

# SECURITIES & EXCHANGE COMMISSION EDGAR FILING

## GUIDED THERAPEUTICS INC

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

**FORM 10-K**

(Mark One)

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

For the fiscal year ended December 31, 2012.

OR

TRANSITION REPORT UNDER SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the transition period from \_\_\_\_\_ to \_\_\_\_\_

Commission file number: 0-22179

**GUIDED THERAPEUTICS, INC.**

(Exact name of registrant as specified in its charter)

Delaware

(State or other jurisdiction of incorporation or organization)

58-2029543

(I.R.S. Employer Identification No.)

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

30092  
(Zip Code)

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

Securities registered under Section 12(b) of the Exchange Act: None

Securities registered under Section 12(g) of the Act: Common Stock, \$0.001 par value  
(Title of class)

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes  No

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes  No

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes  No

Indicate by check mark whether the registrant 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 if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K.

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company.

Large accelerated filer  Accelerated filer

Non-accelerated filer  Smaller reporting company

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

The aggregate market value of the voting and non-voting common stock held by non-affiliates of the registrant was approximately \$44,097,260 as of June 29, 2012 (the last business day of the registrant's most recently completed second fiscal quarter), based upon the closing sales price of the registrant's Common Stock of \$0.79, reported for such date by the OTC Bulletin Board.



As of March 26, 2013, the registrant had outstanding 64,821,980 shares of Common Stock.

**DOCUMENTS INCORPORATED BY REFERENCE.**

None.

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## PART I

### Item 1. Business

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

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 wholly owned subsidiary, InterScan, which originally had been incorporated as “Guided Therapeutics.”

#### **Non-Invasive Cervical Cancer Detection**

We believe LuViva 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. On November 14, 2012 we filed an amended PMA with FDA. Assuming we receive FDA approval in 2013, we currently anticipate a late 2013 or early 2014 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, from 2008 until early 2013 we had worked exclusively 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 primarily for the detection of esophageal cancer. On February 6, 2013, we announced that we had terminated and replaced our existing agreements with Konica Minolta with a new license agreement allowing us to manufacture and to develop a non-invasive esophageal cancer detection product from Konica Minolta and based on our biophotonic technology platform (see “—Lung and Esophageal Cancer Detection —Konica Minolta”).

#### Our Business Strategy

Our mission is to build a profitable business that develops and commercializes medical products that improve people’s lives and increases stockholder value. To achieve this mission, we have completed the FDA pivotal trial for our first product, called LuViva, filed our PMA application with the FDA, and have raised capital for the development and launch of the LuViva device system. Development of our cancer diagnostic technology has been financed to date through a combination of government grants, strategic partners and direct investment. Bringing LuViva to market is the main focus of our business. In order to adequately finance the completion of the FDA review process, complete product development, and prepare for marketing of LuViva, additional capital will be needed; however, we cannot be assured of the availability of adequate capital (see Item 1A. “Risk Factors”).

We believe that our technology, as developed for cervical cancer detection, can be modified and then applied to other cancers. Because development of our technology for additional cancers is costly and resource intensive, we sought a strategic partner to help defray costs and otherwise assist in the expansion of our cancer detection technology into other cancers. This resulted in our various collaborative agreements with Konica Minolta, including agreements related to the development of a prototype device specifically for esophageal cancer detection and our current license agreement with Konica Minolta (see “—Lung and Esophageal Cancer Detection —Konica Minolta”). Subsequent to December 31, 2012, the Company does not anticipate receiving future funding from Konica Minolta for research and development activities and the Company has reached an agreement with Konica Minolta to license certain of their technology.

## Industry Overview

### ***Cervical Cancer Detection***

#### **Background**

According to the American Cancer Society, cancer is a group of many related diseases. All forms of cancer involve the out-of-control growth and spread of abnormal cells. Normal body cells grow, divide, and die in an orderly fashion. Cancer cells, however, continue to grow and divide and can spread to other parts of the body. In America, half of all men and one-third of all women will develop cancer during their lifetimes. According to the American Cancer Society, the sooner a cancer is found and treatment begins, the better a patient's chances are of being cured. We began investigating the applications of our technologies to cancer detection before 1997, when we initiated a market analysis for these uses. We concluded that our biophotonic technologies had applications for the detection of a variety of cancers through the exposure of tissue to light. We selected cervical cancer and skin cancer from a list of the ten most attractive applications as categories of cancer to pursue initially, and currently are focused primarily on the development of our non-invasive cervical cancer detection product.

#### **Cervical Cancer**

Cervical cancer is a cancer that begins in the lining of the cervix (which is located in the lower part of the uterus). Cervical cancer forms over time and may spread to other parts of the body if left untreated. There is generally a gradual change from a normal cervix to a cervix with precancerous cells to cervical cancer. For some women, precancerous changes may go away without any treatment. While the majority of precancerous changes in the cervix do not advance to cancer, if precancers are treated, the risk that they will become cancers can be greatly reduced. The Pap smear screening test, or Pap test, which involves a sample of cervical tissue being placed on a slide and observed in a laboratory, is currently the most common form of cervical cancer screening.

#### **Cervical Cancer Market**

The National Cancer Institute ("NCI") estimates that in 2013, about 12,340 cases of invasive cervical cancer will be diagnosed and about 4,030 women will die from cervical cancer in the United States. According to published data, cervical cancer results in about 200,000 deaths annually worldwide, with 470,000 new cases reported each year.

We believe that our major market opportunities related to cervical cancer are in diagnosis and screening. Since the introduction of better screening and diagnostic methods, the number of cervical cancer deaths in the United States has declined dramatically, due mainly to the increased use of the Pap test. However, over the last five years, the incidences have been increasing. Moreover, the Pap test has a wide variation in sensitivity, which is the ability to detect the disease, and specificity, which is the ability to exclude false positives. A study by Duke University for the U.S. Agency for Health Care Policy and Research published in 1999 showed Pap test performance ranging from a sensitivity of 22% and specificity of 78% to sensitivity of 95% and specificity of 10%. About 60 million Pap tests are given annually in the United States. The average price of a Pap test in the United States is about \$26. New technologies improving the sensitivity and specificity of the Pap test have recently been introduced and are finding acceptance in the marketplace.

After screening for cervical cancer by use of a Pap test, if necessary, a visual examination of the cervix using a colposcope is usually followed by a biopsy, or tissue sampling at one or more locations. This method looks for visual changes attributable to cancer. There are about two million colposcope examinations annually in the United States and Europe. In 2003, the average cost of a stand-alone colposcope examination in the United States was \$185 and the average cost of a colposcopy with biopsy was \$277.

In 2006, a new vaccine for certain strains of the human papilloma virus, or HPV, was approved by the FDA. Most cervical cancers are associated with certain strains of HPV. The vaccine is administered in three doses, and according to guidelines, preferably to girls before they become sexually active. The approved vaccine is effective against 70% of the strains of HPV thought to be responsible for cervical cancer. Due to the limited availability and lack of 100% protection against all potentially cancer-causing strains of HPV, we believe that the vaccine will have a limited impact on the cervical cancer screening and diagnostic market for many years.

## **Our Non-invasive Cervical Cancer Product**

LuViva is a non-invasive cervical cancer detection product, based on our proprietary biophotonic technology. The device is designed to identify cervical cancers and precancers painlessly, non-invasively and at the point-of-care by scanning the cervix with light, then analyzing the light reflected or emanating from the cervix. The information presented by the light would be used to indicate the likelihood of cervical cancer or precancers and/or to produce a map or image of diseased tissue. This test, unlike the Pap test or biopsy, has the potential to preserve the perspective and positional information of disease on the cervix, allowing for more accurate diagnosis. Our system also could allow doctors to make intelligent choices in triaging patients for biopsy or treatment and potentially for selecting biopsy sites that could be expanded for use in assisting in the detection of cancerous margins for cancer removal. Our product, in addition to detecting the structural changes attributed to cervical cancer, is also designed to detect the biochemical changes that precede the development of visual lesions. In this way, cervical cancer may be detected earlier in its development, which should increase the chances of effective treatment. The product is expected to incorporate a single-use, disposable calibration and alignment component. FDA approval of the intended use of our device is required and initial approval may be for a limited set of the above potential capabilities. Our strategy is to launch LuViva first in Canada and the developed countries of Europe, while continuing steps to procure FDA approval in the United States.

To date, more than 3,000 women have been tested with various LuViva prototype devices in multiple clinical settings. During 2000, we conducted human clinical feasibility studies of laboratory prototypes at two U.S. research centers, detecting 31% more cervical precancerous lesions than conventional Pap tests. The results were presented at the World Health Organization/European Research Organization on Genital Infection and Neoplasia Joint Experts Conference in Paris in April 2000. The study population included 133 women scheduled for colposcopy and biopsy, if indicated. A total of 318 tissue-specific comparisons were made between our device and colposcopy/biopsy results. Of the 318 patients included in this study, 20 had high-grade precancers, 36 had low-grade precancers, 146 had benign lesions and 116 had normal tissues. Compared to the Pap test, our product detected 31% more precancers and 25% more high-grade precancers without increasing the false positive rate.

In 2005, we continued to conduct our pivotal clinical trial, which had collected data on over 900 women by the end of the year. In 2005, we also completed work on our commercial prototype. In 2006 and 2007, we continued to enroll subjects in our pivotal clinical trial and, by the end of 2007, had enrolled 1,400 subjects.

In September 2006, we announced that the National Cancer Institute ("NCI") awarded a grant of approximately \$690,000 for development of our non-invasive cervical cancer detection technology. This grant was used to further the ongoing FDA pivotal clinical trial. In 2006 and 2007, we received approximately \$523,000 and \$398,000, respectively, of NCI grant funds. On October 5, 2009, we were awarded a \$2.5 million matching grant by the NCI to bring to market and expand the array features for LuViva. The award provided resources to complete the regulatory process and begin manufacturing ramp up for LuViva and a single-patient-use disposable patient interface for the device and will be received over a period of three years. Under the award, we recorded revenue of approximately \$68,000 in 2012 and approximately \$912,000 in 2011. We are eligible to receive a maximum of approximately \$150,000 in 2013.

On February 23, 2012, we announced that we had successfully completed an audit of our quality system and were recertified under ISO 13485:2003. This designation means that we are eligible to issue a conformity mark ("CE mark") for LuViva once development is complete. The CE mark is necessary to sell LuViva in the European Union and certain other markets. On October 4, 2011, we announced that LuViva was selected for inclusion in a review of new technologies by the United Kingdom's NICE program. On December 14, 2011, we announced that Health Canada granted marketing approval for the device.

We completed enrollment in our FDA pivotal trial in 2008 and on November 18, 2010, the FDA accepted our completed 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 2013, we currently anticipate a late 2013 or early 2014 product launch, but cannot be assured we will be able to launch on that timetable, or at all.

Sales or leases of LuViva are expected to include a single-patient-use disposable patient interface. We expect the device itself to be priced at less than \$20,000, with the disposable interface priced around \$30 to \$40. Profit margins on the disposable are expected to be approximately 90%. In the United States, we plan on establishing and training a 10-person sales force during the first year after launch, which will initially focus on early adopters in the larger population centers. Internationally, we plan on contracting with country-specific or regional distributors. We believe that the international market will be larger than the U.S. market. We have been in contact with more than 100 potential distributors, have formal distribution agreements in place covering 15 countries and expect to announce additional agreements over the next several months.

The market for cervical cancer screening is currently dominated by lab-based cytological screening of samples obtained from patients. The market for primary screening is dominated by Hologic, Inc., which markets the Thin Prep Pap test and Qiagen, Inc., which markets another method of cervical cancer screening, HPV detection. Qiagen is attempting to gain permission to use its device for primary screening. The Qiagen HPV test is already approved for use as a follow-up to ambiguous Pap test results and as an adjunct to the Pap test for screening women aged 30 and over. We have conducted marketing research related to the cervical cancer market and the impact of the growth of the lab-based cytological screening products. We are reviewing the impact of the changing competitive landscape related to our product development pace and our initial and potential positioning. We will have to demonstrate clinical and commercial effectiveness to be able to change current medical practice behavior and capture market share and cannot be sure that we will be able to do so.

### ***Lung and Esophageal Cancer Detection***

According to the World Health Organization, there are 1.2 million cases of lung cancer diagnosed each year worldwide, with at least half of these resulting in death. In the United States, lung cancer is the leading cause of death due to cancer, with 228,190 new cases and more than 159,480 deaths annually, according to the NCI's 2013 estimates. Lung cancer is also a serious health issue in other parts of the world where cigarette smoking is endemic (Japan, for example, with more than 63,000 deaths annually). Despite this enormous and tragic toll, no effective method of early screening has been able to improve upon these rates. Historically, chest x-rays have been employed, but typically these identify later stage cancers, which are difficult to cure. Sputum tests to identify cancer markers in at-risk individuals have not been widely adopted and CT or other scanning technology is likely to be too expensive in the foreseeable future for screening or widespread use. Once a mass has been identified, usually by chest x-ray or physical symptoms such as bloody sputum, a bronchoscopy with biopsy and histopathological diagnosis of the mass is performed.

Worldwide, new cases of esophageal cancer are estimated at 410,000, with more than 17,990 new cases and 15,210 deaths in the United States alone, according to the NCI's 2013 estimates. A precursor to esophageal cancer is a condition known as Barrett's esophagus, which is caused by excessive acid reflux. Patients with this condition may be subjected to repeated and sometimes poorly directed biopsies of areas of the esophagus thought to contain cancerous or pre-cancerous (neoplastic) cells. Because there may be several areas of suspicion, the clinical challenge is to try to identify those areas of the esophagus with greatest likelihood of neoplastic change. Endoscopic techniques, using regular white light, have only limited ability to accomplish this and defensively-minded practitioners often resort to multiple biopsies that are expensive and painful in order to increase the odds of finding disease.

Since the processes associated with cancer development show similarities between cervical cancer and other cancers, we believe our technology, if integrated with an endoscopic system, may have the potential to more accurately, or in an earlier state, detect lung and esophageal cancers and precancers. To that end, we have worked with Konica Minolta to adapt our cervical cancer detection technology for detection of lung cancer and esophageal cancer (see "—Konica Minolta"). However, we are only in the early stages of clinical trials to evaluate this potential. We recently announced that we had received Institutional Review Board approval for testing the technology in humans and were granted a non-significant risk designation for the device. We have two clinics in the Atlanta, Georgia metropolitan area where we have been conducting a small scale study. The goal of the study, completed in 2012, was to establish feasibility of the product design and clinical implementation. As part of our feasibility study, qualified subjects underwent a standard EGD (Esophago Gastro Duodenoscopy) procedure and measurements with our device. Biopsy samples were taken in accordance with the standard of care.

