EDAP TMS SA
Form 20-F
April 02, 2015

As filed with the Securities and Exchange Commission on April 2, 2015

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

FORM 20-F

o REGISTRATION STATEMENT PURSUANT TO SECTION 12(B) OR (G) OF THE SECURITIES EXCHANGE ACT OF 1934,

OR

x ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(D) OF THE SECURITIES EXCHANGE ACT OF 1934
For the Fiscal Year Ended December 31, 2014

OR

o TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(D) OF THE SECURITIES EXCHANGE ACT OF 1934
For the transition period from _____ to _____

OR

o SHELL COMPANY REPORT PURSUANT TO SECTION 13 OR 15(D) OF THE SECURITIES EXCHANGE ACT OF 1934
Date of the event requiring this shell company report_____

000-29374
(Commission file number)

EDAP TMS S.A.
(Exact name of registrant as specified in its charter)

France
(Jurisdiction of incorporation or organization)

Parc d'Activites la Poudrette-Lamartine
4/6, rue du Dauphiné
69120 Vaulx-en-Velin, France
(Address of principal executive offices)

Mrs. Blandine Confort
Tel. +33 4 72 15 31 50, E-mail: bconfort@edap-tms.com
Parc d'Activites la Poudrette-Lamartine, 4/6, rue du Dauphiné, 69120 Vaulx-en-Velin, France
(Name, Telephone, E-mail and Address of Company Contact Person)

Securities registered or to be registered pursuant to Section 12(b) of the Act:

Title of each class	Name of each exchange on which registered
American Depositary Shares, each representing	NASDAQ Global Market

One Ordinary Share
Ordinary Shares, nominal value €0.13 per share NASDAQ Global Market

Securities registered or to be registered pursuant to Section 12(g) of the Act: None

Securities for which there is a reporting obligation pursuant to Section 15(d) of the Act: None

Outstanding shares of each of the issuer's classes of capital or common stock as of December 31, 2014: 24,865,420 Ordinary Shares

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

If this report is an annual or transition report, indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934. Yes _____No__X__

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

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Website , if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). YesX No

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, or a non-accelerated filer. See definition of "accelerated filer and large accelerated filer" in Rule 12b-2 of the Exchange Act. (Check one):
Large accelerated filer _____ Accelerated filer X Non-accelerated filer _____

Indicate by check mark which basis of accounting the registrant has used to prepare the financial statements included in this filing:
U.S. GAAP X International Financial Reporting Standards as issued by the International Accounting Standards Board Other ___

If "Other" has been checked in response to the previous question indicate by check mark which financial statement item the registrant has elected to follow. Item 17 ____ Item 18 ___

If this is an annual report, indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act).
Yes _____ No X

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PRESENTATION OF FINANCIAL AND OTHER INFORMATION

Unless the context otherwise requires, references herein to “we,” “us,” “our” or “group” are to EDAP TMS S.A. and its consolidated subsidiaries and references herein to the “Company,” “EDAP” or “EDAP TMS” are to EDAP TMS S.A.

We prepare our consolidated financial statements in conformity with United States generally accepted accounting principles (‘‘U.S. GAAP’’). In this annual report, references to ‘‘euro’’ or ‘‘€’’ are to the legal currency of the countries of the European Monetary Union, including the Republic of France, and references to ‘‘dollars,’’ ‘‘U.S. dollars’’ or ‘‘$’’ are to the legal currency of the United States of America. Solely for the convenience of the reader, this annual report contains translations of certain euro amounts into dollars at specified rates. These translations should not be construed as representations that the euro amounts actually represent such dollar amounts or could be converted into dollars at those rates. See Item 3, ‘‘Key Information—Exchange Rates’’ for information regarding certain currency exchange rates and Item 11, ‘‘Quantitative and Qualitative Disclosures about Market Risk’’ for a discussion of the effects of fluctuations in currency exchange rates on the Company.

The following are registered trademarks of the Company in the United States: EDAP TMS® & associated logo, EDAP®, Technomed®, Ablatherm®, Ablasonic®, Ablapak®, Sonolith®, Sonolith i-sys®, Sonolith i-move®, @-REGISTRY®. The Focal One trademark is currently under review by the US Trademark Office. This annual report also makes references to trade names and trademarks of companies other than the Company.

CAUTIONARY STATEMENT ON FORWARD-LOOKING INFORMATION

This annual report includes certain forward-looking statements within the meaning of Section 27A of the U.S. Securities Act of 1933 (the “Securities Act”) or Section 21E of the U.S. Securities Exchange Act of 1934 (the “Exchange Act”), which may be identified by words such as ‘‘believe,’’ ‘‘plan,’’ ‘‘intend,’’ “should,” ‘‘estimate,’’ ‘‘expect’’ and ‘‘ similar expressions, which reflect our views about future events and financial performance. Forward-looking statements involve inherent known and unknown risks and uncertainties including matters not yet known to us or not currently considered material by us. Actual events or results may differ materially from those expressed or implied in such forward-looking statements as a result of various factors that may be beyond our control. Factors that could affect future results or cause actual events or results to differ materially from those expressed or implied in forward-looking statements include, but are not limited to:

- the success of our HIFU technology;
- the clinical and regulatory status of our HIFU devices;
- the uncertainty of market acceptance for our HIFU devices;
- the uncertainty in the U.S. FDA approval process for any of our devices and changes in FDA recommendations and guidance;
- effects of intense competition in the markets in which we operate;
- the uncertainty of reimbursement status of procedures performed with our products;
- the market potential for our Sonolith i-move and our Focal Onedevices;
- the impact of government regulation, particularly relating to public healthcare systems and the commercial distribution of medical devices;
- dependence on our strategic suppliers;
- any event or other occurrence that would interrupt operations at our primary production facility;
- reliance on patents, licenses and key proprietary technologies;
- product liability risk;
- risk of exchange rate fluctuations, particularly between the euro and the U.S. dollar and between the euro and the Japanese yen;
- fluctuations in results of operations due to the seasonal nature of demand for medical devices;
- risks associated with the current uncertain worldwide economic and financial environment;

–risks associated with the March 2012 and May 2013 Warrants;
–risks relating to ownership of our securities; and
–risks relating to ongoing litigation, including securities litigation involving class actions

You should also consider the information contained in Item 3, ‘‘Key Information—Risk Factors’’ and Item 5, ‘‘Operating and Financial Review and Prospects,’’ as well as the information contained in our periodic filings with the Securities and Exchange Commission (the “SEC”) (including our reports on Form 6-K) for further discussion of the risks and uncertainties that may cause such differences to occur. Forward-looking statements speak only as of the date they are made. Other than required by law, we do not undertake any obligation to update them in light of new information or future developments.

PART I

Item 1. Identity of Directors, Senior Management and Advisors

Not applicable.

Item 2. Offer Statistics and Expected Timetable

Not applicable.

Item 3. Key Information

Selected Financial Data

The following table sets forth selected consolidated financial data for the periods indicated. This information is qualified by and should be read in conjunction with the consolidated financial statements and the Notes thereto included in Part III of this annual report, as well as Item 5, ‘‘Operating and Financial Review and Prospects.’’ The selected balance sheet data as of December 31, 2014, 2013 and 2012 and the selected income statement data for the years ended December 31, 2014, 2013 and 2012 set forth below have been derived from our consolidated financial statements included in this annual report. These financial statements, together with our consolidated financial statements have been prepared in accordance with U.S. GAAP. To date, we have not been required, and presently are not required under French law, to prepare consolidated financial statements under French GAAP or IFRS, nor have we done so.

	Year Ended and at December 31,				
In thousands of euro, except per share data in euro	2014	2013	2012	2011	2010
INCOME STATEMENT DATA					
Total revenues	26,785	24,080	26,065	22,292	23,708
Total net sales	26,252	24,065	26,018	22,272	23,202
Gross profit	11,201	9,319	10,433	8,857	9,455
Operating expenses	(12,937)	(12,074)	(12,463)	(11,353)	(13,272)
Income (loss from operations)	(1,736)	(2,755)	(2,030)	(2,497)	(3,818)
Income (loss) before income taxes	(396)	(4,886)	(7,358)	(543)	(11,778)
Income tax (expense) benefit	(116)	(135)	(118)	(395)	(939)
Net income (loss)	(512)	(5,021)	(7,475)	(938)	(12,717)
Basic earnings (loss) per share	(0.02)	(0.24)	(0.43)	(0.07)	(0.98)
Diluted earnings (loss) per share	(0.02)	(0.24)	(0.43)	(0.07)	(0.98)
Dividends per share(1)	—	—	—	—	—
Basic weighted average shares outstanding	23,601,428	20,593,720	17,556,395	13,345,004	13,008,401
Diluted weighted average shares outstanding	23,601,428	20,593,720	17,556,395	13,345,004	13,008,401
BALANCE SHEET DATA					
Total current assets	26,615	22,125	24,729	25,032	29,865
Property and equipment, net	2,122	1,655	2,035	2,534	2,877
Total current liabilities	12,158	11,589	13,124	19,717	14,658
Total assets	32,154	26,874	30,444	32,238	35,938
Long-term debt, less current portion	2,434	3,678	6,585	720	10,075
Total shareholders’ equity	15,141	9,284	8,161	8,714	8,900

(1) No dividends were paid with respect to fiscal years 2010 through 2013 and subject to approval of the annual shareholders' meeting to be held in 2015 the Company does not anticipate paying any dividend with respect to fiscal year 2014. See Item 8, ''Financial Information — Dividends and Dividend Policy.''

EXCHANGE RATES

Fluctuations in the exchange rate between the euro and the dollar will affect the dollar amounts received by owners of American Depositary Shares (‘‘ADSs’’) representing ordinary shares of the Company (‘‘Shares’’) on conversion by the Depositary of dividends, if any, paid on the Shares in the form of ADSs. Moreover, such fluctuations may affect the dollar price of our ADSs on NASDAQ.

The following table sets forth, for each of the years indicated, the high, low, average and year-end Noon Buying Rates expressed in euro per $1.00. The rate is derived from the noon buying rate in The City of New York for cable transfers in euro as certified for customs purposes by the Federal Reserve Bank of New York (the ‘‘Noon Buying Rate’’).

Year ended December 31,	High	Low	Average(1)	End of Year
	€	€	€	€
2010	0.82	0.69	0.75	0.75
2011	0.77	0.67	0.72	0.77
2012	0.83	0.74	0.78	0.76
2013	0.78	0.72	0.75	0.73
2014	0.83	0.72	0.75	0.83

(1) The average of the Noon Buying Rates on the last business day of each month during the year indicated. See ‘‘Presentation of Financial and Other Information’’ elsewhere in this annual report.

The following table sets forth, for each of the previous six months, the high and low Noon Buying Rates expressed in euro per $1.00.

	High	Low	Average(1)	End of Month
	€	€	€	€
2014				
September	0.79	0.76	0.78	0.79
October	0.80	0.78	0.79	0.80
November	0.81	0.80	0.80	0.80
December	0.83	0.80	0.81	0.83
2015				
January	0.89	0.83	0.86	0.89
February	0.89	0.87	0.88	0.89
March, through March 20, 2015	0.95	0.89	0.93	0.93

(1) The average of the Noon Buying Rate on each business day of the month.

On March 20, 2015, the Noon Buying Rate was U.S.$1.00 = €0.93.

RISK FACTORS

In addition to the other information contained in this annual report, the following risk factors should be carefully considered in evaluating us and our business. These statements are intended to highlight the material risk factors that may cause actual financial, business, research or operating results to differ materially from expectations disclosed in this annual report. See also factors disclosed under "Cautionary statement on forward-looking information".

Risks Relating to Our Business

We have a history of operating losses and it is uncertain when and if we will reach profitability.

We have incurred operating losses in each fiscal year since 1998 and may never achieve profitability. We expect that our marketing, selling and research and development expenses will increase as we attempt to develop and commercialize our lithotripsy and High Intensity Focused Ultrasound ("HIFU") devices. We may not, however, generate a sufficient level of revenue to offset these expenses and may not be able to adjust spending in a timely manner to respond to any unanticipated decline in revenue. For example, although our net sales for HIFU grew in 2014, this was not sufficient to offset the negative operating income in our UDS division, nor the cost of the clinical trials for our U.S. Food and Drug Administration ("FDA") pre-market approval ("PMA") submission and regulatory process for our Ablatherm device for treatment of low risk, localized prostate cancer and the cost of our corporate activities, thus resulting in a consolidated operating loss. We cannot guarantee that we will realize sufficient revenue to become profitable in the future. See Item 5, ''Operating and Financial Review and Prospects.''

Our future revenue growth and income depend, among other things, on the success of our HIFU technology.

Our Extracorporeal Shockwave Lithotripsy ("ESWL") line of products competes in a mature market that has experienced declining unit sales prices in recent years. However, we depend on the success of our HIFU technology for future revenue growth and net income. In particular, we are dependent on the successful development and commercialization of other product lines, such as medical devices based on HIFU, particularly the Ablatherm and the Focal One to generate significant additional revenues and achieve and sustain profitability in the future. The Ablatherm is commercialized in the European Union, Canada and other countries; the Focal One is commercialized in the European Union, Saudi Arabia and Canada. However, neither the Ablatherm nor the Focal One is approved for commercial distribution in the United States. We submitted a PMA for Ablatherm in January 2013.

