct labor and manufacturing overhead, are stated at the lower of cost, determined by the moving average method, or market. At each balance sheet date, we evaluate inventories for excess quantities and identified obsolescence. Our evaluation includes an analysis of historical sales levels by product and projections of future demand, as well as estimates of quantities required to support warranty and other repairs. To the extent that we determine there are excess quantities based on our projected levels of sales and other requirements, or obsolete material in inventory, we record valuation reserves against all or a portion of the value of the related parts or products. If future demand or market conditions are different than our projections, a change in recorded inventory valuation reserves may be required and would be reflected in cost of revenues in the period the revision is made.

### Amortization Periods

We record amortization of intangible assets using the straight-line method over the estimated useful lives of these assets. We base the determination of these useful lives on the period over which we expect the related assets to contribute to our cash flows or in the case of patents, their legal life, whichever is shorter. If our assessment of the useful lives of intangible assets changes, we may change future amortization expense.

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### Deferred Tax Assets and Liabilities

Our deferred tax assets and liabilities are determined based on differences between the financial statement and tax bases of assets and liabilities using enacted tax rates in effect for the year in which the differences are expected to reverse. Deferred tax assets are reduced by a valuation allowance when a determination is made that it is more likely than not that a portion or all of the deferred tax assets will not be realized.

### Loss Contingencies

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We are subject to claims and lawsuits in the ordinary course of our business, including claims by employees or former employees, with respect to our products and involving commercial disputes. Our financial statements do not reflect any material amounts related to possible unfavorable outcomes of claims and lawsuits to which we are currently a party because we currently believe that such claims and lawsuits are either adequately covered by insurance or otherwise indemnified, and are not expected, individually or in the aggregate, to result in a material adverse effect on our financial condition. However, it is possible that our results of operations, financial position and cash flows in a particular period could be materially affected by these contingencies if we change our assessment of the likely outcome of these matters.

### Goodwill Impairment

We perform goodwill impairment tests on an annual basis and as needed if events or circumstances indicate that goodwill may have been impaired. In response to changes in industry and market conditions, we may be required to strategically realign our resources and consider restructuring, disposing, or otherwise exiting businesses, which could result in an impairment of goodwill. Impairment is measured by the difference between the recorded value of goodwill and its implied fair value when the fair value of the reporting unit is less than its net book value.

### Impairment of Long-Lived Assets

Long-lived assets and certain identifiable intangible assets to be held and used are reviewed for impairment whenever events or changes in circumstances indicate that the carrying amount of such assets may not be recoverable. Determination of recoverability is based on an estimate of undiscounted future cash flows resulting from the use of the group of assets and their eventual disposition. Measurement of an impairment loss for long-lived assets and certain identifiable intangible assets that management expects to hold and use is based on the fair value of the asset. Long-lived assets and certain identifiable intangible assets to be disposed of are reported at the lower of carrying amount or fair value less costs to sell.

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### Stock-Based Compensation

We account for stock-based employee compensation using the intrinsic value method of accounting. Under this method, employee stock-based compensation expense is based on the difference, if any, on the date of the grant between the fair value of the Company's stock and the exercise price of the award. We account for stock options issued to non-employees using the fair value method of accounting, which requires us to assign a value to the stock options issued based on an option pricing model, and to record that value as compensation expense. We use the Black-Scholes option pricing model. If we were to account for stock options issued to employees using the fair value method of accounting rather than the intrinsic value method, our results of operations would be significantly affected.

### SPECIAL NOTE REGARDING FORWARD LOOKING STATEMENTS

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The information provided in this Quarterly Report on Form 10-Q contains in addition to historic information, "forward looking" statements or statements which arguably imply or suggest certain things about our future. Statements which express that we "believe", "anticipate", "expect", or "plan to" as well as other statements which are not historical fact, are forward looking statements

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within the meaning of the Private Securities Litigation Reform Act of 1995. These include, but are not limited to statements about: any competitive advantage we may have as a result of our installed base of electrosurgical generators in the neurosurgery market; our belief that our products exceed industry standards or favorably compete with other companies' new technological advancements; the future success of our new products and disposable instrumentation in the neurosurgery and other markets; and our ability, along with the third parties with whom we contract, to effectively distribute and sell our products and the continued acceptance of our products in the marketplace. These statements are based on assumptions that we believe are reasonable, but a number of factors could cause our actual results to differ materially from those expressed or implied by these statements including:

- o general economic and business conditions;
- o our expectations and estimates concerning future financial performance of our products and the impact of competition;
- o existing and future regulations affecting our business; and
- o other risk factors described in the sections entitled "Factors that Might Affect Future Results" in this report.

We do not intend to update or revise these forward looking statements.

