

Stereotaxis, Inc.
Form 10-Q
August 09, 2006
Table of Contents

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

FORM 10-Q

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

For the quarterly period ended June 30, 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: 000-50884

STEREOTAXIS, INC.

(Exact name of registrant as specified in its charter)

Delaware
(State of Incorporation)

94-3120386
(I.R.S. employer identification no.)

4320 Forest Park Avenue

63108

Suite 100

St. Louis, Missouri

Edgar Filing: Stereotaxis, Inc. - Form 10-Q

(Address of principal executive offices)

(Zip Code)

Registrant's telephone number, including area code: (314) 678-6100

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 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.

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 outstanding shares of the registrant's common stock on July 31, 2006 was 33,951,036.

Table of Contents

STEREOTAXIS, INC.

INDEX TO FORM 10-Q

	Page
Part I Financial Information	
Item 1. <u>Financial Statements (unaudited)</u>	3
<u>Balance Sheets</u>	3
<u>Statements of Operations</u>	4
<u>Statements of Cash Flows</u>	5
<u>Notes to Financial Statements</u>	6-11
Item 2. <u>Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	11-15
Item 3. <u>Quantitative and Qualitative Disclosures About Market Risk</u>	16
Item 4. <u>Controls and Procedures</u>	16
Part II <u>Other Information</u>	
Item 1 <u>Legal Proceedings</u>	17
Item 1A. <u>Risk Factors</u>	17-29
Item 1B. <u>Unresolved Staff Comments</u>	29
Item 2. <u>Issuer Purchases of Equity Securities</u>	29
Item 3. <u>Defaults upon Securities</u>	29
Item 4. <u>Submission of Matters to a Vote of Security Holders</u>	29
Item 5. <u>Other Information</u>	29
Item 6. <u>Exhibits and Reports on Form 8-K</u>	30
<u>Signatures</u>	31
<u>Exhibit Index</u>	32

Table of Contents**ITEM 1. FINANCIAL STATEMENTS****STEREOTAXIS, INC.****BALANCE SHEETS**

	June 30,	December 31,
	2006	2005
	(Unaudited)	
Assets		
Current assets:		
Cash and cash equivalents	\$ 31,142,137	\$ 3,598,493
Short-term investments	13,574,666	7,137,094
Accounts receivable, net of allowance of \$134,638 and \$29,576 in 2006 and 2005, respectively	7,226,838	5,897,072
Current portion of long-term receivables	473,301	461,520
Inventories	11,666,666	9,404,792
Prepaid expenses and other current assets	2,686,861	5,128,852
Total current assets	66,770,469	31,627,823
Property and equipment, net	4,391,721	3,078,313
Intangible assets, net	1,611,111	1,677,778
Long-term receivables		146,520
Other assets	122,931	127,755
Total assets	\$ 72,896,232	\$ 36,658,189
Liabilities and stockholders' equity		
Current liabilities:		
Current maturities of long-term debt	\$ 1,000,000	\$ 1,000,000
Accounts payable	4,031,913	4,866,156
Accrued liabilities	5,746,875	5,648,693
Deferred contract revenue	4,606,067	4,216,255
Total current liabilities	15,384,855	15,731,104
Long-term debt, less current maturities	1,472,222	1,972,222
Long-term deferred contract revenue	996,679	801,005
Other liabilities	24,219	28,016
Stockholders' equity:		
Preferred stock, par value \$0.001; 10,000,000 shares authorized at 2006 and 2005, none outstanding at 2006 and 2005		
Common stock, par value \$0.001; 100,000,000 shares authorized at 2006, and 2005; 33,991,187 and 27,835,611 issued at 2006 and 2005, respectively	33,991	27,836
Additional paid-in capital	241,658,977	179,286,612
Deferred compensation		(2,569,760)
Treasury stock, 40,151 and 36,519 shares at 2006 and 2005, respectively	(205,999)	(162,546)
Notes receivable from sales of stock		(180,619)
Accumulated deficit	(186,436,902)	(158,231,069)
Accumulated other comprehensive loss	(31,810)	(44,612)
Total stockholders' equity	55,018,257	18,125,842
Total liabilities and stockholders' equity	\$ 72,896,232	\$ 36,658,189

See accompanying notes.

Table of Contents**STEREOTAXIS, INC.****STATEMENTS OF OPERATIONS****(Unaudited)**

	Three Months Ended		Six Months Ended	
	June 30		June 30,	
	2006	2005	2006	2005
Systems revenue	\$ 2,860,101	\$ 5,465,000	\$ 3,842,698	\$ 10,092,490
Disposables, service and accessories revenue	953,919	681,226	1,703,114	1,140,137
Total revenue	3,814,020	6,146,226	5,545,812	11,232,627
Cost of revenue	2,182,425	3,197,449	3,414,416	5,634,809
Gross margin	1,631,595	2,948,777	2,131,396	5,597,818
Operating expenses:				
Research and development	5,539,759	3,885,746	11,669,627	7,693,348
General and administration	4,286,408	3,479,160	8,306,152	6,489,326
Sales and marketing	5,715,392	4,295,111	10,588,776	7,609,765
Royalty Settlement		2,923,111		2,923,111
Total operating expenses	15,541,559	14,583,128	30,564,555	24,715,550
Operating loss	(13,909,964)	(11,634,351)	(28,433,159)	(19,117,732)
Interest income	629,839	357,601	1,110,832	565,976
Interest expense	(330,404)	(56,727)	(883,506)	(120,084)
Net loss	\$ (13,610,529)	\$ (11,333,477)	\$ (28,205,833)	\$ (18,671,840)
Net loss per common share:				
Basic and diluted	\$ (0.41)	\$ (0.42)	\$ (0.88)	\$ (0.69)
Weighted average shares used in computing net loss per common share:				
Basic and diluted	33,221,875	27,272,322	32,187,229	27,222,101

See accompanying notes.

Table of Contents**STEREOTAXIS, INC.****STATEMENTS OF CASH FLOWS****(Unaudited)**

	Six Months Ended	
	2006	June 30, 2005
Cash flows from operating activities:		
Net loss	\$ (28,205,833)	\$ (18,671,840)
Adjustments to reconcile net loss to cash used in operating activities:		
Depreciation	575,255	368,016
Amortization	632,428	66,666
Noncash compensation	2,072,839	174,835
Interest receivable from sale of stock	48,992	
Noncash interest receivable	(63,970)	(5,942)
Loss on asset disposal	6,806	42,328
Changes in operating assets and liabilities:		
Accounts receivable	(1,329,766)	(1,767,778)
Long-term receivables	134,739	(423,139)
Inventories	(2,261,874)	(589,933)
Prepaid expenses and other current assets	1,767,679	70,928
Other assets	4,824	(2,864)
Accounts payable	(834,243)	4,388,546
Accrued liabilities	98,182	1,332,458
Deferred contract revenue	585,486	(438,381)
Other	(3,797)	10,929
Net cash used in operating activities	(26,772,253)	(15,445,171)
Cash flows from investing activities:		
Sale of equipment	10,072	
Purchase of equipment	(1,905,541)	(518,799)
Proceeds from the maturity/sale of available-for-sale investments	8,871,645	22,543,000
Purchase of available-for-sale investments	(15,126,967)	(8,033,925)
Net cash (used in) provided by investing activities	(8,150,791)	13,990,276
Cash flows from financing activities:		
Payments under long-term debt	(500,000)	(514,141)
Proceeds from issuance of stock and warrants, net of issuance costs	62,875,441	562,459
Purchase of treasury stock	(43,453)	
Payments received on notes receivable from sale of common stock	134,700	
Net cash provided by financing activities	62,466,688	48,318
Net increase (decrease) in cash and cash equivalents	27,543,644	(1,406,577)
Cash and cash equivalents at beginning of period	3,598,493	16,907,516
Cash and cash equivalents at end of period	\$ 31,142,137	\$ 15,500,939

See accompanying notes.

Table of Contents

STEREOTAXIS, INC.

NOTES TO FINANCIAL STATEMENTS

(Unaudited)

Basis of Presentation

The accompanying unaudited financial statements of Stereotaxis, Inc. (the Company) have been prepared in accordance with generally accepted accounting principles for interim financial information and with the instructions to Form 10-Q. Accordingly, they do not include all the disclosures required by U.S. generally accepted accounting principles for complete financial statements. In the opinion of management, they include all adjustments, consisting only of normal recurring adjustments, necessary for a fair presentation of the results for the interim periods presented. Operating results for the three and six month periods ended June 30, 2006 are not necessarily indicative of the results that may be expected for the year ended December 31, 2006 or for future operating periods. These interim financial statements and the related notes should be read in conjunction with the annual financial statements and notes included in the Company's Annual Report on Form 10-K as filed with the Securities and Exchange Commission on March 16, 2006 for the year ended December 31, 2005. Certain prior period amounts have been reclassified to conform with the 2006 presentation.

Net Loss per Common Share

Basic net loss per common share is computed by dividing the net loss for the period by the weighted average number of common shares outstanding during the period. Diluted loss per share is computed by dividing the loss for the period by the weighted average number of common and common equivalent shares outstanding during the period.

The Company has deducted shares subject to repurchase from the calculation of shares used in computing net loss per share, basic and diluted. The Company has excluded all outstanding options, stock appreciation rights, warrants and unearned restricted shares from the calculation of diluted loss per common share because all such securities are anti-dilutive for all periods presented. As of June 30, 2006, the Company had 2,578,834 shares of common stock issuable upon the exercise of outstanding options and stock appreciation rights at a weighted average exercise price of \$7.04 per share and 1,205,550 shares of common stock issuable upon the exercise of outstanding warrants at a weighted average exercise price of \$8.12 per share. The Company had a weighted average of 546,129 unearned restricted shares excluded from the calculation of net loss per common share for the six months ended June 30, 2006.

Stock-Based Compensation

Effective January 1, 2006, the Company adopted the fair value recognition provisions of Financial Accounting Standards Board Statement No. 123(R), *Share-Based Payment* (SFAS 123(R)), using the modified prospective transition method to account for its grants of stock options, stock appreciation rights, restricted shares and its employee stock purchase plan. SFAS 123(R) supersedes the provisions of Accounting Principles Board (APB) Opinion No. 25, *Accounting for Stock Issued to Employees* (APB Opinion No. 25) and requires recognition of an expense when goods or services are provided. SFAS 123(R) requires the determination of the fair value of the share-based compensation at the grant date and the recognition of the related expense over the period in which the share-based compensation vests. Prior to January 1, 2006, the Company accounted for those plans under the provisions of APB Opinion No. 25, and related interpretations in accounting for stock-based employee compensation as permitted by SFAS 123, *Accounting for Stock-Based Compensation*. Prior to the adoption of SFAS 123(R), stock-based compensation for grants of stock options was included as a pro forma disclosure in the Notes to the Consolidated Financial Statements as permitted by SFAS 123. Results for prior periods have not been restated.