On November 6, 2014, following negative votes from the July 30, 2014 FDA Gastroenterology and Urology Devices Panel ("GUDP") of experts, we received a letter from the FDA indicating that the Ablatherm was not approvable in its current form and providing specific guidance and recommendations as to a path forward. Following further discussions with the FDA, we now plan to seek clearance of Ablatherm HIFU by way of a direct de novo 510(k) application as opposed to the PMA application amendment we had been pursuing. Discussions with the FDA are still ongoing on the information required to support the application and although our team is now diligently focused on preparing the de novo application, given the challenging recommendations of the FDA with regards to our Ablatherm approval process, we do not know when we will be able to submit our de novo application. Once we submit our de novo application, the review of our submission may take longer than expected or may not meet the FDA's requirements or recommendations which could delay approval, if we receive it at all.
Further, even if we do receive the required approvals, we may not receive them on a timely basis and we may not be able to satisfy the conditions of such approval, if any. The failure to receive product approval by the FDA, or any significant delay in receipt thereof, will have a material adverse effect on our business, financial condition or results of operations. See "—Our clinical trials for products using HIFU technology may not be successful" and Item 4, "Information on the Company—HIFU Division—HIFU Division Clinical and Regulatory Status."

We may not have sufficient funds to fund the FDA approval process for our Ablatherm device through completion and our ongoing operations.

We have been funding our clinical trials and panel preparation to support the FDA PMA submission for our Ablatherm device using the $17.4 million (€12.0 million) and $8.3 million (€6.1 million) net proceeds from financings we completed in October 2007 and June 2014, respectively. As of December 31, 2014, we had €12.1 million in cash and cash equivalents and short terms investments on hand. While we believe our working capital is, as of the date of this annual report, sufficient for our present working capital requirements, including to fund the de novo 510(k) application to the FDA for our Ablatherm, we may need to raise additional capital in the event of any changes in FDA regulatory process or recommendations regarding our application, significant delays with the FDA review, to fund our U.S. Ablatherm marketing roll-out strategy if and when clearance is granted or to fund new development projects. If funding is not available on acceptable terms, or at all, we may need to delay the approval process or decrease our operating expenses. See Item 5, “Operating and Financial Review and Prospect—Liquidity and Capital Resources.”

Our clinical trials for products using HIFU technology may not be successful and we may not be able to obtain FDA or other regulatory approval necessary for commercialization.

Before obtaining regulatory approvals for the commercial sale of any of our devices under development, we must demonstrate through preclinical testing and clinical trials that the device is safe and effective for use in each indication. Product development, including pre-clinical studies and clinical trials is a long, expensive and uncertain process, and is subject to delays and failures at any stage. The results from preclinical testing and early clinical trials may not predict the results that will be obtained in large scale clinical trials. Companies can suffer significant setbacks in advanced clinical trials, even after promising results in earlier trials. Furthermore, data obtained from a trial can be insufficient to demonstrate that our products are safe, effective, and marketable. The commencement, continuation or completion of any of our clinical trials may be delayed or halted, or inadequate to support approval of an application to regulatory authorities for numerous reasons including, but not limited to:

- the FDA or other regulatory authorities do not approve a clinical trial protocol or a clinical trial, or place a clinical trial on hold; See Item 4, ''Information on the Company—High Intensity Focused Ultrasound Division—HIFU Division Clinical and Regulatory Status.''
- slower than expected rates of patient recruitment and enrolment;
- inability to adequately monitor patient during or after treatment;
- failure of patients to complete the clinical trial;
- prevalence and severity of adverse events and other unforeseen safety issues;
- third-party organizations not performing data collection and analysis in a timely and accurate manner;
- governmental and regulatory delays or changes in regulatory requirements, policies or guidelines;
- the interim or final results of a clinical trial are inconclusive or unfavorable as to safety or efficacy; and
- the FDA or other regulatory authorities concluding that our trial design is inadequate to demonstrate safety and efficacy.

Additionally, the FDA may disagree with our interpretation of the data from our pre-clinical studies and clinical trials, or may find the clinical trial design, conduct or results inadequate to prove safety or efficacy, and may require us to pursue additional pre-clinical studies or clinical trials, which would increases costs and could further delay the approval of our products. If we are unable to demonstrate the safety and efficacy of our products in our clinical trials, we will be unable to obtain regulatory approval to market our products. The data we collect from our current clinical trials, our pre-clinical studies and other clinical trials may not be sufficient to support FDA approval. Discussions with regulatory authorities to improve our clinical protocol may prove difficult and lengthy. We, the FDA or other regulatory authorities may suspend or terminate clinical trials at any time and regulating agencies such as the FDA may even refuse to grant exemptions to pursue clinical trials.

We may also be required to abandon previous strategies for regulatory approval, despite having made significant financial and time investments, or refocus our efforts on alternative regulatory strategies, resulting in increased costs and efforts of management, without any guarantee of success, which could materially adversely affect our business, financial condition and results of operations.

For example, with respect to our PMA application with the FDA for Ablatherm, the FDA Gastroenterology and Urology Devices Panel (GUDP) voted negatively on the safety, efficacy and risk/benefit ratio for the use of our Ablatherm for the treatment of low-risk localized prostate cancer. On November 6, 2014, we received a letter from the FDA indicating that the Ablatherm was not approvable in its current form and providing specific guidance and recommendations as to a path forward. As a result of further discussions with the FDA, we now plan to seek clearance of Ablatherm HIFU for a prostate tissue ablation claim by way of a direct de novo 510(k) application as opposed to pursuing the PMA.

Our HIFU devices that have not received regulatory approval may not prove to be effective or safe in clinical trials or may not be approved by the appropriate regulatory authorities. If our HIFU devices do not prove to be effective and safe in clinical trials to the satisfaction of the relevant regulatory authorities, our business, financial condition and results of operations could be materially adversely affected.

We operate in a highly regulated industry and our future success depends on obtaining and maintaining government regulatory approval of our products, which we may not receive or be able to maintain or which may be delayed for a significant period of time.

Government regulation significantly impacts the development and marketing of our products, particularly in the United States. We are regulated in each of our major markets with respect to preclinical and clinical testing, manufacturing, labeling, distribution, sale, marketing, advertising and promotion of our products. To market and sell products still in the clinical trial stage, we are required to obtain approval or clearance from the relevant regulatory agencies, including the FDA. The process of applying for regulatory approval is unpredictable, often lengthy and requires the expenditure of substantial resources. For example, we are currently pursuing FDA approval for our Ablatherm device. Our U.S. ENLIGHT study of Ablatherm for treatment of low risk, localized prostate cancer began in 2007. Following the December 11, 2009 recommendations of the GUDP of the FDA's Medical Devices Advisory Committee and our discussions with the FDA, after thoroughly evaluating all options, in April 2010, we decided to discontinue enrollment of patients in the HIFU comparative arm of the study, completed the treatment of 134 patients in June 2010 and then entered into the required two-year follow-up phase, which was completed in June 2012. On January 31, 2013, we submitted our PMA to the FDA for our Ablatherm for treatment of low risk, localized prostate cancer. Following further discussions with the FDA, we now plan to seek clearance of Ablatherm HIFU by way of a direct de novo 510(k) application as opposed to the PMA application amendment we had been pursuing. Discussions with the FDA are still ongoing on the information required to support the application. Although our team is now diligently focused on preparing the de novo application, given the challenging recommendations of the FDA with regards to our Ablatherm approval process, we do not know when we will be able to submit our de novo application. Once we submit our de novo application, the review of our submission may take longer than expected or may not meet the FDA's requirements which could delay approval, if we receive it at all.

Further, there can be no assurance that we will receive the required approvals for our products from the FDA or other regulatory authorities or, if we do receive the required approvals, that we will receive them on a timely basis, on the conditions and for the indications we seek, or that we will otherwise be able to satisfy the conditions of such approval, if any.

Even if regulatory approval to market a product is granted, it may include limitations on the indicated uses for which the product may be marketed. Failure to comply with regulatory requirements can result in fines, suspension or withdrawal of regulatory approvals, product recalls, seizure of products, operating restrictions and criminal prosecutions. Regulatory policy may change and additional government regulations may be established that could prevent or delay regulatory approval of our products. Any delay, failure to receive regulatory approval or the loss of previously received approvals could have a material adverse effect on our business, financial condition and results of operations. For more information on the regulation of our business, see Item 4, ''Information on the Company—Government Regulation'' and "High Intensity Focused Ultrasound Division—HIFU Division Clinical and Regulatory Status."

Furthermore, changes to regulatory policy or the adoption of additional statutes or regulations that affect our business could impose substantial additional costs or otherwise have a material adverse effect on our business, financial condition and results of operations.

HIFU technology may not be accepted and adopted by the medical community.

Our HIFU devices represent new therapies for the conditions that they are designed to treat. Notwithstanding any positive clinical results that our HIFU devices may have achieved or may achieve in the future in terms of safety and efficacy and any marketing approvals that we have obtained or may obtain in the future, there can be no assurance that such products will gain acceptance in the medical community. Physician acceptance depends, among other things, on evidence of the cost effectiveness of a therapy as compared to existing therapies and on adequate reimbursement from

healthcare payers, which has not been provided for our HIFU products in any country, except for full public reimbursement in Germany and Italy, in France, under certain conditions and partial reimbursement from private insurers in the United Kingdom.. On April 18, 2014, the French healthcare government authorities announced the reimbursement of prostate cancer treatment procedures using HIFU as part of an innovative process to further validate breakthrough therapies and to accelerate their related reimbursement process based on clinical trials and data registries. Under this innovative process, French healthcare government authorities will review the clinical data gathered within the next five years in view of granting definitive reimbursement for HIFU. However, we cannot guarantee that a definitive reimbursement code will be granted. Furthermore, acceptance by patients depends in part on physician recommendations, as well as other factors, including the degree of invasiveness, the rate and severity of complications and other side effects associated with the therapy as compared to other therapies.

If our HIFU devices do not achieve an adequate level of acceptance by physicians, patients, health care payers and the medical community, we may not generate or maintain positive cash flows and we may not become profitable or be able to sustain profitability. If we do achieve market acceptance of our products, we may not be able to sustain it or otherwise achieve it to a degree which would support the ongoing viability of our operations.

Our cash flow is highly dependent on demand for our products.

Our cash flow has historically been subject to significant fluctuations over the course of any given financial year due to seasonal demand for medical devices, and the resulting annual and quarterly fluctuations in trade and other receivables and inventories. This has in the past resulted in significant variations in working capital requirements and operating cash flows. In 2014, 2013 and 2012 and, moreover, our operating cash flow was negative due to the cash requirements of operating activities, working-capital cash requirements, cash requirements of investing activity to expand our mobile activity and to expand the leasing of our products as part of our revenue-per-procedure ("RPP") model, and sponsoring of the clinical trials in support of our PMA submission to the FDA of our Ablatherm solution for the treatment of prostate cancer in the United States and to expand our commercial lithotripsy activities in the United States, which we financed using cash and cash equivalents on hand. Since we anticipate relying on cash flow from operating activities to meet our liquidity requirements, a decrease in the demand for our products, or the inability of our customers to meet their financial obligations to us, would reduce the funds available to us. Our future cash flow may also be affected by the expected continued expansion of the leasing of our products, or the continued expansion of our mobile activity (which is invoiced on a RPP basis), since each of these activities generates smaller immediate revenues than device sales. In the future, our liquidity may be constrained and our cash flows may be uncertain, negative or significantly different from period to period. Our future cash flow will be affected by increased expenses in sales efforts as well as marketing and promotion tools, while there is no assurance that this will result in the increase in the demand for our products and services. It will also be affected by the expenses for our FDA de novo 510(k) application and regulatory process to seek the FDA's clearance for our Ablatherm solution for ablation of prostatic tissue in the United States. There is no assurance that our cash flow will in fact be enough to do so or that clinical trials will be successful or that the FDA will grant approval to market our device.

Competition in the markets in which we operate is intense and is expected to increase in the future.

Competition in the markets in which we operate is intense and is expected to increase in the future. In each of our main businesses, we face competition both directly from other manufacturers of medical devices that apply the same technologies that we use, as well as indirectly from existing or emerging therapies for the treatment of urological disorders.

We believe that because ESWL has long been the standard treatment for urinary tract calculus disease, competition in that market comes principally from current manufacturers of lithotripters, including Siemens, Storz and Dornier. In the markets that we target for our HIFU products, competition comes from new market entrants and alternative therapies, as well as from current manufacturers of medical devices. In the HIFU market, our devices, in particular the Ablatherm and the Focal One, compete with all current treatments for localized tumors, including surgery, external beam radiotherapy, brachytherapy and cryotherapy. Other companies working with HIFU technology for the minimally invasive treatment of tumors include SonaCare Medical, a U.S. company which markets a device called the Sonablate SB500 for the treatment of localized prostate cancer. Insightec, an Israeli company owned mainly by General Electric and Elbit Medical Imaging, has developed a device using HIFU technology to treat uterine fibroids, painful bone tumors and brain disorders. Haifu, a Chinese company, is developing HIFU products addressing various types of cancers. Philips Healthcare, a Dutch company, is also developing HIFU devices addressing uterine fibroids, breast tumors and drug delivery activated by HIFU. See Item 4, ''Information on the Company—High Intensity Focused Ultrasound Division— HIFU Competition'' and Item 4, ''Information on the Company—Urology Devices and Services Division.''