### FACTORS THAT MIGHT AFFECT FUTURE RESULTS

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The Medical Device Industry Is Highly Competitive, And We May Be Unable to Compete Effectively with Other Companies.

In general, the medical technology industry is characterized by intense competition. We compete with established medical technology and pharmaceutical companies. Competition also comes from early stage companies that have

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alternative solutions for the markets we serve or intend to serve. Many of our competitors have access to greater financial, technical, research and development, marketing, manufacturing, sales, distribution services and other resources than we do. Further, our competitors may be more effective at implementing their technologies to develop commercial products.

Our competitive position will depend on our ability to achieve market acceptance for our products, develop new products, implement production and marketing plans, secure regulatory approval for products under development, and protect our intellectual property. We may need to develop new applications for our products to remain competitive. Technological advances by one or more of our current or future competitors could render our present or future products obsolete or uneconomical. Our future success will depend upon our ability to compete effectively against current technology as well as to respond effectively to technological advances. Competitive pressures could adversely affect our profitability.

The largest competitor for our neurosurgical generator is the Valleylab division of Tyco International Ltd. In addition, our product lines could compete with smaller specialized companies or larger companies that do not otherwise focus on neurosurgery. Our dental business is small compared to its principal competitors, which sell laser devices. Our new multi-functional bipolar electrosurgical system will compete with monopolar devices manufactured by the Valleylab division of Tyco International Ltd. Finally, in certain cases our products compete primarily against medical practices that treat a condition with medications.

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Our Business Depends Significantly On Key Relationships With Third Parties, Which We May Be Unable To Establish And Maintain.

Our current business model depends on our entering into and maintaining distribution or alliance agreements with third parties concerning product marketing and sales. Our most important agreement is with the Codman & Shurtleff, Inc., an affiliate of Johnson & Johnson, for the sale of our neurosurgery products. Sales to Codman accounted for 66% of our sales for the first quarter of fiscal 2005, 86% of our sales in fiscal 2004, and 95% of our sales in fiscal 2003. On October 15, 2004, we entered into a new agreement with Codman extending an exclusive distributorship relationship until March 31, 2005 and a nonexclusive distribution relationship until December 31, 2005. Termination or nonrenewal of this relationship would require us to develop other means to distribute our neurosurgery products and could adversely affect our sales, operations and growth.

Our ability to enter into agreements with third parties depends in part on convincing them that our technology can help them achieve their goals and execute their strategies. This may require substantial time, effort and expense on our part with no guarantee that a relationship will result. We may not be able to establish or maintain these relationships on commercially acceptable terms. Our future agreements may not ultimately be successful. Even if we enter into distribution or alliance agreements, the contracting parties could terminate these agreements, or these agreements could expire before meaningful milestones are reached. The termination or expiration of any of these relationships could have a material adverse effect on our business.

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Much of the revenue that we may receive under third party distribution or alliance agreements will depend upon our distributors' ability to successfully introduce, market and sell our products. Our success depends in part upon the performance by these distributors of their responsibilities under these agreements. Some distributors may not perform their obligations when and as we expect. Thus, revenues to be derived from distributors may vary significantly over time and be difficult to forecast. Some of the companies we currently have distribution agreements with or are targeting as potential allies offer products competitive with our products or may develop competitive production technologies or competitive products without our participation, which could have a material adverse effect on our competitive position.

### Our Operating Results May Fluctuate

We have experienced operating losses at various times since our inception. Our operating results, including components of operating results, such as gross margin on product sales, may fluctuate from time-to-time which could affect our stock price. 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:

- o the introduction of new product lines;
- o the level of market acceptance of our products;
- o the timing of research and development expenditures;
- o timing of the receipt of orders from, and product shipments to, distributors and customers;
- o timing of expenditures;
- o changes in the distribution arrangements for our products;
- o manufacturing or supply delays;
- o the time needed to educate and train a distributor's sales force;
- o costs associated with product introduction;
- o product returns; and

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- o receipt of necessary regulation approvals.

Our Products May Not Be Accepted In The Market Or May Not Effectively Compete With Other Products Or Technologies.

We cannot be certain that our current products or any other products that we may develop or market will achieve or maintain market acceptance. Certain of the medical indications that can be treated by our devices can also be treated by other medical devices or by medical practices that do not include a device. The medical community widely accepts many alternative treatments, and certain of these other treatments have a long history of use.

We cannot be certain that our devices and procedures will be able to replace those established treatments or that either physicians or the medical community in general will accept and utilize our devices or any other medical products that we may develop. For example, we cannot be certain that the medical

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community will accept our new multifunctional electrosurgical generator and proprietary hand-switching bipolar electrosurgical instruments over traditional monopolar electrosurgical generators.

In addition, our future success depends, in part, on our ability to develop additional products. Competitors may develop products that are more effective, cost less, or are ready for commercial introduction before our products. If we are unable to develop additional commercially viable products, our future prospects could be adversely affected.