### **Konica Minolta**

Since April 2008, we have worked with Konica Minolta to explore the feasibility of adapting our microporation and biophotonic cancer detection technologies to other areas of medicine and to determine potential markets for these products in anticipation of a development agreement.

On April 28, 2009, we signed a one-year exclusive negotiation and development agreement of optimization of our microporation system for manufacturing, regulatory approval, commercialization and clinical utility with Konica Minolta. We renewed the agreement in 2010, 2011 and 2012 for additional one-year terms and changed the licensed technology to our biophotonic cancer detection technology. We received approximately \$750,000 in 2011 from Konica Minolta under this option to license agreements and received a total of \$400,000 in 2012.

On January 28, 2010, we entered into another agreement with Konica Minolta for development of our biophotonic platform specific to the detection of esophageal cancer. In this agreement, we provided Konica Minolta with technical, regulatory and clinical development of our biophotonic platform device for esophageal cancer detection. In March 2011, we extended this agreement for an additional year, effective May 1, 2011. We received approximately \$1.72 million in 2011 from Konica Minolta under these development agreements and received a total of \$1.3 million for the third year of development (original period of May 1, 2012 to April 30, 2013). In February 2013, we replaced our existing agreements with Konica Minolta with a new agreement, pursuant to which, subject to the payment of a nominal license fee due upon FDA approval, Konica Minolta has granted us a five-year, world-wide, non-transferable and non-exclusive right and license to manufacture and to develop a non-invasive esophageal cancer detection product from Konica Minolta and based on our biophotonic technology platform. The license permits us to use certain related intellectual property of Konica Minolta. In return for the license, we have agreed to pay Konica Minolta a royalty for each licensed product we sell. We continue to have the right to seek new collaborative partners to further develop our technology. Subsequent to December 31, 2012, the Company does not anticipate receiving future funding from Konica Minolta for research and development activities.

### **Research, Development and Engineering**

To date, we have been engaged primarily in the research, development and testing of our LuViva non-invasive cervical cancer detection product and our core biophotonic technologies, as well as our since-discontinued glucose monitoring, diabetes detection, infant jaundice products. From inception in 1992 to December 31, 2012, we have incurred about \$58.4 million in research and development expenses, net of about \$24.6 million reimbursed through collaborative arrangements and government grants. Research and development costs were about \$3.2 million and \$2.8 million in 2012 and 2011, respectively.

Since 2008, we have focused our research and development and our engineering resources almost exclusively on development of our biophotonic cancer detection technology, with only limited support of other programs funded through government contracts or third party funding. Because we have not yet launched commercial versions of our technology, only prototypes of our cervical cancer detection product have been tested. Because our research and clinical development programs for other cancers are at a very early stage, substantial additional research and development and clinical trials will be necessary before commercial prototypes of our cancer detection products can be produced.

Several of the components used in our product 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.

### **Manufacturing, Sales Marketing and Distribution**

We have only limited experience in the production planning, quality system management, facility development, and production scaling that will be needed to bring production to commercial levels. We will need to develop additional expertise in order to successfully manufacture market and distribute any future products.

### **Patents**

We have pursued a course of developing and acquiring patents and patent rights and licensing technology. Our success depends in large part on our ability to establish and maintain the proprietary nature of our technology through the patent process and to license from others patents and patent applications necessary to develop our products. As of December 31, 2012, we have 18 granted U.S. patents relating to our biophotonic cancer detection technology and four pending U.S. patent applications. We also have three granted patents that apply to our interstitial fluid analysis system.

Any of the patents held directly by us or licensed by us from third parties, or any of the processes used in the manufacture of our products, may be successfully challenged, invalidated or circumvented. Additionally, we may not otherwise be able to rely on these patents. In addition, we cannot be sure that competitors, many of whom have substantial resources and have made substantial investments in competing technologies, will not seek to 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 foreign markets. If any of our patents are successfully challenged, invalidated or circumvented or our rights or ability to manufacture our products were to be proscribed or limited, our ability to continue to manufacture and market our products could be adversely affected, which would likely have a material adverse effect upon our business, financial condition and results of operations.

### **Competition**

The medical device industry in general and the markets for cervical cancer detection in particular, are intensely competitive. If successful in our product development, we will compete with other providers of cervical cancer detection and prevention products.

Current cervical cancer screening tests, primarily the Pap test and colposcopy, are well established and pervasive. Improvements and new technologies for cervical cancer detection and prevention, such as Thin-Prep from Hologic and HPV testing from Qiagen, have led to other new competitors. In addition, there are other companies attempting to develop products using forms of biophotonic technologies in cervical cancer detection, such as MediSpectra, Inc. (since acquired by Spectrascience, Inc.). MediSpectra was granted a very limited FDA approval in March 2006 to market its device for detection of cervical cancers. The limited approval limits use of the MediSpectra device only after a colposcopy, as an adjunct. We will be required to develop devices that are more accurate, easier to use or less costly to administer to create devices that have a competitive advantage.

In June 2006, the FDA approved the HPV vaccine Gardasil from drug maker Merck & Co., Inc. Gardasil is a prophylactic HPV vaccine, meaning that it is designed to prevent the initial establishment of HPV infections. For maximum efficacy, it is recommended that girls receive the vaccine prior to becoming sexually active. Since Gardasil will not block infection with all of the HPV types that can cause cervical cancer, the vaccine should not be considered a substitute for routine Pap tests. On October 16, 2009, GlaxoSmithKline PLC was granted approval in the United States for a similar preventive HPV vaccine, known as Cervarix.

## **Government Regulation**

All of our products are, or will be, regulated as medical devices. Medical device products are subject to rigorous FDA and other governmental agency regulations in the United States and may be subject to regulations of relevant foreign agencies. Noncompliance with applicable requirements can result in import detentions, fines, civil penalties, injunctions, suspensions or losses of regulatory approvals or clearances, recall or seizure of products, operating restrictions, denial of export applications, governmental prohibitions on entering into supply contracts, and criminal prosecution. Failure to obtain regulatory approvals or the restriction, suspension or revocation of regulatory approvals or clearances, as well as any other failure to comply with regulatory requirements, would have a material adverse effect on our business, financial condition and results of operations.

The FDA regulates the clinical testing, design manufacture, labeling, packaging, marketing, distribution and record-keeping for these products to ensure that medical products distributed in the United States are safe and effective for their intended uses.

In the United States, medical devices are classified into one of three classes on the basis of the controls deemed necessary by the FDA to reasonably assure the devices' safety and effectiveness. Under FDA regulations, Class I devices are subject to general controls, such as labeling requirements, notification to the FDA before beginning marketing activities and adherence to specified good manufacturing practices. Class II devices are subject to general and special controls, such as performance standards, surveillance after beginning market activities, patient registries, and FDA guidelines. Generally, Class III devices are those which must receive premarket approval from the FDA to ensure their safety and effectiveness. Examples of Class III devices include life-sustaining, life-supporting and implantable devices, as well as new devices that have not been found substantially equivalent to legally marketed Class I or II devices.

A medical device manufacturer may seek clearance to market a medical device by filing a 510(k) premarket notification with the FDA if the manufacturer establishes that a newly developed device is substantially equivalent to either a device that was legally marketed before May 28, 1976, the date upon which the Medical Device Amendments of 1976 were enacted, or to a device that is currently legally marketed and has received 510(k) premarket clearance from the FDA. The 510(k) premarket notification must be supported by appropriate information, which may include data from clinical trials to establish the claim of substantial equivalence. Commercial distribution of a device for which a 510(k) premarket notification is required can begin only after the FDA determines the device to be substantially equivalent to a legally marketed device. The FDA has recently been requiring a more rigorous demonstration of substantial equivalence than in the past. It generally takes from three to 12 months from the date of submission to obtain clearance of a 510(k) submission, but it may take substantially longer. The FDA may determine that a proposed device is not substantially equivalent to a legally marketed device, or may require additional information.

An adverse determination or a request for additional information could delay the market introduction of new products that fall into this category, such as LuViva, which could have a material adverse effect on our business, financial condition and results of operations. For LuViva, any of our future products that have to be cleared through the PMA or 510(k) process, including modifications or enhancements that could significantly affect the safety or effectiveness of the device or that constitute a major change to the intended use of the device will require new PMA application and approval or a 510(k) premarket notification. Any modified device for which a new PMA or 510(k) premarket notification is required cannot be distributed until the PMA is approved or 510(k) clearance is obtained. We may not be able to obtain PMA approval or 510(k) clearance in a timely manner, if at all, for LuViva or any future devices or modifications to LuViva or such devices for which we may submit a PMA 510(k) application.

A PMA application must be submitted if a proposed device is not substantially equivalent to a legally marketed Class I or Class II device or for specified Class III devices. The application must contain valid scientific evidence to support the safety and effectiveness of the device, which includes the results of clinical trials, all relevant bench tests, and laboratory and animal studies. The application must also contain a complete description of the device and its components, as well as a detailed description of the methods, facilities and controls used for its manufacture, including, where appropriate, the method of sterilization and its assurance. In addition, the application must include proposed labeling, advertising literature and any required training methods. If human clinical trials of a device are required in connection with an application and the device presents a significant risk, the sponsor of the trial is required to file an application for an

investigational device exemption before beginning human clinical trials. Usually, the manufacturer or distributor of the device is the sponsor of the trial. The application must be supported by data, typically including the results of animal and laboratory testing, and a description of how the device will be manufactured. If the application is reviewed and approved by the FDA and one or more appropriate institutional review boards, human clinical trials may begin at a specified number of investigational sites with a specified number of patients. If the device presents a non-significant risk to the patient, a sponsor may begin clinical trials after obtaining approval for the study by one or more appropriate institutional review boards, but FDA approval for the commencement of the study is not required. Sponsors of clinical trials are permitted to sell those devices distributed in the course of the study if the compensation received does not exceed the costs of manufacture, research, development and handling. A supplement for an investigational device exemption must be submitted to and approved by the FDA before a sponsor or an investigator may make a significant change to the investigational plan that may affect the plan's scientific soundness or the rights, safety or welfare of human subjects.

Upon receipt of a PMA application, the FDA makes a threshold determination as to whether the application is sufficiently complete to permit a substantive review. If the FDA makes this determination, it will accept the application for filing. Once the submission is accepted for filing, the FDA begins an in-depth review of the application. An FDA review of a PMA application generally takes one to two years from the date the application is accepted for filing. However, this review period is often significantly extended by requests for more information or clarification of information already provided in the submission. During the review period, the submission may be sent to an FDA-selected scientific advisory panel composed of physicians and scientists with expertise in the particular field. The FDA scientific advisory panel issues a recommendation to the FDA that may include conditions for approval. The FDA is not bound by the recommendations of the advisory panel. Toward the end of the PMA application review process, the FDA will conduct an inspection of the manufacturer's facilities to ensure that the facilities are in compliance with applicable good manufacturing practice. If the FDA evaluations of both the PMA application and the manufacturing facilities are favorable, the FDA will issue a letter. This letter usually contains a number of conditions, which must be met in order to secure final approval of the application. When those conditions have been fulfilled to the satisfaction of the FDA, the agency will issue an approval letter authorizing commercial marketing of the device for specified indications and intended uses.

The PMA application review process can be expensive, uncertain and lengthy. A number of devices for which a premarket approval has been sought have never been approved for marketing. The FDA may also determine that additional clinical trials are necessary, in which case the premarket approval may be significantly delayed while trials are conducted and data is submitted in an amendment to the PMA application. Modifications to the design, labeling or manufacturing process of a device that has received premarket approval may require the FDA to approve supplements or new applications. Supplements to a PMA application often require the submission of additional information of the same type required for an initial premarket approval, to support the proposed change from the product covered by the original application. The FDA generally does not call for an advisory panel review for PMA supplements, though applicants may request one. If any PMAs are required for our products, we may not be able to meet the FDA's requirements or we may not receive any necessary approvals. Failure to comply with regulatory requirements or to receive any necessary approvals would have a material adverse effect on our business, financial condition and results of operations.

Regulatory approvals and clearances, if granted, may include significant labeling limitations and limitations on the indicated uses for which the product may be marketed. In addition, to obtain regulatory approvals and clearances, the FDA and some foreign regulatory authorities impose numerous other requirements with which medical device manufacturers must comply. FDA enforcement policy strictly prohibits the marketing of approved medical devices for unapproved uses. Any products we manufacture or distribute under FDA clearances or approvals are subject to pervasive and continuing regulation by the FDA. The FDA also requires us to provide it with information on death and serious injuries alleged to have been associated with the use of our products, as well as any malfunctions that would likely cause or contribute to death or serious injury.

The FDA requires us to register as a medical device manufacturer and list our products. We are also subject to inspections by the FDA and state agencies acting under contract with the FDA to confirm compliance with good manufacturing practice. These regulations require that we manufacture our products and maintain documents in a prescribed manner with respect to manufacturing, testing, quality assurance and quality control activities. The FDA also has promulgated final regulatory changes to these regulations that require, among other things, design controls and maintenance of service records. These changes will increase the cost of complying with good manufacturing practice requirements.

We are also subject to a variety of other controls that affect our business. Labeling and promotional activities are subject to scrutiny by the FDA and, in some instances, by the Federal Trade Commission. The FDA actively enforces regulations prohibiting marketing of products for unapproved users. We are also subject, as are our products, to a variety of state and local laws and regulations in those states and localities where our products are or will be marketed. Any applicable state or local regulations may hinder our ability to market our products in those regions. Manufacturers are also subject to numerous federal, state and local laws relating to matters such as safe working conditions, manufacturing practices, environmental protection, fire hazard control and disposal of hazardous or potentially hazardous substances. We may be required to incur significant costs to comply with these laws and regulations now or in the future. These laws or regulations may have a material adverse effect on our ability to do business.

International sales of our products are subject to the regulatory requirements of each country in which we market our products. The regulatory review process varies from country to country. The European Union has promulgated rules that require medical products to affix the CE mark, an international symbol of adherence to quality assurance standards and compliance with applicable European medical directives. The appropriate ISO certification is one of the CE mark requirements. We maintain ISO 13485:2003 certification, which allows us to issue a CE mark for our non-invasive cervical cancer detection device once development is complete and sell the device in the European Union and other markets. Losing the right to affix the CE mark to our cervical cancer detection device or any future products could have a material adverse effect on our business, financial condition and results of operations.