Many of our competitors have significantly greater financial, technical, research, marketing, sales, distribution and other resources than us and may have more experience in developing, manufacturing, marketing and supporting new medical devices. In addition, our future success will depend in large part on our ability to maintain a leading position in technological innovation, and we cannot assure investors that we will be able to develop new products or enhance our current ones to compete successfully with new or existing technologies. Rapid technological development by competitors may result in our products becoming obsolete before we recover a significant portion of the research, development and commercialization expenses incurred with respect to those products.

We also face competition for our maintenance and service contracts. Larger hospitals often utilize their in-house maintenance departments instead of contracting with equipment manufacturers like us to maintain and repair their medical equipment. In addition, third-party medical equipment maintenance companies increasingly compete with equipment manufacturers by offering broad repair and maintenance service contracts to hospitals and clinics. This increased competition for medical devices and maintenance and service contracts could have a material adverse effect on our business, financial condition and results of operations.

The success of our products depends on whether procedures performed by those products are eligible for reimbursement which depends on the decisions of national health authorities and third-party payers.

Our success depends, among other things, on the extent to which reimbursement can be obtained from healthcare payers in the United States and elsewhere for procedures performed with our products. In the United States, we are dependent upon favorable decisions by the Centers for Medicare & Medicaid Services (''CMS'') for Medicare reimbursement, individual managed care organizations, private insurers and other payers. These decisions may be revised from time to time, which could affect reimbursement for procedures performed using our devices. Outside the United States, and in particular in the European Union and Japan, third-party reimbursement is generally conditioned upon decisions by national health authorities. In the European Union, there is no harmonized procedure for obtaining reimbursement and, consequently, we must seek regulatory approval in each Member State. If we fail to establish reimbursement from healthcare payers or government and private healthcare payers' policies change, it could have a material adverse effect on our business, financial condition and results of operations.

Lithotripsy procedures currently are reimbursed by public healthcare systems in the European Union, in Japan and in the United States. However, a decision in any of those countries to modify reimbursement policies for these procedures could have a material adverse effect on our business, financial conditions and results of operations. In contrast, procedures performed with our Ablatherm devices are not reimbursed in the European Union with the exception of Italy, Germany, in France under certain conditions, and in the UK where procedures are partially reimbursed by either public healthcare systems or private insurers. We cannot assure investors that additional reimbursement approvals will be obtained in the near future. If reimbursement for our products is unavailable, limited in scope or amount or if pricing is set at unsatisfactory levels, our business could be materially harmed.

Our manufacturing operations are highly regulated and failure to comply with those regulations would harm our business.

Our manufacturing operations must comply with regulations established by regulatory agencies in the United States, the European Union and other countries, and in particular with the Current Good Manufacturing Practices (''CGMP'') mandated by the FDA and European Union standards for quality assurance and manufacturing process control. Since such standards may change, we may not, at all times, comply with all applicable standards and, as a result would be unable to manufacture our products for commercial sale. Our manufacturing facilities are subject to inspection by regulatory authorities at any time. If any inspection by the regulatory authorities reveals deficiencies in manufacturing, we could be required to take immediate remedial actions, suspend production or close the current and future production facilities, which would disrupt our manufacturing processes. Accordingly, failure to comply with these regulations could have a material adverse effect on our business, financial condition and results of operations.

We depend on a single site to manufacture our products, and any interruption of operations could have a material adverse effect on our business.

Most of our manufacturing currently takes place in a single facility located in Vaulx-en-Velin, on the outskirts of Lyon, France. In the event of a significant interruption in the operations of our sole facility for any reason, such as fire, flood or other natural disaster or a failure to obtain or maintain required regulatory approvals, we would have no other means of manufacturing our products until we were able to restore the manufacturing capabilities at our facility

or develop alternative facilities, which could take considerable time and resources and have a material adverse effect on our business, financial condition and results of operations. If we are unable to manufacture a sufficient or consistent supply of our products or products we are developing, or if we cannot do so efficiently, our revenue, business and financial prospects would be adversely affected.

For certain components or services we depend on a single supplier who, due to events beyond our control may fail to deliver sufficient supplies to us or increase the cost of items supplied, which would interrupt our production processes or negatively impact our results of operations.

We purchase the majority of the components used in our products from a number of suppliers, but rely on a single supplier for some key components. In addition, we rely on single suppliers for certain services. If the supply of certain components or services were interrupted for any reason, our manufacturing and marketing of the affected products would be delayed. These delays could be extensive, especially in situations where a component substitution would require regulatory approval. In addition, such suppliers could decide unilaterally to increase the price of supplied items and therefore cause additional charges for the Company. We expect to continue to depend upon our suppliers for the foreseeable future. Failure to obtain adequate supplies of components or services in a timely manner and at the agreed price could have a material adverse effect on our business, financial condition and results of operations.

Intellectual property rights are essential to protect our medical devices, and any dispute with respect to these rights could be costly and have an uncertain outcome.

Our success depends in large part on our ability to develop proprietary products and technologies and to establish and protect the related intellectual property rights, without infringing the intellectual property rights of third parties. The validity and scope of claims covered in medical technology patents involve complex legal and factual questions and, therefore, the outcome of such claims may be highly uncertain. The medical device industry has been characterized by extensive patents and other intellectual property rights litigation. From time to time we receive letters from third parties drawing our attention to their patent rights. Our products, including our HIFU devices, may be subject to litigation involving claims of patent infringement or violation of other intellectual property rights of third parties. The defense and prosecution of intellectual property suits, patent opposition proceedings and related legal and administrative proceedings are both costly and time consuming and may result in a significant diversion of effort and resources by our technical and management personnel. An adverse determination in any such litigation or proceeding to which we become a party could subject us to significant liability to third parties, require us to seek licenses from third parties and pay ongoing royalties, require us to redesign certain products or subject us to injunctions preventing the manufacture, use or sale of the affected products. In addition to being costly, drawn-out litigation to defend or prosecute intellectual property rights could cause our customers or potential customers to defer or limit their purchase or use of our products until the litigation is resolved. See Item 4, ‘‘Information on the Company—High Intensity Focused Ultrasound Division—HIFU Division Patents and Intellectual Property’’ and Item 4, ‘‘Information on the Company—Urology Devices and Services Division—UDS Division Patents and Intellectual Property.’’

We own patents covering several of our technologies and have additional patent applications pending in the United States, the European Union, Japan and elsewhere. The process of seeking patent protection can be long and expensive and there can be no assurance that our patent applications will result in the issuance of patents. We also cannot assure investors that our current or future patents are or will be sufficient to provide meaningful protection or commercial advantage to us. Our patents or patent applications could be challenged, invalidated or circumvented in the future. The failure to maintain or obtain necessary patents, licenses or other intellectual property rights from third parties on acceptable terms or the invalidation or cancellation of material patents could have a material adverse effect on our business, financial condition or results of operations. Litigation may be necessary to enforce patents issued to us or to determine the enforceability, scope and validity of the proprietary rights of others. Our competitors, many of which have substantial resources and have made substantial investments in competing technologies, may apply for and obtain patents that will interfere with our ability to make, use or sell certain products, including our HIFU devices, either in the United States or in foreign markets.

We also rely on trade secrets and proprietary know-how, which we seek to protect through non-disclosure agreements with employees, consultants and other parties. It is possible, however, that those non-disclosure agreements will be breached, that we will not have adequate remedies for any such breach, or that our trade secrets will become known to, or independently developed by, competitors. Litigation may be necessary to protect trade secrets or know-how owned by us. In addition, effective copyright and trade secret protection may be unavailable or limited in certain countries.

The occurrence of any of the foregoing could have a material adverse effect on our business, financial condition and result of operations.

We face a significant risk of exposure to product liability claims in the event that the use of our products results in personal injury or death.

Our products are designed to be used in the treatment of severe affections and conditions. Despite the use of our products, patients may suffer personal injury or death, and we may, as a result, face significant product liability claims. We maintain separate product liability insurance policies for the United States and Canada and for the other

markets in which we sell our products. Product liability insurance is expensive and there can be no assurance that it will continue to be available on commercially reasonable terms or at all. In addition, our insurance may not cover certain product liability claims or our liability for any claims may exceed our coverage limits. A product liability claim or series of claims brought against us with respect to uninsured liabilities or in excess of our insurance coverage, or any claim or product recall that results in significant cost to or adverse publicity against us could have a material adverse effect on our business, financial condition and results of operations. Also, if any of our products prove to be defective, we may be required to recall or redesign the product which could result in costly corrective actions and harm to our business reputation, which could materially affect our business, financial condition and results of operations.

We are currently and may in the future be the target of securities class action or other litigation, which could be costly and time consuming to defend.

In the past, securities class action litigation has often been brought against companies following a decline in the market price of its securities. This risk is especially relevant for us because innovative life sciences and medical device companies have experienced significant stock price volatility in recent years.

On August 4, 2014, a purported class action lawsuit was filed in the United States District Court for the Southern District of New York, asserting that the Company, Marc Oczachowski, and Eric Soyer violated federal securities laws by issuing materially false and misleading statements that caused the price of our ADSs to be artificially inflated. An amended complaint alleges that the Company and Mr. Oczachowski breached their obligations under the Exchange Act in various ways, including by misrepresenting and failing to disclose allegedly material information about the safety and efficacy of treatment with Ablatherm-HIFU, and the Company's interactions with the FDA. The complaint seeks unspecified damages, interest, costs, and fees, including attorneys' and experts' fees. On December 31, 2014, we accrued $250,000 (€206,000) as legal costs to be incurred by the Company in relation to this litigation. In February 2015, the defendants, including the Company, filed a motion to dismiss. We cannot predict the outcome of this motion to dismiss. We believe we have valid defenses to this matter and intend to deny liability and defend our position vigorously. We have notified our insurance carriers of this litigation and no determination can be made at this stage as to the likely outcome of the ongoing procedures and whether it will be material to us. Therefore, no loss contingency beyond legal costs of $250,000 has been booked with regard to this matter.

Such litigation, regardless of its outcome, and any additional litigation, if instituted, causes and could cause us to incur substantial costs and our management resources are and could be diverted to defending such litigation, which could adversely affect our financial condition or results of operations.

We sell our products in many parts of the world and, as a result, our business is affected by fluctuations in currency exchange rates.

We are exposed to foreign currency exchange rate risk because the mix of currencies in which our costs are denominated is different from the mix of currencies in which we earn our revenue. In 2014, approximately 81% of our total costs of sales and operating expenses were denominated in euro, while approximately 32% of our sales were denominated in currencies other than euro (primarily the U.S. dollar and the Japanese yen). Our operating profitability could be materially adversely affected by large fluctuations in the rate of exchange between the euro and other currencies. For instance, a decrease in the value of the U.S. dollar or the Japanese yen against the euro would have a negative effect on our revenues, which may not be offset by an equal reduction in operating expenses and would therefore negatively impact operating profitability. From time to time we enter into foreign exchange forward sale contracts to hedge against fluctuations in the exchange rates of the principal foreign currencies in which our receivables are denominated (in particular, the U.S. dollar and the Japanese yen), but there can be no assurance that such hedging activities will limit the effect of movements in exchange rates on our results of operations. As of December 31, 2014, we had no outstanding hedging instruments. In addition, since any dividends that we may declare will be denominated in euro, exchange rate fluctuations will affect the U.S. dollar equivalent of any dividends received by holders of ADSs. For more information concerning our exchange rate exposure, see Item 11. "Quantitative and Qualitative Disclosures about Market Risk."

Our results of operations have fluctuated significantly from quarter to quarter in the past and may continue to do so in the future.

Our results of operations have fluctuated in the past and are expected to continue to fluctuate significantly from quarter to quarter depending upon numerous factors, including, but not limited to, the timing and results of clinical trials, changes in healthcare reimbursement policies, seasonality of demand for our products, changes in pricing

policies by us or our competitors, new product announcements by us or our competitors, customer order deferrals in anticipation of new or enhanced products offered by us or our competitors, product quality problems and exchange rate fluctuations. Furthermore, because our main products have relatively high unit prices, the amount and timing of individual orders can have a substantial effect on our results of operations in any given quarter.

Our results of operations and financial condition could be adversely affected by the adverse economic and financial developments.

The current economic and financial environment has affected the level of public and private spending in the healthcare sector generally. A cautious or negative business outlook may cause our customers to further delay or cancel investment in medical equipment, which would adversely affect our revenues.

In addition, we rely on the credit market to secure dedicated lease financings to fund the development of our RPP activity. Due to the limited availability of lending in the current market environment, we may be unable to access sufficient lease financing. Without lease financing, we may be unable to continue the development of our RPP activity or we may need to fund such activity out of our existing working capital. Similarly, some of our clients rely on lease financing to finance their purchases of equipment. Limited availability of lease financing facilities may also affect their purchasing decisions and may adversely impact our equipment sales.