Market acceptance of our products depends on many factors, including our ability to convince third party distributors and customers that our technology is an attractive alternative to other technologies, to manufacture products in sufficient quantities and at acceptable costs, and to supply and service sufficient quantities of our products directly or through our distribution alliances. In addition, limited funding available for product and technology acquisitions by end users of our products, as well as internal obstacles to end user approval of purchases of our products, could harm acceptance of our products. The industry is subject to rapid and continuous change arising from, among other things, consolidation and technological improvements. One or more of these factors may vary unpredictably, which could materially adversely affect our competitive position. We may not be able to adjust our plan of development to meet changing market demands.

Changes In The Health Care Industry May Require Us To Decrease The Selling Price For Our Products Or Could Result In A Reduction In The Size Of The Market For Our Products, Each Of Which Could Have A Negative Impact On Our Financial Performance.

Trends toward managed care, health care cost containment, and other changes in government and private sector initiatives in the United States and other countries in which we do business are placing increased emphasis on the delivery of more cost-effective medical therapies that could adversely affect the sale and/or the prices of our products. For example:

- o there has been a consolidation among health care facilities and purchasers of medical devices in the United States who prefer to limit the number of suppliers from whom they purchase medical products, and these entities may decide to stop purchasing our products or demand discounts on our prices;
- o major third-party payors of hospital services, including Medicare, Medicaid and private health care insurers, have substantially revised

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- o their payment methodologies, which has resulted in stricter standards for reimbursement of hospital charges for certain medical procedures;
- o Medicare, Medicaid and private health care insurer cutbacks could create downward price pressure on our products;
- o numerous legislative proposals have been considered that would result in major reforms in the U.S. health care system that could have an adverse effect on our business;
- o there is economic pressure to contain health care costs in international markets; and
- o there have been initiatives by third-party payors to challenge the prices charged for medical products that could affect our ability to sell products on a competitive basis.

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Both the pressures to reduce prices for our products in response to these trends and the decrease in the size of the market as a result of these trends could adversely affect our levels of revenues and profitability of sales.

To Market Our Products under Development We Will First Need To Obtain Regulatory Approval. A Failure To Comply With Extensive Governmental Regulations Could Subject Us To Penalties And Could Preclude Us From Marketing Our Products.

Our research and development activities and the manufacturing, labeling, distribution and marketing of our existing and future products are subject to regulation by numerous governmental agencies in the United States and in other countries. The Food and Drug Administration (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 diagnostic and human therapeutic use.

Products we have under development are subject to FDA approval or clearance prior to marketing for commercial use. The process of obtaining necessary FDA approvals or clearances can take years and is expensive and full of uncertainties. Our inability to obtain required regulatory approval or clearance on a timely or acceptable basis 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. Further 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 significant changes to the product.

Furthermore, another risk of application to the FDA relates to the regulatory classification of new products or proposed new uses for existing products. In the filing of 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 (PMA) application rather than allowing us to market for approved uses while we seek broader approvals or requires extensive additional clinical data, the time and expense required to obtain the required approval might be significantly increased or approval might not be granted. Approved and cleared products are subject to continuing FDA requirements relating to quality control and quality assurance, maintenance of records, reporting of adverse events and product recalls, documentation, and labeling and promotion of medical devices.

The FDA as well as foreign 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



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before it may be used. 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. In addition, failure to comply with applicable regulatory requirements could subject us to enforcement action, including product seizures, recalls,

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withdrawal of clearances or approvals, restrictions on or injunctions against marketing our product or products based on our technology, and civil and criminal penalties.

Our Intellectual Property Rights May Not Provide Meaningful Commercial Protection For Our Products And 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 of our patents have expired and others will expire in the future. In addition, challenges may be made to our patents and, as a result, our patents could be narrowed, invalidated or rendered unenforceable. 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 foreign countries. Further, there is a substantial backlog of patent applications at the U.S. Patent and Trademark Office, and the approval or rejection of patent applications may take several years.

Our Competitive Position Depends, In Part, Upon Unpatented Trade Secrets Which We May Be Unable To Protect.

Our competitive position is furthermore dependent upon unpatented trade secrets. Trade secrets are difficult to protect. We cannot assure you that others will not independently develop substantially equivalent proprietary information and techniques or otherwise gain access to our trade secrets, that our trade secrets will not be disclosed, or that we can effectively protect our rights to unpatented trade secrets.

In an effort to protect our trade secrets, we generally require our employees, consultants and advisors to execute proprietary information and invention assignment agreements upon commencement of employment or consulting relationships with us. These agreements typically provide that, except in specified circumstances, all confidential information developed or made known to the individual during the course of their relationship with us must be kept confidential. We cannot assure you, however, that these agreements will provide meaningful protection for our trade secrets or other proprietary information in the event of the unauthorized use or disclosure of confidential information.

