GUIDED THERAPEUTICS INC
Form POS AM
April 02, 2012
As filed with the Securities and Exchange Commission on April 2, 2012

Registration No. 333-169755

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

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Post Effective Amendment No. 2
to
Form S-1

REGISTRATION STATEMENT UNDER THE SECURITIES ACT OF 1933

Guided Therapeutics, Inc.
(Exact name of registrant as specified in its charter)

Delaware	3845	58-2029543
(State or other jurisdiction of incorporation or organization)	(Primary Standard Industrial Classification Code Number)	(I.R.S. Employer Identification Number)

5835 Peachtree Corners East, Suite D
Norcross, Georgia 30092
(770) 242-8723
(Address, including zip code, and telephone number, including area code, of registrant's principal executive offices)

Mark L. Faupel
President and Chief Executive Officer
Guided Therapeutics, Inc.
5835 Peachtree Corners East, Suite D
Norcross, Georgia 30092
(770) 242-8723
(Name, address, including zip code, and telephone number, including area code, of agent for service)

Copy to:

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Heith D. Rodman , Esq.
Jones Day
1420 Peachtree Street, N.E.
Suite 800
Atlanta, Georgia 30309-3053
(404) 521-3939

Approximate date of commencement of proposed sale to the public: From time to time following the effective date of this registration statement

If any of the securities being registered on this Form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933, check the following box. þ

If this Form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, please check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. o

If this Form is a post-effective amendment filed pursuant to Rule 462(c) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. o

If this Form is a post-effective amendment filed pursuant to Rule 462(d) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. o

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.

Large accelerated filer	Accelerated filer	Non-accelerated filer	Smaller reporting company
o	o	o	þ

The registrant hereby amends this registration statement on such date or dates as may be necessary to delay its effective date until the registrant shall file a further amendment which specifically states that this registration statement shall thereafter become effective in accordance with Section 8(a) of the Securities Act of 1933 or until this registration statement shall become effective on such date as the Securities and Exchange Commission, acting pursuant to said Section 8(a), may determine.

EXPLANATORY NOTE

This Post-Effective Amendment No. 2 to the registration statement on Form S-1 (File No. 333-169755) (the "Registration Statement"), is being filed pursuant to the undertakings in Item 17 of the Registration Statement to update and supplement the information contained in the Registration Statement, as originally declared effective by the Securities and Exchange Commission on December 8, 2010, to (i) include the information contained in the registrant's Annual Report on Form 10-K for the fiscal year ended December 31, 2011, filed on March 28, 2012, and (ii) make certain other updating revisions to the information contained herein.

The information in this prospectus is not complete and may be changed. The selling stockholders may not sell or offer these securities until the registration statement filed with the Securities and Exchange Commission is declared effective. This prospectus is not an offer to sell these securities and neither Guided Therapeutics nor the selling stockholders are soliciting an offer to buy these securities in any state where the offer or sale is not permitted.

PROSPECTUS

Subject to completion, dated April 2, 2012

28,392,337 Shares of Common Stock

of

Guided Therapeutics, Inc.

_____

This prospectus relates to 28,392,337 shares of our common stock issued or issuable upon the exercise of warrants at an exercise price of $0.01 per share. The shares offered by this prospectus may be sold from time to time by the selling stockholders listed in this prospectus at prevailing market prices or prices negotiated at the time of sale. See “Plan of Distribution” and “Selling Stockholders.”

We will not receive any cash proceeds from the sale of shares by the selling stockholders, but to the extent that the warrants are exercised in whole or in part, we will receive payment for the exercise price. We will pay the expenses of registering these shares.

Our common stock is dually listed on the OTC Bulletin Board (OTCBB) and the OTCQB quotation systems under the symbol “GTHP.” The last reported sale price of our common stock on the OTCBB on March 27, 2012 was $0. 93 per share. The selling stockholders will sell at a prevailing market price per share as quoted on the OTCBB.

Investing in our common stock involves a high degree of risk. These risks are described under the caption “Risk Factors” that begins on page 3 of this prospectus.

Neither the Securities and Exchange Commission, or SEC, nor any state securities commission has approved or disapproved of the common stock that may be offered under this prospectus, nor have any of these organizations determined if this prospectus is truthful or complete. Any representation to the contrary is a criminal offense.

The date of this prospectus is _____, 2012.

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ABOUT THIS PROSPECTUS

You should rely only on the information contained in this prospectus or a prospectus supplement. We have not authorized any other person to provide you with different information. If anyone provides you with different or inconsistent information, you should not rely on it. This prospectus is an offer to sell only the common stock offered hereby, but only under circumstances and in jurisdictions where it is lawful to do so. You should assume that the information appearing in this prospectus is accurate only as of the date hereof. Our business, financial condition, results of operations and prospects may have changed.

