

SECURITIES AND EXCHANGE COMMISSION

FORM 8-K

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FILER

GUIDED THERAPEUTICS INC

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SIC: **3845** Electromedical & electrotherapeutic apparatus

Mailing Address

4955 AVALON RIDGE PKWY
SUITE 300
NORCROSS GA 30071

Business Address

4955 AVALON RIDGE PKWY
SUITE 300
NORCROSS GA 30071
7702428723

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 8-K

CURRENT REPORT

Pursuant to Section 13 or 15(d) of the
Securities Exchange Act of 1934

Date of Report (Date of Earliest Event) May 14, 2013; (May 15, 2013)

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

Delaware
(State or Other Jurisdiction of
Incorporation)

0-22179
(Commission File Number)

58-2029543
(IRS 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**

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Section 2.02 Results of Operations and Financial Condition

On May 14, 2013, the registrant publicly released its financial results for the first quarter ended March 31, 2013, as more fully described in the press release, a copy of which is furnished as Exhibit 99.1 hereto and which information is incorporated herein by reference.

Section 7.01 (Regulation FD Disclosure)

On May 15, 2013, the registrant conducted a conference call discussing its financial results for the first quarter and year ended March 31, 2013 and other matters concerning the operation of the company, as more fully described in the prepared transcript of the call, a copy of which is furnished as Exhibit 99.2 hereto and which information is incorporated herein by reference.

Item 9.01 Financial Statements and Exhibits.

(d) *Exhibits.*

NumberExhibit

[99.1](#) Press Release dated May 14, 2013

[99.2](#) Conference call transcript

SIGNATURES

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

GUIDED THERAPEUTICS, INC.

By: /s/ Mark L. Faupel, Ph.D.

Mark L. Faupel, Ph.D.

CEO & President

Date: May 15, 2013



5835 Peachtree Corners East • Norcross, GA 30092
Telephone (770) 242-8723 Fax (770) 242-8639

Contacts

Bill Wells, Guided Therapeutics – 770-242-8723
Investors: Alison Ziegler, Cameron Associates – 212-554-5469

Guided Therapeutics Reports First Quarter 2013 Results

Key Highlights:

- Initial Edition 3 CE Marked LuViva® Advanced Cervical Scan unit shipped
- LuViva® featured at major medical scientific meetings
- Clinical trial results to be published in journal *Gynecologic Oncology*
- Awaiting FDA Response

Norcross, GA (May 14, 2013) -- Guided Therapeutics, Inc. (OTCBB: GTHP) (OTCQB: GTHP) today announced its operating results for the first quarter ended March 31, 2013.

Revenue and other income for the first quarter of 2013 was approximately \$374,000, including \$132,000 in sales of LuViva® devices and disposables, with the remainder of revenue representing royalty and grant income. This compares to revenue of approximately \$718,000 in the first quarter of 2012, which was comprised solely of contract and grant revenue. The year-over-year decline in revenue was primarily due to the decline in contract revenue from Konica Minolta, as a result of bringing the worldwide rights to the Company's esophageal cancer detection technology back in house.

The net loss attributable to common stockholders for the first quarter of 2013 was approximately \$1.8 million, or \$0.03 per share. This compares to a net loss attributable to common stockholders of approximately \$1.0 million, or \$0.02 per share, in the comparable quarter of 2012.

Cash on hand at March 31, 2013 was approximately \$1.1 million, as compared to approximately \$1.0 million at December 31, 2012. During the first quarter of 2013, the Company received approximately \$1.65 million from warrant exercises. Management believes that the Company's anticipated future sales, as well as other funds from partnerships and grants, should be sufficient to support existing operations through the second quarter of 2013. The Company has historically sought additional funding from a variety of sources and will continue to do so.

"While we await a response from the FDA regarding LuViva, we continue to actively promote the product in key international markets," said Mark L. Faupel, Ph.D., Chief Executive Officer and President of Guided Therapeutics. "Following a major medical meeting in the United Kingdom, where LuViva was presented by a key opinion leader to 400 top gynecology health professionals, this week we are supporting our distributor in Turkey at a six-country Mediterranean congress. Next month, we will be in Canada at an important scientific meeting supporting our distributor there. After having recently received review board approval, we are expected to begin Canadian marketing clinical studies that are sponsored in part by the National Cancer Institute."

“During the first quarter, as previously announced, we shipped eight devices to Canada, as well as one unit to our distributor in Finland, and recently shipped our first Third-Edition CE Marked product to Turkey. We continue to expect to ship 15 to 20 devices in the second quarter and are in the process of building inventory to support demand. We were also pleased to have received notice that our clinical trial results for LuViva will be published in an upcoming issue of the major peer-reviewed journal Gynecologic Oncology later this year.”

