SECURITIES AND EXCHANGE COMMISSION

FORM 8-K

Current report filing

Filing Date: **2013-01-09** | Period of Report: **2013-01-09**
SEC Accession No. 0001121781-13-000004

(HTML Version on secdatabase.com)

FILER

GUIDED THERAPEUTICS INC
CIK:**924515**| IRS No.: **582029543** | State of Incorp.:**DE** | Fiscal Year End: **1231**
Type: **8-K** | Act: **34** | File No.: **000-22179** | Film No.: **13520678**
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

Copyright © 2013 www.secdatabase.com. All Rights Reserved.
Please Consider the Environment Before Printing This Document

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) January 9, 2013; (January 7, 2013)

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

Delaware	**0-22179**	**58-2029543**
(State or Other Jurisdiction of Incorporation)	(Commission File Number)	(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))

Copyright © 2013 www.secdatabase.com. All Rights Reserved.
Please Consider the Environment Before Printing This Document

Section 7.01 (Regulation FD Disclosure)

On January 7, 2013, the registrant publicly issued a press release announcing it had successfully completed Canadian Standards Association and Edition 3 CE Mark third-party product safety requirements for LuViva® Advanced Cervical Scan 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.

Item 9.01 Financial Statements and Exhibits.

(d) *Exhibits.*

Number	Exhibit
99.1	Press Release dated January 7, 2013

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: January 9, 2013

Copyright © 2013 www.secdatabase.com. All Rights Reserved.
Please Consider the Environment Before Printing This Document

Copyright © 2013 www.secdatabase.com. All Rights Reserved.
Please Consider the Environment Before Printing This Document

EXHIBIT 99.1

5835 Peachtree Corners East, Suite D
Norcross, GA 30092

Guided Therapeutics Successfully Completes Canadian Standard Association Requirements for LuViva® Advanced Cervical Scan

Edition 3 CE Mark third-party product safety testing complete

NORCROSS, GA (January 7, 2013) – Guided Therapeutics, Inc., (OTCBB: GTHP) (OTCQB: GTHP), today announced that it has successfully completed third-party testing of the LuViva® Advanced Cervical Scan. This puts LuViva in compliance with Canadian Standards Association (CSA®) requirements which, while not required for marketing in Canada, are preferred by certain larger medical institutions. It also puts the company one step closer to applying the Edition 3 CE Mark to LuViva.

"The completion of CSA standards certification is an independent validation of the safety and integrity of LuViva's design," said Mark L. Faupel, CEO and President of Guided Therapeutics, Inc. "In addition to further opening up the Canadian market, the certification documentation can be used as a basis for obtaining regulatory approval and subsequent sales in certain Latin American and Asian countries."

The testing for the certification was conducted in parallel with CE Mark testing by SGS U.S. Testing Company, Inc. - a Nationally Recognized Test Lab. LuViva will carry the SGS USTC Mark for both Canada and the U.S.

With all third-party testing complete, the remaining steps for the Edition 3 CE Mark are to complete final mechanical tests and submit for review final documentation, a process which is expected to take a few weeks. Guided Therapeutics plans to then immediately apply the Edition 3 CE Mark to the LuViva in order to support its international product launch in the first quarter of 2013.

LuViva currently has marketing approval from Health Canada and received its first CE Mark, an ISO 60601 Edition 2 Notification, in July. Guided Therapeutics was awarded ISO 13485 certification in January 2011. Additionally, LuViva has been under U.S. Food and Drug Administration Premarket review since September 23, 2010. After meetings with the FDA, the Company filed an amended PMA application with the agency in November 2012.

About LuViva® Advanced Cervical Scan

LuViva is a technologically advanced diagnostic device that scans the cervix with light and uses spectroscopy to measure how light interacts with the cervical tissue. Spectroscopy identifies chemical and structural indicators of precancer that may be below the surface of the cervix or misdiagnosed as benign. This technique is called biophotonics. Unlike Pap, HPV tests or biopsies, LuViva does not require laboratory analysis or a tissue sample, and is designed to provide results immediately, which eliminates costly, painful and unnecessary testing. LuViva is designed for use with women who have undergone initial screening and are called back for follow up with a colposcopy examination, which in many cases, involves taking a biopsy of the cervix. The device is used in conjunction with the LuViva® Cervical Guide single-use patient interface and calibration disposable.

About Guided Therapeutics

Guided Therapeutics, Inc. (OTCBB: GTHP) (OTCQB: GTHP) is developing a rapid and painless testing platform for the early detection of disease based on its patented biophotonic technology that utilizes light to detect disease at the cellular level. The Company's first planned product is the LuViva® Advanced Cervical Scan, a non-invasive device used to detect cervical disease instantly and at the

Copyright © 2013 www.secdatabase.com. All Rights Reserved.
Please Consider the Environment Before Printing This Document

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 has also entered into a partnership with Konica Minolta to develop 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.

CSA® is a registered trademark of the Canadian Standards Association.

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, 2011, and subsequent quarterly reports.

# # #

Contacts:

Investors: Alison Ziegler, Cameron Associates, 212-554-5469

Bill Wells, Guided Therapeutics, 770-242-8723 Ext. 241

Copyright © 2013 www.secdatabase.com. All Rights Reserved.
Please Consider the Environment Before Printing This Document