We will be responsible for obtaining and maintaining regulatory approvals for our products. The inability or failure to comply with the varying regulations or the imposition of new regulations would materially adversely affect our business, financial condition and results of operations.

### **Employees and Consultants**

As of December 31, 2012, we had 34 regular employees and consulting or other contract arrangements with six additional persons to provide services to us on a full- or part-time basis. Of the 40 people employed or engaged by us, 22 are engaged in research and development activities, four are engaged in sales and marketing activities, one is engaged in clinical testing and regulatory affairs, five are engaged in manufacturing and development, and eight are engaged in administration and accounting. No employees are covered by collective bargaining agreements, and we believe we maintain good relations with our employees.

Our ability to operate successfully and manage our potential future growth depends in significant part upon the continued service of key scientific, technical, managerial and finance personnel, and our ability to attract and retain additional highly qualified personnel in these fields. Two of these key employees have an employment contract with us; none are covered by key person or similar insurance. In addition, if we are able to successfully develop and commercialize our products, we likely 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. The loss of key personnel or our inability to hire and retain additional qualified personnel in the future could have a material adverse effect on our business, financial condition and results of operations.

### **Item 1A. Risk Factors**

*In addition to the other information in this annual report on Form 10-K, the following risk factors should be considered carefully in evaluating us.*

***Although we will be required to raise additional funds by the second quarter of 2013, 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 new 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 consolidated financial statements as of and for the year ended December 31, 2012, 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 \$91.7 million at December 31, 2012, summarized as follows:

Accumulated deficit from inception to fiscal year ended 2010	<u>\$78.4 million</u>
Net Loss for fiscal year 2011, ended 12/31/2011	<u>\$6.6 million</u>
Accumulated deficit at fiscal year ended 12/31/2011	<u>\$85.0 million</u>
Net Loss for fiscal year 2012, ended 12/31/2012	<u>\$4.4 million</u>
Deemed dividends for fiscal year 2012, ended 12/31/2012	<u>\$2.7 million</u>
Accumulated deficit, from inception to 12/31/2012	<u>\$92.1 million</u>

In addition, 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 through 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 report, along with funds from government contracts and grants, and collaborative arrangements with new partners, will be sufficient to support planned operations through the second 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 \$91.7 million at December 31, 2012.

***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, 2012, 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, four 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 26.4% of our outstanding common stock as of December 31, 2012. 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
- 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.

## **FORWARD LOOKING STATEMENTS**

Statements in this report, 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 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 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.

**Item 1B. Unresolved Staff Comments**

None.

**Item 2. Properties**

Our corporate offices, which also comprise our administrative, research and development, marketing and production facilities, are located at 5835 Peachtree Corners East, Suite D, Norcross, Georgia 30092, where we lease approximately 23,000 square feet under a lease that expires in June 2017.

**Item 3. Legal Proceedings**

We are subject to claims and legal actions that arise in the ordinary course of business. However, we are not currently subject to any claims or actions that we believe would have a material adverse effect on our financial position or results of operations.

**Item 4. Mine Safety Disclosures**

Not applicable.

## PART II

### Item 5. Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities

#### Market for Common Stock; Holders

Our common stock is dually listed on the OTC Bulletin Board (OTCBB) and the OTCQB quotation systems under the ticker symbol "GTHP." The number of record holders of our common stock at March 26, 2013 was 224.

The high and low sales prices for the calendar years 2012 and 2011, as reported by the OTCBB, are as follows:

	2012		2011	
	HIGH	LOW	HIGH	LOW
First Quarter	\$ 1.74	\$ 0.69	\$ 1.46	\$ 0.77
Second Quarter	\$ 0.90	\$ 0.64	\$ 1.07	\$ 0.85
Third Quarter	\$ 0.94	\$ 0.68	\$ 1.00	\$ 0.74
Fourth Quarter	\$ 0.76	\$ 0.52	\$ 1.52	\$ 0.69

#### Dividend Policy

We have not paid any dividends since our inception and do not intend to pay any dividends in the foreseeable future.

#### Securities Authorized for Issuance Under Equity Compensation Plans

All the securities we have provided our employees, directors and consultants have been issued under our stock option plans, which are approved by our stockholders. We have issued common stock to other individuals that are not employees or directors, in lieu of cash payments, that are not part of any plan approved by our stockholders.

Securities authorized for issuance under equity compensation plans:

Plan category	Number of securities to be issued upon exercise of outstanding options, warrants and rights (a)	Weighted-average exercise price of outstanding options, warrants and rights (b)	Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column (a)) (c)
Equity compensation plans approved by security holders	6,463,206	\$ 0.67	6,792,013
Equity compensation plans not approved by security holders	—	—	—
<b>TOTAL</b>	<b>6,463,206</b>	<b>\$ 0.67</b>	<b>6,792,013</b>

#### Item 6. Selected Financial Data

Not applicable.

#### Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations

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 LuViva non-invasive cervical cancer detection device and extension of our cancer detection

technology into other cancers, including esophageal. Our technology, including products in research and development, primarily relates to biophotonics technology for the non-invasive detection of cancers.

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 wholly owned subsidiary, InterScan, which originally had been incorporated as “Guided Therapeutics.”

Since our inception, we have raised capital through the private sale of preferred stock and debt securities, public and private sales of common stock, funding from collaborative arrangements, and grants.

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 December 31, 2012, we have an accumulated deficit of about \$92.1 million. To date, we have engaged primarily in research and development efforts. We 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 requires substantial development, regulatory, sales and marketing, manufacturing and other expenditures. We expect our operating losses to continue through at least the end of 2013 as we continue to expend substantial resources to introduce LuViva, 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.

Our product revenues to date have been limited. In 2012 and 2011, the majority of our revenues were from grants from the NCI and NHI and our collaborative arrangements with Konica Minolta. We expect that the majority of our revenue in 2013 will be derived from similar sources.

### **Recent Developments**

As of March 26, 2013, we have received a total of \$4.6 million from the exercise of outstanding warrants to purchase an aggregate of 8.3 million shares of our common stock. On February 6, 2013, we announced that we had terminated and replaced our existing agreements with Konica Minolta with a new license agreement allowing us to manufacture and to develop a non-invasive esophageal cancer detection product from Konica Minolta and based on our biophotonic technology platform (see “—Lung and Esophageal Cancer Detection —Konica Minolta”).

In February 2013, we replaced our existing agreements with Konica Minolta with a new agreement, pursuant to which, subject to the payment of a nominal license fee due upon FDA approval, Konica Minolta has granted us a five-year, world-wide, non-transferable and non-exclusive right and license to manufacture and to develop a non-invasive esophageal cancer detection product from Konica Minolta and based on our biophotonic technology platform. The license permits us to use certain related intellectual property of Konica Minolta. In return for the license, we have agreed to pay Konica Minolta a royalty for each licensed product we sell. We continue to have the right to seek new collaborative partners to further develop our technology. Subsequent to December 31, 2012, the Company does not anticipate receiving future funding from Konica Minolta for research and development activities.

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 Edition 3 CE Mark for sale of LuViva in the European Union. On February 14, 2013, we announced that we passed our annual independent quality audit and, with all external and mechanical testing completed, plan to apply the Edition 3 CE Mark to LuViva for expanded commercial introduction of the product in select European countries. Passing the annual ISO audit and completing all the testing required to apply the Edition 3 CE Mark to LuViva are major accomplishments for us and allows management to accelerate its planned product rollout, in tandem with production ramp up.

### **Critical Accounting Policies**

Our material accounting policies, which we believe are the most critical to an investors understanding 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.

**Revenue Recognition:** We recognize revenue from contracts on a straight line basis, over the terms of the contract. We recognize revenue from grants based on the grant agreement, at the time the expenses are incurred. Revenue from the sale of the Company’s products is recognized upon shipment of such products to its customers.

**Valuation of Deferred Taxes:** We account for income taxes in accordance with the liability method. Under the liability method, we recognize deferred assets and liabilities based upon anticipated future tax consequences attributable to differences between financial statement carrying amounts of assets and liabilities and their respective tax bases. We establish 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 Employee, 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. See Note 3 to the consolidated financial statements accompanying this report for the assumptions used in the Black-Scholes valuation.

**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.

**Inventory Valuation:** All inventories are stated at lower of cost or market, with cost determined substantially on a "first-in, first-out" basis. Selling, general, and administrative expenses are not inventoried, but are charged to expense when purchased.

## Results of Operations

### Comparison of 2012 and 2011

General: Net loss attributable to common stockholders decreased to approximately \$4.4 million or \$0.08 per share in 2012, from \$6.6 million or \$0.14 per share in 2011.

Revenue from Grants and other Agreements: Total revenues decreased to approximately \$3.3 million in 2012, from \$3.6 million in 2011. During the years ended December 31, 2012 and 2011, we recorded revenue of approximately \$68,000 and \$912,000 from the NCI grant, respectively. In 2012, we recorded approximately \$2.5 million of revenue was recorded in connection with our agreements with Konica Minolta, compared to approximately \$2.0 million for the same period in 2011. There were no costs of sales associated with this revenue in 2012 and 2011.

Sales Revenue, Cost of Sales and Gross Loss from Devices and Disposables: Revenue from the sale of demonstration LuViva devices, for the year ended December 31, 2012 and 2011, were approximately \$72,000 and \$25,000, respectively. Related cost of sales were approximately \$130,000 and \$106,000, respectively, which resulted in a gross loss on the device of approximately \$58,000 and \$81,000, respectively.

Claim Settlement: Claim settlement expense was approximately \$3.6 million in 2011, and consisted of a one-time expense associated with the issuance of warrants to purchase approximately 2.6 million shares of our common stock in settlement of a claim. There were no expenses for claim settlement in the year ended December 31, 2012.

Research and Development Expenses: Research and development expenses increased to approximately \$3.2 million in 2012, compared to approximately \$2.8 million in 2011, due to an increase in expenses associated with preparation for production of demonstration devices and new engineers hired in 2011.

Sales and Marketing Expenses: Sales and marketing expenses increased to approximately \$424,000 in 2012, compared to approximately \$287,000 in 2011, due to an increase in expenses associated with preparation for the marketing efforts for LuViva.

General and Administrative Expense: General and administrative expense increased to about \$3.9 million in 2012, from about \$3.6 million in 2011. The increase is primarily related increase in accrued expenses for the year ended December 31, 2012, offset in part by a one-time write-off of obsolete materials in 2011, due to improved technology and design of our device, of approximately \$270,000.

Other Income: Other income was approximately zero in 2012, compared to approximately \$192,000 in 2011. The decrease is primarily related to approximately \$120,000 received from Konica Minolta as reimbursement for the costs of a Konica Minolta employee seconded to us as part of our collaboration arrangement with Konica Minolta, as well as approximately \$60,000 gain on debt restructured in the year then ended December 31, 2011.

Interest Expense: Interest expense decreased to approximately \$72,000 for the year ended December 31, 2012, as compared to expenses of approximately \$80,000 for the same period in 2011. The decrease is primarily due to the February 26, 2010 conversion of indebtedness into common stock, as well as a decrease in 2011 interest expense on a smaller principle amount of outstanding indebtedness that resulted from the repayment of outstanding indebtedness in the prior year.

There was no income tax benefit recorded for the years ended December 31, 2012 and 2011, due to recurring net operating losses.

### **Liquidity and Capital Resources**

Since our inception, we have raised capital through the private sale of preferred stock and debt securities, public and private sales of common stock, funding from collaborative arrangements, and grants. At December 31, 2012, we had cash of approximately \$1.0 million and a negative working capital of approximately \$84,000.

Our major cash flows in the year ended December 31, 2012, consisted of cash out-flows of \$3.7 million from operations, including approximately \$4.4 million of net loss, cash outflow of \$552,000 from investing activities and a net change from financing activities of \$3.1 million, which primarily represents the proceeds received from exercise of outstanding warrants and options.

For the year ended December 31, 2012, we received approximately \$1.7 million from Konica Minolta in connection with our prior collaboration and licensing agreements. On February 6, 2013, we announced that we had replaced our existing agreements with Konica Minolta with a new license agreement allowing us to manufacture and to develop a non-invasive esophageal cancer detection product from Konica Minolta and based on our biophotonic technology platform.

In July 2012, we completed a warrant exchange program, pursuant to which we exchanged warrants exercisable for a total of 15,941,640 shares of common stock, or 56.29% of the warrants eligible to participate, for three classes of new warrants. The first class of new warrants expired on September 17, 2012 and carried an exercise price of \$0.40, \$0.45 or \$0.50, depending on the date exercised. The second class of new warrants carries a one-year extension from the original expiration date and is exercisable at \$0.65. The third class of new warrants carries a two-year extension from the original expiration date and is exercisable at \$0.80. As of December 31, 2012, we had and issued 5,825,957 shares of common stock and received approximately \$2.9 million in cash, in connection with the exercise of the new warrants.

We will be required to raise additional funds through public or private financing, additional collaborative relationships or other arrangements. We believe our existing and available capital resources will be sufficient to satisfy our funding requirements through the second quarter of 2013. 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.

Substantial capital will be required to develop our products, including completing product testing and clinical trials, obtaining all required U.S. 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 consolidated financial statements contained herein and in the report of our independent registered public accounting firm accompanying our financial statements.

### **Off-Balance Sheet Arrangements**

We have no material off-balance sheet arrangements; no special purpose entities; nor do activities that include non-exchange-traded contracts account for at fair value.

### **Item 7A. Quantitative and Qualitative Disclosures about Market Risk.**

Not applicable

### **Item 8. Financial Statements and Supplementary Data**

**Report of Independent Registered Public Accounting Firm**

**To the Board of Directors and  
Stockholders of Guided Therapeutics, Inc. Guided Therapeutics, Inc.**

We have audited the accompanying consolidated balance sheets of Guided Therapeutics, Inc. and Subsidiary (the "Company") as of December 31, 2012 and 2011, and the related consolidated statements of operations, stockholders' equity, and cash flows for the years then ended. The Company's management is responsible for these consolidated financial statements. Our responsibility is to express an opinion on these consolidated financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. Our audit included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion. An audit also includes examining, on a test basis, evidence supporting the amounts and disclosures in the consolidated financial statements, assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall consolidated financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of Guided Therapeutics, Inc. and Subsidiary as of December 31, 2012 and 2011, and the results of their operations and their cash flows for the years then ended in conformity with accounting principles generally accepted in the United States of America.