While we believe our working capital is, as of the date of this annual report, sufficient for our present working capital requirements, including to fund the de novo 510(k) application with the FDA for our Ablatherm through completion, we may need to raise additional capital in the event of any changes in FDA regulatory process or recommendations regarding our de novo 510(k) application, or significant delays in the preparation of our de novo 510(k) application or the FDA review thereof, and/or to fund our U.S. Ablatherm marketing roll-out strategy if and when clearance is granted or to fund new development projects. If funding is not available on acceptable terms, or at all, we may need to delay the approval process, launch of new developments or decrease our operating expenses.

The issuance of ADSs upon exercise of outstanding warrants will cause immediate and substantial dilution to our existing shareholders.

The issuance of ADSs upon exercise of the warrants issued in March 2012 (the “March 2012 Warrants”) and in May 2013 (the “May 2013 Warrants”) will result in dilution of other shareholders since the selling shareholders may ultimately sell the full amount of ADSs issuable on exercise. Based on the total number of outstanding warrants as of April 2, 2015, and on the total number outstanding options to subscribe to new shares, up to 4,088,996 ADSs are issuable upon exercise, representing approximately 16.1% of our issued and outstanding share capital. Although no single warrant holder may exercise its Warrants if such exercise would cause it to own more than 9.99% of our outstanding ordinary shares, this restriction does not prevent each holder from exercising a portion of its holdings and selling those securities. In this way, each holder could sell more than this limit while never holding more than such limit.

On April 22, 2014, we filed a Form F-3 registration statement with the SEC to register ordinary shares and warrants for a maximum amount of $50 million, hence providing for registration of any future new ordinary shares issued for the purpose of raising capital. This registration statement was declared effective by the SEC on May 5, 2014. We issued and registered shares under this registration statement on June 2, 2014.

On June 30, 2014, our shareholders extended the validity of existing resolutions, and renewed the June 17, 2013 authorization to issue a maximum of 10 million new shares.

The sale of ADSs issued upon exercise of outstanding warrants could encourage short sales by third parties which could further depress the price of our ADSs.

Any downward pressure on the price of ADSs caused by the sale of ADS issued upon the exercise of the outstanding warrants could encourage short sales by third parties. In a short sale, a prospective seller borrows shares from a shareholder or broker and sells the borrowed shares. The prospective seller hopes that the share price will decline, at which time the seller can purchase shares at a lower price for delivery back to the lender. The seller profits when the

share price declines because it is purchasing shares at a price lower than the sale price of the borrowed shares. Such sales could place downward pressure on the price of our ADSs by increasing the number of ADSs being sold, which could further contribute to any decline in the market price of our ADSs.

Risks Relating to Ownership of Securities

Our securities may be affected by volume fluctuations, and may fluctuate significantly in price, causing you to lose some or all of your investment.

Our ADSs are currently traded on the NASDAQ Global Market. The average daily trading volume of our ADSs in 2014 was 152,874, the high and low bid price of our ADSs for the last two financial years ended on December 31, 2014 and December 31, 2013, was $6.05 and $1.15, and $4.94 and $1.98, respectively. Our ADSs have experienced, and are likely to experience in the future, significant price and volume fluctuations, which could adversely affect the market price of our ADSs without regard to our operating performance. For example, average daily trading volume of our ADSs in December 2013 was 77,719 as opposed to 144,032 for the same period of 2014. The price of our securities and our ADSs in particular, may fluctuate as a result of a variety of factors beyond our control, including changes in our business, operations and prospects, regulatory considerations, results of clinical trials of our products or those of our competitors, developments in patents and other proprietary rights, and general market and economic conditions.

These broad market and industry factors may adversely affect the market price of our ADSs, regardless of our operating performance. If you invest in our ADSs, you could lose some or all of your investment.

In addition, following periods of volatility in the market price of a company's securities, securities class action litigation has often been instituted. We are currently the subject of such litigation, and such litigation, regardless of its outcome, and any additional litigation, if instituted, causes and could cause us to incur substantial costs and our management resources are and could be diverted to defending such litigation, which could adversely affect our financial condition or results of operations.

We may issue additional securities that may be dilutive to our existing shareholders.

As described above, on June 30, 2014, our shareholders adopted resolutions allowing the Board of Directors to issue new shares in an aggregate maximum amount of 10 million shares. As of April 2, 2015, the maximum number of shares available to be issued is still 10 million.

The issuance of additional ordinary shares, including any additional ordinary shares issuable pursuant to the exercise of preferential subscription rights that may not be available to all of our shareholders, would reduce the proportionate ownership and voting power of the then-existing shareholders.

We are subject to different corporate disclosure standards that may limit the information available to holders of our ADSs.

As a foreign private issuer, we are not required to comply with the notice and disclosure requirements under the Exchange Act relating to the solicitation of proxies for shareholder meetings. Although we are subject to the periodic reporting requirements of the Exchange Act, the periodic disclosure required of foreign private issuers under the Exchange Act is more limited than the periodic disclosure required of U.S. issuers. Therefore, there may be less publicly available information about us than is regularly published by or about other public companies in the United States.

We currently do not intend to pay dividends, and cannot assure shareholders that we will make dividend payments in the future.

We have never paid any dividend on our shares and do not anticipate paying any dividends for the foreseeable future. Thereafter, declaration of dividends on our shares will depend upon, among other things, future earnings, if any, the

operating and financial condition of our business, our capital requirements, general business conditions and such other factors as our Board of Directors deems relevant. See Item 8, “Financial Information—Dividends and Dividend Policy.”

Judgments of U.S. courts, including those predicated on the civil liability provisions of the federal securities laws of the United States, may not be enforceable in French courts.

An investor in the United States may find it difficult to:

- effect service of process upon or obtain jurisdiction over us or our non-U.S. resident directors and officers in the United States;
- enforce U.S. court judgments based upon the civil liability provisions of the U.S. federal securities laws against us and our non-U.S. resident directors and officers in France; or the United States; or
- bring an original action in a French court to enforce liabilities based upon the U.S. federal securities laws against us and our non-U.S. resident directors and officers.

Holders of ADSs have fewer rights than shareholders and must act through the Depositary to exercise those rights.

Holders of ADSs do not have the same rights as shareholders and accordingly, cannot exercise rights of shareholders against us. The Bank of New York Mellon, as Depositary (the "Depositary"), is the registered shareholder of the deposited shares underlying the ADSs, and therefore holders of ADSs will generally have to exercise the rights attached to those shares through the Depositary. We have used and will continue to use reasonable efforts to request that the Depositary notify the holders of ADSs of upcoming votes and ask for voting instructions from them. If a holder fails to return a voting instruction card to the Depositary by the date established by it for receipt of such voting instructions, or if the Depositary receives an improperly completed or blank voting instruction card, or if the voting instructions included in the voting instruction card are illegible or unclear, then such holder will be deemed to have instructed the Depositary to vote its shares and the Depositary shall vote such shares in favor of any resolution proposed or approved by our Board of Directors and against any resolution not so proposed or approved.

Preferential subscription rights may not be available for U.S. persons.

Under French law, shareholders have preferential rights to subscribe for cash issuances of new shares or other securities giving rights to acquire additional shares on a pro rata basis. U.S. holders of our securities may not be able to exercise preferential subscription rights for their shares unless a registration statement under the Securities Act is effective with respect to such rights or an exemption from the registration requirements imposed by the Securities Act is available. We may, from time to time, issue new shares or other securities giving rights to acquire additional shares (such as warrants) at a time when no registration statement is in effect and no Securities Act exemption is available. If so, U.S. holders of our securities will be unable to exercise their preferential rights and their interests will be diluted. We are under no obligation to file any registration statement in connection with any issuance of new shares or other securities.
For holders of ADSs, the Depositary may make these rights or other distributions available to holders after we instruct it to do so and provide it with evidence that it is legal to do so. If we fail to do this and the Depositary determines that it is impractical to sell the rights, it may allow these rights to lapse. In that case the holders of ADSs will receive no value for them.

Holders of our ADSs may be exposed to increased transaction costs as a result of proposed European financial transaction taxes.

On February 14, 2013, the EU Commission adopted a proposal for a Council Directive (the "Draft Directive") on a common financial transaction tax (the "FTT"). According to the Draft Directive, the FTT should have been implemented and should have entered into effect in eleven EU Member States (Austria, Belgium, Estonia, France, Germany, Greece, Italy, Portugal, Spain, Slovakia, and Slovenia, the "Participating Member States") towards the middle of 2014. Pursuant to the Draft Directive, the FTT was to be payable on financial transactions provided at least one party to the financial transaction is established or deemed established in a Participating Member State and there is a financial institution established or deemed established in a Participating Member State which is a party to the financial transaction, or is acting in the name of a party to the transaction. The rates of the FTT were to be fixed by each Participating Member State but for transactions involving financial instruments other than derivatives would have amounted to at least 0.1% of the taxable amount. The taxable amount for such transactions was in general to be determined by reference to the consideration paid or owed in return for the transfer.

The Draft Directive has not been adopted. A proposal combining a broader scope and lower rates is currently being discussed between Participating Member States, with the objective to make the FTT applicable as from January 1, 2016.

Prospective holders should therefore note, in particular, that any sale, purchase, or exchange of the Shares or ADSs could become subject to the FTT. The holder may be liable to itself pay this charge or reimburse a financial institution

for the charge, and / or may affect the value of the Shares or ADSs.

The Draft Directive is still subject to negotiation between the Participating Member States and therefore may be changed at any time. Moreover, once the Draft Directive has been adopted (the "FTT Directive"), it will need to be implemented into the respective domestic laws of the Participating Member States and the domestic provisions implementing the FTT Directive might deviate from the FTT Directive itself. See Item 10, "Certain Income Tax Considerations."

Item 4. Information on the Company

We develop and market the Ablatherm and Focal One devices, advanced choices for HIFU treatment of localized prostate cancer. HIFU treatment is shown to be a minimally invasive and effective treatment option for localized prostate cancer with a low occurrence of side effects. Ablatherm is generally recommended for patients with localized prostate cancer (stages T1-T2) who are not candidates for surgery or who prefer an alternative option. It is also used for patients who failed a radiotherapy treatment. Focal One is a robot assisted HIFU device dedicated to the focal treatment of prostate cancer. In addition, we are developing HIFU technology for the treatment of certain other types of tumors. We also produce and commercialize medical equipment for treatment of urinary tract stones using ESWL and distribute other types of urology devices in certain countries.

History and Development of the Company

Our legal name is EDAP TMS S.A. and our commercial name is EDAP TMS. EDAP TMS S.A. was incorporated on December 3, 1979 as a société anonyme organized under the laws of the Republic of France for a duration of 60 years from the date of incorporation. Our principal executive offices are located at Parc d'Activités la Poudrette- Lamartine, 4/6, rue du Dauphiné, 69120 Vaulx-en-Velin, France and our telephone number is +33 (0) 4 72 15 31 50. Corporation Service Company, 1090 Vermont Avenue, Suite 430, Washington, D.C. 20005 – United States, is our agent for service of process in the United States.

Founded in 1979, we originally specialized in the manufacturing and distribution of lithotripters (devices which use shockwaves to disintegrate urinary calculi) and produced the first piezoelectric lithotripter (using electric shocks produced by a piezo-component) in 1985. In 1994, we acquired most of the assets of Technomed International S.A. (''Technomed'') out of liquidation, including the ownership of, and full distribution rights to, the Prostatron, the Sonolith series of lithotripters (Sonolith Praktis, Sonolith Vision) and the Ablatherm device.

In August 2011, we received marketing clearance from the U.S. Food and Drug Administration, or the FDA, for our Sonolith i-move device, a technologically advanced compact mobile lithotripter. The FDA has cleared our Sonolith i-move device for fragmentation of kidney stones, ESWL procedures and endourology applications.

On January 19, 2012, we entered into an Exchange Agreement with all of the holders of our outstanding 9% Senior Convertible Debentures due October 29, 2012 (the "October 2007 Convertible Debentures") and warrants, whereby all October 2007 Convertible Debentures and warrants were exchanged for New Debentures, 1,948,871 newly issued ordinary shares, new warrants (the "January 2012 Warrants") and $500,000 in cash, or a combination thereof.

On March 28, 2012, we issued 2,812,500 ordinary shares in the form of ADSs to certain institutional investors in a registered direct placement (the "March 2012 Placement"), at a price of $2.00 per share, with warrants attached that allow investors to purchase up to 1,406,250 shares in the form of ADSs, at an exercise price of $2.75 per share. We also issued warrants to purchase up to 168,750 shares to the placement agent, Rodman & Renshaw LLC, at an exercise price of $2.50 per share. On May 9, 2012, we used $2.0 million of the net proceeds from the March 2012 Placement to partially reimburse the New Debentures, thus reducing the amount outstanding under our New Debentures to $8.0 million.

On May 31, 2012, we aligned our management team to focus on the U.S. opportunities both in the lithotripsy market and the HIFU regulatory program and our CEO consequently relocated to the United States.