“We are very pleased by the early, positive response we have seen for LuViva in our initial markets,” added Dr. Faupel. “We have a committed group of distributors and together we are working hard to change the way cervical disease is detected and managed.”

Conference Call

Guided Therapeutics will hold a conference call at 11:00 a.m. EDT on Wednesday, May 15, 2013, to discuss its financial results and corporate developments. Interested parties are invited to listen to the call live over the Internet at <http://www.guidedinc.com/investors.htm> or <http://www.viaavid.net>. The live call will also be available by dialing (888) 438-5535 or for international callers (719) 325-2429.

A replay of the teleconference will be available on <http://www.guidedinc.com/investors.htm>. A replay will also be available, until May 22, 2013, by dialing (877) 870-5176 or for international callers (858) 384-5517, and using pin number 1602803.

About Guided Therapeutics

Guided Therapeutics, Inc. (OTCBB: GTHP) (OTCQB: GTHP) is developing a rapid and painless testing platform based on its patented biophotonic technology that utilizes light for the early detection of disease at the cellular level. The Company’s first product is the LuViva® Advanced Cervical Scan, a non-invasive device used to detect cervical disease instantly and at the point of care. In a multi-center clinical trial, with women at risk for cervical disease, the technology was able to detect cervical cancer up to two years earlier than conventional modalities, according to published reports. Guided Therapeutics is also developing a non-invasive test for the early detection of esophageal cancer using the technology platform. For more information, visit: www.guidedinc.com.

The Guided Therapeutics LuViva® Advanced Cervical Scan is an investigational device and is limited by federal law to investigational use. LuViva, the wave logo and "Early detection, better outcomes" are registered trademarks owned by Guided Therapeutics, Inc.

Forward-Looking Statements Disclaimer: A number of the matters and subject areas discussed in this news release that are not historical or current facts deal with potential future circumstances and developments. The discussion of such matters and subject areas is qualified by the inherent risks and uncertainties surrounding future expectations generally and also may materially differ from Guided Therapeutics’ actual future experience involving any of or more of such matters and subject areas. Such risks and uncertainties include those related to the early stage of products in development, the uncertainty of market acceptance of products, the uncertainty of development or effectiveness of distribution channels, the intense competition in the medical device industry, the uncertainty of capital to develop products, the uncertainty of regulatory approval of products, dependence on licensed intellectual property, as well as those that are more fully described from time to time under the heading “Risk Factors” in Guided Therapeutics’ reports filed with the SEC, including Guided Therapeutics’ Annual Report on Form 10-K for the fiscal year ended December 31, 2012, and subsequent quarterly reports.

GUIDED THERAPEUTICS, INC. AND SUBSIDIARIES
UNAUDITED CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
FOR THE THREE AND TWELVE MONTHS ENDED DECEMBER 31, 2013 AND 2012
(In Thousands, Except Per Share Data)

In Thousands, except per share data	Three Months Ended March 31	
	<u>2013</u>	<u>2012</u>
Revenue		
Contract and grant revenue	\$ 167	\$ 718
Sales – Devices and disposables	132	—
Cost of goods sold	158	—
Gross (loss), profit	(26)	—
Operating Expenses		
Research & Development	813	714
Sales & Marketing	164	70
General & Administration	1,039	930
Total Operating Expense	2,016	1,714
Operating Loss	(1,875)	(996)
Other Income	75	—
Interest & Other Expense	(15)	(17)
Net Loss	\$ (1,815)	\$ (1,013)
Basic and Diluted Net Loss per Share	\$ (0.03)	\$ (0.02)
Basic and Diluted Weighted Average Shares Outstanding	63,671	52,471

	<u>March 31, 2013</u>	<u>December 31, 2012</u>
Cash & Cash Equivalents	\$1,109	\$1,044
Working Capital	421	(472)
Total Assets	3,585	3,478
Accumulated Deficit	(93,913)	(92,098)
Stockholders' Equity	1,862	1,133

Selected Balance Sheet Data (Unaudited)
(In Thousands)

###END###

1Q2013 Conference Call Script
May, 15 - 11:00 a.m.

Opening – Alison Ziegler

Good morning and welcome to the Guided Therapeutics conference call and webcast to discuss first quarter 2013 results.

For today's call we have: Guided Therapeutics CEO and President Dr. Mark L. Faupel and company controller Charles Rufai (Roof-eye) Certified Public Accountant.

