GUIDED THERAPEUTICS INC
Form 10-Q/A
November 12, 2010

UNITED STATES SECURITIES AND
EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-Q/A

(Amendment No. 1)

[X] QUARTERLY REPORT UNDER SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the quarterly period ended September 30, 2010

Commission File No. 0-22179

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

GUIDED THERAPEUTICS, INC.
(Exact Name of Registrant as Specified in Its Charter)

Delaware	58-2029543
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)

5835 Peachtree Corners East, Suite D
Norcross, Georgia 30092
(Address of principal executive offices) (Zip Code)

(770) 242-8723
(Registrant's telephone number, including area code)

Indicate by check mark whether the registrant: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days: Yes [X] 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 Regulation S-T during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). 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 definitions of "large accelerated filer," "accelerated filer" and "smaller reporting

company" in Rule 12b-12 of the Exchange Act (Check one):

Large Accelerated filer _____ Accelerated filer ____ Non-accelerated filer_____ 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 [ ] No [X]

As of November 1, 2010, the registrant had outstanding 46,480,950 shares of Common Stock.

EXPLANATORY NOTE

The Company is filing this Amendment No. 1 on Form 10-Q/A (this "Amendment") to its Quarterly Report on Form 10-Q for the quarter ended September 30, 2010 (the "Form 10-Q"). The Form 10-Q was originally filed with the Securities and Exchange Commission (SEC) on November 10, 2010. The purpose of this Amendment is to delete outdated disclosure regarding our glucose monitoring business and our pivotal trial funding needs for our cervical cancer detection product, previously disclosed in the 12th paragraph under Item 2. “Management’s Discussion and Analysis of Financial Condition and Results of Operations– Liquidity and Capital Resources” of Part I of the Form 10-Q.

As required by Rule 12b-15 under the Securities Exchange Act of 1934, the Company has set forth in this Amendment the complete text of Part I, Item 2, as amended. This Amendment does not change any other information set forth in the Form 10-Q.

As a result of this Amendment, the Company is also including updated exhibits with respect to the certifications required under Section 302 of the Sarbanes-Oxley Act of 2002.

This Amendment does not reflect events occurring after the date of the Form 10-Q nor does it modify or update the disclosure contained in the Form 10-Q in any way other than as required to reflect the amendments discussed above and reflected below. Accordingly, this Amendment should be read in conjunction with the Form 10-Q.

GUIDED THERAPEUTICS, INC. AND SUBSIDIARIES

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PART I - FINANCIAL INFORMATION

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

Statements in this report which express "belief," "anticipation" or "expectation," as well as other statements which are not historical facts, are forward-looking statements within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934. These forward-looking statements are subject to certain risks and uncertainties that could cause actual results to differ materially from historical results or anticipated results, including those set forth under "Risk Factors" below and elsewhere in this report. Examples of these uncertainties and risks include, but are not limited to:

- access to sufficient debt or equity capital to meet our operating and financial needs;
- the effectiveness and ultimate market acceptance of our products;
- whether our products in development will prove safe, feasible and effective;
- whether and when we or any potential strategic partners will obtain approval from the U.S FDA and corresponding foreign agencies;
- our need to achieve manufacturing scale-up in a timely manner, and our need to provide for the efficient manufacturing of sufficient quantities of our products;
- the lack of immediate alternate sources of supply for some critical components of our products;
- our patent and intellectual property position;
- the need to fully develop the marketing, distribution, customer service and technical support and other functions critical to the success of our product lines; and
- the dependence on potential strategic partners or outside investors for funding, development assistance, clinical trials, distribution and marketing of some of our products.

The following discussion should be read in conjunction with our financial statements and notes thereto included elsewhere in this report.