On January 31, 2013, we submitted our PMA application to the FDA for our Ablatherm HIFU device for treatment of low risk, localized prostate cancer. Our submission included data from the ENLIGHT U.S. Phase II/III clinical trial, as well as data from our extensive worldwide database of treatment information and follow-up data from patients who have undergone HIFU therapy for prostate cancer. On June 3, 2013 we held our 100-day meeting with

the FDA to discuss our PMA file and address questions and requests from the FDA reviewing team.

On May 28, 2013, we issued 3,000,000 ordinary shares in the form of ADSs to certain institutional investors in a registered direct placement (the "May 2013 Placement"), at a price of $4.00 per share, with warrants attached that allow investors to purchase up to 1,500,000 shares in the form of ADSs, at an exercise price of $4.25 per share. We also issued warrants to purchase up to 180,000 shares to the placement agent, HC Wainwright and Co. LLC, at an exercise price of $5.00 per share. Following our May 2013 Placement, on June 14, 2013, we fully redeemed our $8.0 million outstanding long-term debt by using a portion of the net proceeds from the $12.0 million May 2013 Placement.

On June 2, 2014, we issued 3,000,000 ordinary shares in the form of ADSs to certain institutional investors in a registered direct placement (the "June 2014 Placement"), at a price of $3.11 per share.

Following the June 3, 2014 meeting with FDA, we provided the FDA with the requested additional information on our PMA file and completed our set of answers to the FDA's questions on March 19, 2014.

On July 30, 2014, the FDA GUDP meeting was held in Washington DC to review our PMA file. The panel's experts voted negatively on the safety, efficacy and risk/benefit ratio for the use of our Ablatherm for the treatment of localized low risk prostate cancer.

On November 6, 2014, we received a letter from the FDA indicating that the Ablatherm was not approvable in its current form and providing specific guidance and recommendations as to a path forward. To continue with the approval process and conforming FDA recommendations, we were required to submit a major amendment to our PMA, including additional information requested by the FDA, by April 29, 2015.

On March 9, 2015, we announced that based on a recent meeting with the FDA, we plan to seek clearance of Ablatherm HIFU by way of a direct de novo 510(k) application as opposed to the PMA application amendment we had been pursuing.

The FDA indicated that while PMA approval would be required for specific claims regarding treatment of prostate cancer, a prostate tissue ablation claim could be cleared via a direct de novo 510(k) application. The de novo process was introduced by FDA for instances where a device is novel and there is therefore no suitable predicate device to support a standard 510(k) submission. To qualify for the de novo pathway, the new device must also present no more than moderate risk. Therefore, the Company plans to pursue a de novo pathway based on the discussions with FDA.

Business Overview & Strategy

EDAP TMS S.A. is a holding company and is responsible for providing common services to its subsidiaries, including preparation and consolidation of the financial statements for the group, complying with the requirements of various regulatory agencies and maintaining the listing of its publicly held securities and, in conjunction with its Board of Directors, directing the overall strategy of our group.

Our activity is organized in two divisions: HIFU and UDS (including lithotripsy activities). Through these two divisions, we develop, produce and market minimally invasive medical devices, mainly for urological diseases. We believe that the creation of these two divisions has allowed us to expand our market share by optimizing worldwide distribution capabilities, all of which is coordinated through our subsidiaries.

Our HIFU and UDS divisions operate in Europe, the Americas, Asia and the rest of the world. Total net sales for the HIFU division (in net contributions to total consolidated sales) were €8.2 million, €5.1 million and €5.6 million for 2014, 2013 and 2012, respectively. Those sales are generated in Europe and the rest of the world, excluding certain countries in Asia (including Japan) and the United States where our HIFU devices are not approved yet. Total net sales for the UDS division were €18.1 million (including €7.5 million in Asia and €10.6 million in Europe and the rest of the world), €19.0 million (including €8.2 million in Asia and €10.7 million in Europe and the rest of the world) and €20.4 million (including €11.4 million in Asia and €9.0 million in Europe and the rest of the world), each for 2014, 2013 and 2012, respectively.

See Note 26 to our consolidated financial statements for a breakdown of total sales and revenue during the past three fiscal years by operating division and Item 5, "Operating and Financial Review and Prospects."

HIFU Division

The HIFU division is engaged in the development, manufacturing and marketing of medical devices based on HIFU technology for the minimally invasive treatment of urological and other clinical indications. Our HIFU business is quite seasonal and generally linked to lengthy hospital decision and investment processes. Hence our quarterly revenues are often impacted and fluctuate according to these parameters, generally resulting in a higher purchasing activity in the last quarter of the year. The HIFU division contributed €8.2 million to our consolidated net sales during the fiscal year ended December 31, 2014.

HIFU Division Business Overview

The HIFU division currently develops, manufactures and markets devices for the minimally invasive destruction of certain types of localized tumors using HIFU technology. HIFU technology uses a high-intensity convergent ultrasound beam generated by high power transducers to produce heat. HIFU technology is intended to allow the surgeon to destroy a well-defined area of diseased tissue without damaging surrounding tissue and organs, thereby eliminating the need for incisions, transfusions and general anesthesia and associated complications. The HIFU Division markets two HIFU devices: the Ablatherm and the Focal One. The Ablatherm is dedicated to the treatment of organ-confined prostate cancer, referred to as T1-T2 stage. Ablatherm can be used for patients who are not candidates for surgery or who have failed a radiotherapy treatment. Ablatherm is approved for commercial distribution in the European Union, South Korea, Canada, Australia, Taiwan, South Africa, New Zealand, the Philippines, Argentina, Mexico, Brazil, Russia, Venezuela, Peru and Ecuador.

With respect to the United States, following discussions with the FDA, we now plan to seek clearance of Ablatherm HIFU by way of a direct de novo 510(k) application as opposed to the PMA application amendment we had been pursuing. The FDA indicated that while PMA approval would be required for specific claims regarding treatment of prostate cancer, a prostate tissue ablation claim could be cleared via a direct de novo 510(k) application.

HIFU Division also produces and markets the Focal One device, a HIFU robotic device fully dedicated to the focal therapy of localized prostate cancer, thereby destroying targeted cancer cells only. Focal One is approved for commercial distribution in the European Union, Canada and Saudi Arabia. As of December 31, 2014, the HIFU division had an installed base of 98 Ablatherm machines, nine Focal One and 295 trained clinical sites worldwide were using this technology.

In addition to developing, manufacturing and marketing HIFU devices, the HIFU division also generates revenues from leasing equipment, as well as from the sale of disposables, spare parts and maintenance services. Our HIFU mobile treatment option provides access to the HIFU devices without requiring hospitals and clinics to make an up-front investment in the equipment. Instead, hospitals and clinics perform treatments using these devices and remunerate us on a RPP basis (i.e., on the basis of the number of individual treatments provided). With this model, once the treatment is established in the medical community, a permanent installation may become more attractive, leading to the sale of the device in some of the larger locations.

HIFU Division Business Strategy

The HIFU division's business strategy is to capitalize on its expertise in HIFU and its position in urology to achieve long-term growth as a leader in the development, manufacturing, marketing and distribution of minimally invasive medical devices for urological and other indications, using HIFU technology, while preserving patient quality of life. The HIFU division believes that minimally invasive treatments using HIFU could provide an alternative to current invasive therapies on the basis of reduced cost and reduced morbidity for a number of different indications. The key elements of the HIFU division's strategy to achieve that objective are:

- Provide Minimally Invasive Solutions to Treat Localized Prostate Cancer using HIFU. Building upon our established position in the ESWL market, our HIFU division is striving to become the leading provider of our minimally invasive treatment option for prostate cancer. We believe that there is a large market opportunity with an increase in incidence linked to the aging male population, an increase in screening and recent campaigns to increase awareness. We also believe that HIFU could represent a credible alternative to surgery, external beam radiotherapy, brachytherapy and cryotherapy for the treatment of organ-confined prostate cancer without the cost, in-patient hospitalization and adverse side effects associated with those therapies. With the growing demand for more focused treatments destroying the tumor only (focal therapy) while continuously controlling the disease, HIFU and its focused approach, is well positioned to address this new clinical approach. The HIFU division intends to achieve

this through a direct sales network in key European countries and through selected distributors in other European countries and in Asia. The HIFU division has built a strong clinical credibility based on clinical articles published in peer-reviewed journals. We ensure effective patient and physician education through a focused communication program. The HIFU division is seeking FDA approval to enter the U.S. market with our Ablatherm device. For more information on our FDA approval process, see “HIFU Clinical and Regulatory Status”.

- Achieve Long-Term Growth by Expanding HIFU Applications Beyond Prostate Cancer. The HIFU division's long-term growth strategy is to apply our HIFU technology toward the minimally invasive treatment of other medical conditions beyond prostate cancer. We believe that HIFU could represent an alternative to surgery and radiotherapy for the treatment of many tumors without the cost, in-patient hospitalization and adverse side effects associated with those therapies. The HIFU division is working on various other applications where HIFU could provide an alternative to current invasive therapies. We recently entered into a multi-partner liver cancer development project organized by the HECAM (HEpatocellular CArcinoma Multi-technological) consortium. This project aims at developing innovative diagnostic, imaging and therapeutic technologies to address liver cancer. EDAP's focus within the HECAM consortium is on developing a novel HIFU treatment for liver cancer in cooperation with its long-term academic partner INSERM and leading cancer centers. To fund this development program, EDAP will receive €2.4 million in non-dilutive financing from Bpifrance over the 5 year project period. In 2014, the HIFU division maintained expenses at levels similar to 2013 on research and development ("R&D") projects to develop HIFU applications beyond prostate cancer. The division is considering maintaining similar levels of R&D spending in 2015 and future years to strengthen its technological leadership in HIFU and expand its application beyond urology.

HIFU Products

Currently, the Company commercializes two products utilizing the HIFU technology. For both HIFU products, cell destruction by HIFU is accomplished by a combination of thermal and cavitation effects caused by focused application of piezoelectric-generated high-intensity ultrasound; HIFU procedures are performed under general or spinal anesthesia.

The Ablatherm is an ultrasound guided HIFU device for the treatment of organ-confined prostate cancer. It consists of a treatment module, including a HIFU endorectal probe, a control table with a computer and a computer screen, and a diagnostic ultrasound device connected to the treatment module. After insertion of an endorectal probe, the physician visualizes the prostate using ultrasound imaging and defines the area to be treated. The computer automatically calculates the optimum treatment distribution of lesions. During the treatment, the probe automatically moves and fires HIFU beams at each predefined lesion until the entire targeted area has been treated. At the same time, the physician is able to control and visualize the treatment in real time due to the integrated imaging system.

The Ablatherm is cleared for distribution in the European Union, South Korea, Canada, Australia, South Africa, New Zealand, the Philippines Taiwan, Mexico, Argentina, Brazil, Russia, Venezuela, Peru, Costa Rica and Ecuador. In support of our PMA for approval to enter the U.S. market, we filed data from our ENLIGHT U.S. Phase II/III clinical trial with the FDA on January 31, 2013. The FDA approval process is still ongoing. See ''—HIFU Division Clinical and Regulatory Status.''

The Focal One is a HIFU robotic device fully dedicated to the focal therapy of prostate cancer. Focal One combines the three essential components to efficiently perform a focal treatment of localized prostate cancer: (i) high-quality imaging to localize tumors with the use of magnetic resonance imaging (MRI) combined with real-time ultrasound, (ii) high precision of HIFU treatment focused on identified targeted cancer areas and (iii) immediate feedback on treatment efficacy utilizing Contrast-Enhanced Ultrasound Imaging. Focal One provides an effective and accurate ablative treatment of localized tumors with the capacities of being flexible and repeatable, while preserving patient quality of life. The Focal One device received CE Marking for European market clearance in June 2013 and is also approved in Canada and Saudi Arabia. We are also working to obtain clearance in other parts of the world.

HIFU Division Patents and Intellectual Property

As of December 31, 2014, the HIFU division's patent portfolio contained 37 patents consisting of 15 patents in the United States, 20 patents in the European Union and Japan and two patents in both Israel and the rest of the world.

They belong to 20 groups of patents covering key technologies related to therapeutic ultrasound principles, systems and associated software.

During 2014, one U.S. patent covering specific HIFU treatment parameters expired. One patent covering the multi-channels HIFU transducer design was granted in Europe. A second patent covering an original transducer shape was granted in Europe, as well. These two patents are specifically dedicated to new applications in which a large volume of tissue necrosis is required in a short time.

Fourteen additional patents covering certain other aspects of our HIFU technology in the European Union and Japan (six), the United States (four), and the rest of the world (four) are also under review. These patents relate to new transducer designs and associated electronics. One specifically covers the new technology embedded in the Focal One device. This patent was filed in France in 2013 and extended to Europe, Japan, the United States and China in 2014. Our ongoing research and development objectives are to maintain our leadership position in the treatment of prostate cancer and to extend the HIFU technology to new applications and minimally invasive systems. These research projects are conducted in cooperation with the French National Institute for Health and Medical Research ("INSERM") which give rise in some cases to the filing, followed by the grant of co-owned patents. We have entered into various license agreements with INSERM whereby we commit to pay a fixed amount of royalties to INSERM based on the net revenues generated from the sales of HIFU devices using co-owned patents. Under these agreements, which last for the life of each co-owned patents we have the exclusive right to the commercial use of the co-owned patents, including the right to out-license such commercial rights.