Under the modified prospective transition method of SFAS 123(R), the Company recognized stock-based compensation expense related to 1) the remaining unvested portion of all stock option, stock appreciation right and restricted share awards granted prior to January 1, 2006, based on the grant date fair value estimated in accordance with the original provisions of SFAS 123; and 2) expense related to all stock option, stock appreciation right and restricted share awards granted on or subsequent to January 1, 2006, based on the grant date fair value estimated in accordance with the provisions of SFAS 123(R). The Company utilizes the Black-Scholes valuation model to determine the fair value of share-based payments at the date of grant with the following inputs: 1) expected dividend rate of 0%; 2) expected volatility based on the Company's historical volatility and a review of the volatilities of comparable companies; 3) risk-free interest rate based on the Treasury yield on the date of grant and; 4) expected term for grants made subsequent to the adoption of SFAS 123(R) determined in accordance with Staff Accounting Bulletin No. 107 using the simplified method. The resulting compensation expense is recognized over the requisite service period, generally one to four years. Compensation expense is recognized only for those awards expected to vest, with forfeitures estimated based on the Company's historical experience and future expectations. Prior to the adoption of SFAS 123(R), the effect of forfeitures on the pro forma

expense amounts was recognized as the forfeitures occurred.

Table of Contents

Stock options or stock appreciation rights issued to non-employees, including individuals for scientific advisory services, are recorded at their fair value as determined in accordance with SFAS 123 and Emerging Issues Task Force (EITF) No. 96-18, *Accounting for Equity Instruments That Are Issued to Other Than Employees for Acquiring, or in Conjunction With Selling, Goods or Services*, and recognized over the service period. Deferred compensation for options granted to non-employees is periodically remeasured through the vesting or forfeiture date.

Restricted shares granted to employees are valued at the fair market value at the date of grant. The Company amortizes the amount to expense over the service period on a straight-line basis. If the shares are subject to performance objectives, the resulting compensation expense is amortized over the anticipated vesting period and is subject to adjustment based on the actual achievement of objectives. Under APB 25, if the shares granted were subject to variable performance criteria, the compensation expense was periodically remeasured through the vesting or forfeiture date.

Shares purchased by employees under the 2004 Employee Stock Purchase Plan are considered to be compensatory and are accounted for in accordance with SFAS 123(R). Under APB 25, these shares were not considered to be compensatory and were not included in expense but were included in the pro forma expense calculation.

As a result of adopting SFAS 123(R), the Company recorded approximately \$1.2 and \$2.1 million of share based compensation during the three and six months ended June 30, 2006. As a result, the Company's net loss for the three and six month periods ended June 30, 2006 was approximately \$0.4 million and \$0.8 million lower, respectively, than if it had continued to account for share-based compensation under APB No. 25. Net loss per share for the three and six month periods ended June 30, 2006 are \$0.01 and \$0.03 lower, respectively than if the Company had continued to account for share-based compensation under Opinion 25.

At June 30, 2006, the total compensation cost related to options, stock appreciation rights and nonvested stock granted to employees under the Company's stock award plans but not yet recognized was approximately \$9.4 million, net of estimated forfeitures of approximately \$2.0 million. This cost will be amortized over the next four years on a straight-line basis over the estimated service periods and will be adjusted for subsequent changes in estimated forfeitures.

Stock Award Plans

The Company has various stock plans that permit the Company to provide incentives to employees and directors of the Company in the form of equity participation. In 2002, the Board of Directors adopted a stock incentive plan (the 2002 Stock Incentive Plan) and a nonemployee directors stock plan (the 2002 Director Plan). In 1994, the Board of Directors adopted the 1994 Stock Option Plan (the 1994 Stock Option Plan). Each of these plans were subsequently approved by the Company's stockholders. At June 30, 2006, the Board of Directors has reserved a total of 2,938,438 shares, of the Company's common stock to provide for current and future grants under the 2002 Stock Incentive Plan and the 2002 Director Plan and for all current grants under the 1994 Stock Option Plan. In 2002, the Board of Directors adopted a provision providing for an annual increase in the number of shares reserved for stock options of the lesser of 3.25% of outstanding common shares or 833,333 shares, on January 1 of each year through January 1, 2007.

The 2002 Stock Incentive Plan allows for the grant of incentive stock options, non-qualified stock options, stock appreciation rights and restricted shares to employees, directors, and consultants. Options expire no later than ten years from the date of grant. Stock appreciation rights expire no later than five years from the date of grant. The exercise price of each stock option is not less than 100% of the fair value of the stock subject to the option on the date the option is granted. The vesting provisions of individual options may vary, but incentive stock options generally vest 25% on the first anniversary of each grant and 1/48 per month over the next three years. Non-qualified stock options generally vest ratably over a period of two to four years. Stock appreciation rights granted generally vest 25% on the first anniversary of such grant and 1/48 per month over the next three years and expire no later than five years from the date of grant.

The 2002 Director Plan allows for the grant of non-qualified stock options to the Company's nonemployee directors. Options granted under the 2002 Director Plan expire no later than ten years from the date of grant. The exercise price of options under the 2002 Director Plan is not less than 100% of the fair value of the stock subject to the option on the date the option is granted. Initial grants of options to new directors generally vest over a two-year period. Annual grants to directors generally vest upon the earlier of one year from the date of grant or the next shareholder meeting.

The 1994 Stock Option Plan allowed for the grant of incentive stock options and non-qualified stock options to employees, directors, and consultants to the Company. Options granted under the 1994 Stock Option Plan expire no later than ten years from the date of grant and generally vest over a period of two to four years. Options granted may be exercised prior to vesting, in which case the related shares would be subject to repurchase by the Company at original purchase price until vested. The Company no longer grants options under the 1994 Stock Option Plan.

Table of Contents

A summary of the option and stock appreciation rights activity for the six months ended June 30, 2006 is as follows:

	Number of Shares	Range of Exercise Price	Weighted Average Price per Share
Outstanding, December 31, 2005	2,456,488	\$ 0.25-\$11.54	\$ 6.09
Granted	357,500	\$ 9.90-\$12.35	\$ 11.47
Exercised	(225,292)	\$ 0.25-\$11.54	\$ 3.56
Forfeited	(9,862)	\$ 5.94-\$11.54	\$ 8.83
Outstanding, June 30, 2006	2,578,834	\$ 0.25-\$12.35	\$ 7.04

As of June 30, 2006, the weighted average remaining term of outstanding options and stock appreciation rights was 6.2 years. Of the 2,578,834 options that were outstanding, 1,491,881 were vested with a weighted average exercise price of \$5.70 per share as of June 30, 2006 and a weighted average remaining term of 6.4 years.

The intrinsic value of options and stock appreciation rights is calculated as the difference between the exercise price of the underlying awards and the quoted price of the Company's common stock for the 2,297,134 options that were in-the-money at June 30, 2006. The intrinsic value of the options outstanding at June 30, 2006 was approximately \$10.0 million based on a closing share price of \$10.79 on June 30, 2006. The intrinsic value of fully vested options and stock appreciation rights vested and outstanding at June 30, 2006 was approximately \$7.6 million based on a closing price of \$10.79 on June 30, 2006. During the three and six months ended June 30, 2006, the aggregate intrinsic value of options exercised under the Company's stock option plans was approximately \$1.1 million and \$1.5 million, respectively, determined at the date of exercise.

The 2002 Stock Incentive Plan allows for the grant of restricted shares to employees. These grants expire no later than five years from the date of grant. Restricted share grants under the 2002 Stock Incentive Plan are either time-based or performance-based. Time-based restricted shares generally vest 25% on each anniversary of such grant. Performance-based restricted shares vest upon the achievement of performance objectives which are determined by the Company's Compensation Committee.

A summary of the restricted share grant activity for the six months ended June 30, 2006 is as follows:

	Number of Shares	Weighted Average Grant Price per Share
Outstanding, December 31, 2005	359,100	\$ 7.70
Granted	321,484	\$ 11.91
Vested	(20,225)	\$ 7.80
Forfeited	(20,410)	\$ 8.86
Outstanding, June 30, 2006	639,949	\$ 9.77

A summary of the restricted stock outstanding as of June 30, 2006 is as follows:

	Number of Shares
Time based restricted shares	144,889
Performance based restricted shares	495,060

Edgar Filing: Stereotaxis, Inc. - Form 10-Q

Outstanding, June 30, 2006

639,949

The intrinsic value of restricted shares outstanding at June 30, 2006 was approximately \$6.9 million based on a closing share price of \$10.79 as of June 30, 2006. During the three and six months ended June 30, 2006, the aggregate intrinsic value of restricted shares vested was approximately \$34,000 and \$61,000, respectively, determined at the date of vesting.

Table of Contents***2004 Employee Stock Purchase Plan***

The 2004 Employee Stock Purchase Plan was effective upon the initial public offering of the Company's stock in August 2004. 277,777 shares of common stock were reserved for issuance pursuant to the plan. The Company offered employees the opportunity to participate in the plan beginning January 1, 2005 with an initial purchase date of June 30, 2005. Eligible employees have the opportunity to participate in a new purchase period every six months. Under the terms of the plan, employees can purchase shares of stock at 85% of the fair market value of the stock at the beginning or the end of the purchase period. As of June 30, 2006, 69,186 shares had been purchased under this plan.

Pro Forma Net Loss

The following table illustrates the effect on net loss if the Company had applied the fair value recognition provisions of SFAS 123 to stock-based employee compensation:

	3 Months Ended	6 Months Ended
	June 30, 2005	June 30, 2005
Net loss as reported	\$ (11,333,477)	\$ (18,671,840)
Add stock-based compensation included in net loss	72,938	174,835
Deduct stock-based compensation under fair value method	(649,806)	(1,367,847)
Pro-forma net loss	\$ (11,910,345)	\$ (19,864,852)
Net loss per share, as reported	\$ (0.42)	\$ (0.69)
Net loss per share, pro-forma	\$ (0.44)	\$ (0.73)

For the purpose of the above pro forma disclosure, the fair value of each option or stock appreciation right was estimated on the date of grant using the Black-Scholes option pricing model using the following principal assumptions: dividend yield of 0%, expected volatility ranging from 50% to 120%, risk free interest rates ranging from 3.08% to 5.39% and an initial expected life ranging from five to ten years. Expected volatility was based on the historical volatility of the Company's stock. The risk-free rate for the expected term of the option was based on the U.S. Treasury rate at the date of grant.

Comprehensive Loss

Comprehensive loss for the three-month period ended June 30, 2006 and 2005 was \$(13,619,940) and \$(11,364,393), respectively. Comprehensive loss for the six-month period ended June 30, 2006 and 2005 was \$(28,218,635) and \$(18,660,592), respectively. The only adjustment to net loss in arriving at comprehensive loss is the unrealized gain or loss on investments available for sale.

Table of Contents**Investments**

Investments consist of the following available-for-sale securities at fair value:

	June 30,	December 31,
	2006	2005
Short-term investments:		
Corporate debt	\$ 3,613,114	\$ 1,791,370
U.S. Government agency	2,548,490	5,345,724
Commercial paper	5,378,794	
Certificates of Deposit	2,034,268	
 Total short-term investments	 \$ 13,574,666	 \$ 7,137,094

Inventory

Inventory consists of the following:

	June 30,	December 31,
	2006	2005
Raw materials	\$ 4,172,163	\$ 2,803,516
Work in process	482,510	111,632
Finished goods	7,261,007	6,533,082
Reserve for obsolescence	(249,014)	(43,438)
 Total inventory	 \$ 11,666,666	 \$ 9,404,792

Prepaid Expenses and Other Assets

Prepaid expenses and other assets consist of the following:

	June 30,	December 31,
	2006	2005
Prepaid expenses	\$ 1,279,585	\$ 3,129,967
Other assets	1,530,206	2,126,640
	2,809,791	5,256,607
Less: Long-term other assets	(122,930)	(127,755)
 Total prepaid expenses and other assets	 \$ 2,686,861	 \$ 5,128,852

Property and Equipment

Property and equipment consist of the following:

Edgar Filing: Stereotaxis, Inc. - Form 10-Q

	June 30,	December 31,
	2006	2005
Equipment	\$ 5,362,264	\$ 3,876,947
Equipment held for lease	303,412	303,412
Leasehold improvements	1,309,715	1,162,582
	6,975,391	5,342,941
Less accumulated depreciation	(2,583,670)	(2,264,628)
Total property and equipment	\$ 4,391,721	\$ 3,078,313

Equipment held for lease consists of medical equipment provided to customers under operating lease arrangements, where the Company is the lessor.