During this call the Company will be making forward-looking statements. These statements can obviously differ from actual results, so to rely on them is subject to risk. Factors that could cause forward-looking statements in this call to differ materially from actual results are discussed in the company's Form 10-K for the year ended December 31, 2012, any subsequent filings with the Securities and Exchange Commission

So at this time I will turn the conference call over to Mark.

Welcome – MLF

Thank you, Alison and welcome everyone.

Let me begin with a quick update on the FDA.

We are still awaiting word from the FDA on our amended premarket approval application for the LuViva Advanced Cervical Scan. The filing, which was submitted in November, included a new analyses of existing data that addressed, among other things, the new cervical cancer screening guidelines regarding younger women. We also included segregated data from the two device versions used in the clinical trial to be reviewed separately. As we have stated previously, we expect to hear from FDA this quarter.

To put the timing into historical perspective, the 180 day period to respond is an internal FDA guideline. It is not unusual for the agency to take longer. For example, back in the fall before we filed the formal Amended PMA, the agency was late by about three weeks regarding a 90 day guideline.

As soon as we receive any indication from the agency, we will report the results to you. While we await the FDA's decision, we have made considerable progress with our launch internationally.

During the first quarter we shipped eight units to Canada to support our distributor's efforts in multiple sales territories and for small marketing clinical studies with Key Opinion Leaders. The marketing studies, which are being paid for by the National Cancer Institute, will help build a body of evidence for use in marketing the product and help us fulfill grant obligations. The next major event for the product will be the Annual Clinical meeting of the Society of Obstetricians and Gynecologists of Canada in June. This meeting is significant because the society represents about thirty-five hundred obstetricians, gynecologists, and other allied health professionals. It is also the organization responsible for guiding the practice of obstetrics and gynecology in Canada. We will be supporting our partner at the meeting with staff and collateral materials.

Additional sales in the first quarter included a unit to our distributor in Finland. We also sold two units to our Italian distributor, which we plan to ship this quarter.

As a part of the planned EU rollout, we shipped our first Third-Edition CE Marked unit to our distributor in Turkey in the second quarter. We are supporting our dealer at the 11th National Congress of Gynecology and Obstetrics taking place this week in Antalya. The product will be presented to hundreds of key opinion leaders from across the Mediterranean region.

We plan on accepting additional orders this quarter as part of our target to ship a total of 15-20 units by the end of June. In addition to Turkey, we have plans to ship product to Europe and Africa in the quarter along with a number of disposable cervical guides.

Turning to the U.K., we recently attended the scientific meeting of the British Society of Colposcopy and Cervical Pathology in Scotland. As part of a presentation of new technology, LuViva was presented to about 400 key opinion leaders by Dr. Pierre Martin-Hirsch, Professor of Gynecology at Lancaster University and Deputy Editor-in-Chief of the British Journal of Obstetrics and Gynaecology. We have also been asked to enroll LuViva in a clinical trial by Dr. Martin Hirsch whereby it would be part of the diagnostic standard of care for the U.K. cervical disease in conjunction with HPV screening. Dr. Martin-Hirsch believes LuViva potentially would be an excellent addition to the trial to help deal with anticipated increases in false positives that typically comes with the use

of HPV in screening. The trial results would also be used to include LuViva into a recommendation for use by the National Institute for Health and Care Excellence.

As we have commitments for our existing inventory, we are in the process of acquiring additional device components to meet demand. Our sales team is very excited by the early response and the opportunities they see, however we continue to control the pace of our launch to minimize the impact of any unforeseen issues that can arise with the introduction of any new product. As part of meeting demand for the product, we have hired a production assistant to support our manufacturing effort.

As a reminder, we have 17 countries under definitive distribution agreements in Europe, North America and Africa, which represents only about eight percent of the international opportunity. These agreements bring the aggregated potential revenues over the next two and one-half years from JUST the contractually agreed to minimum orders, as defined in ONLY the definitive supply agreements, to over 35 million dollars. As we have mentioned previously, this is a conservative number given that it is just the contractual minimums and doesn't include any preliminary or future agreements. I would still advise our investors that achieving these goals is subject to the acquisition and maintenance of local approvals in an environment of increasing regulatory stringency, as well as the successful and timely launch of the product, and the performance of our distributors.

We are staging the formal engagement of new distributors for the remainder of the year to meet expected production and available marketing resources. During the second half of the year, we expect new distribution partners in Europe, South Asia and Latin America.

Today, we have distributor candidates from more than two-dozen countries that we are in the final stages of qualifying and that we plan to bring on board over the next eight months.