In August 2004, we licensed our HIFU technology for the specific treatment of the ‘‘cervicofacial’’ lesions, including the thyroid, to Theraclion, a French company created by our former director of research and development. On January 11, 2011, we extended the above license by granting Theraclion exclusivity for the treatment of benign breast tumors and by granting a non-exclusive license for the treatment of malignant breast tumors. This license agreement provides for the payment of certain royalties calculated on the basis of Theraclion's future sales of devices. We determined that we could not invest in these specific applications at that time and this license agreement therefore allows Theraclion to pursue the development of HIFU for these applications. We own no interest in Theraclion. In December 2012, Theraclion obtained CE Marking for their HIFU device dedicated to the treatment of benign breast tumors.

Although we believe that our HIFU patents are valid and should be enforceable against third parties and that our patent applications should, if successfully pursued, result in the issuance of additional enforceable patents, there can be no assurance that any or all of these patents or patent applications will provide effective protection for the HIFU division's proprietary rights in such technology. HIFU devices, as they are currently or may in the future be designed, may also be subject to claims of infringement of patents owned by third parties, which could result in an adverse effect on our ability to market HIFU systems. See Item 3, "Risk Factors – Risks relating to Intellectual Property Rights."

HIFU Division Clinical and Regulatory Status

Clinical and Regulatory Status in Europe

The HIFU division has conducted an extensive clinical trial for the Ablatherm in the European Union. This trial, the European Multicentric Study, involved a total of 652 patients suffering from localized prostate cancer and included six sites in France, Germany and The Netherlands. The primary goals of the trial were to assess the safety and effectiveness of the Ablatherm. The diagnosis of prostate cancer has two steps. The first step is the evaluation of the Prostate Specific Antigen ("PSA"), which although not specific to cancer tumors, measures the increase of cells' activity inside the prostate. During the second step a sextant biopsy is performed inside the prostate to reveal the presence of a tumor. An interim analysis performed on the first 559 patients included 402 patients treated with the Ablatherm device as a first-line therapy. Of these patients, 81.4% had a normal PSA and 87.2% had negative biopsies at the last follow-up and were considered cancer free. The trials also included 157 patients who underwent an Ablatherm treatment as a salvage therapy after a previous failed therapy (hormone therapy, radiation or prostatectomy). Of these patients, 80.7% and 67.9% had negative biopsies and normal PSA after treatment, respectively.

Based on these results, in May 1999, we obtained a CE Marking that allows us to market the Ablatherm in the European Union.

Clinical and Regulatory Status in France

In 2001, the French Urology Association (‘‘AFU’’) conducted an independent clinical trial to confirm the efficacy and safety results observed in the European Multicentric Study, and to evaluate the therapy-related costs. Patient recruitment was successfully performed at eight investigational sites. Patient enrollment was completed in an 11-month period with 117 patients included. Patient follow-up is ongoing, with intermediate assessment at one year. The two-year follow-up results were presented at the AFU congress in November 2004. Follow-up with these patients will continue to evaluate the long-term efficacy of the treatment.

In March 2004, we obtained CE Marking, which currently allows us to market Ablatherm for the treatment of patients who failed radiotherapy.

In 2005, a clinical trial was started in France to validate the efficacy and safety of Ablatherm as rescue treatment in patients after brachytherapy failure. This clinical study was successfully completed in 2011 with satisfactory safety and efficacy results. Following the study, in January 2012, we submitted to the European certification body an

application for an extension of Ablatherm CE marking addressing brachytherapy failures. Extension was accepted in February 2012.

In 2007, a new clinical trial using Ablatherm and dedicated to the treatment of patients with high risk disease who are not candidates for radical surgery because of their age and/or co-morbidities was started in France. This clinical trial was terminated in March 2012 due to low patient enrollment.

Also in 2007, a clinical trial to evaluate the utility of Contrast-Enhanced UltraSound ("CEUS") for the early diagnosis of local cancer recurrence after HIFU treatment was started in France. The preliminary results assessed that contrast-enhanced ultrasound is efficient in distinguishing residual viable prostate tissue from ablated tissue after HIFU prostate ablation. This study provides evidence that contrast ultrasound can diagnose early cancer recurrences. In May 2011, preliminary results related to good detection potential of CEUS after HIFU treatment, were published by Edouard Herriot Hospital, Lyon, France, in the journal Radiology. Patient follow-up was completed in February 2012. CEUS technology was adopted for use in the new Focal One HIFU device.

In 2009, a new clinical trial was started in France to validate a new strategy of minimally invasive treatment of prostatic adenocarcinomas localized in a single lobe with HIFU. This concept of partial treatment is proposed as an intermediate option between active surveillance and whole prostate treatment. Partial treatment for this trial is hemiablation of the prostate in which a single prostatic lobe is ablated using HIFU in patients with prostate cancer that has a low risk of recurrence and for which the imaging and biopsy assessments show a unilateral cancer. The goal of hemiablation is to reduce the complications associated with standard treatments, notably the risks of incontinence and impotence. Clinical trial is still underway. Over the past three years, more investigational centers have been included in the study and, currently 20 French investigational centers are recruiting patients. Positive outcomes stemming from the trial were presented for the first time at the French Association of Urology conference in November 2012 and 2013.

In September 2010, a new clinical trial commenced in France and Norway to validate the new strategy of hemi-ablation treatment in radio-recurrent prostate cancer localized in a single lobe. This objective of focal treatment in patients with prostate cancer recurrence after radiotherapy is to reduce the risks of side effects in a very fragile population of patients. The preliminary results of the study were presented in June 2012 at the 5th International Symposium on Focal Therapy and Imaging in Prostate and Kidney Cancer at Duke University (NC, USA). This clinical trial has been expanded to include a cohort of 100 patients and to confirm the preliminary outcomes obtained on the first 48 patients.

In June 2011, a new clinical trial began in France and then extended to Belgium in 2012 to evaluate the new technical improvements in HIFU technology: the Dynamic Focusing technology. This technology gives the ability to target a more precise area within the prostate making the dynamic focusing technology the perfect tool for focal therapy. It also allows for the treatment of bigger prostates and for a more precise contouring of the gland providing a better control over sensitive areas responsible for continence and sexual functions. As a result, the Dynamic Focusing technology has been incorporated into the new Focal One HIFU device.

In January 2014, a new clinical trial on multifocal HIFU treatments with the Focal One device began in France in six investigational centers. The aim of this study is to evaluate the efficacy and safety results of different focal HIFU treatment strategies. Thanks to Focal One technical capacities (Dynamic Focusing technology, elastic fusion of MRI and ultrasound images and Contrast Enhanced Ultrasound treatment validation) many focal treatments approaches are possible allowing for treatment that is individually tailored to the patient's disease. In January 2015, the last patient was included in the above study, clinical results will be analyzed after 12 months follow-up.

Clinical and Regulatory Status in the United States

In December 2001, our request for an additional Investigational Device Exemption ("IDE") from the FDA to conduct clinical trials in the United States for the Ablatherm as a primary therapy was rejected. After redesigning the clinical protocol, we resumed the clinical trials in order to obtain FDA approval of the Ablatherm.

In March 2009, facing patient enrollment issues on the cryoablation comparative arm of the U.S. ENLIGHT study, we met with the FDA to propose alternatives to the approved protocol and its prospective comparative study.

In December 2009, a Gastroenterology and Urology Devices Panel of the Medical Devices Advisory Committee (the "2009 Panel") was convened by the FDA which clearly indicated that prospective data was recommended for endpoint evaluation of treatments for localized prostate cancer. As a result of the 2009 Panel's discussion, we met with the FDA in January 2010 to further address options and alternatives to move forward with our HIFU trial in the U.S. The FDA confirmed the 2009 Panel's recommendation for a prospective study and reiterated the 2009 Panel's concerns regarding the concept of patient randomization and the follow-up period.

After thoroughly evaluating all options based on input from our clinical and regulatory advisors, in April 2010, we decided to discontinue enrollment of patients in the HIFU comparative arm of the study and informed the FDA of such decision. We completed the treatment of 134 patients in June 2010 the required two year follow-up phase was completed in June 2012. Clinical outcomes from these patients combined with our strong European long-term database formed the foundation of our PMA submission to the FDA on January 31, 2013.

On March 4, 2013, we received a positive administrative acceptance review notification from the FDA for our PMA application and on March 26, 2013, we received a Filing Review Notification from the FDA confirming that our PMA file contained all of the information needed to proceed with the substantive review.

On June 3, 2013 we held our 100-day meeting with the FDA to discuss our PMA file and to address the questions and requests from the FDA reviewing team. Following the 100-day meeting, we provided the FDA with the requested additional information on our PMA file and on March 19, 2014, we completed our set of answers to the FDA's questions.

On July 30, 2014, the FDA GUDP meeting of experts was held to review our PMA. The panel voted negatively on the safety, the efficacy and the risk/benefit ratio for the use of our Ablatherm for the treatment of low-risk localized prostate cancer.

On November 6, 2014, we received a letter from the FDA indicating that the Ablatherm was not approvable in its current form and providing specific guidance and recommendations as to a path forward. These recommendations included (i) altering the indication for use to specify a patient population called "intermediate risk" and (ii) the possibility of using our existing European registry of patients as well as safety data from our previous IDE to support our PMA file. To continue with the approval process, and conforming FDA recommendations, we must submit a major amendment to our PMA, including additional information requested by the FDA, by April 29, 2015.

On March 9, 2015, we announced that based on a recent meeting with the FDA, we plan to seek clearance of Ablatherm HIFU by way of a direct de novo 510(k) application as opposed to the PMA application amendment we had been pursuing.

The FDA indicated that while PMA approval would be required for specific claims regarding treatment of prostate cancer, a prostate tissue ablation claim could be cleared via a direct de novo 510(k) application. The de novo process was introduced by FDA for instances where a device is novel and there is therefore no suitable predicate device to support a standard 510(k) submission. To qualify for the de novo pathway, the new device must also present no more than moderate risk. Therefore, the Company plans to pursue a de novo pathway based on the discussions with FDA.

Discussions with the FDA are still ongoing on the information required to support the application. Although our team is now diligently focused on preparing the de novo application, given the challenging recommendations of the FDA with regards to our Ablatherm approval process, we do not know when we will be able to submit our de novo application. Once we submit our de novo application, the review of our submission may take longer than expected or may not meet the FDA's requirements which could delay approval, if we receive it at all.

See Item 3, “Risk Factors” – “We operate in a highly regulated industry and our future success depends on government regulatory approval of our products, which we may not receive or which may be delayed for a significant period of time.”

Clinical and Regulatory Status in Japan

In June 2000, the HIFU division applied for approval by the Japanese Ministry of Health for the Ablatherm to be marketed in Japan. We retrieved the application in 2005 to update it and review the process. We are still assessing the opportunity to file a new application. The process of requesting approval to market the Ablatherm in Japan may be long and may never result in the approval to market the Ablatherm in Japan. See Item 3, ‘‘Key Information—Risk Factors—Our future revenue growth and income depend, among other things, on the success of our HIFU technology.’’

Clinical and Regulatory Status in China

On August 2, 2010, we entered into an exclusive distribution agreement with Shaw Han Biomedical Co. Ltd to distribute Ablatherm throughout China, once approved by Chinese authorities. This agreement involves a two-stage process: Shaw Han will first be responsible for processing the marketing clearance application with China's Food and Drug Administration for Ablatherm, then they will lead the marketing and distribution of the device in China for four years post approval. As of the date of this annual report on Form 20-F, the marketing clearance application was still is progress with the Chinese authorities.

HIFU Clinical Data

To date, our clinical Ablatherm results have been published in more than 75 renowned peer-reviewed journals. In 2010, the results of a major multicentric study on 803 patients were published showing a local control of the disease in 77.9% of the patients. In 2013, three long-term studies presenting results obtained over a period of more than 14 years on 538 patients, 704 patients and 1002 patients were published, showing excellent cancer-specific and metastasis-free survival in primary patients (Ganzer et al. BJU 2013, Thuroff et al. Journal of Urology 2013 and Crouzet et al. European Urology 2013).

In 2014, the first clinical results of focal treatments with Ablatherm were published by Baco et al. in the British Journal of Urology International ("BJUInt") and Van Velthoven et al. in Prostate Cancer magazine. Baco et al. published promising results of hemi-salvage HIFU (treatment of one lobe of the prostate) after External Beam Radiation Therapy ("EBRT") and brachytherapy recurrences. In this fragile population of patients, the treatment of the infected lobe is reported to provide better functional outcomes and preserves quality of life. A similar approach of HIFU prostate hemi-ablation was presented by Van Velthoven et al. for primary care patients. With a maximum follow-up of 61 months the study showed a rate of 100% full continence and 75% erectile function preservation combined with only 11% of salvage treatment (re-HIFU in the contralateral lobe). Authors concluded primary zonal HIFU is a valid focal therapy strategy, safe and feasible in a day-to-day practice showing good promising results.