Table of Contents

Stockholders Equity

In February 2006, the Company completed a public offering of 5,500,000 shares of its common stock at \$12.00 per share which included the exercise by the underwriters of an option to purchase an additional 500,000 shares. In conjunction with these transactions, the Company received approximately \$61.9 million in net proceeds after deduction of underwriting discounts and commissions and payment of offering expenses.

Product Warranty Provisions

The Company's standard policy is to warrant all NIOBE systems against defects in material or workmanship for one year following installation. The Company's estimate of costs to service the warranty obligations is based on historical experience and current product performance trends. A regular review of warranty obligations is performed to determine the adequacy of the reserve and adjustments are made to the estimated warranty liability as appropriate.

During the quarter ended June 30, 2006, the Company expensed approximately \$237,000 related to a warranty obligation for a system installed at a hospital whose President and Chief Executive Officer is a member of our board of directors.

Commitments and Contingencies

The Company at times becomes a party to claims in the ordinary course of business. Management believes that the ultimate resolution of pending or threatened proceedings will not have a material effect on the financial position, results of operations or liquidity of the Company.

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

The following discussion and analysis should be read in conjunction with our financial statements and notes thereto included in this report on Form 10-Q and in our Annual Report on Form 10-K for the year ended December 31, 2005. Operating results are not necessarily indicative of results that may occur in future periods.

This report includes various forward-looking statements that are subject to risks and uncertainties, many of which are beyond our control. Our actual results could differ materially from those anticipated in these forward looking statements as a result of various factors, including those set forth below under Part II Item 1A Risk Factors. Forward-looking statements discuss matters that are not historical facts. Forward-looking statements include, but are not limited to, discussions regarding our operating strategy, sales and marketing strategy, regulatory strategy, industry, economic conditions, financial condition, liquidity and capital resources and results of operations. Such statements include, but are not limited to, statements preceded by, followed by or that otherwise include the words believes, expects, anticipates, intends, estimates, projects, can, could, may, will, would, or similar expressions. For those statements, we claim the protection of the safe harbor for forward-looking statements contained in the Private Securities Litigation Reform Act of 1995. You should not unduly rely on these forward-looking statements, which speak only as of the date on which they were made. They give our expectations regarding the future, but are not guarantees. We undertake no obligation to update publicly or revise any forward-looking statements, whether as a result of new information, future events or otherwise, unless required by law.

Overview

Stereotaxis designs, manufactures and markets an advanced cardiology instrument control system for use in a hospital's interventional surgical suite to enhance the treatment of arrhythmias and coronary artery disease. The Stereotaxis System is designed to enable physicians to complete more complex interventional procedures by providing image guided delivery of catheters and guidewires through the blood vessels and chambers of the heart to treatment sites. This is achieved using externally applied magnetic fields that govern the motion of the working tip of the catheter or guidewire, resulting in improved navigation, efficient procedures and reduced x-ray exposure. The core components of the Stereotaxis System have received regulatory clearance in the U.S., Canada and Europe.

Critical Accounting Policies and Estimates

Our discussion and analysis of our financial condition and results of operations are based on our financial statements, which have been prepared in accordance with U.S. generally accepted accounting principles. The preparation of these financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, revenues and expenses and related disclosures. We review our estimates and judgments on an on-going basis. We base our

Table of Contents

estimates and judgments on historical experience and on various other assumptions that we believe to be reasonable under the circumstances. Actual results may differ from these estimates. We believe the following accounting policies are critical to the judgments and estimates we use in preparing our financial statements.

Revenue Recognition

We recognize systems revenue from system sales made directly to end users upon installation, provided there are no uncertainties regarding acceptance, persuasive evidence of an arrangement exists, the sales price is fixed and determinable, and collection of the related receivable is reasonably assured. When installation is required for revenue recognition, the determination of acceptance is made by our employees based on criteria set forth in the terms of the sale. Revenue from system sales made to distributors is recognized upon shipment since these arrangements do not include an installation element or right of return privileges. If uncertainties exist regarding collectability, we recognize revenue when those uncertainties are resolved. Amounts collected prior to satisfying the above revenue recognition criteria are reflected as deferred revenue. Amounts due beyond 12 months are reflected as long term receivables in the balance sheet. Revenue from services is derived primarily from the sale of annual product maintenance plans. Revenue from services, whether sold individually or as a separable unit of accounting in a multi-element arrangement, is deferred and amortized over the service period, which is typically one year. We recognize revenue from disposable device sales or accessories upon shipment and establish an appropriate reserve for returns.

For arrangements with multiple deliverables, we allocate the total revenue to each deliverable based on its relative fair value in accordance with the provisions of Emerging Issues Task Force (EITF) Issue No. 00-21, *Revenue Arrangements with Multiple Deliverables*, and recognize revenue for each separate element as the above criteria are met.

Stock-based Compensation

Effective January 1, 2006, the Company adopted the fair value recognition provisions of Financial Accounting Standards Board Statement No. 123(R), *Share-Based Payment* (SFAS 123(R)), using the modified prospective transition method to account for its grants of stock options, stock appreciation rights, restricted shares and share purchases under its employee stock purchase plan. Prior to January 1, 2006, the Company accounted for those plans under the provisions of Accounting Principles Board (APB) Opinion No. 25, *Accounting for Stock Issued to Employees*, and related interpretations in accounting for stock-based employee compensation as permitted by SFAS 123, *Accounting for Stock-Based Compensation*. SFAS 123(R) supersedes APB Opinion No. 25 and requires the determination of the fair value of the share-based compensation at the grant date and the recognition of the related expense over the period in which the share-based compensation vests.

Stock compensation expense, which is a noncash charge, results from stock option and stock appreciation rights grants made to employees, directors and consultants at the fair value of the option granted, from grants of restricted shares to employees and from share purchases by employees under our employee stock purchase plan. The fair value of options and stock appreciation rights granted was determined using the Black-Scholes valuation method which gives consideration to the estimated value of the underlying stock at the date of grant, the exercise price of the option, the expected dividend yield and volatility of the underlying stock, the expected life of the option and the corresponding risk-free interest rate. When we were a private company, the deemed fair value of the underlying common stock was determined by management and the Board of Directors based on their best estimates using information from preferred stock financing transactions or other significant changes in the business. The fair value of the grants of restricted shares, all of which was granted after we became a public company, was determined based on the closing price of our stock on the date of grant. Stock compensation expense for options, stock appreciation rights and for time-based restricted share grants is amortized on a straight-line basis over the vesting period of the underlying issue, generally over four years except for grants to directors which generally vest over one to two years. Stock compensation expense for performance-based restricted shares is amortized on a straight-line basis over the anticipated vesting period and is subject to adjustment based on the actual achievement of objectives. Compensation expenses related to option grants to non-employees is periodically remeasured through the vesting date. Compensation expense is recognized only for those options expected to vest, with forfeitures estimated based on our historical experience and future expectations.

The amount of compensation expense to be recorded in future periods may increase if we make additional grants of options, stock appreciation rights or restricted shares or if employees continue to purchase shares under our employee stock purchase plan or if we determine that actual forfeiture rates are less than anticipated. The amount of expense to be recorded in future periods may decrease if we do not achieve the performance objectives on which certain restricted shares are contingent, if the requisite service periods are not completed or if the actual forfeiture rates are greater than anticipated.

Table of Contents

Additional detail regarding the adoption of SFAS 123(R) may be found in the notes to the financial statements.

Results of Operations

Comparison of the Three Months Ended June 30, 2006 and 2005

Revenues. Revenues decreased to \$3.8 million for the three months ended June 30, 2006 from \$6.1 million for the three months ended June 30, 2005, a decrease of approximately 38%. Revenues from the sale of systems decreased because of a decrease in the number of systems delivered from six to three. Revenues from sales of disposable interventional devices, service and accessories increased to \$954,000 for the three months ended June 30, 2006 from \$681,000 for the three months ended June 30, 2005, an increase of approximately 40%. This increase was attributable to the increased base of installed systems as well as additional revenue related to recently approved interventional devices.

Purchase orders and other commitments for our magnetic navigation system were approximately \$40.0 million at June 30, 2006. The Company does not include orders for disposables, service, or other revenues in the backlog data. There can be no assurance that we will recognize revenue in any particular period or at all because some of our purchase orders and other commitments are subject to contingencies that are outside our control. In addition, these orders and commitments may be revised, modified or canceled, either by their express terms, as a result of negotiations, or by project changes or delays.

Cost of Revenues. Cost of revenue decreased to \$2.2 million for the three months ended June 30, 2006 from \$3.2 million for the three months ended June 30, 2005, a decrease of approximately 32%. This decrease in cost of revenues was attributable primarily to the decreased number of systems sold and associated cost of systems sold. While the average selling price of the systems was approximately 12% greater than in the year ago quarter, the unit cost of the systems sold was approximately 15% higher than the 2005 quarter due to unabsorbed overhead costs associated with the reduced production and installation schedules during the current quarter. Gross margin was 43% for the current quarter compared to 48% for the 2005 quarter and was also adversely affected by one warranty replacement that occurred in the current quarter.

Research and Development Expenses. Research and development expenses increased to \$5.5 million for the three months ended June 30, 2006 from \$3.9 million for the three months ended June 30, 2005, an increase of approximately 43%. The increase was due principally to an increase in research and development projects, including continued integration and development related to disposable interventional devices, further development of the NIOBE platform technology and user interface improvements.

General and Administrative Expenses. General and administrative expenses increased to \$4.3 million for the three months ended June 30, 2006 from \$3.5 million for the three months ended June 30 2005, an increase of 23%. The increase relates to increased stock compensation costs due to the adoption of SFAS 123(R) and expanded activity in training, clinical compliance and regulatory affairs.

Sales and Marketing Expenses. Sales and marketing expenses increased to \$5.7 million for the three months ended June 30, 2006 from \$4.3 million for the three months ended June 30, 2005, an increase of approximately 33%. The increase related primarily to increased salary, benefits and travel expenses associated with hiring additional sales personnel and expanded marketing programs.

Royalty Settlement. Royalty Settlement expenses related to the resolution of a patent licensing dispute with the University of Virginia were \$2.9 million during the three months ended June 30, 2005. There were no such settlement expenses in 2006.

Interest Income. Interest income increased to \$630,000 for the three months ended June 30, 2006 from \$358,000 for the three months ended June 30, 2006, an increase of 76% due principally to greater invested balances generated from the common stock offering in the first quarter of 2006.

Interest Expense. Interest expense increased approximately 482% to \$330,000 for the three months ended June 30, 2006 from \$57,000 for the three months ended June 30, 2005 due to the amortization of commitment fees related to the affiliate line of credit entered into in the fourth quarter of 2005.