As described in Note 1 to the consolidated financial statements, the accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern. The Company's recurring losses from operations and accumulated deficit raise substantial doubt about its ability to continue as a going concern. Management's plans concerning these matters are also discussed in Note 1 to the consolidated financial statements. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

/s/ UHY LLP

**UHY LLP**

**Sterling Heights, Michigan**

**March 27, 2013**

**GUIDED THERAPEUTICS, INC. AND SUBSIDIARY**  
**CONSOLIDATED BALANCE SHEETS**  
**AS OF DECEMBER 31, 2012 AND 2011**  
(In Thousands)

ASSETS	2012	2011
<b>CURRENT ASSETS:</b>		
Cash and cash equivalents	\$ 1,044	\$ 2,200
Accounts receivable, net of allowance for doubtful accounts of \$12 and \$20 at December 31, 2012 and 2011, respectively	107	117
Inventory, net of reserves of \$ 52 and \$64 at December 31, 2012 and 2011, respectively	524	520
Other current assets	198	54
Total current assets	<u>1,873</u>	<u>2,891</u>
Property and equipment, net	1274	1,033
Other assets	331	386
Total noncurrent assets	<u>1,605</u>	<u>1,419</u>
TOTAL ASSETS	<u>\$ 3,478</u>	<u>\$ 4,310</u>
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
<b>CURRENT LIABILITIES:</b>		
Short-term notes payable	\$ 79	\$ 30
Current portion of long term debt	4	25
Notes payable – past due	419	362
Accounts payable	765	1,102
Accrued liabilities	1,038	757
Deferred revenue	40	453
Total current liabilities	<u>2,345</u>	<u>2,729</u>
Long-term loan payable, less current portion	—	4
TOTAL LIABILITIES	<u>2,345</u>	<u>2,733</u>
<b>COMMITMENTS &amp; CONTINGENCIES (Note 5)</b>		
<b>STOCKHOLDERS' EQUITY:</b>		
Common stock, \$.001 par value; 145,000 and 100,000 shares authorized, 62,282 and 52,211 shares issued and outstanding as of December 31, 2012 and 2011, respectively	62	52
Additional paid-in capital	93,273	86,614
Treasury stock, at cost	(104)	(104)
Accumulated deficit	(92,098)	(85,089)
TOTAL GUIDED THERAPEUTICS STOCKHOLDERS' EQUITY	<u>1,133</u>	<u>1,473</u>
Non-controlling interest	—	104
TOTAL STOCKHOLDERS' EQUITY	<u>1,133</u>	<u>1,577</u>
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	<u>\$ 3,478</u>	<u>\$ 4,310</u>

The accompanying notes are an integral part of these consolidated statements.

**GUIDED THERAPEUTICS, INC. AND SUBSIDIARY**  
**CONSOLIDATED STATEMENTS OF OPERATIONS**  
**FOR THE YEARS ENDED DECEMBER 31, 2012 AND 2011**  
(In Thousands Except Per Share Data)

	<u>2012</u>	<u>2011</u>
<b>REVENUE:</b>		
Contract and grant revenue	\$ 3,338	\$ 3,597
Sales – devices and disposables	72	25
Cost of goods sold	117	106
Gross loss	<u>(45)</u>	<u>(81)</u>
<b>OPERATING EXPENSES:</b>		
Claim settlement	—	3,622
Research and development	3,227	2,779
Sales and marketing	424	287
General and administrative	3,923	3,584
Total operating expenses	<u>7,574</u>	<u>10,272</u>
Operating loss	<u>(4,281)</u>	<u>(6,756)</u>
<b>OTHER INCOME</b>	—	192
<b>INTEREST EXPENSE</b>	<u>(72)</u>	<u>(80)</u>
<b>LOSS FROM OPERATIONS</b>	<u>(4,353)</u>	<u>(6,644)</u>
<b>PROVISION FOR INCOME TAXES</b>	—	—
<b>NET LOSS</b>	<u>\$ (4,353)</u>	<u>\$ (6,644)</u>
<b>BASIC AND DILUTED NET LOSS PER SHARE</b>	<u>\$ (0.08)</u>	<u>\$ (0.14)</u>
<b>WEIGHTED AVERAGE SHARES OUTSTANDING</b>	<u>57,429</u>	<u>48,868</u>

The accompanying notes are an integral part of these consolidated statements.

**GUIDED THERAPEUTICS, INC. AND SUBSIDIARY**  
**CONSOLIDATED STATEMENTS OF STOCKHOLDERS EQUITY**  
**FOR THE YEARS ENDED DECEMBER 31, 2012 AND 2011**  
(In Thousands)

	Preferred Stock Series A		Common Stock		Additional Paid-In Capital	Treasury Stock	Accumulated Deficit	Non- Controlling Interest	TOTAL
	Shares	Amount	Shares	Amount					
BALANCE, January 1, 2011	-	\$ -	47,299	\$ 47	\$ 79,515	\$ (104)	\$ (78,445)	\$ 104	\$ 1,117
Issuance of warrants for claim settlement	-	-	-	-	3,622	-	-	-	3,622
Issuance of common stock	-	-	2,090	2	1,765	-	-	-	1,767
Exercise of warrants/options	-	-	2,609	3	815	-	-	-	818
Conversion of debts into common stock	-	-	34	-	27	-	-	-	27
Stock-based compensation expense	-	-	179	-	870	-	-	-	870
Net Loss	-	-	-	-	-	-	(6,644)	-	(6,644)
BALANCE, December 31, 2011	-	\$ -	52,211	\$ 52	\$ 86,614	\$ (104)	\$ (85,089)	\$ 104	\$ 1,577
Issuance of stock	-	-	195	-	162	-	-	-	162
Exercise of warrants/options	-	-	9,876	10	3,092	-	-	-	3,102
Stock-based compensation expense	-	-	-	-	645	-	-	-	645
Deemed dividends	-	-	-	-	2,656	-	(2,656)	-	-
Acquisition of minority interest	-	-	-	-	104	-	-	(104)	-
Net Loss	-	-	-	-	-	-	(4,353)	-	(4,353)
BALANCE, December 31, 2012	-	\$ -	62,282	\$ 62	\$ 93,273	\$ (104)	\$ (92,098)	\$ -	\$ 1,133

The accompanying notes are an integral part of these consolidated statements.

**GUIDED THERAPEUTICS, INC. AND SUBSIDIARY**  
**CONSOLIDATED STATEMENTS OF CASH FLOWS**  
**FOR THE YEARS ENDED DECEMBER 31, 2012 AND 2011**  
(In Thousands)

	<u>2012</u>	<u>2011</u>
<b>CASH FLOWS FROM OPERATING ACTIVITIES:</b>		
Net loss	\$ (4,353)	\$ (6,644)
Adjustments to reconcile net loss to net cash used in operating activities:		
Bad debt (recovery) expense	(3)	18
Depreciation	361	34
Issuance of warrants for legal settlement	—	3,622
Stock-based compensation	645	870
Changes in operating assets and liabilities:		
Accounts receivable	13	(50)
Inventory	(4)	(520)
Other current assets	(144)	(24)
Other assets	55	(180)
Accounts payable	(337)	187
Deferred revenue	(413)	121
Accrued liabilities	513	(168)
Total adjustments	<u>299</u>	<u>3,910</u>
Net cash used in operating activities	<u>(3,666)</u>	<u>(2,734)</u>
<b>CASH FLOWS FROM INVESTING ACTIVITIES:</b>		
Additions to capitalized software costs	—	(260)
Additions to fixed assets	(552)	(444)
Net cash used in investing activities	<u>(552)</u>	<u>(704)</u>
<b>CASH FLOWS FROM FINANCING ACTIVITIES:</b>		
Proceeds from debt financing	86	—
Proceeds from issuance of common stock	—	1,767
Payments made on notes payable	(125)	(215)
Proceeds from options and warrants exercised	<u>3,102</u>	<u>818</u>
Net cash provided by financing activities	<u>3,063</u>	<u>2,370</u>
<b>NET CHANGE IN CASH AND CASH EQUIVALENTS</b>	<b>(1,155)</b>	<b>(1,068)</b>
<b>CASH AND CASH EQUIVALENTS, beginning of year</b>	<b><u>2,200</u></b>	<b><u>3,268</u></b>
<b>CASH AND CASH EQUIVALENTS, end of year</b>	<b><u>\$ 1,045</u></b>	<b><u>\$ 2,200</u></b>
<b>SUPPLEMENTAL SCHEDULE OF:</b>		
Cash paid for:		
Interest	<u>\$ 48</u>	<u>\$ 183</u>
<b>NONCASH INVESTING AND FINANCING ACTIVITIES:</b>		
Acquisition of minority interest	<u>\$ 104</u>	<u>\$ —</u>
Conversion of accrued expenses into common stock	<u>\$ 162</u>	<u>\$ 27</u>
Purchase of fixed assets by issuing notes payable	<u>\$ 50</u>	<u>\$ —</u>
Conversion of interest to principal	<u>\$ —</u>	<u>\$ 63</u>
Deemed dividends in the form of warrants to purchase common stock.	<u>\$ 2,656</u>	<u>\$ —</u>

The accompanying notes are an integral part of these consolidated statements.

**GUIDED THERAPEUTICS, INC. AND SUBSIDIARY**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**  
**DECEMBER 31, 2012 AND 2011**

**1. Organization, Background, and Basis of Presentation**

Guided Therapeutics, Inc. (formerly SpectRx, Inc.), together with its wholly owned subsidiary, InterScan, Inc. (formerly Guided Therapeutics, Inc.), collectively referred to herein as the "Company", is a medical technology company focused on developing innovative medical devices that have the potential to improve healthcare. The Company's primary focus is the development of its LuViva™ non-invasive cervical cancer detection device and extension of its cancer detection technology into other cancers, including esophageal. The Company's technology, including products in research and development, primarily relates to biophotonics technology for the non-invasive detection of cancers.

**Basis of Presentation**

All information and footnote disclosures included in the consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States.

The Company's 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. The Company has experienced net losses since its inception and, as of December 31, 2012, it had an accumulated deficit of approximately \$91.7 million. Through December 31, 2012, the Company has devoted substantial resources to research and development efforts. The Company first generated revenue from product sales in 1998, but does not have significant experience in manufacturing, marketing or selling its products. The Company's development efforts may not result in commercially viable products and it may not be successful in introducing its products. Moreover, required regulatory clearances or approvals may not be obtained. The Company's products may not ever gain market acceptance and the Company may not ever achieve levels of revenue to sustain further development costs and support ongoing operations or achieve profitability. The development and commercialization of the Company's products will require substantial development, regulatory, sales and marketing, manufacturing and other expenditures. The Company expects operating losses to continue through the foreseeable future as it continues to expend substantial resources to complete development of its products, obtain regulatory clearances or approvals and conduct further research and development.

**Going Concern**

The Company's consolidated financial statements have been prepared and presented on a basis assuming it will continue as a going concern. The factors below raise substantial doubt about the Company's ability to continue as a going concern. The financial statements do not include any adjustments that might be necessary from the outcome of this uncertainty. Notwithstanding the foregoing, the Company believes it has made progress in recent years in stabilizing its financial situation by execution of multiyear contracts from Konica Minolta Opto, Inc., a subsidiary of Konica Minolta, Inc., a Japanese corporation based in Tokyo ("Konica Minolta") and grants from the National Cancer Institute ("NCI"), while at the same time simplifying its capital structure and significantly reducing debt. However, the Company has replaced its prior agreements with Konica Minolta with a new licensing agreement, and therefore will no longer receive direct payments from Konica Minolta, and will have to pay a royalty to Konica Minolta should the Company sell any products licensed from Konica Minolta.

At December 31, 2012, the Company's had negative working capital of approximately \$472,000, accumulated deficit of \$92.1 million, and incurred a net loss of \$4.4 million for the year then ended. Stockholders' equity totaled approximately \$1.1 million at December 31, 2012, primarily due to recurring net losses from operations, offset by proceeds from the exercise of options and warrants and proceeds from sales of stock.

As of December 31, 2012, the Company was past due on payments due under its notes payable in the amount of approximately \$419,000. These notes are unsecured and management is working on a payment arrangement with the holders.

The Company's capital-raising efforts are ongoing. If sufficient capital cannot be raised during the second quarter of 2013, the Company has plans to curtail operations by reducing discretionary spending and staffing levels, and attempting to operate by only pursuing activities for which it has external financial support, such as under the Konica Minolta license agreement (see below) and additional NCI, NHI or other grant funding. However, there can be no assurance that such external financial support will be sufficient to maintain even limited operations or that the Company will be able to raise additional funds on acceptable terms, or at all. In such a case, the Company 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.

The Company has warrants exercisable for approximately 20.8 million shares of its common stock outstanding at December 31, 2012, a substantial majority of which have an exercise price of \$0.65 per share. Exercises of these warrants would generate a total of approximately \$14.2 million in cash, assuming full exercise, although the Company cannot be assured that holders will exercise any warrants. Management may obtain additional funds through the private sale of preferred stock or debt securities, public and private sales of common stock, funding from collaborative arrangements, and grants, if available, and believes that such financing will be sufficient to support planned operations through the second quarter of 2013.

Assuming the Company receives FDA approval for its LuViva cervical cancer detection device in 2013, the Company currently anticipates a late 2013 or early 2014 product launch in the United States. Product launch outside the United States is expected in the second half of 2013, but cannot be assured it will be able to launch on these timetables, or at all.

## **2. Summary of Significant Accounting Policies**

### **Use of Estimates**

The preparation of financial statements in conformity with accounting principles generally accepted in the United States requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. Actual results could differ from those estimates. Significant areas where estimates are used include the allowance for doubtful accounts, inventory valuation and input variables for Black-Scholes calculations.

### **Principles of Consolidation**

The accompanying consolidated financial statements as of and for the year ended December 31, 2012 includes the accounts of Guided Therapeutics, Inc. and its wholly owned subsidiary. The accompanying consolidated financial statements as of and for the year ended December 31, 2011 include the accounts of Guided Therapeutics and its majority owned subsidiary. As disclosed in Note 3, the Company purchased the remaining 49% interest in its subsidiary during December 2012.

### **Cash Equivalents**

The Company considers all highly liquid investments with an original maturity of three months or less when purchased to be a cash equivalent.

### **Concentrations of Credit Risk**

The Company, from time to time during the years covered by these consolidated financial statements, may have bank balances in excess of its insured limits. Management has deemed this a normal business risk.