We have set up an extensive worldwide patient database called "@-registry." This on-line database is designed to compile treatment information and follow-up data for patients who have undergone HIFU for prostate cancer. The goal of the @-registry is to further demonstrate the safety, effectiveness and durability of Ablatherm. Information from the registry will be submitted to medical conferences for presentation and to peer-reviewed medical journals for publication. Based on more than 10,000 patients included into our @-registry database, we presented at the European Association of Urology (EAU) held in Paris in February 2012, an abstract presentation covering 5,662 primary patients, and an abstract covering 929 patients treated with Ablatherm after radiorecurrence with seven years follow-up that was elected "best poster" by the scientific committee. Thüroff et al presented a poster at the American Urology Association (AUA) 2014 on the long term HIFU retreatment rate, evaluating 2,632 patients. Thüroff et al concluded that technical development and adjuvant transurethral radical prostatectomy ("TURP") before HIFU resulted in higher local efficacy and lower HIFU retreatment rates.

HIFU Division Market Potential

Prostate cancer is currently the first or second most common form of cancer among men in many populations. In the United States, the American Cancer Society estimates the number of new prostate cancers diagnosed every year to be approximately 220,800, of which approximately 70% are diagnosed with localized stage prostate cancer. Additionally, the HIFU division believes, based on figures provided by the World Health Organization that the worldwide incidence of localized prostate cancer is approximately twice this U.S. figure. A more effective diagnostic method for prostate cancer, the PSA test, has increased public awareness of the disease in developed countries since its introduction. PSA levels jump sharply when cancer is present. Prostate cancer is an age-related disease, and its incidence in developed countries is expected to increase as the population ages.

The HIFU division believes that HIFU therapy could be expanded to other medical conditions, such as certain localized thyroid, breast, gynecological, bladder, kidney, liver, brain, pancreatic and retroperitoneal tumors. For example, we recently entered into a multi-partner liver cancer development project organized by the HECAM (HEpatocellular CArcinoma Multi-technological) consortium. This project aims at developing innovative diagnostic, imaging and therapeutic technologies to address liver cancer. EDAP's focus within the HECAM consortium is on developing a novel HIFU treatment for liver cancer in cooperation with its long-term academic partner INSERM and leading cancer centers. To fund this development program, EDAP will receive €2.4 million in non-dilutive financing from Bpifrance over the 5 year project period. However, the expansion of the use of HIFU to other areas of treatment will require a significant investment in research and development, an investment we will undertake gradually while focusing on the acceptance of HIFU as a treatment for localized prostate cancer. For example, our licensee, Theraclion, obtained CE Marking for their HIFU device dedicated to the treatment of benign breast tumors. See Item 4, "HIFU Division Patents and Intellectual Property."

HIFU Competition

The principal current therapies for prostate cancer carry side effects that can seriously affect a patient's quality of life. One of the current therapies is radical prostatectomy (surgery), which involves the ablation of the entire prostate gland. Radical prostatectomy requires several days of hospital stay and several weeks of recovery, usually with catheterization, and may result in partial and/or total urinary incontinence. In addition, it almost invariably renders patients impotent. A new surgical technique, nerve-sparing prostatectomy, has been developed to address that problem. However, the procedure can only be applied when the tumor is not located close to the surface of the prostate and requires a very skilled surgeon. Other therapies for localized prostate cancer include brachytherapy, a therapy that involves the implantation of radioisotopes into the prostate gland, EBRT and cryotherapy.

Our HIFU devices compete with all current treatments for localized tumors, which include surgery, brachytherapy, radiotherapy, cryotherapy and hormonotherapy. We believe that HIFU competes against those treatments on the basis of efficacy, limited side effects and cost-effectiveness.

We also believe that Focal One will be well positioned to address the growing demand for a "focal" approach of localized prostate cancer which cannot be answered by surgery or radiation therapy. "Focal" treatment (also known as "partial" or "zonal" treatment, as opposed to "radical" treatment) provides an effective and accurate ablative treatment of localized tumors with the capacities of being flexible and repeatable, while preserving patient quality of life.

Other companies are working with HIFU for the minimally invasive treatment of tumors. See Item 3, "Risk Factors – Risks Relating to Competition."

Certain existing and potential competitors of our HIFU division may have substantially greater financial, research and development, sales and marketing and personnel resources than us and may have more experience in developing, manufacturing, marketing and supporting new products. We believe that an important factor in the potential future market for HIFU treatments will be the ability to make the substantial investments in research and development in advancing the technology beyond the treatment of prostate cancer. This future investment is wholly dependent on the successful acceptance of the device for the treatment of prostate cancer.

HIFU Division Sales and Distribution of Products

The HIFU division markets and sells its products through our own direct marketing and sales organization as well as through selected third-party distributors and agents in several countries. Using our direct subsidiaries or representative offices network, the HIFU division maintains direct marketing and sales forces in France, Germany, Russia and Italy, which currently represent its largest HIFU markets. Additionally, the HIFU division markets and sells its products through our distribution platform in the Middle East, South Korea and South East Asia.

The HIFU division's customers are located worldwide and have historically been principally public and private hospitals and urology clinics. The HIFU division believes that as it increases its customer base it will gain further access to the urological community, which will enable it to monitor the urological market, introduce new products and conduct trials under satisfactory conditions. No single customer of the HIFU division represents a significant portion of the division's installed base.

The HIFU division's marketing efforts include the organization of information and training programs for urologists, mainly in key European countries where HIFU awareness is growing, comprehensive media and web programs to educate patients on the availability of HIFU technology to treat localized prostate cancer and strong participation in focused dedicated urological events. Our dedicated web site www.hifu-planet.com for patients and physicians is visited regularly. The information contained on that website is not incorporated by reference herein.

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UDS Division

The UDS division is engaged in the development, marketing, manufacturing and servicing of medical devices for the minimally invasive diagnosis or treatment of urological disorders, mainly urinary stones, and other clinical indications. The UDS division contributed €18.1 million to our consolidated net sales during the fiscal year ended December 31, 2014.

Our UDS business is quite seasonal and generally linked to lengthy hospital decision and investment processes and their activities. Hence our quarterly revenues are often impacted and fluctuate according to these parameters, generally resulting in a higher selling activity in the last quarter of the year.

UDS Division Business Overview

The UDS division's primary business is producing and marketing devices, known as lithotripters, for the treatment of urinary tract stones by means of ESWL technology. ESWL uses extracorporeal shockwaves, which can be focused at urinary stones within the human body to fragment the stones, thereby permitting their natural elimination and preventing the need for incisions, transfusions, general anesthesia, and the resulting complications. The UDS division currently manufactures two models of lithotripters: the Sonolith i-move and the Sonolith i-sys. As of December 31, 2014, the UDS division has sold 775 ESWL lithotripters worldwide to this date and actively maintained or otherwise serviced 608 installed lithotripters.

In addition to its manufacturing and selling of lithotripters, the UDS division also generates revenues from the leasing of lithotripters, as well as from the sale of disposables, spare parts and maintenance services.

UDS Division Business Strategy

The business strategy for the UDS division is to capitalize on its expertise in ESWL and its position in urology to achieve long-term growth as a leader in the development, production, marketing and distribution of minimally invasive medical devices for urological and other clinical indications. The UDS division manufactures its own products as part of EDAP TMS France SAS ("EDAP TMS France"), our wholly owned subsidiary. The key elements of the UDS division's strategy are:

- Capitalize on the Current ESWL Installed Base. The UDS division's long-term growth strategy relies on its ability to capitalize on its extensive installed base of ESWL lithotripters to recognize ongoing revenue from sales of disposables, accessories, services and replacement machines. We believe that a combination of continued investment in lowering end-user costs and offering innovative units that are easily adaptable to various treatment environments, as well as a commitment to quality and service will allow the UDS division to achieve this goal. See ''—UDS Division Products''.

- Capitalize on an Established Distribution Platform in Urology by Expanding Distribution Possibilities. We believe that we can achieve additional long-term growth by offering our established distribution platform in urology to other developers of medical technologies and acting as a distributor for their devices. Our distribution platform in urology consists of a series of well-established subsidiaries in Europe and Asia as well as a network of third-party distributors worldwide.

- Provide Manufacturing Solutions to Other Developers of Medical Technologies. Building upon its established position in the high-tech medical devices market, we believe that the UDS division can become a provider of manufacturing alternatives to other developers of medical technologies that do not have or do not wish to invest in their own manufacturing facilities. We believe that our FDA-inspected, ISO 9001 (V:2008) certified and ISO 13485 (V:2003) certified facilities allow us to offer manufacturing services to a wide range of potential medical equipment

developers.

UDS Division Products

The UDS division offers the Sonolith i-move (replacing Sonolith Praktis) to small and mid-size hospitals, while the Sonolith i-sys is offered to large hospitals that can afford a fully dedicated and integrated lithotripter. The UDS division also sells disposable parts for lithotripters, including the piezoelectric elements of the LT02, a machine we discontinued manufacturing in 2002) and the electrodes of the Sonolith line, which need to be replaced approximately every ten treatments, respectively. These parts incorporate key proprietary technologies, and the UDS division has retained sole marketing rights for these parts.

Product	Procedure	Development Stage	Clinical and Regulatory Status
Sonolith i-move	Electroconductive treatment of urinary stones	Commercial Production	Approved for distribution: European Union South Korea South-East Asia Peru Colombia Venezuela Japan United States Taiwan Singapore Costa Rica Mexico Saudi Arabia Brazil
Sonolith i-sys	Electroconductive treatment of urinary stones	Commercial Production	Approved for distribution: European Union South Korea United States Japan Australia Colombia Peru South-East Asia Argentina Venezuela Taiwan Mexico Costa Rica Saudi Arabia Singapore

The Sonolith i-move and the Sonolith i-sys rely on the electroconductive technology for shockwave generation. The electroconductive technology, which is derived from the electrohydraulic technology on which the first ESWL lithotripters were based, permits improved focusing of the shockwave, reduces the variability in the shockwave pressure and allows a better transfer of energy to the calculus. These features result in a faster, more effective treatment as compared to electrohydraulic lithotripters.

The UDS division's ESWL customers are located worldwide and have historically been principally large hospitals, urology clinics and research institutions. To increase its penetration of the market segment of smaller hospitals and outpatient clinics, the UDS division developed the Sonolith i-move, an electroconductive lithotripter designed for smaller clinics. It is more compact than the Sonolith i-sys, which is more fully integrated and dedicated to larger hospitals and can be used as a urological workstation to perform endourological procedures. The Sonolith i-move, launched in 2010, brings a novel approach to the market by offering a wide range of configurations to suit various budgets and various local market needs. The Sonolith i-move has also been very successful thanks to its innovative

Visio-Track ultrasound stone localization: a unique three dimensional virtual system that uses infrared stereovision technology to guide the treatment robotically.

UDS Division Patents and Intellectual Property

As of December 31, 2014, the UDS division's patent portfolio contained nine patents consisting of one patent in the United States, six patents in the European Union and Japan and two patents in both Israel and the rest of the world. They belong to five groups of patents covering key technologies relating to ESWL systems and associated software capabilities.

Six patents, two in the United States, and four in the European Union and in Japan, are also in the examination process. These patents concern Sonolith i-sys and Sonolith i-move lithotripters. The UDS division's patents cover both piezoelectric and electroconductive technologies associated to ESWL generator, localization systems and device design. The UDS division's ongoing R&D objectives in ESWL are to further increase the clinical efficacy, the cost-effectiveness and the ease of use of its products to make them accessible to wider patient and user populations.

As with the development of our HIFU technology, we cooperate with INSERM to develop our ESWL technology. This cooperation gave rise to co-owned patents in some cases. We have entered into various license agreements with INSERM whereby we commit to pay a fixed amount of royalties to INSERM based on the net revenues generated from the sales of ESWL devices using co-owned patents. Under these agreements, we have the exclusive right to the commercial use of the co-owned patents, including the right to out-license such commercial rights.

UDS Division Regulatory Status

The Sonolith i-move is available for commercial distribution in the European Union, South Korea, South-East Asia, Peru, Venezuela, Colombia, Costa Rica, Japan, United States, Taiwan, Singapore, Saudi Arabia, Mexico and Brazil. The Sonolith i-sys is available in the European Union, South Korea, Canada, United States, Peru, Colombia, Argentina, Venezuela, Mexico, Costa Rica, Japan, Australia, South-East Asia, Singapore, Saudi Arabia and Taiwan. The UDS division continues to provide disposables, replacement parts and services for the current installed base of LT02 machines and Sonolith Praktis, even though we discontinued the manufacture of these machines.

UDS Division Market Potential

We estimate that roughly 2% to 3% of the world population suffers from kidney or ureteric stones during their lifetime and that urinary calculi are responsible for 10% of urological hospital admissions worldwide. Although urinary calculi may be eliminated naturally by the body, natural elimination is frequently accompanied by considerable pain and very often by serious complications, such as obstruction and infection of the urinary tract.