Comparison of the Six Months Ended June 30, 2006 and 2005

Revenues. Revenues decreased to \$5.5 million for the six months ended June 30, 2006 from \$11.2 million for the six months ended June 30, 2005, a decrease of approximately 51%. Revenues from the sale of systems decreased because of a decrease in the number of units delivered. Revenues from sales of disposable interventional devices, service and accessories increased to \$1.7 million for the six months ended June 30, 2006 from \$1.1 million for the six months ended June 30, 2005, an increase of approximately 49%. This increase was attributable to the increased base of installed systems as well as additional revenue related to recently approved interventional devices.

Edgar Filing: Stereotaxis, Inc. - Form 10-Q

Cost of Revenues. Cost of revenue decreased to \$3.4 million for the six months ended June 30, 2006, from \$5.6 million for the six months ended June 30, 2005. This decrease in cost of revenue was principally due to a decrease in the number of

Table of Contents

systems sold during 2006. Although the average selling price of the system increased by approximately 5% in 2006 as contrasted with 2005, margin declined from 50% during the six months ended June 30, 2005 to 38% in the comparable period in 2006 due primarily to unabsorbed overhead costs associated with the reduced production and installation schedules.

Research and Development Expenses. Research and development expenses increased to \$11.7 million for the six months ended June 30, 2006 from \$7.7 million for the six months ended June 30, 2005, a increase of approximately 52%. The increase was due principally to an increase in research and development projects, including continued integration and development related to disposable interventional devices, further development of the NIOBE platform technology and user interface improvements.

General and Administrative Expenses. General and administrative expenses increased to \$8.3 million for the six months ended June 30, 2006 from \$6.5 million for the six months ended June 30, 2005, an increase of 28%. The increase relates to increased stock compensation costs due to the adoption of SFAS 123(R) and expanded activity in training, clinical compliance and regulatory affairs.

Sales and Marketing Expenses. Sales and marketing expenses increased to \$10.6 million for the six months ended June 30, 2006 from \$7.6 million for the six months ended June 30, 2005, an increase of approximately 39%. The increase related primarily to increased salary, benefits and travel expenses associated with hiring additional sales personnel and expanded marketing programs.

Royalty Settlement. Royalty settlement expenses related to the resolution of a patent licensing dispute with the University of Virginia were \$2.9 million during the six months ended June 30, 2005. There were no such settlement expenses in 2006.

Interest Income. Interest income increased to \$1.1 million for the six months ended June 30, 2006 from \$566,000 for the six months ended June 30, 2005, an increase of 96%. Interest income increased due to greater invested balances and higher realized rates on investments during the six months ended June 30, 2006.

Interest Expense. Interest expense increased approximately 636% to \$884,000 for the six months ended June 30, 2006 from \$120,000 for the six months ended June 30, 2005 due to the amortization of commitment fees related to the affiliate line of credit entered into in the fourth quarter of 2005.

Liquidity and Capital Resources

Liquidity refers to the liquid financial assets available to fund our business operations and pay for near-term obligations. These liquid financial assets consist of cash and cash equivalents, as well as investments. In addition to our cash and cash equivalent balances, we maintained \$13.6 million and \$7.1 million of investments in corporate debt securities, U.S. government agency notes, commercial paper and certificates of deposit at June 30, 2006 and December 31, 2005, respectively. At June 30, 2006, we had working capital of approximately \$51.4 million, compared to \$15.9 million at December 31, 2005.

The following table summarizes our cash flow by operating, investing and financing activities for each of six month periods ended June 30, 2006 and 2005 (in thousands):

	Six Months Ended	
	2006	2005
Cash Flow used in operating activities	\$ (26,772)	\$ (15,445)
Cash Flow provided by (used in) investing activities	(8,151)	13,990
Cash Flow provided by financing activities	62,467	48

Net cash used in operating activities. We used approximately \$26.8 million and \$15.4 million of cash for operating activities during the six months ended June 30, 2006 and 2005, respectively, primarily as a result of operating losses during these periods. Cash used for working capital purposes was \$1.8 million during the six months ended June 30, 2006 compared to \$2.6 million generated from working capital purposes during the same period in 2005. The use of working capital was due to an increase in inventory in anticipation of outsourcing production and an increase in accounts receivable offset by a decrease in prepaid expenses.

Net cash provided by (used in) investing activities. We used approximately \$8.2 million of cash in investing activities during the six months ended June 30, 2006, principally for the purchase of investments. During the six months ended June 30, 2005, we generated \$14.0 million of

cash, substantially all from the maturity or sale of investments.

Table of Contents

Net cash provided by financing activities. We generated approximately \$62.5 million from financing activities during the six months ended June 30, 2006 primarily from the proceeds of our common stock offering in the first quarter of 2006 as well as option exercises, offset by scheduled repayment of our equipment loans. We received approximately \$48,000 from financing activities during the six months ended June 30, 2005, due principally to the exercise of stock options and warrants.

As of June 30, 2006, we had outstanding balances under various equipment loan agreements consisting of an aggregate of approximately \$1.5 million. As of June 30, 2006, we had approximately \$1.0 million outstanding under our working capital line of credit and had an unused line of \$9.0 million with borrowing capacity of \$8.8 million, secured by qualifying receivables and inventory balances.

These credit facilities are secured by substantially all of our assets. The credit agreements include customary affirmative, negative and financial covenants. For example, we are restricted from incurring additional debt, disposing of or pledging our assets, entering into merger or acquisition agreements, making certain investments, allowing fundamental changes to our business, ownership, management or business locations, and from making certain payments in respect of stock or other ownership interests, such as dividends and stock repurchases. Under our loan arrangements, we are required to maintain a ratio of quick assets (cash, cash equivalents, accounts receivable and short-term investments) to current liabilities minus deferred revenue of at least 1.25 to 1. We were also required under the credit agreements to maintain our primary operating account and the majority of our cash and investment balances in accounts with the lender. As of June 30, 2006, we are in compliance with all covenants of this agreement.

In November 2005, we entered into a six-month commitment with certain affiliates providing for the availability of up to \$20.0 million in unsecured borrowings. This commitment was available to drawn against at any time through May 10, 2006, the initial six-month commitment period. The commitment period, as well as the maturity date on any funds drawn under the commitment, was subject to one six-month extension, through November 2006, at our sole election. The lenders received five-year warrants to purchase shares of our common stock upon commitment of the funds. We did not draw funds under this agreement nor did we extend the commitment period beyond its May 2006 expiration.

In February 2006, we completed a public offering of 5,500,000 shares of our common stock at \$12.00 per share which included the exercise by the underwriters of an option to purchase an additional 500,000 shares. In conjunction with these transactions, we received approximately \$61.9 million in net proceeds after deduction of underwriting discounts and commissions and payment of offering expenses.

We expect to have negative cash flow from operations through most of 2007. Throughout 2006, we expect to continue the development and commercialization of our products, the continuation of our research and development programs and the advancement of new products into clinical development. We expect that our research and development expenditures will continue to increase above the 2005 levels during 2006 and our selling, general and administrative expenses will continue to increase in order to support our product commercialization efforts and to implement procedures required by our status as a public company. Until we can generate significant cash flow from our operations, we expect to continue to fund our operations with existing cash resources that were primarily generated from the proceeds of our public offerings, private sales of our equity securities and working capital and equipment financing loans. In the future, we may finance future cash needs through the sale of other equity securities, strategic collaboration agreements and debt financings. We cannot accurately predict the timing and amount of our utilization of capital, which will depend on a number of factors outside of our control.

While we believe our existing cash, cash equivalents and investments will be sufficient to fund our operating expenses and capital equipment requirements through the next 12 months, we cannot assure you that we will not require additional financing before that time. We also cannot assure you that such additional financing will be available on a timely basis on terms acceptable to us or at all, or that such financing will not be dilutive to our stockholders. If adequate funds are not available to us, we could be required to delay development or commercialization of new products, to license to third parties the rights to commercialize products or technologies that we would otherwise seek to commercialize ourselves or to reduce the marketing, customer support or other resources devoted to our products, any of which could have a material adverse effect on our business, financial condition and results of operations.

Off-Balance Sheet Arrangements

We do not currently have, nor have we ever had, any relationships with unconsolidated entities or financial partnerships, such as entities often referred to as structured finance or special purpose entities, which would have been established for the purpose of facilitating off-balance sheet arrangements or other contractually narrow or limited purposes. In addition, we do not engage in trading activities involving non-exchange traded contracts. As a result, we are not materially exposed to any financing, liquidity, market or credit risk that could arise if we had engaged in these relationships.

Table of Contents

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

We have exposure to currency fluctuations. We operate mainly in the U.S., Europe and Asia and we expect to continue to sell our products both within and outside of the U.S. We expect to transact this business primarily in U.S. dollars and in Euros, although we may transact business in other currencies to a lesser extent. Future fluctuations in the value of these currencies may affect the price competitiveness of our products. In addition, because we have a relatively long installation cycle for our systems, we will be subject to risk of currency fluctuations between the time we execute a purchase order and the time we deliver the system and collect payments under the order, which could adversely affect our operating margins. We have not hedged exposures in foreign currencies or entered into any other derivative instruments. As a result, we will be exposed to some exchange risks for foreign currencies. For example, if the currency exchange rate were to fluctuate by 10%, we believe that our revenues could be affected by as much as 2 to 3%.

We also have exposure to interest rate risk related to our investment portfolio and our borrowings. The primary objective of our investment activities is to preserve principal while at the same time maximizing the income we receive from our invested cash without significantly increasing the risk of loss.

Our interest income is sensitive to changes in the general level of U.S. interest rates, particularly since the majority of our investments are in short-term debt instruments. We invest our excess cash primarily in U.S. government securities and marketable debt securities of financial institutions and corporations with strong credit ratings. These instruments generally have maturities of two years or less when acquired. We do not utilize derivative financial instruments, derivative commodity instruments or other market risk sensitive instruments, positions or transactions. Accordingly, we believe that while the instruments we hold are subject to changes in the financial standing of the issuer of such securities, we are not subject to any material risks arising from changes in interest rates, foreign currency exchange rates, commodity prices, equity prices or other market changes that affect market risk sensitive instruments.

We do not believe that inflation has had a material adverse impact on our business or operating results during the periods covered by this report.

ITEM 4. CONTROLS AND PROCEDURES

Disclosure Controls and Procedures: The Company's management, with the participation of the Company's Chief Executive Officer and Chief Financial Officer, has evaluated the effectiveness of the Company's disclosure controls and procedures (as such term is defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended (the "Exchange Act")), as of the end of the period covered by this report. Any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives, and management is required to apply its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based on such evaluation, the Company's Chief Executive Officer and Chief Financial Officer have concluded that, as of the end of such period, the Company's disclosure controls and procedures provided reasonable assurance that the disclosure controls and procedures are effective in recording, processing, summarizing and reporting, on a timely basis, information required to be disclosed by the Company in reports that it files or submits under the Exchange Act.

Changes In Internal Control Over Financial Reporting: The Company's management, with the participation of the Company's Chief Executive Officer and Chief Financial Officer, also conducted an evaluation of the Company's internal control over financial reporting to determine whether any changes occurred during the period covered by this report that have materially affected, or are reasonably likely to materially affect, the Company's internal control over financial reporting. Based on that evaluation, there has been no such change during the period covered by this report.

Table of Contents

STEREOTAXIS, INC.

