Stereotaxis, Inc.
Form 10-Q
November 06, 2014
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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 September 30, 2014

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

For the transition period from __________ to __________

Commission File Number: 001-36159

STEREOTAXIS, INC.

(Exact name of registrant as specified in its charter)

Delaware	**94-3120386**
(State of Incorporation)	**(I.R.S. employer identification no.)**
4320 Forest Park Avenue Suite 100	
St. Louis, Missouri	**63108**
(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. x Yes ¨ No

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Registration S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). x Yes ¨ No

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of large accelerated filer, accelerated filer and smaller reporting company in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer ¨	Accelerated filer ¨
Non-accelerated filer ¨ (Do not check if a smaller reporting company)	Smaller reporting company x

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

The number of outstanding shares of the registrant s common stock on October 20, 2014 was 20,462,232.

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STEREOTAXIS, INC.

BALANCE SHEETS

	September 30, 2014 (Unaudited)	December 31, 2013
Assets		
Current assets:		
Cash and cash equivalents	$ 8,724,395	$ 13,775,130
Accounts receivable, net of allowance of $599,400 and $383,077 in 2014 and 2013, respectively	7,027,781	7,558,152
Inventories	6,586,303	4,879,039
Prepaid expenses and other current assets	1,435,121	1,945,206
Total current assets	23,773,600	28,157,527
Property and equipment, net	897,321	1,184,589
Intangible assets, net	1,454,611	1,679,486
Long-term receivables		20,431
Other assets	31,580	34,363
Total assets	$ 26,157,112	$ 31,076,396
Liabilities and stockholders deficit		
Current liabilities:		
Current maturities of long-term debt	$	$ 49,733
Accounts payable	2,505,155	3,512,339
Accrued liabilities	6,526,610	7,079,381
Deferred revenue	8,015,860	7,519,754
Warrants	3,504,908	5,644,626
Total current liabilities	20,552,533	23,805,833
Long-term debt, less current maturities	18,435,843	18,481,478
Long-term deferred revenue	974,095	491,080
Stockholders deficit:		
Preferred stock, par value $0.001; 10,000,000 shares authorized, none outstanding at 2014 and 2013		
Common stock, par value $0.001; 300,000,000 shares authorized, 20,465,997 and 19,311,390 shares issued at 2014 and 2013, respectively	20,466	19,311
Additional paid in capital	445,842,292	441,888,155
Treasury stock, 4,015 shares at 2014 and 2013	(205,999)	(205,999)
Accumulated deficit	(459,462,118)	(453,403,462)
Total stockholders deficit	(13,805,359)	(11,701,995)
Total liabilities and stockholders deficit	$ 26,157,112	$ 31,076,396

See accompanying notes.

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STEREOTAXIS, INC.

STATEMENTS OF OPERATIONS

(Unaudited)

	Three Months Ended September 30, 2014	Three Months Ended September 30, 2013	Nine Months Ended September 30, 2014	Nine Months Ended September 30, 2013
Revenue:				
Systems	$ 2,181,088	$ 4,449,598	$ 4,669,224	$ 10,000,926
Disposables, service and accessories	6,673,013	6,371,846	20,587,084	18,962,129
Total revenue	8,854,101	10,821,444	25,256,308	28,963,055
Cost of revenue:				
Systems	1,318,456	2,338,175	2,958,668	5,132,007
Disposables, service and accessories	1,019,476	1,161,449	2,983,111	3,032,150
Total cost of revenue	2,337,932	3,499,624	5,941,779	8,164,157
Gross margin	6,516,169	7,321,820	19,314,529	20,798,898
Operating expenses:				
Research and development	1,214,405	1,300,287	4,030,594	4,313,590
Sales and marketing	3,717,670	4,102,968	11,445,089	13,213,528
General and administrative	2,763,667	2,987,408	9,537,043	9,688,116
Total operating expenses	7,695,742	8,390,663	25,012,726	27,215,234
Operating loss	(1,179,573)	(1,068,843)	(5,698,197)	(6,416,336)
Other income (expense)	2,034,731	(48,160,084)	2,139,718	(46,660,340)
Interest income	1,736	1,306	5,665	3,973
Interest expense	(834,224)	(7,640,821)	(2,505,842)	(11,722,679)
Net income (loss)	$ 22,670	$ (56,868,442)	$ (6,058,656)	$ (64,795,382)
Net earnings (loss) per common share:				
Basic	$ 0.00	$ (4.49)	$ (0.31)	$ (6.72)
Diluted	$ 0.00	$ (4.49)	$ (0.31)	$ (6.72)
Weighted average shares used in computing net earnings (loss) per common share:				
Basic	20,326,169	12,666,414	19,767,545	9,640,249
Diluted	20,518,757	12,666,414	19,767,545	9,640,249