### **Inventory Valuation**

All inventories are stated at lower of cost or market, with cost determined substantially on a "first-in, first-out" basis. Selling, general, and administrative expenses are not inventoried, but are charged to expense when purchased. At December 31, 2012 and December 31, 2011, our inventories were as follows (in thousands):

	December 31, 2012	December 31, 2011
Raw materials	\$ 518	\$ 433
Work in process	21	149
Finished goods	37	2
Inventory reserve	(52)	(64)
Total	<u>\$ 524</u>	<u>\$ 520</u>

### Property and Equipment

Property and equipment are recorded at cost. Depreciation is computed using the straight-line method over estimated useful lives of three to seven years. Leasehold improvements are depreciated at the shorter of the useful life of the asset or the remaining lease term. Depreciation expense is included in general and administrative expense on the statement of operations. Expenditures for repairs and maintenance are expensed as incurred. Property and equipment are summarized as follows at December 31, 2012 and 2011 (in thousands):

	Year Ended December 31,	
	2012	2011
Equipment	\$ 1,196	\$ 1,484
Software	730	640
Furniture and fixtures	124	605
Leasehold Improvement	170	170
	<u>2,220</u>	<u>2,899</u>
Less accumulated depreciation	(946)	(1,866)
Total	<u>\$ 1,274</u>	<u>\$ 1,033</u>

### Patent Costs (Principally Legal Fees)

Costs incurred in filing, prosecuting, and maintaining patents are recurring, and expensed as incurred. Maintaining patents are expensed as incurred as the Company has not yet received FDA approval and recovery of these costs is uncertain. Such costs aggregated approximately \$46,000 and \$56,000 in 2012 and 2011, respectively.

### Accounts Receivable

The Company performs periodic credit evaluations of its customers' financial conditions and generally does not require collateral. The Company reviews all outstanding accounts receivable for collectability on a quarterly basis. An allowance for doubtful accounts is recorded for any amounts deemed uncollectable. The Company does not accrue interest receivable on past due accounts receivable.

### Capitalized Costs of Internally Developed Software (FASB 985):

Costs of producing product masters incurred subsequent to establishing technological feasibility are capitalized. Those costs include coding and testing performed subsequent to establishing technological feasibility.

Software production costs for computer software that is to be used as an integral part of a product or process are not capitalized until technological feasibility has been established for the software and all research and development activities for the other components of the product have been completed.

Capitalization of computer software costs ceases when the product is available for general release to customers. Costs of maintenance and customer support are charged to expense when related revenue is recognized or when those costs are incurred, whichever occurs first.

Costs of internally developed software are capitalized during the development stage of the software. The cost will be transferred to property and equipment and will be depreciated over the expected life of the software, which is estimated to be three years once the software becomes functional.

The Company had capitalized software costs of \$640,000 from inception through the December 31, 2011. These costs were transferred to property, plant, and equipment (PP&E) during 2011. These costs are now being depreciated over 36 months. There were no capitalized costs in the year ended December 31, 2012.

### Other Assets

Other assets primarily consist of long-term deposits for various tooling projects that are being constructed for the Company. At December 31, 2012 and 2011, such balances were approximately \$283,000 and \$386,000, respectively.

### Accrued Liabilities

Accrued liabilities are summarized as follows at December 31, 2012 and 2011 (in thousands):

	As of December 31,	
	2012	2011
Accrued compensation	\$ 706	\$ 463
Accrued professional fees	191	126
Accrued rent	77	82
Other accrued expenses	64	86
<b>Total</b>	<b>\$ 1,038</b>	<b>\$ 757</b>

### Revenue Recognition

Revenue from the sale of the Company's products is recognized upon shipment of such products to its customers. The Company recognizes revenue from contracts on a straight line basis, over the terms of the contracts. The Company recognizes revenue from grants based on the grant agreements, at the time the expenses are incurred.

### Significant Customers

In 2012 and 2011, the majority of the Company's revenues were from two customers. Revenue from these customers totaled approximately \$2.9 million or 85% and approximately \$3.1 million or 85% of total revenue for the year ended December 31, 2012 and 2011, respectively. Accounts receivable due from the customers represents 48% and 43% as of December 31, 2012 and 2011, respectively.

### Research and Development

Research and development expenses consist of expenditures for research conducted by the Company and payments made under contracts with consultants or other outside parties and costs associated with internal and contracted clinical trials. All research and development costs are expensed as incurred.

### Income Taxes

The Company uses the liability method of accounting for income taxes. Under this method, deferred tax assets and liabilities are determined based on differences between the financial reporting and tax bases of assets and liabilities and are measured using the enacted tax rates and laws that will be in effect when the differences are expected to reverse. Management provides valuation allowances against the deferred tax assets for amounts that are not considered more likely than not to be realized.

### Uncertain Tax Positions

Effective January 1, 2007 the Company adopted ASC guidance regarding accounting for uncertainty in income taxes. This guidance clarifies the accounting for income taxes by prescribing the minimum recognition threshold an income tax position is required to meet before being recognized in the financial statements and applies to all income tax positions. Each income tax position is assessed using a two-step process. A determination is first made as to whether it is more likely than not that the income tax position will be sustained, based upon technical merits, upon examination by the taxing authorities. If the income tax position is expected to meet the more likely than not criteria, the benefit recorded in the financial statements equals the largest amount that is greater than 50% likely to be realized upon its ultimate settlement. At December 31, 2012, there were no uncertain tax positions.

The Company is current with its federal and applicable state tax returns filings. Although we have been experiencing recurring losses, we are obligated to file tax returns for compliance with Internal Revenue Service ("IRS") regulations and that of applicable state jurisdictions. As of December 31, 2012, the Company has approximately \$61.8 million of net operating loss eligible to be carried forward for tax purposes at federal and applicable states level.

None of the Company's federal or state income tax returns are currently under examination by the IRS or state authorities. However, fiscal years 2009 and later remain subject to examination by the IRS and respective states.

### **Stock Based Compensation**

The Company records compensation expense related to options granted to non-employees based on the fair value of the award.

Compensation cost is recorded as earned for all unvested stock options outstanding at the beginning of the first year based upon the grant date fair value estimates, and for compensation cost for all share-based payments granted or modified subsequently based on fair value estimates.

For the years ended December 31, 2012 and 2011, share-based compensation for options attributable to employees and officers were approximately \$645,000 and \$870,000, respectively. These amounts have been included in the Company's statements of operations. Compensation costs for stock options which vest over time are recognized over the vesting period. As of December 31, 2012, the Company had approximately \$1.4 million of unrecognized compensation costs related to granted stock options to be recognized over the remaining vesting period of approximately three years.

## **3. Stockholders' Equity**

### **Common Stock**

The Company has authorized 145 million shares of common stock with \$0.001 par value, of which 62.2 million were issued and outstanding as of December 31, 2012. For the year ended December 31, 2011, there were 100 million shares of common stock with \$0.001 par value, of which 52.2 million were issued and outstanding.

On November 21, 2011, the Company completed a private placement of 2,056,436 shares of common stock at a purchase price of \$0.84 per share, pursuant to which it raised approximately \$1.7 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, 285,186 shares) at an exercise price of \$1.05 per share. The warrants have a five-year term.

In December 2012, the Company entered into an agreement to purchase the remaining 49% interest in InterScan, Inc. In exchange, the Company has agreed to issue warrants equal to 49% of the fair value of InterScan, Inc., as determined by a third party. The Company is currently awaiting the result of this valuation; however, the agreement calls for a minimum value purchase price of \$147,000 or approximately 198,000 warrants, based upon the closing stock price at the date of the agreement, and a maximum purchase price of 2,500,000 warrants. The agreement requires the seller to exercise one quarter of their outstanding warrants with the Company, subject to a minimum of \$450,000 in warrants exercise payments prior to March 1, 2013. The seller exercised all required warrants in accordance with the purchase agreement.

### **Preferred Stock**

The Company has authorized 5,000,000 shares of preferred stock with a \$.001 par value, none of which were issued or outstanding as of December 31, 2012. The board of directors has the authority to issue these shares and to set dividends, voting and conversion rights, redemption provisions, liquidation preferences, and other rights and restrictions.

### **Redeemable Convertible Preferred Stock**

The board of directors designated 525,000 shares of the preferred stock as redeemable convertible preferred stock, none of which remain outstanding.

### **Stock Options**

Under the Company's 1995 Stock Plan (the "Plan"), a total of 6,792,013 shares remained available at December 31, 2012 and 6,463,206 shares were subject to stock options outstanding as of that date, bringing the total number of shares subject to stock options outstanding and those remaining available for issue to 13,255,219 shares of common stock as of December 31, 2012. The Plan allows the issuance of incentive stock options, nonqualified stock options, and stock purchase rights. The exercise price of options is determined by the Company's board of directors, but incentive stock options must be granted at an exercise price equal to the fair

market value of the Company's common stock as of the grant date. Options historically granted have generally become exercisable over four years and expire ten years from the date of grant.

The fair value of stock options granted in 2012 and 2011 were estimated using the Black-Scholes option pricing model. A summary of the assumptions used in determining the fair value of options follows:

	2012	2011
Expected volatility	141%	146%
Expected option life in years	10.0	10.0
Expected dividend yield	0.00%	0.00%
Risk-free interest rate	1.84%	1.94%
Weighted average fair value per option at grant date	\$ 0.76	\$ 1.18

Application of the Black-Scholes option pricing model involves assumptions that are judgmental and affect compensation expense. Historical information is the primary basis for the selection of expected volatility, expected option life and expected dividend yield. Expected volatility is based on the most recent historical period equal to the expected life of the option. The risk-free interest rate is based on yields of U.S. Treasury zero-coupon issues with a term equal to the expected life of the option on the date the stock options were granted.

Stock option activity for each of the two years ended December 31 is as follows:

	2012		2011	
	Shares	Weighted Average Exercise Price	Shares	Weighted Average Exercise Price
Outstanding at beginning of year	6,862,167	\$ 0.70	5,738,167	\$0.41
Options granted	96,500	\$ 0.79	2,143,000	\$1.20
Options exercised	(326,461)	\$ 0.28	( 980,000)	\$0.07
Options expired/forfeited	(169,000)	\$2.60	( 39,000)	\$1.52
Outstanding at end of year	6,463,206	\$ 0.67	6,862,167	\$0.70
Options vested and exercisable at year-end	4,373,807	\$ 0.50	4,800,354	\$0.47
Options available for grant at year-end	6,792,013		1,393,052	
Aggregate intrinsic value – options exercised	\$ 93,088		\$ 72,990	
Aggregate intrinsic value – options outstanding	\$1,332,965		\$5,624,479	
Aggregate intrinsic value – options vested and Exercisable	\$1,208,831		\$5,055,690	

The Company estimates the fair value of stock options using a Black-Scholes valuation model. Key input assumptions used to estimate the fair value of stock options include the expected term, expected volatility of the Company's common stock, the risk free interest rate, option forfeiture rates, and dividends, if any. The expected term of the options is based upon the historical term until exercise or expiration of all granted options. The expected volatility is derived from the historical volatility of the Company's stock on the OTCBB market for a period that matches the expected term of the option. The risk-free interest rate is the constant maturity rate published by the U.S. Federal Reserve Board that corresponds to the expected term of the option.

## Warrants

In July 2012, the Company completed a warrant exchange program, pursuant to which it exchanged warrants exercisable for a total of 15,941,640 shares of common stock, or 56.29% of the warrants eligible to participate, for three classes of new warrants. These exchanges resulted in a deemed dividend of approximately \$2.66 million, reflected as a non-cash disclosure in this quarterly financial statement of cash flows. The first class of new warrants expired on September 17, 2012 and carried an exercise price of \$0.40, \$0.45 or \$0.50, depending on the date exercised. The second class of new warrants carries a one-year extension from the original expiration date and is exercisable at \$0.65. The third class of new warrants carries a two-year extension from the original expiration date and is exercisable at \$0.80.

The following table summarizes transactions involving the Company's outstanding warrants to purchase common stock for the year ended December 31, 2012:

	<b>Warrants (Underlying Shares)</b>
Outstanding, January 1, 2012	31,217,117
Issuances	—
Canceled / Expired	(844,966)
Exercised	(9,570,639)
Outstanding, December 31, 2012	<u>20,801,512</u>

The Company had the following shares reserved for the warrants outstanding as of December 31, 2012:

Warrants (Underlying Shares) Exercise Price Expiration Date 12,384,777 (1) \$0.65 03/01/2013 471,856 (2) \$0.65 07/26/2013 3,590,525 (3) \$0.65 03/01/2014 471,856 (4) \$0.80 07/26/2014 3,590,522 (5) \$0.80 03/01/2015 6,790 (6) \$1.01 09/10/2015 285,186 (7) \$1.05 11/20/2016 20,801,512

- (1) Consists of outstanding warrants issued in connection with various financings, but amended or originally issued on February 26, 2010 to expire on March 1, 2013.
- (2) Consists of outstanding warrants issued in connection with the warrant exchange program in June 2012, to expire on July 26, 2013.
- (3) Consists of outstanding warrants issued in connection with the warrant exchange program in June 2012, to expire on March 1, 2014.
- (4) Consists of outstanding warrants issued in connection with the warrant exchange program in June 2012, to expire on July 26, 2014.
- (5) Consists of outstanding warrants issued in connection with the warrant exchange program in June 2012, to expire on March 1, 2015.
- (6) Consists of outstanding warrants issued in conjunction with a private placement on September 10, 2010, to expire on September 10, 2015.
- (7) Consists of outstanding warrants issued in conjunction with a private placement on November 21, 2011, to expire on November 20, 2016.

#### 4. Income Taxes

The Company has incurred net operating losses ("NOLs") since inception. As of December 31, 2012, the Company had NOL carryforwards available through 2032 of approximately \$61.8 million to offset its future income tax liability. The NOL carryforwards began to expire in 2008. The Company has recorded a valuation allowance for all deferred tax assets related to the NOLs. Utilization of existing NOL carryforwards may be limited in future years based on significant ownership changes. The Company is in the process of analyzing its NOLs and has not determined if it has had any change of control issues that could limit the future use of NOL.