PART II OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

We are involved from time to time in various lawsuits and claims arising in the ordinary course of business. Although the outcomes of these lawsuits and claims are uncertain, we do not believe any of them will have a material adverse effect on our business, financial condition or results of operations.

ITEM 1A. RISK FACTORS

The following uncertainties and factors, among others, could affect future performance and cause actual results to differ materially from those expressed or implied by forward looking statements.

Hospital decision-makers may not purchase our Stereotaxis System or may think that it is too expensive.

The market for our products and related technology is not well established. To achieve continued sales, hospitals must purchase our products, and in particular, our NIOBE cardiology magnet system. The NIOBE cardiology magnet system, which is the core of our Stereotaxis System, is a novel device, and hospitals and physicians are traditionally slow to adopt new products and treatment practices. In addition, hospitals may delay their purchase or installation decision based on the disposable interventional devices that have received regulatory clearance or approval. Moreover, the Stereotaxis System is an expensive piece of capital equipment, representing a significant portion of the cost of a new or replacement cath lab. If hospitals do not widely adopt our Stereotaxis System, or if they decide that it is too expensive, we may never become profitable. Any failure to sell as many Stereotaxis Systems as our business plan requires could also have a seriously detrimental impact on our results of operations, financial condition and cash flow.

Physicians may not use our products if they do not believe they are safe and effective.

We believe that physicians will not use our products unless they determine that the Stereotaxis System provides a safe, effective and preferable alternative to interventional methods in general use today. Currently, there is only limited clinical data on the Stereotaxis System with which to assess safety and efficacy. If longer-term patient studies or clinical experience indicate that treatment with our system or products is less effective, less efficient or less safe than our current data suggest, our sales would be harmed, and we could be subject to significant liability. Further, unsatisfactory patient outcomes or patient injury could cause negative publicity for our products, particularly in the early phases of product introduction. In addition, physicians may be slow to adopt our products if they perceive liability risks arising from the use of these new products. It is also possible that as our products become more widely used, latent defects could be identified, creating negative publicity and liability problems for us and adversely affecting demand for our products. If physicians do not use our products, we likely will not become profitable or generate sufficient cash to survive as a going concern.

Our collaborations with Siemens, Philips, Biosense Webster or other parties may fail, or we may not be able to enter into additional partnerships or collaborations in the future.

We are collaborating with Siemens, Philips, Biosense Webster and other parties to integrate our instrument control technology with their respective imaging products or disposable interventional devices and to co-develop additional disposable interventional devices for use with our Stereotaxis System. For the immediate future, a significant portion of our revenues from system sales will be derived from these integrated products. In addition, Siemens has agreed to provide post-installation maintenance and support services to our customers for our integrated systems and we are in discussions with Philips to provide the same.

Our product commercialization plans could be disrupted, leading to lower than expected revenue and a material and adverse impact on our results of operations and cash flow, if:

any of our collaboration partners delays or fails in the integration of its technology with our Stereotaxis System as planned;

Edgar Filing: Stereotaxis, Inc. - Form 10-Q

any of our collaboration partners does not co-market and co-promote our integrated products diligently or does not provide maintenance and support services as we expect; or

we become involved in disputes with one or more of our collaboration partners regarding our collaborations.

Table of Contents

Siemens, Philips and Biosense Webster, as well as some of our other collaborators, are large, global organizations with diverse product lines and interests that may diverge from our interests in commercializing our products. Accordingly, our collaborators may not devote adequate resources to our products, or may experience financial difficulties, change their business strategy or undergo a business combination that may affect their willingness or ability to fulfill their obligations to us. In particular, we have had only limited experience with respect to the integration of our system with Philips imaging products.

The failure of one or more of our collaborations could have a material adverse effect on our financial condition, results of operations and cash flow. In addition, if we are unable to enter into additional partnerships in the future, or if these partnerships fail, our ability to develop and commercialize products could be impacted negatively and our revenues could be adversely affected.

Investors may have difficulty evaluating our business and operating results because we are still in the early stages of commercializing our products.

We have been engaged in research and product development since our inception in 1990. Our initial focus was on the development of neurosurgical applications for our technology, and during the first several years following our inception, we devoted our resources primarily to developing prototypes and performing research and development activities in this area. Starting around 1998, we shifted our primary focus over the next two years to developing applications for our technology to treat cardiovascular disease and, in 2003, began limited commercial shipments of products we developed for treatment in this area. To date, our investments in our products have produced relatively little revenue, and our operating expenses are high relative to that revenue. Our lack of a significant operating history also impairs an investor's ability to make a comparative evaluation of us, our products and our prospects.

We have limited experience selling, marketing and distributing products, which could impair our ability to increase revenues.

We currently market our products in the U.S., Europe and the rest of the world through a direct sales force of sales specialists, distributors and sales agents, supported by account managers that provide training, clinical support, and other services to our customers. If we are unable to increase our sales force or effectively utilize our existing sales force significantly in the foreseeable future, we may be unable to generate the revenues we have projected in our business plan. Factors that may inhibit our sales and marketing efforts include:

our inability to recruit and retain adequate numbers of qualified sales and marketing personnel;

the inability of sales personnel to obtain access to or persuade adequate numbers of hospitals and physicians to purchase and use our products;

unforeseen costs associated with maintaining and expanding an independent sales and marketing organization; and

increased government scrutiny with respect to marketing activities in the health care industry.

In addition, if we fail to effectively use distributors or contract sales persons for distribution of our products where appropriate, our revenues and profitability would be adversely affected.

Our marketing strategy is dependent on collaboration with physician thought leaders.

Our research and development efforts and our marketing strategy depend heavily on obtaining support and collaboration from highly regarded physicians at leading commercial and research hospitals, particularly in the U.S. and Europe. If we are unable to gain and/or maintain such support and collaboration or if the reputation or standing of these physicians is impaired or otherwise adversely affected, our ability to market the Stereotaxis System and, as a result, our financial condition, results of operations and cash flow could be materially and adversely affected.

We may not be able to rapidly train physicians in numbers sufficient to generate adequate demand for our products.

Edgar Filing: Stereotaxis, Inc. - Form 10-Q

In order for physicians to learn to use the Stereotaxis System, they must attend one or more training sessions in order to familiarize themselves with a sophisticated user interface. Market acceptance could be delayed by lack of physician willingness to attend training sessions or by the time required to complete this training. An inability to train a sufficient number of physicians to generate adequate demand for our products could have a material adverse impact on our financial condition and cash flow.

Table of Contents

Customers may choose to purchase competing products and not ours.

Our products must compete with established manual interventional methods. These methods are widely accepted in the medical community, have a long history of use and do not require the purchase of an additional expensive piece of capital equipment. In addition, many of the medical conditions that can be treated using our products can also be treated with existing pharmaceuticals or other medical devices and procedures. Many of these alternative treatments are widely accepted in the medical community and have a long history of use.

We also face competition from companies that are developing drugs or other medical devices or procedures to treat the conditions for which our products are intended. The medical device and pharmaceutical industries make significant investments in research and development, and innovation is rapid and continuous. For example, we are aware that two private companies are developing non-magnetic assisted navigation devices that could compete directly with the Stereotaxis System. However, to the best of our knowledge, these products have not been commercialized. If these or other new products or technologies emerge that provide the same or superior benefits as our products at equal or lesser cost, it could render our products obsolete or unmarketable. We cannot be certain that physicians will use our products to replace or supplement established treatments or that our products will be competitive with current or future products and technologies.

Most of our other competitors also have longer operating histories, significantly greater financial, technical, marketing and other resources, greater name recognition and a larger base of customers than we do. In addition, as the markets for medical devices develop, additional competitors could enter the market. We cannot assure you that we will be able to compete successfully against existing or new competitors. Our revenues would be reduced or eliminated if our competitors develop and market products that are more effective and less expensive than our products.

If we are unable to fulfill our current purchase orders and other commitments on a timely basis or at all, we may not be able to achieve future sales growth.

We currently have outstanding purchase orders and other commitments for our systems. There can be no assurance that we will recognize revenue in any particular period or at all because some of our purchase orders and other commitments are subject to contingencies that are outside our control. In addition, these orders and commitments may be revised, modified or canceled, either by their express terms, as a result of negotiations or by project changes or delays. The installation of our system is inherently controlled by the cath lab construction or renovation process which comprises multiple stages, all of which are outside of our control. Although the actual installation of our system requires only a few weeks, and can be accomplished by either our staff or by subcontractors, successful installation of our system can be subjected to delays related to the overall construction or renovation process. If we experience any failures or delays in completing the installation of these systems, our reputation would suffer and we may not be able to sell additional systems. Substantial delays in the installation process also increase the risk that a customer would attempt to cancel a purchase order. This would have a negative effect on our revenues and results of operations.

We will likely experience long and variable sales and installation cycles, which could result in substantial fluctuations in our quarterly results of operations.

We anticipate that our system will continue to have a lengthy sales cycle because it consists of a relatively expensive piece of capital equipment, the purchase of which requires the approval of senior management at hospitals, inclusion in the hospitals' cath lab budget process for capital expenditures, and, in some instances, a certificate of need from the state or other regulatory approval. In addition, our system has historically been installed six to eight months after the receipt of a purchase order from a hospital depending on the construction cycle for the new or replacement interventional suite in which the equipment will be installed. In some cases, this time frame has been extended further to as much as 12 to 24 months because the interventional suite construction is part of a larger construction project at the customer site (typically the construction of a new building), which may occur with our existing and future purchase orders. Recently, these factors, in particular within the context of FDA approval delays for some of our disposable devices, have resulted in a conversion cycle of nine months or longer between the date of a given purchase order and recognition of that purchase order into revenue. This in turn has contributed, and may continue to contribute to substantial fluctuations in our quarterly operating results, particularly in the near term and during any other periods in which our sales volume is relatively low. As a result, in future quarters our operating results could fall below the expectations of securities analysts or investors, in which event our stock price would likely decrease.

Table of Contents

If the magnetic fields generated by our system are not compatible with, or interfere with, other widely used equipment in the cath lab, sales of our products would be negatively affected.

Our system generates magnetic fields that directly govern the motion of the internal, or working, tip of disposable interventional devices. If other equipment in the cath lab or elsewhere in a hospital is incompatible with the magnetic fields generated by our system, or if our system interferes with such equipment, we may be required to install additional shielding, which may be expensive and which may not solve the problem. Although we have modified our shielding approach, if magnetic interference is a problem at additional institutions, it would increase our installation costs at those institutions and could limit the number of hospitals that would be willing to purchase and install our systems, either of which would adversely affect our financial condition, results of operations and cash flow.

The use of our products could result in product liability claims that could be expensive, divert management's attention and harm our reputation and business.

Our business exposes us to significant risks of product liability claims. The medical device industry has historically been litigious, and we could face product liability claims if the use of our products were to cause injury or death. The coverage limits of our product liability insurance policies may not be adequate to cover future claims, and we may be unable to maintain product liability insurance in the future at satisfactory rates or adequate amounts. A product liability claim, regardless of its merit or eventual outcome, could divert management's attention, result in significant legal defense costs, significant harm to our reputation and a decline in revenues.

Our costs could substantially increase if we receive a significant number of warranty claims.