The terms “Guided Therapeutics,” “our,” “we,” and “us,” as used in this prospectus, refer to Guided Therapeutics, Inc. and its wholly owned subsidiary.

SUMMARY

This summary highlights information contained elsewhere in this prospectus. This summary is not complete and may not contain all of the information that may be important to you. We urge you to read the entire prospectus carefully, including the ‘‘Risk Factors’’ section, before making an investment decision.

Our Company

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 LuViva™ non-invasive cervical cancer detection device and extension of our cancer detection technology into other cancers, especially lung and esophageal. Our technology, including products in research and development, primarily relate to biophotonics technology for the non-invasive detection of cancers, including cervical cancer.

We are a Delaware corporation, originally incorporated in 1992 under the name “SpectRx, Inc.,” and, on February 22, 2008, changed our name to Guided Therapeutics, Inc. At the same time, we renamed our majority owned subsidiary, InterScan, which originally had been incorporated as “Guided Therapeutics.”

Non-Invasive Cervical Cancer Detection

We believe our LuViva cervical cancer detection device will provide a less invasive and painless alternative to conventional tests for cervical cancer detection. We also believe LuViva can improve patient well-being and reduce healthcare costs, since it reduces or eliminates pain, is convenient to use and provides rapid results at the point-of-care. We completed enrollment in our U.S. Food and Drug Administration (“FDA”) pivotal trial of LuViva in 2008 and on November 18, 2010, the FDA accepted our completed premarket approval (“PMA”) application, effective September 23, 2010, for substantive review. On March 7, 2011, we announced that the FDA had inspected two clinical trial sites as part of its review process and raised no formal compliance issues. On January 12, 2012 , we announced our intent to seek an independent panel review of our PMA application after receiving a “not-approvable” letter from the FDA. Assuming we receive FDA approval in 2012 , we currently anticipate an early 2013 product launch, but cannot be assured we will be able to launch on that timetable, or at all.

Other Cancers

We believe our non-invasive cervical cancer detection technology can be applied to other cancers as well. To that end, we are working with Konica Minolta Opto, Inc., a subsidiary of Konica Minolta, Inc., a Japanese corporation based in Tokyo (“Konica Minolta”) to adapt our cervical cancer detection technology for detection of lung cancer and esophageal cancer (see “—Lung and Esophageal Cancer Detection —Konica Minolta”).

Recent Developments

Between January 1st and March 6th, 2012, the Company had received a total of $138,323, from the exercise of outstanding warrants to purchase an aggregate of 212,804 shares of our common stock.

On February 23, 2012, we announced that we had successfully completed an annual audit of our quality system necessary to maintain our ISO 13485 certification, a requirement to secure the CE Mark for sale of LuViva in the European Union.

On January 31, 2012, we announced that we had signed a definitive agreement granting CAN-med Healthcare exclusive distribution rights for LuViva in Canada. The agreement is for three years and initial shipments are currently

anticipated in the second quarter of 2012, with a formal launch expected to begin shortly thereafter. LuViva received Health Canada marketing approval in December 2011 under its former name, LightTouch.

On January 20, 2012, we announced that we plan to seek an independent panel review of our PMA application for LuViva from the FDA, after receiving a “not-approvable” letter from the agency. Meanwhile, we plan to work with FDA to address the outstanding issues so that they can be successfully resolved. We also announced plans to move forward with international sales of LuViva and imminently file for CE mark approval.

The Offering

Common stock that may be offered by selling stockholders	28,392,337 shares of our common stock. See “Selling Stockholders” on page 9.
Use of proceeds	We will not receive any proceeds from the resale of the shares of common stock. However, to the extent the warrants are exercised in whole or in part, we will receive payment for the exercise price. The terms of the warrants are described under “Description of Securities—Warrants and Options.” We expect to use any proceeds we receive from the exercise of the warrants for general corporate purposes, including working capital, capital expenditures and repaying or refinancing our debt obligations. See “Use of Proceeds” on page 9.
Market for the common stock	Our common stock is dually listed on the OTCBB and the OTCQB quotation systems under the symbol “GHTP.” See “Market for Our Common Stock and Related Stockholder Matters” on page 20 .
Risk factors	You should read “Risk Factors” beginning on page 3 for an explanation of the risks of investing in our common stock.

Our principal executive and operations facility is located at 5835 Peachtree Corners East, Suite D, Norcross, Georgia 30092, and our telephone number is (770) 242-8723.

RISK FACTORS

Any investment in our company is subject to risks inherent to our business. Before making an investment decision, you should carefully consider the risks described below together with all of the other information included in this prospectus.

Although we will be required to raise additional funds by the fourth quarter of 2012 , there is no assurance that such funds can be raised on terms that we would find acceptable, or at all.