See accompanying notes.

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STEREOTAXIS, INC.

STATEMENTS OF CASH FLOWS

(Unaudited)

	Nine Months Ended September 30, 2014	2013
Cash flows from operating activities		
Net loss	$ (6,058,656)	$ (64,795,382)
Adjustments to reconcile net loss to cash used in operating activities:		
Depreciation	334,908	705,717
Amortization of intangible assets	224,875	224,875
Amortization of deferred finance costs and debt discount	183,568	7,702,681
Share-based compensation	1,070,049	670,873
Loss on asset disposal		16,886
Adjustment of warrants and convertible debt features	(2,139,718)	46,758,917
Interest due from issuance of stock		551,296
Changes in operating assets and liabilities:		
Accounts receivable	550,802	3,527,328
Inventories	(1,707,264)	360,209
Prepaid expenses and other current assets	329,300	526,672
Accounts payable	(1,007,184)	(362,872)
Accrued liabilities	(552,771)	1,477,987
Deferred revenue	979,121	(2,287,620)
Net cash used in operating activities	(7,792,970)	(4,922,433)
Cash flows from investing activities		
Purchase of equipment	(47,640)	
Net cash used in investing activities	(47,640)	
Cash flows from financing activities		
Payments of term loan		(4,000,000)
Proceeds from revolving line of credit		37,237,131
Payments of revolving line of credit		(41,490,148)
Proceeds from Healthcare Royalty Partners debt		2,500,000
Payments of Healthcare Royalty Partners debt	(95,368)	(263,192)
Proceeds from issuance of stock and warrants, net of issuance costs	2,885,243	11,547,529
Net cash provided (used) by financing activities	2,789,875	5,531,320
Net increase (decrease) in cash and cash equivalents	(5,050,735)	608,887
Cash and cash equivalents at beginning of period	13,775,130	7,777,718
Cash and cash equivalents at end of period	$ 8,724,395	$ 8,386,605

See accompanying notes.

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STEREOTAXIS, INC.

NOTES TO FINANCIAL STATEMENTS

(Unaudited)

Notes to Financial Statements

In this report, Stereotaxis, the Company, Registrant, we, us, and our refer to Stereotaxis, Inc. and its wholly-o subsidiaries. *Epoch* , *Niobe*®, *Odyssey*®, *Odyssey Cinema* , *Vdrive*®, *Vdrive Duo* , *V-CAS* , *V-Loop* , *V-Sono* , *QuikCAS* , *Cardiodrive*®, *PowerAssert* , *Titan*® and *Pegasus* are trademarks of Stereotaxis, Inc. All other trademarks that may appear in this report are the property of their respective owners.

1. Description of Business

Stereotaxis designs, manufactures and markets the *Epoch* Solution, which is an advanced remote robotic navigation system for use in a hospital s interventional surgical suite, or interventional lab , that we believe revolutionizes the treatment of arrhythmias and coronary artery disease by enabling enhanced safety, efficiency and efficacy for catheter-based, or interventional, procedures. The *Epoch* Solution is comprised of the *Niobe* ES Robotic Magnetic Navigation System (*Niobe* ES system), *Odyssey* Information Management Solution (*Odyssey* Solution), and the *Vdrive* Robotic Navigation System (*Vdrive* system).

The *Niobe* ES system is the latest generation of the *Niobe* Robotic Magnetic Navigation System (*Niobe* system), which 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.