We generally warrant each of our products against defects in materials and workmanship for a period of 12 months from the acceptance of our product by a customer. If product returns or warranty claims increase, we could incur unanticipated additional expenditures for parts and service. In addition, our reputation and goodwill in the cath lab market could be damaged. While we have established reserves for liability associated with product warranties, unforeseen warranty exposure in excess of those reserves could materially and adversely affect our financial condition, results of operations and cash flow.

We may not generate cash from operations necessary to commercialize our existing products and invest in new products.

Although we completed a public offering of our common stock in early 2006, we may require additional funds to meet our working capital and capital expenditure needs in the future. We cannot be certain that we will be able to obtain additional financing on favorable terms or at all. If we need additional capital and cannot raise it on acceptable terms, we may not be able to, among other things:

enhance our existing products or develop new ones;

expand our operations;

hire, train and retain employees; or

respond to competitive pressures or unanticipated capital requirements.

Our failure to do any of these things could result in lower revenues and adversely affect our financial condition and results of operations, and we may have to curtail or cease operations.

We have incurred substantial losses in the past and may not be profitable in the future.

We have incurred substantial net losses since inception, and we expect to incur substantial net losses in 2006 as we seek additional regulatory approvals, launch new products and generally continue to scale up our sales and marketing operations to continue the commercialization of our products. A small portion of our accumulated deficit is attributable to investments in development of products for neurosurgical applications, which was our primary focus in the first several years after our inception in 1990. Because we may not be successful in completing the

Edgar Filing: Stereotaxis, Inc. - Form 10-Q

development or commercialization of our technology, your return on these investments may be limited. Moreover, the extent of our future losses and the timing of profitability are highly uncertain, and we may never achieve profitable operations. If we require more time than we expect to generate significant revenues and achieve profitability, we may not be able to continue our operations. Our failure to achieve profitability could negatively impact the market price of our common stock. Even if we do become profitable, we may not be able to sustain or increase profitability on a quarterly or annual basis. Furthermore, even if we achieve significant revenues, we may choose to pursue a strategy of increasing market penetration and presence or expand or accelerate new product development or clinical research activities at the expense of profitability.

Table of Contents

Our increased reliance on contract manufacturers and on suppliers, and in some cases, a single supplier, could harm our ability to meet demand for our products in a timely manner or within budget.

We depend on contract manufacturers to produce and assemble most of the components of our systems and other products such as our guidewires and electrophysiology catheters. We also depend on various third party suppliers for the magnets we use in our NIOBE cardiology magnet systems. In addition, some of the components necessary for the assembly of our products are currently provided to us by a single supplier, including the magnets for our NIOBE cardiology magnet system, and we generally do not maintain large volumes of inventory. Our reliance on these third parties involves a number of risks, including, among other things, the risk that:

we may not be able to control the quality and cost of our system or respond to unanticipated changes and increases in customer orders;

we may lose access to critical services and components, resulting in an interruption in the manufacture, assembly and shipment of our systems; and

we may not be able to find new or alternative components for our use or reconfigure our system and manufacturing processes in a timely manner if the components necessary for our system become unavailable.

If any of these risks materialize, it could significantly increase our costs and impair product delivery.

In addition, if these manufacturers or suppliers stop providing us with the components or services necessary for the operation of our business, we may not be able to identify alternate sources in a timely fashion. Any transition to alternate manufacturers or suppliers would likely result in operational problems and increased expenses and could delay the shipment of, or limit our ability to provide, our products. We cannot assure you that we would be able to enter into agreements with new manufacturers or suppliers on commercially reasonable terms or at all. Additionally, obtaining components from a new supplier may require a new or supplemental filing with applicable regulatory authorities and clearance or approval of the filing before we could resume product sales. Any disruptions in product flow may harm our ability to generate revenues, lead to customer dissatisfaction, damage our reputation and result in additional costs or cancellation of orders by our customers.

We also rely on our collaboration partner, Biosense Webster, and other parties to manufacture a number of disposable interventional devices for use with our Stereotaxis System. If these parties cannot manufacture sufficient quantities of disposable interventional devices to meet customer demand, or if their manufacturing processes are disrupted, our revenues and profitability would be adversely affected.

Risks associated with international manufacturing and trade could negatively impact the availability and cost of our products because materials used to manufacture our magnets, one of our key system components, are sourced from Japan and China.

We purchase the permanent magnets for our NIOBE cardiology magnet system from a manufacturer that uses material produced in Japan, and certain of the production work for these magnets is performed for this manufacturer in China. In addition, we purchase our magnets for our disposable interventional devices directly from a manufacturer in Japan, and a number of other components for our system in foreign jurisdictions, including components sourced locally in connection with installations. Any event causing a disruption of imports, including the imposition of import restrictions, could adversely affect our business. The flow of components from our vendors could also be adversely affected by financial or political instability in any of the countries in which the goods we purchase are manufactured, if the instability affects the production or export of product components from those countries. Trade restrictions in the form of tariffs or quotas, or both, could also affect the importation of those product components and could increase the cost and reduce the supply of products available to us. In addition, decreases in the value of the U.S. dollar against foreign currencies could increase the cost of products we purchase from overseas vendors.

We have limited experience in manufacturing and assembling our products and may encounter problems at our manufacturing facilities or otherwise experience manufacturing delays that could result in lost revenue.

We do not have extensive experience in manufacturing, assembling or testing our products on a commercial scale. In addition, for our NIOBE cardiology magnet systems, we subcontract the manufacturing and assembly of major components. As a result, we may be unable to meet the expected future demand for our Stereotaxis System. In addition, the products we design may not satisfy all of the performance requirements and we may need to improve or modify the design or production process in order to do so. We may also experience quality problems, substantial costs and unexpected delays in our efforts to upgrade and expand our manufacturing, assembly and testing capabilities. If we incur delays due to

quality problems or other

Table of Contents

unexpected events, we will be unable to produce a sufficient supply of systems necessary to meet our future growth expectations. In addition, we design, test and manufacture a portion of the disposable devices that are used with our NIOBE magnetic navigation system. In order to do so, we will need to retain qualified employees for our assembly and testing operations. We could encounter problems at either of these facilities, which could delay or prevent us from assembling or testing our products or maintaining our pilot manufacturing capabilities or otherwise conducting operations.

We may be unable to protect our technology from use by third parties.

Our commercial success will depend in part on obtaining patent and other intellectual property right protection for the technologies contained in our products and on successfully defending these rights against third party challenges. The patent positions of medical device companies, including ours, can be highly uncertain and involve complex and evolving legal and factual questions. We cannot assure you that we will obtain the patent protection we seek, that any protection we do obtain will be found valid and enforceable if challenged or that it will confer any significant commercial advantage. U.S. patents and patent applications may also be subject to interference proceedings and U.S. patents may be subject to reexamination proceedings in the U.S. Patent and Trademark Office, and foreign patents may be subject to opposition or comparable proceedings in the corresponding foreign patent office, which proceedings could result in either loss of the patent or denial of the patent application or loss, or reduction in the scope of one or more of the claims of, the patent or patent application. In addition, such interference, reexamination and opposition proceedings may be costly. Thus, any patents that we own or license from others may not provide any protection against competitors. Our pending patent applications, those we may file in the future or those we may license from third parties may not result in patents being issued. If issued, they may not provide us with proprietary protection or competitive advantages against competitors with similar technology.

Some of our technology was developed in conjunction with third parties, and thus there is a risk that a third party may claim rights in our intellectual property. Outside the U.S., we rely on third-party payment services for the payment of foreign patent annuities and other fees. Non-payment or delay in payment of such fees, whether intentional or unintentional, may result in loss of patents or patent rights important to our business. Many countries, including certain countries in Europe, have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties (for example, the patent owner has failed to work the invention in that country, or the third party has patented improvements). In addition, many countries limit the enforceability of patents against government agencies or government contractors. In these countries, the patent owner may have limited remedies, which could materially diminish the value of the patent. We also cannot assure you that we will be able to develop additional patentable technologies. If we fail to obtain adequate patent protection for our technology, or if any protection we obtain becomes limited or invalidated, others may be able to make and sell competing products, impairing our competitive position.

Our trade secrets, nondisclosure agreements and other contractual provisions to protect unpatented technology provide only limited and possibly inadequate protection of our rights. As a result, third parties may be able to use our unpatented technology, and our ability to compete in the market would be reduced. In addition, employees, consultants and others who participate in developing our products or in commercial relationships with us may breach their agreements with us regarding our intellectual property, and we may not have adequate remedies for the breach.

Our competitors may independently develop similar or alternative technologies or products that are equal or superior to our technology and products without infringing any of our patent or other intellectual property rights, or may design around our proprietary technologies. In addition, the laws of some foreign countries do not protect intellectual property rights to the same extent as do the laws of the U.S., particularly in the field of medical products and procedures.

Third parties may assert that we are infringing their intellectual property rights.

Successfully commercializing our products will depend in part on not infringing patents held by third parties. It is possible that one or more of our products, including those that we have developed in conjunction with third parties, infringes existing patents. We may also be liable for patent infringement by third parties whose products we use or combine with our own and for which we have no right to indemnification. In addition, because patent applications are maintained under conditions of confidentiality and can take many years to issue, there may be applications now pending of which we are unaware and which may later result in issued patents that our products infringe. Whether a product infringes a patent involves complex legal and factual issues and may not become clear until finally determined by a court in litigation. Our competitors may assert that our products infringe patents held by them. Moreover, as the number of competitors in our market grows, the possibility of a patent infringement claim against us increases. If we were not successful in obtaining a license or redesigning our products, we could be subject to litigation. If we lose in this kind of litigation, a court could require us to pay substantial damages or prohibit us from using technologies essential to our products covered by third-party patents. An inability to use technologies essential to our products would have a material adverse effect on our financial condition, results of operations and cash flow and could undermine our ability to continue operating as a going concern.

Table of Contents

Expensive intellectual property litigation is frequent in the medical device industry.

Infringement actions, validity challenges and other intellectual property claims and proceedings, whether with or without merit, can be expensive and time-consuming and would divert management's attention from our business. We have incurred, and expect to continue to incur, substantial costs in obtaining patents and may have to incur substantial costs defending our proprietary rights. Incurring such costs could have a material adverse effect on our financial condition, results of operations and cash flow.

We may not be able to obtain all the licenses from third parties necessary for the development of new products.

As we develop additional disposable interventional devices for use with our system, we may find it advisable or necessary to seek licenses or otherwise make payments in exchange for rights from third parties who hold patents covering technology used in specific interventional procedures. For example, in 2005 we made a substantial payment to the University of Virginia Patent Foundation to eliminate any requirement for us to pay royalties of Stereotaxis products that address clinical applications in the cardiovascular, peripheral vascular and certain other clinical fields. If we cannot obtain the desired licenses or rights, we could be forced to try to design around those patents at additional cost or abandon the product altogether, which could adversely affect revenues and results of operations. If we have to abandon a product, our ability to develop and grow our business in new directions and markets would be adversely affected.

Our products and related technologies can be applied in different industries, and we may fail to focus on the most profitable areas.

The Stereotaxis System is designed to have the potential for expanded applications beyond interventional cardiology and electrophysiology, including congestive heart failure, structural heart repair, interventional neurosurgery, interventional neuroradiology, peripheral vascular, pulmonology, urology, gynecology and gastrointestinal medicine. However, we have limited financial and managerial resources and therefore may be required to focus on products in selected industries and to forego efforts with regard to other products and industries. Our decisions may not produce viable commercial products and may divert our resources from more profitable market opportunities. Moreover, we may devote resources to developing products in these additional areas but may be unable to justify the value proposition or otherwise develop a commercial market for products we develop in these areas, if any. In that case, the return on investment in these additional areas may be limited, which could negatively affect our results of operations.