Components of deferred taxes are as follows at December 31 (in thousands):

	<b>2012</b>	<b>2011</b>
Deferred tax assets:		
Net operating loss carryforwards	\$ 23,474	\$ 23,304
Accrued expenses and allowances	277	209
Deferred tax liabilities:		
Intangible assets and other	—	—
	<u>23,751</u>	<u>23,512</u>
Valuation allowance	<u>(23,751)</u>	<u>(23,512)</u>
	<u>\$ 0</u>	<u>\$ 0</u>

The following is a summary of the items that caused recorded income taxes to differ from taxes computed using the statutory federal income tax rate for the years ended December 31:

	2012	2011
Statutory federal tax rate	34%	34%
State taxes, net of federal benefit	4	4
Nondeductible expenses	—	—
Valuation allowance	(38)	(38)
	<u>0%</u>	<u>0%</u>

## 5. Commitments and Contingencies

### Operating Leases

In December 2009, the Company moved its offices, which comprise its administrative, research and development, marketing and production facilities to 5835 Peachtree Corners East, Suite D, Norcross, Georgia 30092. The Company leases approximately 23,000 square feet under a lease that expires in June 2017. The fixed monthly lease expense is approximately \$14,000 plus common charges. The Company also leases office and automotive equipment under operating lease agreements with monthly payments ranging from \$275 to \$1,960. These leases expire at various dates through April 2016. Future minimum rental payments at December 31, 2012 under non-cancellable operating leases for office space and equipment are as follows (in thousands):

Year	Amount (,000)
2013	\$ 177
2014	179
2015	183
2016	172
2017 and thereafter	83
Total	<u>\$ 794</u>

Rental expense was approximately \$170,000 in 2012 and 2011.

### Litigation and Claims

As previously reported, in October 2010, the Company received a letter from an attorney representing Dolores M. Maloof and James E. Funderburke, two stockholders of the Company (together, the "Claimants"), asserting, among other things, that an August 2005 Warrant Agreement entered into by the Company and the Claimants (the "2005 Agreement") had been modified by a subsequent agreement. While the Company disputed the Claimants' assertion that an agreement modifying the 2005 Agreement had been reached, the Company determined to negotiate with the Claimants with the goal of terminating the 2005 Agreement and the rights granted thereunder to the Claimants. The 2005 Agreement, among other terms, provided for the Company to pay to the Claimants 7.5% of all net proceeds from any license or sale of the Company's cervical cancer detection technology, without limitation.

Upon completion of negotiations with the Claimants, the Company entered into an Agreement and Release, on August 30, 2011 (the "Agreement"), by which the Claimants agreed to terminate all of their rights under the 2005 Agreement and release all claims. Accordingly, under the Agreement, the 2005 Agreement and all rights of the Claimants thereunder, including the right to receive 7.5% of proceeds from the sale or license of the Company's cervical cancer technology, were canceled. In exchange, the Company agreed to issue warrants to the Claimants to purchase an aggregate of 2.6 million shares of the Company's common stock at an exercise price of \$0.01 per share (the "Warrants"), to pay certain royalties related to the sale of disposables in conjunction with the Company's cervical cancer detection technology and to make certain additional payments related to non-ordinary course asset sales or a sale of the Company by merger, with such royalties and related payments subject to certain "caps" limiting their amounts.

The Warrants were issued in September 2011, are immediately exercisable and will expire on March 1, 2013. The royalties payable pursuant to the Agreement to the Claimants consist of a 2% royalty on gross revenues generated from the sale of disposables (only) used in conjunction with the Company's cervical cancer detection technology. The cumulative royalty payable is capped at \$7.2 million, and may not, together with the additional payments due in conjunction with certain non-ordinary course disposition of assets or a merger of the Company, exceed \$12 million. The royalties are payable until the earlier of the sale of the Company by merger and the sale or exclusive license of all or substantially all of the Company's cervical cancer detection technology. The Agreement further provides that, in the event of one or more non-ordinary course asset sales by the Company, or a sale of the Company by merger, the Claimants will be entitled to an aggregate of 3% of the proceeds therefrom (net of any direct and customary transaction expenses), provided that the aggregate payment due under this provision is capped at the lesser of \$9.5 million and the amount by which \$12.0 million exceeds the cumulative amount of all payments previously paid to the Claimants in royalties or by reason of prior non-ordinary course asset sales.



For the year ended December 31, 2011, the Company had issued the 2.6 million warrants and recorded approximately \$3.6 million of warrant expenses relating to the settlement. For the year ended December 31, 2012, there was no accrual recorded for any potential losses related to pending litigation.

## **Contracts**

Under the Company's prior collaboration agreements with Konica Minolta related to the development of lung and esophageal cancer detection products, the Company received approximately \$400,000 and \$1.3 million, respectively. In February 2013, the Company replaced its existing agreements with Konica Minolta with a new agreement, pursuant to which, subject to the payment of a nominal license fee due upon FDA approval, Konica Minolta has granted the Company a five-year, world-wide, non-transferable and non-exclusive right and license to manufacture and to develop a non-invasive esophageal cancer detection product from Konica Minolta and based on the Company's biophotonic technology platform. The license permits the Company to use certain related intellectual property of Konica Minolta. In return for the license, the Company has agreed to pay Konica Minolta a royalty for each licensed product the Company sells. Subsequent to December 31, 2012, the Company does not anticipate receiving future funding from Konica Minolta for research and development activities.

## **6. License and Technology Agreements**

As part of the Company's efforts to conduct research and development activities and to commercialize potential products, the Company, from time to time, enters into agreements with certain organizations and individuals that further those efforts but also obligate the Company to make future minimum payments or to remit royalties ranging from 1% to 3% of revenue from the sale of commercial products developed from the research. The Company generally is required to make minimum royalty payments for the exclusive license to develop certain technology.

## **7. Notes Payable**

### **Short Term Notes Payable**

At December 31, 2012, the Company maintained two notes payable to IQMS, an enterprise resources planning software provider, in the amount of \$33,500, as well as a note to Premium Assignment Corporation, an insurance premium financing company, in the amount of \$ 32,500. These notes are 12 month straight-line amortizing loans dated June 29, 2012 and July 4, 2012, respectively, with monthly principal and interest payments of approximately \$4,500 and \$11,000 per month, respectively.

Total outstanding short term notes at December 31, 2012 was approximately \$ 66,000 due within one year. The notes carry annual interest rates ranging between 5% and 6%.

### **Loan Payable**

At December 31, 2009, the Company maintained a line of credit in the amount of \$75,000 with Pacific International Bank of Seattle, Washington. This line was converted to a 36 months straight-line amortizing loan on February 24, 2010, with monthly principal and interest payment of \$2,226 per month due February 2013. Interest is charged at a rate of 7.5%. At December 31, 2012, a balance of approximately \$4,000 was outstanding, classified as current loan payable.

### **Notes Payable – Past Due**

At December 31, 2010, the Company was past due on four short-term notes totaling approximately \$614,000 of principal and accrued interest. On February 7, 2011, the Company was successful in re-negotiating two of the four remaining past due Notes. These notes are due on demand and interest is charged at rates ranging between 15-18 %. For the year ended December 31, 2011, the Company recorded a gain on debt restructured of approximately \$60,000 from this transaction. The principal and accrued interest balance at December 31, 2012 and 2011 were approximately \$420,000 and \$362,000, respectively.

## 8. Related Party Transactions

None

## 9. Valuation and Qualifying Accounts

### Allowance for Doubtful Accounts

The Company has the following allowances for doubtful accounts (in thousands):

	Year Ended December 31,	
	2012	2011
Beginning balance	\$ 20	\$ 38
Additions / (Adjustments)	(8)	(18)
<b>Balance</b>	<b>\$ 12</b>	<b>\$ 20</b>

### Inventory Reserves

The Company has the following reserves for inventory balance (in thousands):

	Year Ended December 31,	
	2012	2011
Beginning balance	\$ 64	\$ —
Additions / (Adjustments)	(12)	64
<b>Balance</b>	<b>\$ 52</b>	<b>\$ 64</b>

## 10. Loss Per Common Share

Basic net loss per share attributable to common stockholders amounts are computed by dividing the net loss plus preferred stock dividends and deemed dividends on preferred stock by the weighted average number of shares outstanding during the period.

On December 17, 2012, the Company entered into a buy-back agreement with the holder of a 51 percent interest in our subsidiary, InterScan, Inc., pursuant to which the original agreement, dated February 28, 2011, was canceled and ownership of InterScan reverted back to the Company. InterScan is a non-active subsidiary of the company.

## 11. Subsequent Events

On March 7, 2013, the Company announced that it received approximately \$1.65 million from the exercise of warrants that had an expiration date of March 1, 2013. In connection with the exercise of these warrants, the Company issued 2,539,659 shares of its common stock. The exercised warrants had an exercise price of \$0.65 per share. Warrants totaling 9,845,118 and exercisable at \$0.65 were not exercised and expired on March 1, 2013.

On March 2, 2013, the board of directors approved board compensation for the year ended December 31, 2012. The 2012 board compensation consists of common stock and stock options, totaling approximately \$388,000.

In February 2013, the Company terminated and replaced its existing agreements with Konica Minolta with a new agreement, pursuant to which, subject to the payment of a nominal license fee due upon FDA approval, Konica Minolta has granted the Company a five-year, world-wide, non-transferable and non-exclusive right and license to manufacture and to develop a non-invasive esophageal cancer detection product from Konica Minolta and based on the Company's biophotonic technology platform. The license permits the Company to use certain related intellectual property of Konica Minolta. In return for the license, the Company has agreed to pay Konica Minolta a royalty for each licensed product the Company sells.

On February 14, 2013, the Company announced that it passed its annual independent quality audit and, with all external and mechanical testing completed, and plans to apply the Edition 3 CE Mark to the LuViva® Advanced Cervical Scan for expanded commercial introduction of the product in select European countries. Passing the annual ISO audit and completing all the testing required to apply the Edition 3 CE Mark to LuViva are major accomplishments for the Company and allows management to accelerate its planned product rollout, in tandem with production ramp up.



## **Item 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure**

None.

### **Item 9A. Controls and Procedures**

We maintain a set of disclosure controls and procedures designed to ensure that information required to be disclosed by us in reports that we file or submit under the Securities Exchange Act of 1934, as amended (the "Exchange Act") is recorded, processed, summarized, and reported, within the time periods specified in Securities and Exchange Commission ("Commission") rules and forms. We carried out an evaluation under the supervision and with the participation of our management, including the Chief Executive Officer/Acting Chief Financial Officer, Mark Faupel, of the effectiveness of its disclosure controls and procedures. Based on that evaluation, the Chief Executive Officer/Acting Chief Financial Officer has concluded that our disclosure controls and procedures were ineffective as of December 31, 2012, due to the existence of a material weakness in our internal control over financial reporting, described below, that we have yet to fully remediate.

Management's Annual Report on Internal Control over Financial Reporting: Our management, including our Chief Executive Officer/Acting Chief Financial Officer, is responsible for establishing and maintaining adequate internal control over our financial reporting. Internal control over financial reporting is a process designed by, or under the supervision of, our Chief Executive Officer/Chief Financial Officer and implemented by our board of directors, management and other personnel, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles and includes those policies and procedures that: (i) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of our assets; (ii) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that our receipts and expenditures are being made only in accordance with authorization of our management and directors; and (iii) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of our assets that could have a material effect on the financial statements. Because of their inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

Under the supervision and with the participation of our management, including our Principal Executive Officer/Principal Financial Officer, we conducted an evaluation of the effectiveness of our internal control over financial reporting based on the framework in Internal Control – Integrated Framework, issued by the Committee of Sponsoring Organizations of the Treadway Commission.

Based on our evaluation, our management concluded that our internal control over financial reporting was ineffective as of December 31, 2012, due to the existence of the material weakness described below:

The controls and system currently used by the Company to calculate and record inventory are not operating effectively. Additionally, the Company lacks the resources to properly research and account for complex transactions. The combinations of these significant deficiencies have resulted in a material weakness in our internal control over financial reporting.

Management has purchased an enterprise resources planning system that will enhance the inventory process and replace the old system. The Company is also looking into purchasing an option valuation system that will eliminate the current spreadsheet system and will be able to be updated for new pronouncements and complex calculations.

This annual report does not include an attestation report of our independent registered public accounting firm regarding internal control over financial reporting. Management's report was not subject to attestation by our independent registered public accounting firm pursuant to rules of the Commission that permit non-accelerated filers to provide only the management's report in their annual reports on Form 10-K.

Except as described above, there were no changes to the Company's internal controls over financial reporting occurred during the quarter ended December 31, 2012 that have materially affected, or are reasonably likely to materially affect, the Company's internal control over financial reporting.

### **Item 9B. Other Information**

None.

## PART III

### Item 10. Directors, Executive Officers and Corporate Governance

Our executive officers are elected by and serve at the discretion of our board of directors. The following table lists information about our directors and executive officers as of December 31, 2012:

Name	Age	Position with Guided Therapeutics
Mark L. Faupel, Ph.D.	57	Chief Executive Officer, Acting Chief Financial Officer, President and Director
Richard L. Fowler	56	Senior Vice President of Engineering
Shabbir Bambot, Ph.D.	47	Vice President for Research and Development
Ronald W. Allen	71	Chairman and Director
Ronald W. Hart, Ph.D.	70	Vice Chairman and Director
John E. Imhoff, M.D.	63	Director
Michael C. James	54	Director
Jonathan M. Niloff, M.D.	58	Director
Linda Rosenstock, M.D.	62	Director

Except as set forth below, all of the executive officers have been associated with us in their present or other capacities for more than the past five years. Officers are elected annually by the board of directors and serve at the discretion of the board. There are no family relationships among any of our executive officers and directors.

*Mark L. Faupel, Ph.D.* has been a director since 2007 and has more than 26 years of experience in developing non-invasive alternatives to surgical biopsies and blood tests, especially in the area of cancer screening and diagnostics. Dr. Faupel has served as our Chief Executive Officer since May 2007 and prior thereto was our Chief Technical Officer from April 2001 to May 2007. Prior to coming to us in 1998, Dr. Faupel was the co-founder and Vice President of Research and Development at Biofield Corp. His work in early stage cancer detection has won two international awards and he is a former member of the European School of Oncology Task Force. Dr. Faupel has served as a National Institutes of Health reviewer, is the inventor on 15 U.S. patents and has authored numerous scientific publications and presentations, appearing in such peer-reviewed journals as *The Lancet*. Dr. Faupel earned his Ph.D. in neuroanatomy and physiology from the University of Georgia.

Dr. Faupel's extensive experience in founding and managing point of care cancer detection companies includes the basic scientific applications, clinical trials, regulatory affairs and financing. As such, Dr. Faupel, as CEO, advises the board on all aspects of our business. He is currently the Acting Chief Financial Officer.