OVERVIEW

We are a medical technology company focused on developing innovative medical devices that have the potential to improve healthcare. Our primary focus is the development of our Light Touch cervical cancer detection technology and extension of our cancer detection platform into other cancers, especially lung and esophageal. Our technology, including products in research and development, includes: (a) biophotonics technology for the non-invasive detection of cancers, including cervical cancer, and (b) innovative methods of measuring biologically important molecules in blood and interstitial fluid such as glucose, alcohol and cortisol using specialized sensors and collection devices. We also have developed innovative methods for gaining access to interstitial fluid based on intellectual property licensed from a third party, although we no longer retain licenses to technology that are necessary for commercializing an entire system for the measurement of glucose and other analytes in interstitial fluid.

We were incorporated on October 27, 1992 under the name of "SpectRx, Inc." We changed our name to Guided Therapeutics, Inc. on February 22, 2008.

We have a limited operating history upon which our prospects can be evaluated. Our prospects must be considered in light of the substantial risks, expenses and difficulties encountered by entrants into the medical device industry. This industry is characterized by an increasing number of participants, intense competition and a high failure rate. We have experienced operating losses since our inception and, as of September 30, 2010, we have an accumulated deficit of about $78.2 million. To date, we have engaged primarily in research and development efforts. We first generated revenues from product sales in 1998, but do not have significant experience in manufacturing, marketing or selling our

products. Our development efforts may not result in commercially viable products and we may not be successful in introducing our products. Moreover, required regulatory clearances or approvals may not be obtained in a timely manner, or at all. Our products may not ever gain market acceptance and we may not ever generate significant revenues or achieve profitability. The development and commercialization of our products will require substantial development, regulatory, sales and marketing, manufacturing and other expenditures. We expect our operating losses to continue for the foreseeable future as we continue to expend substantial resources to introduce our cervical cancer detection product, further the development of our other products, obtain regulatory clearances or approvals, build our marketing, sales, manufacturing and finance organizations and conduct further research and development.

If sufficient capital cannot be raised at some point by the third quarter of 2011, we might be required to enter into unfavorable agreements or, if that is not possible, be unable to continue operations, and to the extent practicable, liquidate and/or file for bankruptcy protection. These factors raise substantial doubts about our ability to continue as a going concern. Additional debt or equity financing will be required for us to continue our business activities. If additional funds do not become available, we have plans to curtail operations by reducing discretionary spending and staffing levels. If funds are not obtained, we will have to curtail our operations and attempt to operate by only pursuing activities for which we have external financial support, such as pursuant to our agreements with Konica Minolta and through additional NCI or other grant funding, including matching-grant funding, if available. However, there can be no assurance that such external financial support will be sufficient to maintain even limited operations or that we will be able to raise additional funds on acceptable terms, or at all.

Our product revenues to date have been limited. For 2009, a majority of our revenues came from our Konica Minolta contract revenue. We expect that the majority of our revenue in 2010 will be derived from research contract revenue. Our other products for cancer detection are still in development.

CRITICAL ACCOUNTING POLICIES

Our material accounting policies, which we believe are the most critical to an investor understands of our financial results and condition, are discussed below. Because we are still early in our enterprise development, the number of these policies requiring explanation is limited. As we begin to generate increased revenue from different sources, we expect that the number of applicable policies and complexity of the judgments required will increase.

Currently, our policies that could require critical management judgment are in the areas of revenue recognition, reserves for accounts receivable and inventory valuation.

Revenue Recognition: We recognize revenue from sales of products or services upon shipment of products or when services are rendered. We also recognize milestone revenue from collaborative partners when a milestone has been accomplished or when we, and our partner, agree that a milestone has been reached. Service revenues are considered to have been earned when we have substantially accomplished what we must do to be entitled to the benefits represented by the service revenues. Accordingly, we record revenue from service contracts where the service is completed and the customer is invoiced in accordance with the terms of a written, duly executed service contract or purchase order. We also have arrangements to use our intellectual property, which is accounted for systematically over the term of the arrangement.

Valuation of Deferred Taxes: The Company accounts for income taxes in accordance with the liability method. Under the liability method, deferred assets and liabilities are recognized based upon anticipated future tax consequences attributable to differences between financial statement carrying amounts of assets and liabilities and their respective tax bases. The Company establishes a valuation allowance to the extent that it is more likely than not that deferred tax assets will not be utilized against future taxable income.