Additional debt or equity financing will be required for us to continue as a going concern. Management may seek to obtain additional funds for the financing of our cervical cancer detection business, through additional debt or equity financings and/or new collaborative arrangements. Management believes that additional financing, if obtainable, will be sufficient to support planned operations only for a limited period. Management has implemented operating actions to reduce cash requirements. Any required additional funding may not be available on terms attractive to us or at all.

If we cannot obtain additional funds or achieve profitability, we may not be able to continue as a going concern.

Because we must obtain additional funds through further financing transactions or through collaborative arrangements in order to execute our plans to launch our cervical cancer detection product line and to generate revenue from operations, there exists substantial doubt about our ability to continue as a going concern. Therefore, it will be necessary to raise additional funds. There can be no assurance that we will be able to raise these additional funds. If we do not secure additional funding when needed, we will be unable to conduct all of our product development efforts as planned, which may cause us to alter our business plan in relation to the development of our products. Even if we obtain additional funding, we will need to achieve profitability thereafter.

Our independent registered public accountants' report on our financial statements as of December 31, 2011 , indicates that there is substantial doubt about our ability to continue as a going concern because we had suffered recurring losses from operations and had an accumulated deficit of $ 85.0 million at December 31 , 2011, summarized as follows:

Accumulated deficit from inception to fiscal year ended 2009	$73.9 million
Net Loss for fiscal year 2010, ended 12/31/2010	$ 4.5 million
Accumulated deficit at fiscal year ended 12/31/2010	$78.4 million
Net Loss for fiscal year 2011, ended 12/31/2011	$ 6.6 million
Accumulated deficit, from inception to 12/31/2011	$85.0 million
We are also in default on payments due on some short-term loans.	

Our management has implemented reductions in operating expenditures and reductions in some development activities. We have determined to make cervical cancer detection the focus of our business. We are managing the development of our other programs only when funds are made available to us via grants or contracts with government entities or strategic partners. However, there can be no assurance that we will be able to successfully implement or continue these plans.

If we cannot obtain additional funds when needed, we will not be able to implement our business plan.

We will require substantial additional capital to develop our products, including completing product testing and clinical trials, obtaining all required regulatory approvals and clearances, beginning and scaling up manufacturing, and marketing our products. We have historically financed our operations though the private sale of preferred stock and debt securities, public and private sales of common stock, funding from collaborative arrangements, and grants. We believe funds on hand as of date of this prospectus, along with funds from government contracts and grants, and our collaborative arrangement with Konica Minolta , will be sufficient to support planned operations through the first quarter of 2013 , but will not be sufficient to fund our planned operations to the point of commercial introduction of our LuViva cervical cancer detection device . Any failure to achieve adequate funding in a timely fashion would delay our development programs and could lead to abandonment of one or more of our development initiatives. To the extent we cannot obtain additional funding, our ability to continue to develop and introduce products to market will be limited.

Further, financing our operations through the public or private sale of debt or equity, may involve restrictive covenants or other provisions that could limit how we conduct our business or financing our operations. Financing our operations through collaborative arrangements generally means that the obligations of the collaborative partner to fund our expenditures are largely discretionary and depend on a number of factors, including our ability to meet specified milestones in the development and testing of the relevant product. We may not be able to meet these milestones, or the collaborative partner may not continue to fund our expenditures.

We do not have a long operating history, especially in the cancer detection field, which makes it difficult to evaluate our business.

Although we have been in existence since 1992, we have only just begun the process of commercializing our cervical cancer detection technology. Because limited historical information is available on our revenue trends and operations for our cancer detection programs it is difficult to evaluate our business. Our prospects must be considered in light of the substantial risks, expenses, uncertainties and difficulties encountered by entrants into the medical device industry, which is characterized by increasing intense competition and a high failure rate.

We have a history of losses, and we expect losses to continue.

We have never been profitable and we have had operating losses since our inception. We expect our operating losses to continue as we continue to expend substantial resources to complete development of our products, obtain regulatory clearances or approvals, and build our marketing, sales, manufacturing and finance organizations, and conduct further research and development. To date, we have engaged primarily in research and development efforts. The further development and commercialization of our products will require substantial development, regulatory, sales and marketing, manufacturing and other expenditures. We have only generated limited revenues from product sales. Our accumulated deficit was approximately $ 85.0 million at December 31 , 2011.

Our ability to sell our products is controlled by government regulations, and we may not be able to obtain any necessary clearances or approvals.

The design, manufacturing, labeling, distribution and marketing of medical device products are subject to extensive and rigorous government regulation, which can be expensive and uncertain and can cause lengthy delays before we can begin selling our products.

In the United States, the FDA’s actions could delay or prevent our ability to sell our products, which would adversely affect our growth and strategy plans.

In order for us to market our products in the United States, we must obtain clearance or approval from the FDA. We cannot be sure that:

- we, or any collaborative partner, will make timely filings with the FDA;
- the FDA will act favorably or quickly on these submissions;
- we will not be required to submit additional information or perform additional clinical studies; or
- other significant difficulties and costs will not be encountered to obtain FDA clearance or approval.

