EDAP TMS SA
Form 20-F
April 03, 2014
As filed with the Securities and Exchange Commission on April 3, 2014

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

FORM 20-F

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

OR

ý ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(D) OF THE SECURITIES EXCHANGE ACT OF 1934
For the Fiscal Year Ended December 31, 2013

OR

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

OR

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 One Ordinary Share	NASDAQ Global Market
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, 2013: 21,789,670 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). Yes X 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 ____ Non-accelerated filer X

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

TABLE OF CONTENTS

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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 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 One devices;
- 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 to 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.

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, 2013, 2012 and 2011 and the selected income statement data for the years ended December 31, 2013, 2012 and 2011 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	2013	2012	2011	2010	2009
INCOME STATEMENT DATA					
Total revenues	24,080	26,065	22,292	23,708	24,885
Total net sales	24,065	26,018	22,272	23,202	24,839
Gross profit	9,319	10,433	8,857	9,455	10,672
Operating expenses	(12,074)	(12,463)	(11,353)	(13,272)	(13,874)
Income (loss from operations)	(2,755)	(2,030)	(2,497)	(3,818)	(3,202)
Income (loss) before income taxes	(4,886)	(7,358)	(543)	(11,778)	(7,694)
Income tax (expense) benefit	(135)	(118)	(395)	(939)	(72)
Net income (loss)	(5,021)	(7,475)	(938)	(12,717)	(7,766)
Basic earnings (loss) per share	(0.24)	(0.43)	(0.07)	(0.98)	(0.74)
Diluted earnings (loss) per share	(0.24)	(0.43)	(0.07)	(0.98)	(0.74)
Dividends per share(1)	—	—	—	—	—
Basic weighted average shares outstanding	20,593,720	17,556,395	13,345,004	13,008,401	10,510,305
Diluted weighted average shares outstanding	20,593,720	17,556,395	13,345,004	13,008,401	10,510,305
BALANCE SHEET DATA					
Total current assets	22,125	24,729	25,032	29,865	33,248
Property and equipment, net	1,655	2,035	2,534	2,877	3,288
Total current liabilities	11,589	13,124	19,717	14,658	15,175
Total assets	26,874	30,444	32,238	35,938	40,378
Long-term debt, less current portion	3,678	6,585	720	10,075	10,138
Total shareholders’ equity	9,284	8,161	8,714	8,900	12,579

(1) No dividends were paid with respect to fiscal years 2009 through 2012 and subject to approval of the annual shareholders' meeting to be held in 2014 the Company does not anticipate paying any dividend with respect to fiscal year 2013. 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
	€	€	€	€
2009	0.80	0.66	0.72	0.70
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

(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
	€	€	€	€
2013				
September	0.76	0.74	0.75	0.74
October	0.74	0.72	0.73	0.74
November	0.75	0.74	0.74	0.74
December	0.74	0.72	0.73	0.73
2014				
January	0.74	0.73	0.73	0.74
February	0.74	0.73	0.73	0.72
March, through March 21, 2014	0.73	0.72	0.72	0.73

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

On March 21, 2014, the Noon Buying Rate was U.S.$1.00 = 0.73€.

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, in 2011, 2012 and 2013, we had positive operating income in our Urology Devices and Services ("UDS") division, which however was not sufficient to offset the negative operating income in our HIFU 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 assure investors 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 recently launched Focal One is commercialized in the European Union. However, neither the Ablatherm nor the Focal One is approved for commercial distribution 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. Following the December 11, 2009 panel experts' recommendations 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 and completed the treatment of 134 patients in June 2010. The required two-year follow-up phase 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. 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 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 confirmation from the FDA that our PMA submission 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 with the reviewing team. Since then we have been providing all the requested additional information on our PMA file and on March 19, 2014, we completed our set of answers to the FDA's questions. As per the standard FDA review timeframe, the next step is a panel meeting

of experts expected to be held in the next four to six months.. Given the very challenging recommendations of the FDA with regards to our prospective study and its cryoablation comparative arm, there is a risk that 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, 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 PMA submission to the FDA for our Ablatherm device through completion of the approval process and our ongoing operations.

We have been funding our clinical trials to support the FDA PMA submission for our Ablatherm device using the $17.4 million net proceeds from a financing we completed in October 2007. As of December 31, 2013, we had €7.7 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 PMA submission to the FDA for our Ablatherm through completion of the approval process, we may need to raise additional capital in the event of significant delays in the FDA PMA approval. 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.

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 Gastroenterology and Urology Devices Panel 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. On March 26, 2013 we received confirmation from the FDA that our PMA submission 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 with the reviewing team. Since then we have been providing all the requested additional information on our PMA file and on March 19, 2014, we completed our set of answers to the FDA's questions. As per the standard FDA review timeframe, the next step is a panel meeting of experts expected to be held in the next four to six months. Given the very challenging recommendations of the FDA with regards to our prospective study and its cryoablation comparative arm, there is a risk that the review of our submission may take longer than expected or may not meet the FDA's requirements which could delay approval. 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 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 effectiveness, 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 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 and partial reimbursement from private

insurers in the United Kingdom, and evidence of the cost effectiveness of a therapy as compared to existing therapies. In February 2011, the French Health Ministry elected our HIFU technology for the treatment of localized prostate cancer in a special temporary reimbursement protocol. Under this protocol, French healthcare government authorities would review the clinical data gathered within the next five years in view of granting definitive reimbursement for HIFU. However, we cannot guarantee that such special temporary protocol will be actually implemented by the French Health Ministry nor 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 2013, 2012 and 2011, 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 of clinical trials for our FDA PMA regulatory process to seek the FDA's approval on our Ablatherm solution for the treatment of prostate cancer 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 even if the trials are successfully completed.