*Rick Fowler*, Mr. Fowler, Sr. VP of Engineering is an accomplished Executive with significant experience in the management of businesses that sell, market, produce and develop sophisticated medical devices and instrumentation. Mr. Fowler's 25 plus years of experience includes assembling and managing teams, leading businesses and negotiating contracts, conducting litigation, and developing ISO, CE, FDA QSR, GMP and GCP compliant processes and products. He is adept at providing product life cycle management through effective process definition and communication - from requirements gathering, R&D feasibility, product development, product launch, production startup and support. Mr. Fowler combines outstanding analytical, out-of-the-box, and strategic thinking with strong leadership, technical, and communication skills and he excels in dynamic, demanding environments while remaining pragmatic and focused. He is able to deliver high risk projects on time and under budget as well as enhance operational effectiveness through outstanding cross-functional team leadership (R&D, marketing, product development, operations, QA, sales, service, and finance). In addition, Mr. Fowler is well versed in global medical device regulatory and product compliance requirements.

*Shabbir Bambot, Ph.D.* is a co-founder and serves as our Vice President of Product Development. He has been instrumental in the launch of multiple medical diagnostic products notable among which are the OPTI 2® (AVL/Roche) blood chemistry analyzer and the Bilicheck® (Philips/Respironics) neonatal jaundice monitor. He has been awarded multiple NIH SBIR grants totaling in excess of \$6.0 million for developing and clinical testing of devices for cancer diagnosis and has 8 US patents and several pending patent applications. He has a Ph.D. in Chemical Engineering from the University of Pittsburgh, has published extensively in the life sciences and medical diagnosis arena and has served on NIH study sections as well as review panels for scientific and technical publications. He also has extensive experience with FDA 510K and PMA applications as well as quality systems compliance and ISO 13485 certification.

*Ronald W. Allen* was named a Director of Guided Therapeutics in September 2008 and was elected Chairman of the Board in 2011. He is currently the President and CEO and Chairman of the Board of Directors for Aaron's, Inc. Mr. Allen retired as Delta Airline Chairman of the Board, President and Chief Executive Officer in July 1997, and had been its chairman of the board and Chief Executive Officer since 1987. He is a Director of The Coca-Cola Company, Aaron's, Inc., Aircastle Limited and Forward Air Corporation. He also is a board member of the St. Joseph's Translational Research Institute, which endeavors to turn new medical discoveries into tangible cures.

Mr. Allen, as Chairman and CEO of Delta Airlines, pioneered the international expansion of Delta into new markets, much as we are pioneering new technology in the fight against cancer. Mr. Allen has extensive experience serving on many types of boards, both for small and large companies and for medical and non-medical entities. His background in personnel is helpful to the Board as we grow and add new personnel.

*Ronald W. Hart, Ph.D.* has served as a member of our Board of Directors since March 2007 and was elected Vice Chairman of the Board in 2011. He has published over 600 peer-reviewed publications, has been appointed to a number of academic positions and is credited with developing the first direct proof that DNA is causal in certain forms of cancer. He chaired a number of federal committees and task forces, including the development and implementation of the Technology Transfer Act of 1986 and the White House Task Force on Chemical Carcinogenesis. In 1980, Dr. Hart was appointed Director of the National Center for Toxicological Research, the research arm of the FDA, a position he held until 1992. In 1992, Dr. Hart was the first ever Presidential Appointee to the position of Distinguished Scientist in Residence for the US Public Health Service/FDA, a position he held until his retirement in 2000. Dr. Hart received his Ph.D. in physiology and biophysics from the University of Illinois. Dr. Hart has helped in the development of business strategy for a number of start-up companies.

Dr. Hart adds considerable value to the Board in at least four critical areas:

- (1) As a former FDA bureau chief, he advises the Board and management on our FDA relationship and strategy.
- (2) As an active participant in the venture community, he advises the Board on financing and other opportunities.
- (3) As an expert in organizational matters, he advises the Board and management regarding company strategy and potential strategic partnerships.
- (4) As an expert in international trade, he advises the Board and management on international partnering and distribution agreements.

*John E. Imhoff, M.D.* has served as a member of our Board of Directors since April 2006. Dr. Imhoff is an ophthalmic surgeon who specializes in cataract and refractive surgery. He is one of our principal stockholders and invests in many other private and public companies. He has a B.S. in Industrial Engineering from Oklahoma State University, an M.D. from the University of Oklahoma and completed his ophthalmic residency at the Dean A. McGee Eye Institute. He has worked as an ophthalmic surgeon and owner of Southeast Eye Center since 1983.

Dr. Imhoff has experience in clinical trials and in other technical aspects of a medical device company. His background in industrial engineering is especially helpful to our company, especially as Dr. Imhoff can combine this knowledge with clinical applications. His experience in the investment community also lends itself as invaluable to a public company that participates in equity transactions.

*Michael C. James* has served as a member of our Board of Directors since March 2007. Mr. James is also the Managing Partner of Kuekenhof Capital Management, LLC, a private investment management company, Chief Executive Officer and the Chief Financial Officer of Inergetics, Inc., a nutraceutical supplements company and also the Chief Financial Officer of Terra Tech Corporation, which is a hydroponic and agricultural company. He also holds the position of Managing Director of Kuekenhof Equity Fund, L.P. and Kuekenhof Partners, L.P. Mr. James currently sits on the Board of Directors of Inergetics, Inc. Mr. James was Chief Executive Officer of Nestor, Inc. from January 2009 to September 2009 and served on their Board of Directors from July 2006 to June 2009. He was employed by Moore Capital Management, Inc., a private investment management company from 1995 to 1999 and held position of Partner. He was employed by Buffalo Partners, L.P., a private investment management company from 1991 to 1994 and held the position of Chief Financial and Administrative Officer. He began his career in 1980 as a staff accountant with Eisner LLP. Mr. James received a B.S. degree in Accounting from Farleigh Dickinson University in 1980.

Mr. James has experience both in the areas of company finance and accounting, which is invaluable to us during financial audits and offerings. Mr. James has extensive experience in the management of both small and large companies and his entrepreneurial background is relevant as we develop as a company.

*Jonathan M. Niloff, M.D.* was elected as a director in April 2010. Dr. Niloff is Vice President and Executive Medical Director Population Health of McKesson Technology Solutions, a medical software company. Prior to that, Dr. Niloff was the Founder, Chairman of the Board and Chief Medical Officer of MedVentive Inc. Prior to joining MedVentive, Dr. Niloff served as President of the Beth Israel Deaconess Physicians Organization, Medical Director for Obstetrics and Gynecology for its Affiliated Physicians Group, and Chief of Gynecology at New England Deaconess Hospital. He served as an Associate Professor of Obstetrics, Gynecology, and Reproductive Biology at Harvard Medical School. He has deep expertise in all aspects of medical cost and quality improvement, and has published extensively on the topic of gynecologic oncology including the development of the CA125 test for ovarian cancer. Dr. Niloff received his undergraduate education at The Johns Hopkins University, an MD degree from McGill University, and an MBA degree from Boston University.

Dr. Niloff is uniquely qualified to assist the Board and management because he combines his clinical background as a Harvard Ob-Gyn with his business acumen developed through an MBA degree and as CMO of MedVentive. Dr. Niloff has specific experience in evaluating new medical technology (e.g., CA125) and its implications to cost containment and reimbursement. Furthermore, Dr. Niloff has numerous professional contacts in the Ob-Gyn community that can aid in our development and marketing of our cervical cancer detection technology.

*Linda Rosenstock, M.D.* was appointed to the Board in April 2012. Dr. Linda Rosenstock is a Dean Emeritus and Professor of the University of California, Los Angeles (UCLA) Fielding School of Public Health, a position she has held since 2000. She holds appointments as Professor of Medicine and Environmental Health Sciences and is a recognized authority in broad areas of public health and science policy. Internationally, Dr. Rosenstock has been active in teaching and research in many developing countries and has served as an advisor to the World Health Organization. Dr. Rosenstock also chaired the United Auto Workers/General Motors Occupational Health Advisory Board. She is an Honorary Fellow of the Royal College of Physicians and an elected member of the National Academy of Sciences' Institute of Medicine where she has served as a member of their Board on Health Sciences Policy and Chair of the Committee for Preventive Services for Women. In January 2011, she was appointed by President Obama to the Advisory Group on Prevention, Health Promotion and Integrative and Public Health. She has served on the Board of Directors for Skilled Health Care since 2009.

Before coming to UCLA in 2000, Dr. Rosenstock served as Director of the National Institute for Occupational Safety and Health (NIOSH) for nearly seven years. As Director of NIOSH, Dr. Rosenstock led the only federal agency with a mandate to undertake research and prevention activities in occupational safety and health. During her tenure, she was instrumental in creating the National Occupational Research Agenda, a framework for guiding occupational safety and health research, and in expanding the agency's responsibilities. In recognition of her efforts, Dr. Rosenstock received the Presidential Distinguished Executive Rank Award, the highest executive service award in the government and was also the James P. Keogh Award Winner for 2011 in appreciation of a lifetime of extraordinary leadership in occupational health and safety. Dr. Rosenstock received her M.D. and M.P.H. from The Johns Hopkins University. She conducted her advanced training at the University of Washington, where she was Chief Resident in Primary Care Internal Medicine and a Robert Wood Johnson Clinical Scholar.

Dr. Rosenstock is uniquely qualified as a Board Member for Guided Therapeutics. First, as a trained physician who also chairs the Preventive Services for Women Committee of the Institute of National Academy of Sciences Institute of Medicine, she has been directly involved in setting institutional and government policy for breast and cervical cancer screening, which is directly relevant to our LuViva cervical cancer detection device. Secondly, she brings a wealth of international experience in developing countries, which is a focus of our product distribution effort in cancer detection. Thirdly, she has demonstrated a lifetime of extraordinary leadership and her international recognition as an expert in health policy will provide outstanding credibility to Guided Therapeutics as a leading innovator in women's healthcare.

#### **Section 16(a) Beneficial Ownership Reporting Compliance**

Section 16(a) of the Securities Exchange Act of 1934, as amended, requires our directors and executive officers and persons who beneficially own more than 10% of a registered class of our equity securities to file reports of ownership and reports of changes in ownership with the Securities and Exchange Commission. These persons are required by regulations of the Securities and Exchange Commission to furnish us with copies of all Section 16(a) forms they file.

Based solely on our review of the copies of these forms received by us, we believe that, with respect to fiscal year 2012, our officers, directors were in compliance with all applicable filing requirements.

#### **Code of Ethics**

We have adopted a code of ethics that applies to all of our directors, officers and employees. To obtain a copy without charge, contact our Corporate Secretary, Guided Therapeutics, Inc., 5835 Peachtree Corners East, Suite D, Norcross, Georgia 30092. If we amend our code of ethics, other than a technical, administrative or non-substantive amendment, or we grant any waiver, including any implicit waiver, from a provision of the code that applies to our principal executive officer, principal financial officer, principal accounting officer or controller, we will disclose the nature of the amendment or waiver on our website, [www.guidedinc.com](http://www.guidedinc.com), under the "Investor Relations" tab under the tab "About Us." Also, we may elect to disclose the amendment or waiver in a report on Form 8-K filed with the Securities and Exchange Commission.

## Material Changes to Security Holders Nomination Procedure

There has been no material change to the procedures by which security holders may recommend nominees to the registrant's board of directors, since the last disclosure.

## Audit Committee

The Board of Directors of Guided Therapeutics has adopted a written audit committee charter. The Board has determined that each member of the audit committee is "independent," as such term is defined under the rules of the SEC and the Nasdaq Marketplace Rules applicable to audit committee members.

For the fiscal year ended December 31, 2012, Mr. Michael C. James, retired Certified Public Accountant, and Drs. John Imhoff and Jonathan M. Niloff, were members of the Audit Committee. Mr. James is designated the Audit Committee Chairman and Financial Expert.

## Item 11. Executive Compensation

### Summary Compensation Table

The following table lists specified compensation we paid during each of the fiscal years ended December 31, 2012 and 2011 to the chief executive officer and our two other most highly compensated executive officers, collectively referred to as the named executive officers, in 2012:

2012 and 2011 Summary Compensation Table

Name and Principal Position	Year	Salary (\$)	Bonus (\$)	Option Awards	Total (\$)
				(\$)(1)	
Mark Faupel, Ph.D. President, CEO, Acting CFO and Director	2012	243,000	-	-	243,000
	2011	243,000	-	214,500	457,000
Richard Fowler, Senior Vice President of Engineering	2012	195,000	-	-	195,000
	2011	173,400	-	6,250	179,650
Shabbir Bambot, Ph.D. Vice President of Research and Development	2012	193,000	-	-	193,000
	2011	183,750	-	6,000	189,750

(1) See Note 3 to the consolidated financial statements that accompany this report.

Dr. Faupel's 2012 and 2011 compensation consisted of a base salary of \$243,000, and usual and customary company benefits. As of December 31, 2012, Dr. Faupel's remaining deferred salary was approximately \$113,218. On July 2, 2012, Dr. Faupel was issued 153,846 shares of common stock at \$0.65, in partial repayment of debt.

Dr. Bambot's 2012 and 2011 compensation consisted of a base salary of \$193,000, and \$183,750, respectively, and usual and customary company benefits.

Mr. Fowler's 2012 and 2011 compensation consisted of a base salary of \$195,000 and \$173,400, respectively, and usual and customary company benefits. He received no bonus and no stock options in 2012 or 2011. As of December 31, 2012, Mr. Fowler's total deferred salary was approximately \$83,291.

### Outstanding Equity Awards to Officers at December 31, 2012

Name and Principal Position	Number of Securities Underlying Options Exercisable (#)(1)	Number of Securities Underlying Options Un-exercisable (#)	Option Awards	Option Exercise Price (\$)(2)	Option Expiration Date
			Equity Incentive Plan Awards: Number of Securities Underlying Un-exercised Unearned Options (#)		
Mark Faupel, Ph.D. President, CEO & Acting CFO	1,498,500	-	622,500	0.71	12/16/2021
Richard Fowler Senior Vice President of Engineering	367,250	-	93,750	0.61	12/16/2021

Shabbir Bambot, Ph.D.	615,539	-	90,000	0.55	12/16/2021
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Vice President of Research & Development

- (1) Represents fully vested options.
- (2) Based on all outstanding options

## Outstanding Equity Awards to Directors at December 31, 2012

Name and Principal Position	Option Awards	
	Option Awards (#)	Exercise Price (\$)
Ronald W. Allen Chairman and Director	642,500	0.41
Ronald W. Hart, Ph.D. Director	498,750	0.41
John E. Imhoff, M.D. Director	247,500	0.80
Michael C. James Director	51,250	0.88
Jonathan Niloff, M.D. Director	86,667	0.78

The following Board members also serve as consultants to the company:

1. Ronald W. Hart, Ph.D. – Dr. Hart's consulting services include regulatory and clinical issues, especially with advice for the Company with regard to its application to the FDA.
2. Ronald W. Allen – Mr. Allen advises the company with regard to personnel and financing. As such, he plays an important role in identifying potential funding sources.