It can take several years from initial filing of a PMA application and require the submission of extensive supporting data and clinical information. The FDA may impose strict labeling or other requirements as a condition of its clearance or approval, any of which could limit our ability to market our products. Further, if we wish to modify a product after FDA approval of a PMA application, including changes in indications or other modifications that could affect safety and efficacy, additional clearances or approvals will be required from the FDA. Any request by the FDA for additional data, or any requirement by the FDA that we conduct additional clinical studies, could result in a significant delay in bringing our products to market and substantial additional research and other expenditures. Similarly, any labeling or other conditions or restrictions imposed by the FDA could hinder our ability to effectively market our products. Any of the above actions by the FDA could delay or prevent altogether our ability to market and distribute our products. Further, there may be new FDA policies or changes in FDA policies that could be adverse to us.

In foreign countries, including European countries, we are also subject to government regulation, which could delay or prevent our ability to sell our products in those jurisdictions.

In order for us to market our products in Europe and some other international jurisdictions, we and our distributors and agents must obtain required regulatory registrations or approvals. We must also comply with extensive regulations regarding safety, efficacy and quality in those jurisdictions. We may not be able to obtain the required regulatory registrations or approvals, or we may be required to incur significant costs in obtaining or maintaining any regulatory registrations or approvals we receive. Delays in obtaining any registrations or approvals required for marketing our products, failure to receive these registrations or approvals, or future loss of previously obtained registrations or approvals would limit our ability to sell our products internationally. For example, international regulatory bodies have adopted various regulations governing product standards, packaging requirements, labeling requirements, import restrictions, tariff regulations, duties and tax requirements. These regulations vary from country to country. In order to sell our products in Europe, we must obtain and maintain ISO 13485:2003 certification and CE mark certification, which is an international symbol of quality and compliance with applicable European medical device directives. Failure to maintain ISO 13485:2003 certification or CE mark certification or other international regulatory approvals would prevent us from selling in some countries in the European Union.

Even if we obtain clearance or approval to sell our products, we are subject to ongoing requirements and inspections that could lead to the restriction, suspension or revocation of our clearance.

We, as well as any potential collaborative partners, will be required to adhere to applicable FDA regulations regarding good manufacturing practice, which include testing, control, and documentation requirements. We are subject to similar regulations in foreign countries. Ongoing compliance with good manufacturing practice and other applicable regulatory requirements will be strictly enforced in the United States through periodic inspections by state and federal agencies, including the FDA, and in international jurisdictions by comparable agencies. Failure to comply with these regulatory requirements could result in, among other things, warning letters, fines, injunctions, civil penalties, recall or seizure of products, total or partial suspension of production, failure to obtain premarket clearance or premarket approval for devices, withdrawal of approvals previously obtained, and criminal prosecution. The restriction, suspension or revocation of regulatory approvals or any other failure to comply with regulatory requirements would limit our ability to operate and could increase our costs.

Our success largely depends on our ability to obtain and protect the proprietary information on which we base our products.

Our success depends in large part upon our ability to establish and maintain the proprietary nature of our technology through the patent process, as well as our ability to license from others patents and patent applications necessary to develop our products. If any of our patents are successfully challenged, invalidated or circumvented, or our right or ability to manufacture our products was to be limited, our ability to continue to manufacture and market our products could be adversely affected. In addition to patents, we rely on trade secrets and proprietary know-how, which we seek to protect, in part, through confidentiality and proprietary information agreements. The other parties to these agreements may breach these provisions, and we may not have adequate remedies for any breach. Additionally, our trade secrets could otherwise become known to or be independently developed by competitors.

As of December 31 , 2011, we have been issued, or have rights to, 21 U.S. patents (including those under license). In addition, we have filed for, or have rights to, two U.S. patents (including those under license) that are still pending. There are additional international patents and pending applications. One or more of the patents we hold directly or license from third parties, including those for our cervical cancer detection products, may be successfully challenged, invalidated or circumvented, or we may otherwise be unable to rely on these patents. These risks are also present for the process we use or will use for manufacturing our products. In addition, our competitors, many of whom have substantial resources and have made substantial investments in competing technologies, may apply for and obtain patents that prevent, limit or interfere with our ability to make, use and sell our products, either in the United States or in international markets.