In addition to the *Niobe* system and its components, Stereotaxis also has developed the *Odyssey* Solution, which consolidates all lab information enabling doctors to focus on the patient for optimal procedure efficiency. The system also features a remote viewing and recording capability called the *Odyssey Cinema* solution, which is an innovative solution delivering synchronized content for optimized workflow, advanced care and improved productivity. This tool includes an archiving capability that allows clinicians to store and replay entire procedures or segments of procedures. This information can be accessed from locations throughout the hospital local area network and over the global *Odyssey* Network providing physicians with a tool for clinical collaboration, remote consultation and training.

Our *Vdrive* system provides navigation and stability for diagnostic and therapeutic devices designed to improve interventional procedures. The *Vdrive* system complements the *Niobe* ES system control of therapeutic catheters for fully remote procedures and enables single-operator workflow and is sold as two options, the *Vdrive* system and the *Vdrive Duo* system. In addition to the *Vdrive* system and the *Vdrive Duo* system, we also manufacture and market various disposable components which can be manipulated by these systems.

We promote the full *Epoch* Solution in a typical hospital implementation, subject to regulatory approvals or clearances. The full *Epoch* Solution implementation requires a hospital to agree to an upfront capital payment and recurring payments. The upfront capital payment typically includes equipment and installation charges. The recurring payments typically include disposable costs for each procedure, equipment service costs beyond the warranty period, and software licenses. In hospitals where the full *Epoch* Solution has not been implemented, equipment upgrade or expansion can be implemented upon purchasing of the necessary upgrade or expansion.

The core components of Stereotaxis systems have received regulatory clearance in the U.S., European Union, Canada, China, Japan and elsewhere. The *V-Sono* ICE catheter manipulator and the *V-Loop* circular catheter manipulator have received U.S. clearance, and *V-CAS* catheter advancement system has been submitted for review by the U.S. Food and Drug Administration.

Since our inception, we have generated significant losses. As of September 30, 2014 we had incurred cumulative net losses of approximately $459.5 million. In May 2011, the Company introduced the *Niobe* ES system and as of September 30, 2014, the Company had an installed base of 118 *Niobe* ES systems and has received positive feedback from the physicians at these sites. Between 2011 and 2013, the Company implemented a wide ranging plan to rebalance and reduce operating expenses by 15% to 20% on an annual run rate basis. We expect to incur additional losses throughout the remainder of 2014 as we continue the development and commercialization of our products, conduct our research and development activities and advance new products into clinical development from our existing research programs and marketing initiatives. During 2014, we expect operating expenses to be generally consistent with 2013.

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We may be required to raise capital or pursue other financing strategies to continue our operations. Until we can generate significant cash flow from our operations, we expect to continue to fund our operations with cash resources primarily generated from the proceeds of our past and future public offerings, private sales of our equity securities and working capital and equipment financing loans. In the future, we may finance cash needs through the sale of other equity securities or non-core assets, strategic collaboration agreements, debt financings or through distribution rights. 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.

Our existing cash, cash equivalents and borrowing facilities may not be sufficient to fund our operating expenses and capital equipment requirements through the next 12 months, which would require us to obtain additional financing before that time. We cannot assure that 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 sales, 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. In addition, we could be required to cease operations.

2. Summary of Significant Accounting Policies

Basis of Presentation

The accompanying unaudited financial statements of Stereotaxis, Inc. 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 nine month period ended September 30, 2014 are not necessarily indicative of the results that may be expected for the year ended December 31, 2014 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 for the year ended December 31, 2013 as filed with the Securities and Exchange Commission (SEC) on March 27, 2014.

As described in Note 10, on July 10, 2012, the Company effected a one-for-ten reverse stock split of the Company s common stock. All information set forth in the financial statements and related notes gives effect to such reverse stock split.

Financial Instruments

The Company measures certain financial assets and liabilities at fair value on a recurring basis, including warrants and debt conversion features. General accounting principles for fair value measurement established a fair value hierarchy that prioritizes the inputs to valuation techniques used to measure fair value. The hierarchy gives the highest priority to unadjusted quoted prices in active markets for identical assets and liabilities (Level 1) and the lowest priority to unobservable inputs (Level 3). See Note 11 for additional details.