We may be subject to damages resulting from claims that our employees or we have wrongfully used or disclosed alleged trade secrets of their former employers.

Many of our employees were previously employed at universities or other medical device companies, including our competitors or potential competitors. We could in the future be subject to claims that these employees or we have used or disclosed trade secrets or other proprietary information of their former employers. Litigation may be necessary to defend against these claims. If we fail in defending such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel. A loss of key research personnel or their work product could hamper or prevent our ability to commercialize certain potential products, which could severely harm our business. Even if we are successful in defending against these claims, litigation could result in substantial costs and be a distraction to management. Incurring such costs could have a material adverse effect on our financial condition, results of operations and cash flow.

If we or our strategic partners fail to obtain or maintain necessary FDA clearances for our medical device products, or if such clearances or approvals are delayed, we will be unable to continue to commercially distribute and market our products.

Our products are medical devices that are subject to extensive regulation in the U.S. and in foreign countries where we do business. Unless an exemption applies, each medical device that we wish to market in the U.S. must first receive either 510(k) clearance or pre-market approval, or PMA, from the U.S. Food and Drug Administration pursuant to the Federal Food, Drug, and Cosmetic Act. The FDA's 510(k) clearance process usually takes from four to 12 months, but it can take longer. The process of obtaining PMA approval is much more costly, lengthy and uncertain, generally taking from one to three years or even longer. Although we have 510(k) clearance for our current Stereotaxis System, including a limited number of disposable interventional devices, and are able to market our system commercially in the U.S., our business model

Table of Contents

relies significantly on revenues from additional disposable interventional devices for which there is no current FDA clearance or approval. We cannot commercially market our unapproved disposable interventional devices in the U.S. until the necessary clearance or approvals from the FDA have been received. Until such time, we can only supply these devices to research institutions for permitted investigational use. In addition, we are working with third parties with whom we are co-developing disposable products. In some cases, these companies are responsible for obtaining appropriate regulatory clearance or approval to market these disposable devices. If these clearances or approvals are not received or are substantially delayed or if we are not able to offer sufficient array of approved disposable interventional devices, we may not be able to successfully market our system to as many institutions as we currently expect, which could have a material adverse impact on our financial condition, results of operations and cash flow.

Furthermore, obtaining 510(k) clearances, pre-market approvals, or PMAs, or premarket approval supplements, or PMA supplements, from the FDA could result in unexpected and significant costs for us and consume management's time and other resources. The FDA could ask us to supplement our submissions, collect non-clinical data, conduct clinical trials or engage in other time-consuming actions, or it could simply deny our applications. In addition, even if we obtain a 510(k) clearance or PMA or PMA supplement approval, the clearance or approval could be revoked or other restrictions imposed if post-market data demonstrates safety issues or lack of effectiveness. We cannot predict with certainty how, or when, the FDA will act. Obtaining regulatory approvals in foreign markets entails similar risks and uncertainties and can involve additional product testing and additional administrative review periods. If we are unable to obtain the necessary regulatory approvals, our financial condition and cash flow may be adversely affected. Also, a failure to obtain approvals may limit our ability to grow domestically and internationally.

If we or our strategic partners fail to obtain regulatory approvals in other countries for products under development, we will not be able to commercialize these products in those countries.

In order to market our products outside of the U.S., we and our strategic partners must establish and comply with numerous and varying regulatory requirements of other countries regarding safety and efficacy. Approval procedures vary among countries and can involve additional product testing and additional administrative review periods. The time required to obtain approval in other countries might differ from that required to obtain FDA approval. The regulatory approval process in other countries may include all of the risks detailed above regarding FDA approval in the U.S. Regulatory approval in one country does not ensure regulatory approval in another, but a failure or delay in obtaining regulatory approval in one country may negatively impact the regulatory process in others. Failure to obtain regulatory approval in other countries or any delay or setback in obtaining such approval could have the same adverse effects described above regarding FDA approval in the U.S. In addition, we are relying on our strategic partners in some instances to assist us in this regulatory approval process in countries outside the U.S. and Europe, for example, in Japan and China.

We may fail to comply with continuing regulatory requirements of the FDA and other authorities and become subject to substantial penalties.

Even after product clearance or approval, we must comply with continuing regulation by the FDA and other authorities, including the FDA's Quality System Regulation, or QSR, requirements, labeling and promotional requirements and medical device adverse event and other reporting requirements. Any failure to comply with continuing regulation by the FDA or other authorities could result in enforcement action that may include suspension or withdrawal of regulatory approvals, recalling products, ceasing product marketing, seizure and detention of products, paying significant fines and penalties, criminal prosecution and similar actions that could limit product sales, delay product shipment and harm our profitability.

Additionally, any modification to an FDA 510(k)-cleared device that could significantly affect its safety or effectiveness, or that would constitute a major change in its intended use, requires a new 510(k) clearance. Device modifications to a PMA approved device or its labeling may require either a new PMA or PMA supplement approval, which could be a costly and lengthy process. In the future, we may modify our products after they have received clearance or approval, and we may determine that new clearance or approval is unnecessary. We cannot assure you that the FDA would agree with any of our decisions not to seek new clearance or approval. If the FDA requires us to seek clearance or approval for any modification, we also may be required to cease marketing or recall the modified product until we obtain FDA clearance or approval which could also limit product sales, delay product shipment and harm our profitability. In addition, Congress could amend the Federal Food, Drug and Cosmetic Act, and the FDA could modify its regulations promulgated under this law in a way so as to make ongoing regulatory compliance more burdensome and difficult.

In many foreign countries in which we market our products, we are subject to regulations affecting, among other things, product standards, packaging requirements, labeling requirements, import restrictions, tariff regulations, duties and

Table of Contents

tax requirements. Many of these regulations are similar to those of the FDA. In addition, in many countries the national health or social security organizations require our products to be qualified before procedures performed using our products become eligible for reimbursement. Failure to receive, or delays in the receipt of, relevant foreign qualifications could have a material adverse effect on our business, financial condition and results of operations. Due to the movement toward harmonization of standards in the European Union, we expect a changing regulatory environment in Europe characterized by a shift from a country-by-country regulatory system to a European Union-wide single regulatory system. We cannot predict the timing of this harmonization and its effect on us. Adapting our business to changing regulatory systems could have a material adverse effect on our business, financial condition and results of operations. If we fail to comply with applicable foreign regulatory requirements, we may be subject to fines, suspension or withdrawal of regulatory approvals, product recalls, seizure of products, operating restrictions and criminal prosecution.

Our suppliers or we may fail to comply with the FDA quality system regulation.

Our manufacturing processes must comply with the FDA's quality system regulation, or QSR, which covers the methods and documentation of the design, testing, production, control, quality assurance, labeling, packaging and shipping of our products. The FDA enforces the QSR through inspections. We cannot assure you that we would pass such an inspection. Failure to pass such an inspection could force a shut down of our manufacturing operations, a recall of our products or the imposition of other sanctions, which would significantly harm our revenues and profitability. Further, we cannot assure you that our key component suppliers are or will continue to be in compliance with applicable regulatory requirements and will not encounter any manufacturing difficulties. Any failure to comply with the FDA's QSR by us or our suppliers could significantly harm our available inventory and product sales.

Software or other defects may be discovered in our products.

Our products incorporate many components, including sophisticated computer software. Complex software frequently contains errors, especially when first introduced. Because our products are designed to be used to perform complex interventional procedures, we expect that physicians and hospitals will have an increased sensitivity to the potential for software defects. We cannot assure you that our software or other components will not experience errors or performance problems in the future. If we experience software errors or performance problems, we would likely also experience:

loss of revenue;

delay in market acceptance of our products;

damage to our reputation;

additional regulatory filings;

product recalls;

increased service or warranty costs; and/or

product liability claims relating to the software defects.

If we fail to comply with health care regulations, we could face substantial penalties and our business, operations and financial condition could be adversely affected.

While we do not control referrals of health care services or bill directly to Medicare, Medicaid or other third-party payors, many health care laws and regulations apply to our business. We could be subject to health care fraud and patient privacy regulation by both the federal government

Edgar Filing: Stereotaxis, Inc. - Form 10-Q

and the states in which we conduct our business. The regulations that may affect our ability to operate include:

the federal healthcare program Anti-Kickback Law, which prohibits, among other things, persons from soliciting, receiving or providing remuneration, directly or indirectly, to induce either the referral of an individual, for an item or service or the purchasing or ordering of a good or service, for which payment may be made under federal health care programs such as the Medicare and Medicaid programs;

federal false claims laws which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment from Medicare, Medicaid, or other third-party payors that are false or fraudulent, and which may apply to entities like us which provide coding and billing advice to customers;

the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which prohibits executing a scheme to defraud any health care benefit program or making false statements relating to health care matters and which also imposes certain requirements relating to the privacy, security and transmission of individually identifiable health information;

Table of Contents

state law equivalents of each of the above federal laws, such as anti-kickback and false claims laws which may apply to items or services reimbursed by any third-party payor, including commercial insurers, and state laws governing the privacy of health information in certain circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts; and

federal self-referral laws, such as STARK, which prohibits a physician from making a referral to a provider of certain health services with which the physician or the physician's family member has a financial interest.

If our operations are found to be in violation of any of the laws described above or any other governmental regulations that apply to us, we may be subject to penalties, including civil and criminal penalties, damages, fines, loss of reimbursement for our products under federal or state government health programs such as Medicare and Medicaid and the curtailment or restructuring of our operations. Any penalties, damages, fines, curtailment or restructuring of our operations could adversely affect our ability to operate our business and our financial results. The risk of our being found in violation of these laws is increased by the fact that many of them have not been fully interpreted by the regulatory authorities or the courts, and their provisions are open to a variety of interpretations. Any action against us for violation of these laws, even if we successfully defend against it, could cause us to incur significant legal expenses and divert our management's attention from the operation of our business. Moreover, to achieve compliance with applicable federal and state privacy, security, and electronic transaction laws, we may be required to modify our operations with respect to the handling of patient information. Implementing these modifications may prove costly. At this time, we are not able to determine the full consequences to us, including the total cost of compliance, of these various federal and state laws.

The application of state certificate of need regulations and compliance with federal and state licensing or other international requirements could substantially limit our ability to sell our products and grow our business.

Some states require health care providers to obtain a certificate of need or similar regulatory approval prior to the acquisition of high-cost capital items such as our Stereotaxis System. In many cases, a limited number of these certificates are available. As a result of this limited availability, hospitals and other health care providers may be unable to obtain a certificate of need for the purchase of our Stereotaxis System. Further, our sales and installation cycle for the Stereotaxis System is typically longer in certificate of need states due to the time it takes our customers to obtain the required approvals. In addition, our customers must meet various federal and state regulatory and/or accreditation requirements in order to receive payments from government-sponsored health care programs such as Medicare and Medicaid, receive full reimbursement from third party payors and maintain their customers. Our international customers may be required to meet similar or other requirements. Any lapse by our customers in maintaining appropriate licensure, certification or accreditation, or the failure of our customers to satisfy the other necessary requirements under government-sponsored health care programs or other requirements, could cause our sales to decline.