### Risk Oversight

Our board as a whole has responsibility for risk oversight, with reviews of certain areas being conducted by the relevant board committees that report on their deliberations to the full board, as further described below. Given the small size of the board, the board feels that this structure for risk oversight is appropriate (except for those risks that require risk oversight by independent directors only). The audit committee is specifically charged with discussing risk management (primarily financial and internal control risk), and receives regular reports from management and independent auditors on risks related to, among others, our financial controls and reporting. The compensation committee reviews risks related to compensation and makes recommendations to the board with respect to whether the Company's compensation policies are properly aligned to discourage inappropriate risk-taking, and is regularly advised by management. In addition, the Company's management regularly communicates with the board to discuss important risks for their review and oversight, including regulatory risk, and risks stemming from periodic litigation or other legal matters in which we are involved.

### Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters

The following table lists information regarding the beneficial ownership of our common stock as of March 15, 2013 by (i) each person whom we know to beneficially own more than 5% of the outstanding shares of our common stock (a "5% stockholder"), (ii) each director, (iii) each officer named in the summary compensation table below, and (iv) all directors and executive officers as a group. Unless otherwise indicated, the address of each officer and director is 5835 Peachtree Corners East, Suite D. Norcross, Georgia 30092.

Name and Address of Beneficial Owner	Amount and Nature of Beneficial Ownership (1)	Percent of Class (2)
John E. Imhoff (3)	11,028,180	19.19 %
The Whittemore Collection, Ltd. / George Landegger (4) 4 International Drive Rye Brook, NY 10573	6,414,697	12.16 %
Dolores Maloof (5) 2669 Mercedes Drive Atlanta, GA 30345	5,086,466	8.84 %
Richard Blumberg (6) 821 Second Avenue, Suite 2200 Seattle, WA 98116	2,798,469	5.07 %
Michael C. James / Kuekenhof Equity Fund, LLP (7)	2,451,192	4.52 %
Ronald Hart (8)	1,620,435	3.05 %
Mark L. Faupel (9)	1,406,000	2.62 %
Ronald W. Allen (10)	1,009,376	1.89 %
Shabbir Bambot (11)	637,500	1.20 %
Richard L. Fowler (12)	479,343	* %
Jonathan Niloff (13)	125,834	*
All directors and executive officers as a group (8 persons) (14)	18,757,860	29.64 %

(\*) Less than 1%.

- (1) Except as otherwise indicated in the footnotes to this table and pursuant to applicable community property laws, the persons named in the table have sole voting and investment power with respect to all shares of common stock.
- (2) Percentage ownership is based on 52,211,073 shares of common stock outstanding as of March 15, 2012. Beneficial ownership is determined in accordance with the rules of the SEC, based on factors that include voting and investment power with respect to shares. Shares of common stock subject to currently exercisable options, warrants, convertible preferred stock or convertible notes, or any such securities exercisable within 60 days after March 16, 2012, are deemed outstanding for purposes of computing the percentage ownership of the person holding those options, but are not deemed outstanding for purposes of computing the percentage ownership of any other person.
- (3) Consists of 5,996,757 common shares, 4,783,923 warrants to purchase common stock at \$0.65 per share and 247,500 shares subject to stock options. Dr. Imhoff is on the board of directors.
- (4) Consists of 6,129,511 shares of common stock and 285,186 warrants to purchase common stock at \$1.05 per share.
- (5) Consists of warrants to purchase 1,820,000 and 3,266,466 common shares at \$0.01 and 0.65 per share, respectively.
- (6) Consists of 2,798,469 warrants to purchase common stock at \$0.65 per share.
- (7) Consists of 663,368 shares of common stock and 1,736,574 warrants to purchase common stock at \$0.65 per share, held by Kuekenhof Equity Fund, LP, plus 51,250 shares subject to stock options held by Michael C. James personally. Mr. James is on the Board of Directors.
- (8) Consists of 903,275 shares of common stock, 218,410 warrants to purchase common stock at \$0.65 per share and 498,750 shares subject to stock options held by Hart Management, LLC, Ronald Hart, owner. Dr. Hart is on the Board of Directors.
- (9) Consists of 100,000 shares of common stock and 1,306,000 shares subject to stock options.
- (10) Consists of 124,341 shares of common stock, 242,535 warrants to purchase common shares at \$0.65 per share and 642,500 shares subject to stock options held by Ronald Allen. Mr. Allen is on the Board of Directors.
- (11) Consists of 637,500 shares subject to stock options.
- (12) Consists of 87,223 shares of common stock, 56,120 warrants to purchase common shares at \$0.65 per share and 336,000 shares subject to stock options.
- (13) Consists of 39,167 shares of common stock, and 86,667 shares subject to stock options held by Jonathan M. Niloff. Dr. Niloff is on the Board of Directors.
- (14) Consists of 7,914,131 shares of common stock, 7,037,562 warrants to purchase common shares at \$0.65 per share and 3,806,167 shares subject to stock options.

See Item 5 of this report for information regarding Securities Authorized for Issuance under Equity Compensation Plans.

### Item 13. Certain Relationships and Related Transactions and Director Independence

Our Board recognizes that related person transactions present a heightened risk of conflicts of interest. The Audit Committee has the authority to review and approve all related party transactions involving directors or executive officers of the Company.

Under the policy, when management becomes aware of a related person transaction, management reports the transaction to the Audit Committee and requests approval or ratification of the transaction. Generally, the Audit Committee will approve only related party transactions that are on terms comparable to those that could be obtained in arm's length dealings with an unrelated third person. The Audit Committee will report to the full Board all related person transactions presented to it.

Based on the definition of independence of the NASDAQ Stock Market, the board has determined that Messrs. Allen and James, and Drs. Hart, Niloff and Imhoff are independent directors.

### Item 14. Principal Accountant Fees and Services

UHY LLP is our current independent registered public accounting firm. Representatives of UHY LLP are expected to attend the annual meeting of stockholders, will have the opportunity to make a statement if they desire, and will be available to respond to appropriate questions.

We were billed by UHY LLP \$215,000 and \$190,000 during the fiscal years ended December 31, 2012 and 2011, respectively, for professional services, which include fees associated with the annual audit of financial statements and review of our quarterly reports on Form 10-Q, and other SEC filings.

	2012	2011
Audit fees	\$ 202,000	\$ 186,000
Audit related fees	—	—
Tax fees	13,000	4,000
All other fees	—	—
Total Fees	<u>\$ 215,000</u>	<u>\$ 190,000</u>

#### *Audit Committee Pre-Approval Policy and Permissible Non-Audit Services of Independent Registered Public Accounting Firm*

Our Audit Committee pre-approves all audit and permissible non-audit services provided by our independent registered public accounting firm. These services may include audit services, audit-related services, tax services and other services. Pre-approval is generally provided for up to one year, and any pre-approval is detailed as to the particular service or category of services and is generally subject to a specific budget. Our independent registered public accounting firm and management are required to periodically report to the Audit Committee regarding the extent of services provided by the independent registered public accounting firm in accordance with the pre-approval, and the fees for the services performed to date. The Audit Committee may also pre-approve particular services on a case-by-case basis.

## PART IV

### Item 15. Exhibits and Financial Statement Schedules

The consolidated financial statements included in Item 8 of this reported are filed as part of this report.

The exhibits listed below are filed as part hereof, or incorporated by reference into, this Report. All documents referenced below were filed pursuant to the Securities and Exchange Act of 1934 by Guided Therapeutics, Inc. (f/k/a SpectRx, Inc.), file number 0-22179, unless otherwise indicated.

#### EXHIBIT INDEX

EXHIBIT NO.	DESCRIPTION
3.1	Certificate of Incorporation, as amended (incorporated by reference to Exhibit 3.1 to the Quarterly Report on Form 10-Q for the period ended June 30, 2010, filed August 12, 2010).
3.2	Amended and Restated Bylaws (incorporated by reference to Exhibit 3.1 to the current Report on Form 8-K, filed March 23, 2012).
4.1	Specimen Common Stock Certificate (incorporated by reference to Exhibit 4.1 to the Amended Registration Statement on Form S-1/A (No. 333-22429), filed April 24, 1997).
4.2	Amended and Restated Loan Agreement by and among SpectRx, Inc., the Agent, and the Noteholders, dated March 1, 2007 (incorporated by reference to Exhibit 4.1 to the Quarterly Report on Form 10-QSB, filed August 24, 2007).
4.3	First Amendment to the Amended and Restated Loan Agreement (incorporated by reference to Exhibit 4.2 to the Quarterly Report on Form 10-QSB, filed August 24, 2007).
4.4	Amendment to Amended and Restated Loan Agreement (incorporated by reference to Exhibit 4.12 to the Quarterly Report on Form 10-Q for the period ended June 30, 2010, filed August 12, 2010).
4.5	Form of Warrant (incorporated by reference to Annex 1 to the proxy statement on Schedule 14A, filed February 3, 2010).
4.6	Form of Warrant Agreement (incorporated by reference to Exhibit 4.1 to the Current Report on Form 8-K, filed September 14, 2010).
4.7	Form of Warrant Agreement (incorporated by reference to Exhibit 4.1 to the Current Report on Form 8-K, filed September 2, 2011).
4.8	Form of Warrant Agreement (incorporated by reference to Exhibit 4.1 to the Current Report on Form 8-K/A, filed November 28, 2011).
10.1	1995 Stock Plan and form of Stock Option Agreement thereunder (incorporated by reference to Exhibit 10.2 to the Registration Statement on Form S-1 (No. 333-22429) filed February 27, 1997).
10.2	2000 Amendment to the 1995 Stock Plan, as amended (incorporation by reference to Appendix 1 to the Definitive Proxy Statement filed April 24, 2000).
10.3	2005 Amendment No. 2 to the 1995 Stock Plan, as amended (incorporated by reference to Appendix 1 to the proxy statement on Schedule 14A, filed May 10, 2005).
10.4	2010 Amendment to the 1995 Stock Plan (incorporated by reference to Exhibit 10.3 to the Registration Statement on Form S-8 (File No. 333-178261), filed December 1, 2011).
10.5	Consulting and Severance Agreement between SpectRx, Inc. and Mark A. Samuels, dated May 7, 2007 (incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K/A, filed June 5, 2007).
10.6	Assigned Task Agreement (incorporated by reference to Exhibit 10.17 to the Quarterly Report on Form 10-Q for the period ended March 31, 2010, filed May 13, 2010).
10.7	Assigned Task Agreement (incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K, filed April 1, 2011).
10.8	Agreement for Collaboration (incorporated by reference to Exhibit 10.2 to the Current Report on Form 8-K, filed April 1, 2011).
10.9	Agreement for Re-Engineering and Manufacture of New BDS Device (incorporated by reference to Exhibit 10.3 to the Quarterly Report on Form 10-Q for the period ended March 31, 2010, filed May 16, 2011).
10.10	Registration Rights Agreement, dated August 30, 2011 (incorporated by reference to 10.2 to the Current Report on Form 8-K, filed September 2, 2011).
10.11	Agreement and Release, dated August 30, 2011 (incorporated by reference to 10.2 to the Current Report on Form 8-K, filed September 2, 2011).
10.12	Assigned Task Agreement (incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K, filed June 26, 2012).

- 10.13 Agreement for Collaboration in the Development of Spectroscopic Technology (incorporated by reference to Exhibit 10.2 to the Current Report on Form 8-K, filed June 26, 2012).
- 21.1 Subsidiaries (incorporated by reference to Exhibit 21.1 to the Registration Statement on Form S-1 (No. 333-169755) filed October 5, 2010).
- 23.1(1) Consent of UHY LLP.
- 31(1) Rule 13a-14(a) / 15d-14(a) Certification.
- 32(1) Section 1350 Certification.
- 101.1 Interactive Data File. (1)

(1) Filed herewith.

## SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

### GUIDED THERAPEUTICS, INC.

By: /s/ MARK L. FAUPEL

Mark L. Faupel  
President and Chief Executive Officer

Date: March 27, 2013

In accordance with the Exchange Act, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

<b>DATE</b>	<b>SIGNATURE</b>	<b>TITLE</b>
March 27, 2013	<u>/s/ Mark L. Faupel</u> Mark L. Faupel	President, Chief Executive Officer, Acting Chief Financial Officer and Director (Principal Executive Officer)
March 27, 2013	<u>/s/ Ronald W. Allen</u> Ronald W. Allen	Chairman and Director
March 27, 2013	<u>/s/ John E. Imhoff</u> John E. Imhoff	Director
March 27, 2013	<u>/s/ Michael C. James</u> Michael C. James	Director
March 27, 2013	<u>/s/ Ronald W. Hart</u> Ronald W. Hart	Vice Chairman and Director
March 27, 2013	<u>/s/ Jonathan M. Niloff</u> Jonathan M. Niloff	Director
March 27, 2013	<u>/s/ Linda Rosenstock</u> Linda Rosenstock	Director



**Exhibit 23.1**

**CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM**

We hereby consent to the incorporation by reference in the Registration Statements on Form S-3 (Nos. 333-169755, 333-177244 and 333-184944) and the Registration Statements on Form S-8 (Nos. 333-63758, 333-81326, 333-128082, 333-178261 and 333-183312) of our report dated March 27, 2013, relating to the consolidated financial statements, which appears in this Form 10-K for the year ended December 31, 2012.

/s/ UHY LLP

UHY LLP

Sterling Heights, Michigan

March 27, 2013

**Rule 13a-14(a)/15(d)-14(a) Certifications**

I, Mark L. Faupel, certify that:

1. I have reviewed this annual report on Form 10-K of Guided Therapeutics, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f) for the registrant and have:
  - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting.
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

/s/ Mark L. Faupel

Mark L. Faupel

President, Chief Executive Officer and

Acting Chief Financial Officer

Date: March 27, 2013

**SECTION 1350 CERTIFICATION**

In connection with the Annual Report of Guided Therapeutics, Inc. (the "Company") on Form 10-K for the year ended December 31, 2012, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Mark L. Faupel, President, Chief Executive Officer and Acting Chief Financial Officer of the Company, certify, pursuant to 18 U.S.C. Sec. 1350, as adopted pursuant to Sec 906 of the Sarbanes-Oxley Act of 2002, that, to the best of my knowledge:

- (1) the Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
- (2) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: March 27, 2013

/s/ MARK L. FAUPEL

Name: Mark L. Faupel  
Title: President, Chief Executive Officer and  
Acting Chief Financial Officer