The medical device industry has been characterized by extensive litigation regarding patents and other intellectual property rights. In addition, the U.S. Patent and Trademark Office, or USPTO, may institute interference proceedings. The defense and prosecution of intellectual property suits, USPTO proceedings and related legal and administrative proceedings are both costly and time consuming. Moreover, we may need to litigate to enforce our patents, to protect our trade secrets or know-how, or to determine the enforceability, scope and validity of the proprietary rights of others. Any litigation or interference proceedings involving us may require us to incur substantial legal and other fees and expenses and may require some of our employees to devote all or a substantial portion of their time to the proceedings. An adverse determination in the proceedings could subject us to significant liabilities to third parties, require us to seek licenses from third parties or prevent us from selling our products in some or all markets. We may not be able to reach a satisfactory settlement of any dispute by licensing necessary patents or other intellectual property. Even if we reached a settlement, the settlement process may be expensive and time consuming, and the terms of the settlement may require us to pay substantial royalties. An adverse determination in a judicial or administrative proceeding or the failure to obtain a necessary license could prevent us from manufacturing and selling

our products.

We may not be able to generate sufficient sales revenues to sustain our growth and strategy plans.

Our cervical cancer diagnostic activities have been financed to date through a combination of government grants, strategic partners and direct investment. Bringing this product to market is the main focus of our business. In order to complete product development and prepare for marketing of the cervical cancer detection product, additional capital will be needed. We need to complete the FDA filing process for our cervical cancer diagnostic product and obtain capital investment for product development and launch.

Additional product lines involve the modification of the cervical cancer detection technology for use in other cancers. These product lines are only in the earliest stages of research and development and are currently not projected to reach market for several years. Our goal is to receive enough funding from government grants and contracts, as well as payments from strategic partners, to fund development of these product lines without diverting funds or other necessary resources from the cervical cancer program.

Because our products, which use different technology or apply technology in different ways than other medical devices, are or will be new to the market, we may not be successful in launching our products and our operations and growth would be adversely affected.

Our products are based on new methods of cancer detection. If our products do not achieve significant market acceptance, our sales will be limited and our financial condition may suffer. Physicians and individuals may not recommend or use our products unless they determine that these products are an attractive alternative to current tests that have a long history of safe and effective use. To date, our products have been used by only a limited number of people, and few independent studies regarding our products have been published. The lack of independent studies limits the ability of doctors or consumers to compare our products to conventional products.

If we are unable to compete effectively in the highly competitive medical device industry, our future growth and operating results will suffer.

The medical device industry in general and the markets in which we expect to offer products in particular, are intensely competitive. Many of our competitors have substantially greater financial, research, technical, manufacturing, marketing and distribution resources than we do and have greater name recognition and lengthier operating histories in the health care industry. We may not be able to effectively compete against these and other competitors. A number of competitors are currently marketing traditional laboratory-based tests for cervical cancer screening and diagnosis. These tests are widely accepted in the health care industry and have a long history of accurate and effective use. Further, if our products are not available at competitive prices, health care administrators who are subject to increasing pressures to reduce costs may not elect to purchase them. Also, a number of companies have announced that they are developing, or have introduced, products that permit non-invasive and less invasive cancer detection. Accordingly, competition in this area is expected to increase.

Furthermore, our competitors may succeed in developing, either before or after the development and commercialization of our products, devices and technologies that permit more efficient, less expensive non-invasive and less invasive cancer detection. It is also possible that one or more pharmaceutical or other health care companies will develop therapeutic drugs, treatments or other products that will substantially reduce the prevalence of cancers or otherwise render our products obsolete.

We have little manufacturing experience, which could limit our growth.

We do not have manufacturing experience that would enable us to make products in the volumes that would be necessary for us to achieve significant commercial sales, and we rely upon our suppliers. In addition, we may not be able to establish and maintain reliable, efficient, full scale manufacturing at commercially reasonable costs in a timely fashion. Difficulties we encounter in manufacturing scale-up, or our failure to implement and maintain our manufacturing facilities in accordance with good manufacturing practice regulations, international quality standards or other regulatory requirements, could result in a delay or termination of production. To date, our manufacturing activities have included since-discontinued products. We had substantial difficulties in establishing and maintaining manufacturing for these products and those difficulties impacted our ability to increase sales. Companies often encounter difficulties in scaling up production, including problems involving production yield, quality control and assurance, and shortages of qualified personnel.

Since we rely on sole source suppliers for several of our products, any failure of those suppliers to perform would hurt our operations.

Several of the components used in our products or planned products, are available from only one supplier, and substitutes for these components could not be obtained easily or would require substantial modifications to our

products. Any significant problem experienced by one of our sole source suppliers may result in a delay or interruption in the supply of components to us until that supplier cures the problem or an alternative source of the component is located and qualified. Any delay or interruption would likely lead to a delay or interruption in our manufacturing operations. For our products that require premarket approval, the inclusion of substitute components could require us to qualify the new supplier with the appropriate government regulatory authorities. Alternatively, for our products that qualify for premarket notification, the substitute components must meet our product specifications.

Because we operate in an industry with significant product liability risk, and we have not specifically insured against this risk, we may be subject to substantial claims against our products.