We also recently announced that our clinical trial results for LuViva will be published in an upcoming issue of *Gynecologic Oncology*, the official publication of the Society of Gynecologic Oncology and a major peer-reviewed medical journal.

PAUSE

Regarding our non-invasive esophageal cancer detection product, in February, as previously announced, we acquired world-wide rights from Konica Minolta. Under terms of the agreement, we acquired both the rights we had licensed to Konica Minolta, and the rights to certain intellectual property invented by them, mainly related to the endoscope.

Upon FDA approval, Konica Minolta could receive a royalty for its licensed intellectual property, if it is used in the final product. **Most importantly**, we now have full worldwide sales and marketing rights, as opposed to a royalty only, as was anticipated under the previous arrangement. The potential market for this product could be very significant and we believe that retaining the rights at this later stage of development is the best way to maximize shareholder value. While we are responsible for the clinical, regulatory and product development, we do still have the option to partner with a new, more healthcare focused company.

PAUSE

Now let me turn the call over to Charles Rufai, our controller, who will provide some detail on our financial results.

Charles

Thank you Mark.

Total revenue for the three months ended March 31, 2013 was about 374 thousand dollars. This included 132 thousand dollars in sales of LuViva devices and disposables, with the remainder of revenue representing contract, grant revenue and license payments. This compares to revenue of about 718 thousand dollars in the same period last year which was comprised solely of contract and grant revenue. The year over year decline in revenue was primarily due to the decline in revenue from Konica Minolta as a result of bringing the worldwide rights to the esophageal technology back in house.

The **net** loss available to stockholders for the three months ended March 31, 2013 was about 1.8 million dollars, or three cents per share, compared to a loss of about 1.0 million dollars, or two cents per share, for the same period last year. The higher net loss is primarily related to the decline in contract and grant revenue and higher expenses than the same period last year.

Stockholders' equity at the end of the first quarter of 2013 was about 1.9 million dollars compared to equity of about 1.1 million dollars at the end of our fiscal year ended December 31, 2012. The change was mostly due to the shares issued as part of the warrant exchange program.

Cash on hand at the end of the first quarter was about \$1.1 million dollars compared to about 1.0 million dollars at the end of our fiscal year ended December 31, 2012. As

previously announced, in early March we received \$1.65 million from the exercise of approximately 2.5 million warrants priced at 65 cents.

At March 31, 2013, the Company had outstanding warrants exercisable for approximately 8.4 million shares of common stock, which if exercised could bring in an additional 6.2 million in cash over the next four years.

At the end of the quarter the Company had approximately 65,492,000 shares outstanding.

While the Company has historically sought additional funding from a variety of sources and will continue to do so, management believes that its anticipated future sales, as well as other funds from partnerships and grants, should be sufficient to support existing operations through the second quarter of 2013.

At March 31, 2013, the Company had approximately \$439,000 of net inventory on hand.

And our projected monthly burn rate is about 410 thousand dollars.

I'll now turn the call back over to Mark.....

Mark

Thank you Charles.

Finally, before we open the call to your questions, I'd like to update everyone on our goals for the remainder of 2013:

- First, having submitted an Amended PMA in November of 2012 for LuViva, we still anticipate notification from the FDA in the second quarter.
- Next, we plan to continue to ramp up our manufacturing and are supporting the rollout in Canada and in select markets in Europe in the first half of the year. We have additional parts on order to ensure we can support demand in 2013.
- Third, we expect to continue to announce additional definitive agreements for international distribution in Europe, Africa, the Americas and Asia, primarily targeted at the second half of the year in accordance with manufacturing capacity.
- Next, to continue to move our esophageal cancer detection technology forward by lining up doctors and facilities to begin our larger clinical study and work with FDA on the pivotal clinical trial protocol. Also to continue discussions for a new potential partner and additional funding.

- Longer term, we still have plans to identify a third product extension and, when the
- stock allows, we will move our shares to a national stock market such as NASDAQ or Amex.

This is an extremely important time for the Company. When we look at where we are compared to a year ago we have made significant progress on all fronts. From a regulatory standpoint we have shipped our initial Third Edition CE Mark product; we have approvals in Canada and Singapore and hope to be on the verge of hearing from the FDA. We have an excellent group of high quality distributors to help us introduce LuViva while we ramp up production to help meet demand. We have historically sought additional funding from a variety of sources and will continue to do so to further support our international launch.

Thank you for your time. We look forward to updating you on our progress in the months to come. I'll now turn the call over to the operator for your questions.

After taking questions

Thank you operator, thanks to everyone on the call. We look forward to speaking with you again soon.