Since its introduction in clinical practice 30 years ago, ESWL has become the standard treatment for urinary calculi. ESWL consists of fragmenting calculi within the body using extracorporeal shockwaves without any surgery. We believe that the market for lithotripters includes both buyers looking for a sophisticated, higher-priced machine (generally hospitals and larger urology clinics) and buyers looking for simpler and less expensive machines (typically smaller clinics). We also believe that after a period of fast growth in the mid-1980s and early 1990s, the market for lithotripters is now mature and has become primarily a replacement and service and maintenance market in most of the world. Several geographical opportunities remain in under-equipped countries or in some countries where the national health system strategy is being reviewed for hospitals and clinics equipment.

We believe that companies with a large installed base of ESWL lithotripters will be most successful in the replacement market. Consequently, we intend to capitalize on our share of the installed base of ESWL lithotripters to gain a significant position in the replacement market for those machines. We expect the ESWL business to continue to contribute, at historically consistent levels, to the UDS division's financial results despite the mature nature of the market, due to revenues from maintenance contracts and demand for replacement machines. See Item 5, ''Operating and Financial Review and Prospects''.

UDS Division Competition

The ESWL market is characterized by severe price competition among manufacturers, with the result that, in recent years, the average unit price of ESWL lithotripters has declined The UDS division expects this trend to continue. See Item 5, ''Operating and Financial Review and Prospects.'' The UDS division's major competitors in developed countries are Siemens, Storz and Dornier.

UDS Division Sales and Distribution of Products

The UDS division markets, sells and services its products through our direct sales and service platform in France, Italy, Germany, United States, Japan, South Korea, Malaysia and, most recently, in the United Arab Emirates through our representative office in Dubai. The UDS division also markets its products through agents and third-party

distributors in several other countries.

The UDS division's customers are located worldwide and have historically been mainly public and private hospitals and urology clinics. We believe that the division's customer base provides it with excellent access to the urological community and enables it to introduce new products and conduct trials under satisfactory conditions.

No single customer of the UDS division represents a significant portion of the division's installed base. The UDS division's marketing efforts include the organization of training programs for urologists worldwide.

UDS Division Services and Distribution

The UDS division is also pursuing various distribution options that use its strong network of worldwide subsidiaries and agents. The UDS division distributes urodynamics products on behalf of MMS (Medical Measurement Systems) and Andromeda in Japan, and laser urology solutions from Lumenis in France. We believe that the UDS division can successfully market its worldwide distribution platform to a wide range of medical equipment development companies, thus allowing for quick, easy and economically sound entry for these companies into markets covering most of the world.

Manufacturing

Our current manufacturing operations consist of manufacturing medical products in our FDA-approved facility, which is certified under international standards ISO 9001 and ISO 13485. We believe that this facility can extend its outsourced services to provide device and disposable development and manufacturing services to a wide range of medical equipment development companies. Each division manufactures its own products through EDAP TMS France.

We manufacture the critical components for our devices and accessories, unless a subcontractor can manufacture the component more cost-effectively, perform final assembly and quality control processes and maintain our own set of production standards. We purchase the majority of the raw materials used in our products from a number of suppliers, but for several components of our products, rely on a single source. Furthermore, we conduct regular quality audits of suppliers' manufacturing facilities. Our principal suppliers are located in France, Germany, Denmark, South Korea and the United States. Management believes that the relationships with our suppliers are good.

Quality and Design Control

The manufacturing operations of EDAP TMS France must comply with the GMP regulations enacted by the FDA, which establish requirements for assuring quality by controlling components, processes and document traceability and retention, among other things. EDAP TMS France's facilities are also subject to scheduled inspections by the FDA. The FDA last visited our manufacturing site in June 2014 with no findings nor issuance of Form 483 observations. EDAP TMS France has obtained the ISO 9001 (V:2008) and ISO 13485 (V:2003) certifications, which indicate compliance by EDAP TMS France's manufacturing facilities with international standards for quality assurance, design and manufacturing process control. EDAP TMS France also complies with the applicable requirements that will allow it to affix the CE Marking to certain of its products. Our manufacturing site also complies with Taiwanese, Japanese and Canadian regulations, as well as with the U.S. Quality System Regulation. See ''—Government Regulation—Healthcare Regulation in the United States'' and ''—Government Regulation—Healthcare Regulation in the European Union.''

Property and Equipment

We have one principal facility, which is located in Vaulx-en-Velin, on the outskirts of Lyon, France. The premises comprise 4,150 square meters and are leased to us under a renewable nine-year commercial lease agreement signed on November 1, 2011. We use this facility to manufacture our device portofolio. We believe the terms of the lease reflect commercial practice and market rates. The manufacturing facility, and principal offices, which we utilize to manufacture and/or assemble all of our products, have ISO 9001 and ISO 13485 certifications. We are not aware of any environmental issues that could affect utilization of the facility.

In addition, we lease office and/or warehouse facilities in Kuala Lumpur (Malaysia), Rome (Italy), Flensburg (Germany), Austin (U.S.), Moscow (Russia), Seoul (South Korea), Fukuoka, Osaka, Sapporo and Tokyo (Japan).

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Organizational Structure

The following table sets forth the fully consolidated subsidiaries of the Company as of the date of this annual report:

Name of the Company	Jurisdiction of Establishment	Percentage Owned(1)
EDAP TMS France SAS	France	100%
EDAP Technomed Inc.	United States	100%
EDAP Technomed Co. Ltd	Japan	100%
EDAP Technomed Sdn Bhd	Malaysia	100%
EDAP Technomed Srl	Italy	100%
EDAP TMS GmbH	Germany	100%

(1) Percentage of equity capital owned by EDAP TMS S.A. directly or indirectly through subsidiaries (percentage of capital owned and voting rights are the same).

Government Regulation

Government regulation in our major markets, in particular the United States, the European Union and Japan, is a significant factor in the development and marketing of our products and in our ongoing research and development activities. See Item 3, “Risk Factors –Risks Related to Government Regulations.”

Regulation in the United States

We and our products are regulated in the United States by the FDA under a number of statutes including the Federal Food, Drug and Cosmetic Act (‘‘FDC Act’’). Pursuant to the FDC Act, the FDA regulates the preclinical and clinical testing, manufacturing, labeling, distribution, sale, marketing, advertising and promotion of medical devices in the United States. Medical devices are classified in the United States into one of three classes - Class I, II or III - on the basis of the controls reasonably necessary to ensure their safety and effectiveness. Class I devices are those whose safety and effectiveness can be ensured through general controls, such as establishment and registration, medical device listing, FDA-mandated CGMP, labeling, and pre-market notification (known as ‘‘510(k)’’). Most Class I devices are exempt from premarket notification and/or GMP regulations. Class II devices are those whose safety and effectiveness can reasonably be ensured through the use of general controls and ‘‘special controls,’’ such as special labeling requirements, mandatory performance standards, and post-market surveillance. The FDA may require the submission of clinical data as part of pre-market notifications for Class II devices. The FDA recently introduced the de novo 510(k) process for Class II devices for instances where a device is novel and there is therefore no suitable predicate device to support a standard 510(k) submission. To qualify for the de novo pathway, the new device must also present no more than moderate risk. Class III devices are those that must receive PMA by the FDA to ensure their safety and effectiveness. Before a new Class III device may be introduced on the market, the manufacturer generally must obtain FDA approval of a PMA. The PMA process is expensive and often lengthy, typically requiring several years, and may never result in approval. The manufacturer or the distributor of the device must obtain an IDE from the FDA before commencing human clinical trials in the United States in support of the PMA. The lithotripsy range of products has been reclassified by the FDA as a Class II device. Our HIFU devices, Ablatherm or Focal One devices, have been classified so far as Class III devices and have not yet been approved by FDA. However, following a recent meeting with the FDA, the Agency indicated that while PMA approval would be required for specific claims regarding treatment of prostate cancer, a prostate tissue ablation claim could be cleared via a Direct De Novo 510(k) application. Advertising and promotional activities in the United States are subject to regulation by the FDA and, in certain instances, by the U.S. Federal Trade Commission. The FDC Act also regulates our quality control and manufacturing procedures by requiring us to demonstrate and maintain compliance with current GMP regulations. Our manufacturing facilities are in compliance with GMP regulations. No major deficiencies have been observed

during inspections carried out by FDA auditors (or its representative, the GMED, in France) in the past few years. In June 2014, the FDA conducted an inspection of our manufacturing processes and facility with no findings nor issuance of Form 483 observations.

Regulation in the European Union

In the European Union, we have received the ISO 9001 (V:2008) and ISO 13485 (V:2003) certifications, showing that we comply with standards for quality assurance and manufacturing and design process control. In the European Union, our products are also subject to legislation implementing the European Union Council Directive 93/42/EEC concerning medical devices (the ‘‘Medical Device Directive’’). The Medical Device Directive provides that medical devices that meet certain safety standards must bear a certification of conformity, the European Community approval ‘‘CE Marking.’’ Except in limited circumstances, member states of the European Union may not prohibit or restrict the sale, free movement or use for its intended purpose of a medical device bearing the CE Marking. Medical devices marketed throughout the European Union must comply with the requirement of the Medical Device Directive to bear a CE Marking (subject to certain exceptions). All of our products bear the CE Marking.

Pursuant to the Medical Device Directive, medical devices are classified into four classes, Class I, Class IIa, Class IIb and Class III, on the basis of their invasiveness and the duration of their use. The classification serves as a basis for determining the conformity assessment procedures that apply to medical devices to be eligible to receive a CE Marking. The conformity assessment procedures for Class I devices can be carried out, as a general rule, under the sole responsibility of the manufacturer, while for devices of other classes, the involvement of an authorized supervisory body is required. The extent of the involvement of such body in the development and manufacturing of a device varies according to the class under which it falls, with Class III devices being subject to the greatest degree of supervision. All of the devices currently marketed by us are Class IIb devices.

Regulation in Japan

The import and sales of medical devices in Japan is regulated by the Japanese Ministry of Health, Labor and Welfare (‘the “MHLW’’) under the license “Marketing Authorization Holder.”. Our Japanese subsidiary has obtained a general license as well as specific approvals to import our products that have been approved in Japan. The MHLW also administers various national health insurance programs to which each Japanese citizen is required to subscribe. These programs cover, among other things, the cost of medical devices used in operations. The MHLW establishes a price list of reimbursable prices applicable to certain medical devices under the national health insurance programs and until a new device is included in this list its costs are not covered by the programs. The LT02, the Sonolith Praktis, the Sonolith Vision, the Sonolith i-sys and the Sonolith i-move are all included on the MHLW’s list for reimbursement.

Item 4A. Unresolved Staff Comments

Not applicable.

Item 5. Operating and Financial Review and Prospects

The following discussion of our results of operations and liquidity and capital resources for the fiscal years ended December 31, 2014, 2013 and 2012 is based on, and should be read in conjunction with our consolidated financial statements and the notes thereto included in Item 18 of this annual report. The consolidated financial statements have been prepared in accordance with U.S. GAAP and refer to the new topic-based FASB Accounting Standards Codification (‘ASC’).

The following discussion contains certain forward-looking statements that involve risks and uncertainties. Actual results may differ materially from those contained in such forward-looking statements. See ‘‘Cautionary Statement on Forward-Looking Information’’ at the beginning of this annual report.

Critical Accounting Policies

The discussion and analysis of our financial condition and results of operations are based upon the consolidated financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States. The preparation of these financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, revenues and expenses, and related disclosure of contingent assets and liabilities. On an on-going basis, we evaluate our estimates, including those related to revenue recognition, accounts receivable, bad debts, inventories, warranty obligations, litigation and deferred tax assets. We base our estimates on historical experience and on various other assumptions that are believed to be reasonable under the circumstances. These estimates and assumptions form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

We believe our more significant judgments and estimates used in the preparation of our consolidated financial statements are made in connection with the following critical accounting policies.

Revenue Recognition

Sales of goods:

For medical device sales with no significant remaining vendor obligation, payments contingent upon customer financing or, acceptance criteria that can be subjectively interpreted by the customer or tied to the use of the device, revenue is recognized when evidence of an arrangement exists, title to the device passes (depending on terms, either upon shipment or delivery), and the customer has the intent and ability to pay in accordance with contract payment terms that are fixed or determinable. For sales in which payment is contingent upon customer financing, acceptance criteria that can be subjectively interpreted by the customer, or payment depends on use of the device, revenue is recognized when the contingency is resolved. We provide training and provide a minimum of one-year warranty upon installation. We accrue the estimated warranty costs at the time of sale. Revenues related to disposables are recognized when goods are delivered.

Sales of RPP treatments and leases:

Revenues related to the sale of HIFU treatments invoiced on a RPP basis are recognized when the treatment procedure has been completed. Revenues from devices leased to customers under operating leases are recognized on a straight-line basis.

Sales of spare parts and services:

Revenues related to spare parts are recognized when goods are delivered. Maintenance contracts rarely exceed one year and are recognized on a straight-line basis. Billings or cash receipts in advance of services due under maintenance contracts are recorded as deferred revenue.

Debentures and Warrants

Debentures

On October 29, 2007, the Company issued $20 million in aggregate principal amount of non-secured, convertible debentures due October 29, 2012 (the “2007 Convertible Debentures”) with detachable warrants (th