Valuation of Equity Instruments Granted To Employees, Service Providers and Investors: On the date of issuance, the instruments are recorded at their fair value as determined using the Black-Scholes valuation model.

Allowance for Accounts Receivable: We estimate losses from the inability of our customers to make required payments and periodically review the payment history of each of our customers, as well as their financial condition, and revise our reserves as a result.

RESULTS OF OPERATIONS

COMPARISON OF THE THREE MONTHS ENDED SEPTEMBER 30, 2010 AND 2009

Revenue: Net revenue increased to $676,000 for the three months ended September 30, 2010, from $577,000 for the same period in 2009. Net revenue was higher for the three months ended September 30, 2010 than the comparable period in 2009, due to the increase in revenue from contracts relating to our cervical cancer detection technology.

Research and Development Expenses: Research and development expenses increased to approximately $509,000 for the three months ended September 30, 2010, compared to $364,000 for the same period in 2009. The increase, of approximately $145,000, was primarily due to an increase in expenses for research and development of the cervical cancer detection products.

Sales and Marketing Expenses: Sales and marketing expenses were approximately $21,000 during the three months ended September 30, 2010, compared to $14,000 for the same period in 2009. The increase, of approximately $7,000, was primarily due to an increase in expenses relating to marketing efforts for the cervical cancer detection products in

development.

General and Administrative Expenses: General and administrative expenses increased to approximately $751,000 during the three months ended September 30, 2010, compared to $422,000 for the same period in 2009. The increase is primarily related to a significant increase in operating activities with new hiring during the three months ended September 30, 2010.

Loss on debt forgiveness was approximately $782,000 for the three months ended September 30, 2009. The loss on debt forgiveness represents a 15% discount on the principal and accrued interest on the convertible notes issued in 2008. On August 31, 2009, the Company converted these notes into the 2007 Notes, which were subject to automatic conversion into common stock. There was no loss on debt forgiveness for the same period in 2010.

Interest Expense: Interest expense decreased to approximately $30,000 for the three months ended September 30, 2010, as compared to expense of approximately $1.1 million for the same period in 2009. The significant decrease is primarily due to the February 26, 2010 conversion of indebtedness into common stock (see Note 7 to the condensed consolidated financial statements accompanying this report), as well as a decrease in interest expense on lower loan balance for the three months ended September 30, 2010.

Net loss attributable to common stockholders was approximately $635,000 during the three months ended September 30, 2010, compared to a net loss attributable to common stockholders of approximately $2.1 million during the three months ended September 30, 2009.

COMPARISON OF THE NINE MONTHS ENDED SEPTEMBER 30, 2010 AND 2009

Revenue: Net revenue increased to approximately $2.3 million for the nine months ended September 30, 2010, from approximately $1.0 million for the same period in 2009. Net revenue was higher for the nine months ended September 30, 2010 than for the comparable period in 2009, due to the increase in revenue from contracts relating to our cancer detection technology.

Research and Development Expenses: Research and development expenses increased to approximately $1.4 million for the nine months ended September 30, 2010, compared to approximately $1.0 million for the same period in 2009. The increase, of approximately $400,000, was due to an increase in expenses for research and development of the cervical cancer detection products.

Sales and Marketing Expenses: Sales and marketing expenses were approximately $99,000 during the nine months ended September 30, 2010, compared to $42,000 for the same period in 2009. The increase, of approximately $57,000, was primarily due to an increase in expenses relating to marketing efforts for the cervical cancer detection products in development.

General and Administrative Expenses: General and administrative expenses increased to approximately $2.0 million, during the nine months ended September 30, 2010, compared to approximately $1.3 million for the same period in 2009. The increase, of approximately $700,000 or 53.9%, is primarily related to an increase in professional fees relating to our products under development and an increase in operating activities with new hiring during the nine months ended September 30, 2010.