The development, manufacture and sale of medical products entail significant risks of product liability claims. We currently have no product liability insurance coverage beyond that provided by our general liability insurance. Accordingly, we may not be adequately protected from any liabilities, including any adverse judgments or settlements, we might incur in connection with the development, clinical testing, manufacture and sale of our products. A successful product liability claim or series of claims brought against us that result in an adverse judgment against or settlement by us in excess of any insurance coverage could seriously harm our financial condition or reputation. In addition, product liability insurance is expensive and may not be available to us on acceptable terms, if at all.

The availability of third party reimbursement for our products is uncertain, which may limit consumer use and the market for our products.

In the United States and elsewhere, sales of medical products are dependent, in part, on the ability of consumers of these products to obtain reimbursement for all or a portion of their cost from third-party payors, such as government and private insurance plans. Any inability of patients, hospitals, physicians and other users of our products to obtain sufficient reimbursement from third-party payors for our products, or adverse changes in relevant governmental policies or the policies of private third-party payors regarding reimbursement for these products, could limit our ability to sell our products on a competitive basis. We are unable to predict what changes will be made in the reimbursement methods used by third-party health care payors. Moreover, third-party payors are increasingly challenging the prices charged for medical products and services, and some health care providers are gradually adopting a managed care system in which the providers contract to provide comprehensive health care services for a fixed cost per person. Patients, hospitals and physicians may not be able to justify the use of our products by the attendant cost savings and clinical benefits that we believe will be derived from the use of our products, and therefore may not be able to obtain third-party reimbursement.

Reimbursement and health care payment systems in international markets vary significantly by country and include both government-sponsored health care and private insurance. We may not be able to obtain approvals for reimbursement from these international third-party payors in a timely manner, if at all. Any failure to receive international reimbursement approvals could have an adverse effect on market acceptance of our products in the international markets in which approvals are sought.

Our success depends on our ability to attract and retain scientific, technical, managerial and finance personnel.

Our ability to operate successfully and manage our future growth depends in significant part upon the continued service of key scientific, technical, managerial and finance personnel, as well as our ability to attract and retain additional highly qualified personnel in these fields. We may not be able to attract and retain key employees when necessary, which would limit our operations and growth. Only our President and Chief Executive Officer and our Vice President of Engineering have employment contracts with us, and none of our employees are covered by key person or similar insurance. In addition, if we are able to successfully develop and commercialize our products, we will need to hire additional scientific, technical, marketing, managerial and finance personnel. We face intense competition for qualified personnel in these areas, many of whom are often subject to competing employment offers.

We are significantly influenced by our directors, executive officers and their affiliated entities.

Our directors, executive officers and entities affiliated with them beneficially owned an aggregate of about 29.97 % of our outstanding common stock as of December 31 , 2011. These stockholders, acting together, would be able to exert significant influence on substantially all matters requiring approval by our stockholders, including the election of directors and the approval of mergers and other business combination transactions.

Our stock is thinly traded, so you may be unable to sell at or near ask prices or at all.

The shares of our common stock are dually listed on the OTCBB and the OTCQB. Shares of our common stock are thinly traded, meaning that the number of persons interested in purchasing our common shares at or near ask prices at any given time may be relatively small or non-existent. This situation is attributable to a number of factors, including:

- we are a small company that is relatively unknown to stock analysts, stock brokers, institutional investors and others in the investment community that generate or influence sales volume; and
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stock analysts, stock brokers and institutional investors may be risk-averse and be reluctant to follow a company such as ours that faces substantial doubt about its ability to continue as a going concern or to purchase or recommend the purchase of our shares until such time as we became more viable.

As a consequence, our stock price may not reflect an actual or perceived value. Also, there may be periods of several days or more when trading activity in our shares is minimal or non-existent, as compared to a seasoned issuer that has a large and steady volume of trading activity that will generally support continuous sales without an adverse effect on share price. A broader or more active public trading market for our common shares may not develop or if developed, may not be sustained. Due to these conditions, you may not be able to sell your shares at or near ask prices or at all if you need money or otherwise desire to liquidate your shares.

Trading in our common stock is subject to special sales practices and may be difficult to sell.

Our common stock is subject to the Securities and Exchange Commission's "penny stock" rule, which imposes special sales practice requirements upon broker-dealers who sell such securities to persons other than established customers or accredited investors. Penny stocks are generally defined to be an equity security that has a market price of less than $5.00 per share. For purposes of the rule, the phrase "accredited investors" means, in general terms, institutions with assets in excess of $5,000,000, or individuals having a net worth in excess of $1,000,000 or having an annual income that exceeds $200,000 (or that, when combined with a spouse's income, exceeds $300,000). For transactions covered by the rule, the broker-dealer must make a special suitability determination for the purchaser and receive the purchaser's written agreement to the transaction prior to the sale. Consequently, the rule may affect the ability of broker-dealers to sell our securities and also may affect the ability of our stockholders to sell their securities in any market that might develop.