We May Become Subject to a Patent Litigation

The medical device industry has been characterized by extensive litigation regarding patents and other intellectual property rights, and companies in the medical device industry have employed intellectual property litigation to gain a competitive advantage. We cannot assure you that we will not become subject to patent infringement claims or litigation or interference proceedings declared by the United States Patent and Trademark Office to determine the priority of invention.

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It May Be Difficult To Replace Some Of Our Suppliers.

Outside vendors, some of whom are sole-source suppliers, provide key components and raw materials used in the manufacture of our products. For example, we currently subcontract the manufacturing of our disposable cord and tubing sets with a single manufacturer. Although we believe that alternative sources for many of these components and raw materials are available, any supply interruption could harm our ability to manufacture our products until a new source of supply is identified and qualified. In addition, an uncorrected defect or supplier's variation in a component or raw material, either unknown to us or incompatible with our manufacturing process, could harm our ability to manufacture products. We may not be able to find a sufficient alternative supplier in a reasonable time period, or on commercially reasonable terms, if at all, and our ability to produce and supply our products could be impaired. If we were suddenly unable to purchase products from one or more of our suppliers, we could need a significant period of time to qualify a replacement, and the production of any affected products could be disrupted. While it is our policy to maintain sufficient inventory of components so that our production will not be significantly disrupted even if a particular component or material is not available for a period of time, we remain at risk that we will not be able to qualify new components or materials quickly enough to prevent a disruption if one or more of our suppliers ceases production of important components or materials.

If Our Manufacturing Facility Was Damaged And/Or Our Manufacturing Processes Interrupted, We Could Experience Lost Revenues And Our Business Could Be Adversely Affected.

We manufacture our bipolar generators and irrigators at one facility. Damage to this facility due to fire, natural disaster, power loss, communications failure, unauthorized entry or other events could cause us to cease development and manufacturing of some or all of these products. Although we maintain property damage and business interruption insurance coverage on this facility, we may not be able to renew or obtain such insurance in the future on acceptable terms with adequate coverage or at reasonable costs.

We May Have Product Liability Claims and Our Insurance May Not Cover All Claims

Our products involve a risk of product liability claims. We may not be able to obtain insurance for the potential liability on acceptable terms with adequate coverage or at reasonable costs. Any potential product liability claims could exceed the amount of our insurance coverage or may be excluded from coverage under the terms of the policy. Further, our insurance may not be renewed at a cost and level of coverage comparable to that then in effect.

The Market Price of Our Stock May be Highly Volatile

During the first quarter of fiscal 2005 and during fiscal 2004 and 2003, our common stock has traded in a range of \$1.05 and \$2.40 per share. The market price of our common stock could continue to fluctuate substantially due to a variety of factors, including:

- o Our ability to successfully commercialize our products;
- o The execution of new agreements and material changes in our relationships with companies with whom we contract;

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- o Quarterly fluctuations in results of operations;

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- o Announcements regarding technological innovations or new commercial products by us or our competitors or the results of regulatory approval filings;
- o Market reaction to trends in sales, marketing and research and development and reaction to acquisitions;
- o Sales of common stock by existing stockholders; and
- o Economic and political conditions.

The Loss Of Key Personnel Could Harm Our Business.

We believe our success depends on the contributions of a number of our key personnel, including Jerry L. Malis, our President and Chief Executive Officer. If we lose the services of key personnel, those losses could materially harm our business. We do not maintain any significant key person life insurance on Mr. Malis.

### Item 4. CONTROLS AND PROCEDURES

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Our management, including our Chief Executive Officer/Principal Financial Officer, conducted an evaluation of the effectiveness of our disclosure controls and procedures as of December 31, 2004. Based on that evaluation, our management, including our Chief Executive Officer/Principal Financial Officer, has concluded that our disclosure controls and procedures are effective. During the period covered by this report, there was no change in our internal control over financial reporting that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

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## PART II. OTHER INFORMATION

### Item 6. EXHIBITS AND REPORTS ON FORM 8-K

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#### (a) Exhibits

Exhibit 31.1      Certification of the Chief Executive Officer Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002

Exhibit 32.1      Certification of the Chief Executive Officer Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002

#### (b) Current Reports on Form 8-K

On October 21, 2004, Valley Forge Scientific Corp. filed a report on Form 8-K regarding a new agreement entered into with Codman & Shurtleff, Inc.

On October 26, 2004, Valley Forge Scientific Corp. filed a report on Form 8-K regarding a press release concerning new agreements which it entered into.

On December 22, 2004, Valley Forge Scientific Corp. filed a report on Form 8-K regarding an earnings press release.

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VALLEY FORGE SCIENTIFIC CORP.