Loss on debt forgiveness was approximately $782,000 for the nine months ended September 30, 2009. The loss on debt forgiveness represents a 15% discount on the principal and accrued interest on the convertible notes issued in 2008. On August 31, 2009, the Company converted these notes into the 2007 Notes, which were subject to automatic conversion into common stock. There was no loss on debt forgiveness for the same period in 2010.

Interest Expense: Interest expense decreased to approximately $1.3 million for the nine months ended September 30, 2010, as compared to approximately $2.6 million for the same period in 2009. The decrease is primarily due to the February 26, 2010 conversion of indebtedness into common stock (see Note 7 to the condensed consolidated financial statements accompanying this report).

Preferred Stock Dividends: There was approximately $1.7 million of deemed dividends expense for the nine months ended September 30, 2010, resulting from the conversion of the series A preferred stock into common shares and warrants (see Note 7 to the condensed consolidated financial statements accompanying this report). For the same period in 2009, there was approximately $178,000 of dividend expense.

Net loss attributable to common stockholders was approximately $4.3 million during the nine months ended September 30, 2010, compared to a net loss attributable to common stockholders of approximately $4.9 million during the nine months ended September 30, 2009.

LIQUIDITY AND CAPITAL RESOURCES

We have financed our operations since inception primarily through private sales of debt and private and public sales of our equity securities. At September 30, 2010, we had approximately $2.9 million in cash, and working capital of approximately $194,000.

Our major cash flows in the nine months ended September 30, 2010, consisted of cash utilized of approximately $291,000 for operations (including approximately $2.6 million of net loss) and cash utilized in investing activities of approximately $162,000, and cash provided by financing activities of $3.1 million due to proceeds received from issuance of common stock and warrants.

On March 12, 2007, we completed a restructuring of our then-existing indebtedness by entering into a loan agreement with existing and new creditors. Pursuant to the loan agreement, our then-existing indebtedness was restructured and consolidated into the 2007 Notes. The aggregate principal amount of the originally issued 2007 Notes was approximately $4.8 million and was due on March 1, 2010. On February 26, 2010, these 2007 Notes plus accrued interest were converted into common stock (see details below).

On December 1, 2008, we entered into a note purchase agreement with 28 existing and new lenders, pursuant to which we issued approximately $2.3 million in aggregate principal amount of 2008 notes and warrants exercisable for 11,558,878 shares of common stock. Approximately $1.3 million of the proceeds from the issuance of the 2008 notes was used to convert existing debt into 2008 notes, including conversion of an unsecured note issued to Dolores Maloof on April 10, 2008 in the aggregate principal amount of $400,000, plus interest, as well as notes issued under the note purchase agreement, dated between May 23 and July 7, 2008, in aggregate principal amount of $625,000, plus interest, held by John E. Imhoff and eleven other designated investors. The remaining funds were used in product development, working capital and other corporate purposes.

On August 31, 2009, we issued an aggregate of $3.6 million in 2007 Notes in exchange for the extinguishment of an equal amount of debt represented by the 2008 notes and the other outstanding notes issued after the 2007 Notes.

In October of 2009, the loan agreement governing the 2007 Notes was further amended to provide for automatic conversion of the 2007 Notes into a number of shares of common stock equal to the outstanding amounts being so converted divided by the then-current conversion price of $0.65, to be triggered upon a reclassification of our series A convertible preferred stock into common stock and warrants to purchase shares of common stock.

On February 1, 2010, we entered into an agreement with Konica Minolta to co-develop new, non-invasive cancer development products. Pursuant to the agreement, we will receive approximately $1.6 million over a one-year term, in addition to pre-existing option-to-license payments we already received from Konica Minolta, in exchange for Konica Minolta's right to purchase prototype devices and to rely on us to establish the technical approach and regulatory strategy for potential entry of the new products into the U.S. and international markets. The new products are for the detection of esophageal and lung cancer, and are based on our LightTouch non-invasive cervical cancer detection technology, which will be undergoing the U.S. Food and Drug Administration's premarket approval process. We have received approximately $3.1 million since 2008 from Konica Minolta pursuant to various co-development agreements similar to the current agreement, as well as no-shop agreements.