The following methods and assumptions were used by the Company in estimating its fair value disclosures for other financial instruments as of September 30, 2014 and December 31, 2013.

Cash equivalents, accounts receivable, and accounts payable have carrying values which approximate fair value due to the short maturity or the financial nature of these instruments.

Long and short-term debt fair value estimates are based on estimated borrowing rates to discount the cash flows to their present value. See Note 9 for disclosure of the fair value of debt.

Revenue and Costs of Revenue

The Company accounts for revenue using Accounting Standards Codification Topic 605-25, *Multiple-Element Arrangements* (ASC 605-25).

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ASC 605-25 permits management to estimate the selling price of undelivered components of a bundled sale for which it is unable to establish vendor-specific objective evidence (VSOE) or third-party evidence (TPE). This requires management to record revenue for certain elements of a transaction even though it might not have delivered other elements of the transaction, for which it was unable to meet the requirements for establishing VSOE or TPE. The Company believes that the guidance significantly improves the reporting of these types of transactions to more closely reflect the underlying economic circumstances. This guidance also prohibits the use of the residual method for allocating revenue to the various elements of a transaction and requires that the revenue be allocated proportionally based on the relative estimated selling prices.

Under our revenue recognition policy, a portion of revenue for *Niobe* systems, *Vdrive* systems and certain *Odyssey* systems is recognized upon delivery, provided that title has passed, 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. Revenue is recognized for other types of *Odyssey* systems upon completion of installation, since there are no qualified third party installers. When installation is the responsibility of the customer, revenue from system sales is recognized upon shipment since these arrangements do not include an installation element or right of return privileges. The Company does not recognize revenue in situations in which inventory remains at a Stereotaxis warehouse or in situations in which title and risk of loss have not transferred to the customer. Amounts collected prior to satisfying the above revenue recognition criteria are reflected as deferred revenue. Revenue from services and license fees, whether sold individually or as a separate unit of accounting in a multiple-deliverable arrangement, is deferred and amortized over the service or license fee period, which is typically one year. Revenue from services is derived primarily from the sale of annual product maintenance plans. We recognize revenue from disposable device sales or accessories upon shipment and establish an appropriate reserve for returns. The return reserve, which is applicable only to disposable devices, is estimated based on historical experience which is periodically reviewed and updated as necessary. In the past, changes in estimate have had only a de minimis effect on revenue recognized in the period. We believe that the estimate is not likely to change significantly in the future.

Costs of systems revenue include direct product costs, installation labor and other costs, estimated warranty costs, and initial training and product maintenance costs. These costs are recorded at the time of sale. Costs of disposable revenue include direct product costs and estimated warranty costs and are recorded at the time of sale. Cost of revenue from services and license fees are recorded when incurred.

Share-Based Compensation

The Company accounts for its grants of stock options, stock appreciation rights, restricted shares, and restricted stock units and for its employee stock purchase plan in accordance with the provisions of general accounting principles for share-based payments. These accounting principles require 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.

The Company utilizes the Black-Scholes valuation model to determine the fair value of stock options and stock appreciation rights at the date of grant. The resulting compensation expense is recognized over the requisite service period, which is generally 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. Restricted shares granted to employees are valued at the fair market value at the date of grant. The Company amortizes the fair market value to expense over the service period. 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.

Net Earnings (Loss) per Common Share (EPS)

Basic and diluted net earnings (loss) per common share are computed by dividing the net income (loss) for the period by the weighted average number of common shares outstanding during the period.

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The following table sets forth the computation of basic and diluted EPS:

	Three months ended September 30, 2014	Three months ended September 30, 2013	Nine months ended September 30, 2014	Nine months ended September 30, 2013
Numerator:				
Numerator for basic EPS	$ 22,670	$ (56,868,442)	$ (6,058,656)	$ (64,795,382)
Effect of dilutive securities:				
Numerator for diluted EPS	$ 22,670	$ (56,868,442)	$ (6,058,656)	$ (64,795,382)
Denominator:				
Denominator for basic EPS weighted average shares	20,326,169	12,666,414	19,767,545	9,640,249
Effect of dilutive securities:				
Restricted stock units	156,525			