Hospitals or physicians may be unable to obtain reimbursement from third-party payors for procedures using the Stereotaxis System, or reimbursement for procedures may be insufficient to recoup the costs of purchasing our products.

We expect that U.S. hospitals will continue to bill various third-party payors, such as Medicare, Medicaid and other government programs and private insurance plans, for procedures performed with our products, including the costs of the disposable interventional devices used in these procedures. If in the future our disposable interventional devices do not fall within U.S. reimbursement categories and our procedures are not reimbursed, or if the reimbursement is insufficient to cover the costs of purchasing our system and related disposable interventional devices, the adoption of our systems and products would be significantly slowed or halted, and we may be unable to generate sufficient sales to support our business. Our success in international markets also depends upon the eligibility of our products for reimbursement through government-sponsored health care payment systems and third-party payors. In both the U.S. and foreign markets health care cost-containment efforts are prevalent and are expected to continue. These efforts could reduce levels of reimbursement available for procedures involving our products and, therefore, reduce overall demand for our products as well. A failure to generate sufficient sales could have a material adverse impact on our financial condition, results of operations and cash flow.

We may lose our key personnel or fail to attract and retain additional personnel.

We are highly dependent on the principal members of our management and scientific staff. In order to pursue our plans and accommodate planned growth, we may choose to hire additional personnel. Attracting and retaining qualified personnel will be critical to our success, and competition for qualified personnel is intense. We may not be able to attract and retain personnel on acceptable terms given the competition for qualified personnel among technology and healthcare companies and universities. The loss of any of these persons or our inability to attract and retain other qualified personnel could harm our business and our ability to compete. In addition, the loss of members of our scientific staff may significantly delay or prevent product development and other business objectives.

Table of Contents

Our growth will place a significant strain on our resources, and if we fail to manage our growth, our ability to develop, market and sell our products will be harmed.

Our business plan contemplates a period of substantial growth and business activity. This growth and activity will likely result in new and increased responsibilities for management personnel and place significant strain upon our operating and financial systems and resources. To accommodate our growth and compete effectively, we will be required to improve our information systems, create additional procedures and controls and expand, train, motivate and manage our work force. We cannot be certain that our personnel, systems, procedures and controls will be adequate to support our future operations. Any failure to effectively manage our growth could impede our ability to successfully develop, market and sell our products.

We face currency and other risks associated with international sales.

We intend to continue to devote significant efforts to marketing our systems and products outside of the U.S. This strategy will expose us to numerous risks associated with international operations, which could adversely affect our results of operations and financial condition, including the following:

currency fluctuations that could impact the demand for our products or result in currency exchange losses;

export restrictions, tariff and trade regulations and foreign tax laws;

customs duties, export quotas or other trade restrictions;

economic and political instability; and

shipping delays.

In addition, contracts may be difficult to enforce and receivables difficult to collect through a foreign country's legal system.

Risks Related To Our Common Stock

Our principal stockholders continue to own a large percentage of our voting stock, and they have the ability to substantially influence matters requiring stockholder approval.

As of June 30, 2006, our executive officers, directors and individuals or entities affiliated with them beneficially own or control a substantial percentage of the outstanding shares of our common stock. Accordingly, these executive officers, directors and their affiliates, acting as a group, will have substantial influence over the outcome of corporate actions requiring stockholder approval, including the election of directors, any merger, consolidation or sale of all or substantially all of our assets or any other significant corporate transaction. These stockholders may also delay or prevent a change of control, even if such a change of control would benefit our other stockholders. This significant concentration of stock ownership may adversely affect the trading price of our common stock due to investors' perception that conflicts of interest may exist or arise.

We have never paid dividends on our capital stock, and we do not anticipate paying any cash dividends in the foreseeable future.

We have paid no cash dividends on any of our classes of capital stock to date and we currently intend to return our future earnings to fund the development and growth of our business. In addition, the terms of our loan agreement prohibit us from declaring dividends without the prior consent of our lender. As a result, capital appreciation, if any, of our common stock will be your sole source of gain for the foreseeable future.

Our certificate of incorporation and bylaws, Delaware law and one of our alliance agreements contain provisions that could discourage a takeover.

Edgar Filing: Stereotaxis, Inc. - Form 10-Q

Our certificate of incorporation and bylaws and Delaware law contain provisions that might enable our management to resist a takeover. These provisions may:

discourage, delay or prevent a change in the control of our company or a change in our management;

adversely affect the voting power of holders of common stock; and

limit the price that investors might be willing to pay in the future for shares of our common stock.

Table of Contents

In addition, under our alliance with Biosense Webster, either party may terminate the alliance under certain circumstances involving a change of control of Stereotaxis. Any termination must be effected within 90 days of the change of control, but would be effective one year after the change of control. If we terminate under this provision, we must pay a termination fee to Biosense Webster equal to 5% of the total equity value of Stereotaxis in the change of control transaction, up to a maximum of \$10.0 million. We also agreed to notify Biosense Webster if we reasonably consider that we are engaged in substantive discussions in respect of the sale of the company or substantially all of our assets. These provisions may similarly discourage a takeover and negatively affect our share price as described above.

Sales of a substantial number of shares of our common stock in the public market, or the perception that they may occur, may depress the market price of our common stock.

Sales of substantial amounts of our common stock in the public market, or the perception that substantial sales may be made, could cause the market price of our common stock to decline. These sales might also make it more difficult for us to sell equity securities at a time and price that we deem appropriate.

Evolving regulation of corporate governance and public disclosure may result in additional expenses and continuing uncertainty.

Changing laws, regulations and standards relating to corporate governance and public disclosure, including the Sarbanes-Oxley Act of 2002, new SEC regulations and NASDAQ Global Market rules are creating uncertainty for public companies. We continue to evaluate and monitor developments with respect to new and proposed rules and cannot predict or estimate the amount of the additional compliance costs we may incur or the timing of such costs. These new or changed laws, regulations and standards are subject to varying interpretations, in many cases due to their lack of specificity, and as a result, their application in practice may evolve over time as new guidance is provided by courts and regulatory and governing bodies. This could result in continuing uncertainty regarding compliance matters and higher costs necessitated by ongoing revisions to disclosure and governance practices. Maintaining appropriate standards of corporate governance and public disclosure may result in increased general and administrative expenses and a diversion of management time and attention from revenue-generating activities to compliance activities. In addition, if we fail to comply with new or changed laws, regulations and standards, regulatory authorities may initiate legal proceedings against us and our business and reputation may be harmed.

Our future operating results may be below securities analysts or investors' expectations, which could cause our stock price to decline.

The revenue and income potential of our products and our business model are unproven, and we may be unable to generate significant revenues or grow at the rate expected by securities analysts or investors. In addition, our costs may be higher than we, securities analysts or investors expect. If we fail to generate sufficient revenues or our costs are higher than we expect, our results of operations will suffer, which in turn could cause our stock price to decline. Our results of operations will depend upon numerous factors, including:

demand for our products;

the performance of third-party contract manufacturers and component suppliers;

our ability to develop sales and marketing capabilities;

the success of our collaborations with Siemens, Philips and Biosense Webster and others;

our ability to develop, introduce and market new or enhanced versions of our products on a timely basis;

our ability to obtain regulatory clearances or approvals for our new products; and

Edgar Filing: Stereotaxis, Inc. - Form 10-Q

our ability to obtain and protect proprietary rights.

Our operating results in any particular period may not be a reliable indication of our future performance. In some future quarters, our operating results may be below the expectations of securities analysts or investors. If this occurs, the price of our common stock will likely decline.

Table of Contents

We expect that the price of our common stock could fluctuate substantially, possibly resulting in class action securities litigation.

We have only been publicly traded since August 12, 2004. A limited number of our shares trade actively in the market. The market price of our common stock will be affected by a number of factors, including:

actual or anticipated variations in our results of operations or those of our competitors;

the receipt or denial of regulatory approvals;

announcements of new products, technological innovations or product advancements by us or our competitors;

developments with respect to patents and other intellectual property rights;

changes in earnings estimates or recommendations by securities analysts or our failure to achieve analyst earnings estimates; and

developments in our industry.

The stock prices of many companies in the medical device industry have experienced wide fluctuations that have often been unrelated to the operating performance of these companies. Following periods of volatility in the market price of a company's securities, stockholders have often instituted class action securities litigation against those companies. Class action securities litigation, if instituted against us, could result in substantial costs and a diversion of our management resources, which could significantly harm our business.

ITEM 1B. UNRESOLVED STAFF COMMENTS

None.

ITEM 2. ISSUER PURCHASES OF EQUITY SECURITIES

None.

ITEM 3. DEFAULTS UPON SECURITIES

None.

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

At the Annual Meeting of Stockholders held on May 25, 2006 the stockholders of Stereotaxis, Inc. elected Christopher Alafi, Ralph G. Dacey, Jr., Abhijeet J. Lele and Robert J. Messey to the Board of Directors of the Company to terms expiring at the Annual Meeting of Stockholders in the year 2009. The following table sets forth the votes for each director:

	Votes For	Withheld
Christopher Alafi	26,615,133	39,512
Ralph G. Dacey, Jr	26,629,542	25,103
Abhijeet J. Lele	26,625,555	29,090
Robert J. Messey	26,628,392	26,253

Edgar Filing: Stereotaxis, Inc. - Form 10-Q

After the meeting, our Board of Directors consisted of the individuals listed above plus Fred A. Middleton (Chairman), Abhi Acharya, David W. Benfer, Bevil J. Hogg, Gregory R. Johnson, William M. Kelley and William C. Mills, III.

At the Annual Meeting of Stockholders, the stockholders ratified the appointment of Ernst & Young, LLP as the Company's independent registered public accountants to examine the financial statements of the Company for the 2006 fiscal year. The proposal received 26,633,479 votes for ratification, 18,241 against ratification and 2,925 shares abstained.

Total shares eligible to vote at the Annual Meeting were 33,115,195

ITEM 5. OTHER INFORMATION

None.

Table of Contents

ITEM 6. EXHIBITS AND REPORTS ON FORM 8-K

(a) Exhibits: See Exhibit Index herein

Table of Contents

STEREOTAXIS, INC.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

STEREOTAXIS, INC.

(Registrant)

Date: August 9, 2006

By: /s/ Bevil J. Hogg
Bevil J. Hogg, President and
Chief Executive Officer

Date: August 9, 2006

By: /s/ James M. Stolze
James M. Stolze, Vice President and
Chief Financial Officer

Table of Contents

EXHIBIT INDEX

Number	Description
3.1(1)	Restated Certificate of Incorporation of the Company
3.2(1)	Restated Bylaws of the Company
10.1	Amendment to Collaboration Agreement dated May 5, 2006 between the Company and Siemens Aktiengesellschaft, Medical Solutions
31.1	Rule 13a-14(a)/15d-14(a) Certification (pursuant to Section 302 of the Sarbanes-Oxley Act of 2002, executed by Chief Executive Officer).
31.2	Rule 13a-14(a)/15d-14(a) Certification (pursuant to Section 302 of the Sarbanes-Oxley Act of 2002, executed by Chief Financial Officer).
32.1	Section 1350 Certification (pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, executed by Chief Executive Officer).
32.2	Section 1350 Certification (pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, executed by Chief Financial Officer)

-
- (1) This exhibit was previously filed as an exhibit to the Registrant's Quarterly Report on Form 10-Q for the quarter ended September 30, 2004 (filed November 12, 2004) (File No. 000-50884), and is incorporated herein by reference.