On February 26, 2010, we amended our certificate of incorporation to reclassify our series A convertible preferred stock into common stock and warrants to purchase shares of common stock. As a result, all 242,576 outstanding shares of series A convertible preferred stock and accrued dividends were reclassified into 8,084,139 shares of common stock and warrants to purchase an additional 2,799,327 shares of common stock. Upon this reclassification, the $9.1 million in outstanding 2007 Notes and accrued interest were automatically converted into 14 million shares of common stock.

On April 27, 2010, we executed an agreement to extend our license agreement with Konica Minolta to co-develop non-invasive cancer detection products for one year. Konica Minolta will pay us a $750,000 fee for the extension. Additionally, the agreement provides for a subsequent one-year renewal upon the written agreement of the parties. The original agreement was a one-year exclusive negotiation and development agreement of optimization of our microporation system for manufacturing, regulatory approval, commercialization and clinical utility, which we and Konica Minolta entered into in April 2009. We initially received $750,000 under this agreement.

On September 10, 2010, we completed a private placement of 3,771,605 shares of our common stock at a purchase price of $0.81 per share, pursuant to which we raised approximately $3 million. For each share of common stock issued, subscribers received warrants exercisable for the purchase of 1/10 of one share of common stock (in the aggregate, 377,161 shares) at an exercise price of $1.01 per share. The warrants have a five-year term.

On September 27, 2010 we announced that we filed our completed premarket approval application for the LightTouch Cervical Scanner with the FDA for patients at risk for cervical cancer.

We will be required to raise additional funds through public or private financing, additional collaborative relationships or other arrangements in addition to these sources. We believe our existing and available capital resources will be sufficient to satisfy our funding requirements through the third quarter of 2011. We are evaluating various options to further reduce our cash requirements to operate at a reduced rate, as well as options to raise additional funds, including loans using certain assets as collateral.

Substantial capital will be required to develop our products, including completing product testing and clinical trials, obtaining all required United States and foreign regulatory approvals and clearances, and commencing and scaling up manufacturing and marketing our products. Any failure to obtain capital would have a material adverse effect on our business, financial condition and results of operations.

Our financial statements have been prepared and presented on a basis assuming we will continue as a going concern. The above factors raise substantial doubt about our ability to continue as a going concern, as more fully discussed in Note 1 to the condensed consolidated financial statements contained herein and in the report of our independent registered public accounting firm accompanying our financial statements contained in our annual report on Form 10-K for the year ended December 31, 2009.

Off-Balance Sheet Arrangements

We have no material off-balance sheet arrangements, no special purpose entities, and no activities that include non-exchange-traded contracts accounted for at fair value.

PART II - OTHER INFORMATION

ITEM 6. EXHIBITS

EXHIBIT INDEX

EXHIBITS

Exhibit Number	Exhibit Description
3.1	Certificate of Incorporation, as amended February 26, 2010 (incorporated by reference to Exhibit 3.1 of the Company's quarterly report on Form 10-Q for the quarter ended June 30, 2010)
4.1	Form of Warrant Agreement (incorporated by reference to Exhibit 4.1 of the Company’s Form 8-K filed September 14, 2010)
10.1	Form of Subscription Agreement (incorporated by reference to Exhibit 10.1 of the Company’s Form 8-K filed September 14, 2010)
31	Rule 13a-14(a)/15d-14(a) Certification
32	Section 1350 Certification (incorporated by reference to Exhibit 32 to the Company's quarterly report on Form 10-Q for the quarter ended September 30, 2010

SIGNATURES

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

GUIDED THERAPEUTICS, INC.

/s/ MARK L. FAUPEL

By:	Mark L. Faupel President, Chief Executive Officer and Acting Chief Financial Officer
Date:	November 12, 2010