Stockholders should be aware that, according to Securities and Exchange Commission Release No. 34-29093, the market for penny stocks has suffered from patterns of fraud and abuse. Such patterns include:

- control of the market for the security by one or a few broker-dealers that are often related to the promoter or issuer;
- manipulation of prices through prearranged matching of purchases and sales and false and misleading press releases;
- "boiler room" practices involving high-pressure sales tactics and unrealistic price projections by inexperienced sales persons;
- excessive and undisclosed bid-ask differentials and markups by selling broker-dealers; and
- the wholesale dumping of the same securities by promoters and broker-dealers after prices have been manipulated to a desired level, along with the resulting inevitable collapse of those prices and with consequent investor losses.

Our management is aware of the abuses that have occurred historically in the penny stock market. Although we do not expect to be in a position to dictate the behavior of the market or of broker-dealers who participate in the market, management will strive within the confines of practical limitations to prevent the described patterns from being established with respect to our common stock.

Substantial future sales of shares of our common stock in the public market could cause our stock price to fall.

If our stockholders (including those persons who may become stockholders upon exercise of our warrants) sell substantial amounts of our common stock, or the public market perceives that stockholders might sell substantial amounts of our common stock, the market price of our common stock could decline significantly. Such sales also might make it more difficult for us to sell equity or equity-related securities in the future at a time and price that our management deems appropriate.

Our need to raise additional capital in the near future or to use our equity securities for payments could have a dilutive effect on your investment.

In order to continue operations, we will need to raise additional capital. We may attempt to raise capital through the public or private sale of our common stock or securities convertible into or exercisable for our common stock. In addition, from time to time we have issued our common stock or warrants in lieu of cash payments. If we sell additional shares of our common stock or other equity securities, or issue such securities in respect of other claims or indebtedness, such sales or issuances will further dilute the percentage of our equity that you own. Depending upon the price per share of securities that we sell or issue in the future, if any, your interest in us could be further diluted by any adjustments to the number of shares and the applicable exercise price required pursuant to the terms of the agreements under which we previously issued securities.

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FORWARD LOOKING STATEMENTS

Statements in this prospectus, which express "belief," "anticipation" or "expectation," as well as other statements that are not historical facts, are forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, or Securities Act, and Section 21E of the Securities Exchange Act of 1934, or Exchange Act. These forward-looking statements are subject to risks and uncertainties that could cause actual results to differ materially from historical results or anticipated results, including those identified in the foregoing "Risk Factors" and elsewhere in this prospectus. 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 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;
- the dependence on potential strategic partners or outside investors for funding, development assistance, clinical trials, distribution and marketing of some of our products; and
- other risks and uncertainties described from time to time in our reports filed with the SEC.

Forward-looking statements should not be read as a guarantee of future performance or results, and will not necessarily be accurate indications of the times at, or by which, such performance or results will be achieved. Forward-looking information is based on information available at the time and/or management's good faith belief with respect to future events, and is subject to risks and uncertainties that could cause actual performance or results to differ materially from those expressed in the statements.

Forward-looking statements speak only as of the date the statements are made. We assume no obligation to update forward-looking statements to reflect actual results, changes in assumptions or changes in other factors affecting forward-looking information except to the extent required by applicable securities laws. If we update one or more forward-looking statements, no inference should be drawn that we will make additional updates with respect thereto or with respect to other forward-looking statements.

USE OF PROCEEDS

All sales of the common stock covered by this prospectus will be by or for the account of the selling stockholders listed in this prospectus under “Selling Stockholders.” As of March 15, 2012, we have received a total of $936,380, from the exercise of outstanding warrants held by the selling stockholders to purchase an aggregate of 1,440,612 shares of our common stock. We may receive the proceeds from the exercise of the remaining warrants entitling the selling stockholders to purchase shares of our common stock. If all such remaining warrants are exercised, we will receive $0.65 per underlying share of common stock, or an aggregate of $18,455,019, in cash proceeds.

We expect to use any proceeds we receive from the exercise of the warrants for general corporate purposes, including working capital, capital expenditures and repaying or refinancing our debt obligations.

SELLING STOCKHOLDERS

We issued warrants to purchase shares of common stock in a private placement transaction with the selling stockholders exempt from registration under the Securities Act. This prospectus covers the resale of shares of common stock that we have issued or may issue upon exercise of these warrants.

The table below sets forth:

- the names of the selling stockholders;
- the number of shares of common stock, and the percentages of outstanding common stock, beneficially owned by the selling stockholders as of March 15, 2012 , prior to the selling stockholders’ offering of the shares of common stock pursuant to this prospectus;
- the maximum number of shares of common stock which may be offered by the selling stockholders pursuant to this prospectus; and
- the number of shares of common stock, and the percentages of outstanding common stock, to be beneficially owned by the selling stockholders after the offering of common stock pursuant to this prospectus, assuming all such common stock being offered is sold by the selling stockholders and that the selling stockholders do not acquire any additional shares of common stock.

The number of shares disclosed in the table below as ‘‘beneficially owned’’ are those beneficially owned as determined under the rules of the SEC. Such information is not necessarily indicative of ownership for any other purpose.

We obtained the information in the table below from the selling stockholders (other than the information regarding the percentages of outstanding common stock beneficially owned by each selling stockholder). Except as may be noted below or under “Legal Proceedings,” none of the selling stockholders have, or within the past three years has had, any material relationship with us or any of our affiliates.

We cannot advise you as to whether the selling stockholders will in fact sell any or all of such shares of common stock. In addition, the selling stockholders may have sold, transferred or otherwise disposed of, or may sell, transfer or otherwise dispose of, at any time and from time to time, the shares of common stock in transactions exempt from the registration requirements of the Securities Act after the date on which they provided the information set forth in the

table below. Only the selling stockholders referenced in the table below may sell the securities offered hereby, except as otherwise permitted by law. Changed information regarding the selling stockholders will be presented in a prospectus supplement or post-effective amendment to the registration statement of which this prospectus forms a part if and when necessary and required. Except as indicated below, no selling stockholder is a registered broker-dealer or an affiliate of a broker-dealer.

The number of shares of common stock underlying warrants assumes no adjustment in the number of shares issuable upon exercise of the warrants as a result of stock splits and stock dividends.

Name of Selling Stockholder	Beneficial Ownership of Common Stock Prior to Offering		Common Stock Being Offered Pursuant to this Prospectus (maximum number that may be sold)(1)	Beneficial Ownership of Common Stock After Offering	
	Shares	Percentage		Shares	Percentage
John E. Imhoff (2)	10,784,885	21.50 %	4,783,923	6,000,962	23.27 %
Kuekenhof Equity Fund, LP (2)	3,260,616	6.50 %	1,736,574	1,524,042	5.91 %
Ronald W. Allen (2)	872,709	1.74 %	242,535	630,174	2.44 %
Hart Management, LLC (2)	367,583	*	153,846	213,737	*
Ronald W. Hart (2)	994,888	1.98 %	64,564	930,324	3.61 %
Richard L. Fowler (3)	479,343	*	56,120	423,223	1.64 %
Lynne Imhoff (4)	324,451	*	157,214	167,237	*
Susan M. Imhoff (4)	366,376	*	148,648	217,728	*
John C. Imhoff (4)	180,000	*	50,000	130,000	*
Richard Blumberg (5)	3,793,767	7.56 %	2,798,469	995,298	3.86 %
Guided Medical Solutions, LLC (5)	2,143,129	4.27 %	1,038,462	1,104,667	4.28 %
J. E. Funderburke (5)	300,000	*	300,000	-	*
L. Peter Reininger (5)	359,328	*	109,449	249,879	*
Sternfeld Family Trust, c/o Daniel Sternfeld (6)	515,725	1.03 %	363,189	152,536	*
Webster Mrak & Blumberg Profit Sharing Plan, FBO Christine Mrak (6)	357,478	*	292,046	65,432	*
Webster Mrak & Blumberg Profit Sharing Plan, FBO Richard Blumberg (6)	349,849	*	285,808	64,041	*
Germain Halegoua Annuity Trust UTA 6/16/95, FBO Jamie Halegoua (6)	406,393	*	170,369	236,024	*
The Arthur Kontos Foundation (6)	367,583	*	153,846	213,737	*
Mark E. & Maureen C. Brennan, Jt. Tenants (6)	133,723	*	109,001	24,722	*
Germain Halegoua Annuity Trust UTA 6/16/95, FBO Rachel Halegoua (6)	203,197	*	85,185	118,012	*
	203,197	*	85,185	118,012	*

Germain Halegoua Annuity Trust UTA 6/16/95, FBO Jason Halegoua (6)					
Germain Halegoua Annuity Trust UTA 6/16/95, FBO Germaine Halegoua (6)	203,197	*	85,185	118,012	*
Webster Mrak & Blumberg Profit Sharing Plan, FBO James H. Webster (6)	158,750	*	76,923	81,827	*
Catherine Tinney Rome Profit Sharing (6)	101,598	*	42,592	59,006	*
Jeffrey Mosseri, IRA (6)	62,634	*	41,385	21,249	*
Rhoda Intervivos Trust (6)	91,896	*	38,462	53,434	*
Marshall Etra IRA (6)	91,896	*	38,462	53,434	*
Christopher Jordan IRA (6)	55,829	*	23,405	32,424	*
Richard Steiner Rev. Trust UTD 8/25/92 (6)	52,143	*	30,769	21,374	*
Marjorie Rosenstreich IRA (6)	73,396	*			