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, the UK and on a special temporary basis in France, 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. 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 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 2013, approximately 81% of our total costs of sales and operating expenses were denominated in euro, while approximately 41% 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, 2013, 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. Finally, in the specific context of the sovereign debt crisis affecting certain European countries, the alleged or actual disruption in the use of the euro as currency in one or more European Monetary Union countries and the associated fluctuations in currency exchange rates could have a material effect on our financial condition and earnings, the magnitude and consequences of which are unpredictable. 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 PMA process with the FDA for our Ablatherm through completion, we may need to raise additional capital in the event of significant delays with the FDA PMA review, 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 3, 2014, and on the total number outstanding options to subscribe to new share, up to 4,259,000 ADSs are issuable upon exercise, representing approximately 19.2% 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.

We filed a Form F-3 registration statement with the SEC on October 7, 2011 to register ordinary shares and warrants for a maximum amount of $30 million, hence providing for registration of any future new ordinary shares issued for the purpose of raising capital or debt restructuring. This registration statement was declared effective by the SEC on October 21, 2011. We issued and registered shares and warrants under this registration statement on March 28, 2012 and on May 28, 2013. For more information regarding the March 2012 and May 2013 placements, see Item 10 "Material Contracts."

On June 17, 2013, our shareholders extended the validity of existing resolutions, and renewed the June 25, 2012 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.

Our ADSs are currently traded on the NASDAQ Global Market. The average daily trading volume of our ADSs in December 2013 was 77,719, the high and low bid price of our ADSs for the last two financial years ended on December 31, 2013 and December 31, 2012, was $4.94 and $1.98, and $2.85 and $1.43, 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 2012 was 58,241 as opposed to 77,719 for the same period of 2013. 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.

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

As described above, on June 17, 2013, 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 3, 2014, 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 14 February 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 shall be implemented and enter 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 shall 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 shall be fixed by each Participating Member State but for transactions involving financial instruments other than derivatives shall amount to at least 0.1% of the taxable amount. The taxable amount for such transactions shall in general be determined by reference to the consideration paid or owed in return for the transfer.

Prospective holders should therefore note, in particular, that any sale, purchase, or exchange of the Shares or ADSs could be subject to the FTT at a minimum rate of 0.1% provided the abovementioned prerequisites are met. 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 device, an advanced choice 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. In addition, we are developing HIFU technology for the treatment of certain other types of tumors. In March 2013, we introduced a new robot assisted HIFU device dedicated to the focal treatment of prostate cancer, the "Focal One", which received CE marking in June 2013. We also produce and commercialize medical equipment for treatment of urinary tract stones using ESWL.

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.

Based on the May 24, 2011 shareholders' resolutions and in view of our debt restructuring and new projects financing, on October 7, 2011 we filed a Form F-3 registration statement with the SEC to register ordinary shares and warrants for a maximum amount of $30 million. This registration statement was declared effective by the SEC on October 21, 2011.

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 in the United States.

On January 31, 2013, we submitted our PMA application to the FDA for our Ablatherm 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 with the reviewing team. Since then we have been providing all the requested additional information on our PMA file.

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.

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.

March 19, 2014, we completed our set of answers to the FDA's questions. As per the standard FDA review timeframe, the next step is a panel meeting of experts expected to be held in the next four to six months.

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 €5.1 million, €5.6 million and €5.9 million for 2013, 2012 and 2011, 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 €19.0 million (including €8.2 million in Asia and €10.7 million in Europe and the rest of the world), €20.4 million (including €11.4 million in Asia and €9.0 million in Europe and the rest of the world) and €16.4 million (including €7.6 million in Asia and €8.8 million in Europe and the rest of the world), each for 2013, 2012 and 2011, 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 €5.1 million to our consolidated net sales during the fiscal year ended December 31, 2013.

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 Ablatherm is a HIFU-based device developed and marketed by the HIFU division for 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. In June 2012, we completed our US clinical trials and the two-year follow-up phase.

Clinical outcomes from these patients combined with our European long-term database formed the foundation of our PMA submission to the FDA on January 31, 2013. On June 3, 2013 we held our 100-day meeting with the FDA to discuss our PMA file with the reviewing team. Since then we have been providing all the requested additional information on our PMA file and on March 19, 2014, we completed our set of answers to the FDA's questions. As per the standard FDA review timeframe, the next step is a panel meeting of experts expected to be held in the next four to six months. We also produce and market the Focal One device, a new 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 European Union and Saudi Arabia. As of December 31, 2013, the HIFU division had an installed base of 94 Ablatherm machines, one Focal One worldwide and 285 trained clinical sites 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. To that end, on January 31, 2013, we filed a PMA with the FDA 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 with the reviewing team. Since then we have been providing all the requested additional information on our PMA file and on March 19, 2014, we completed our set of answers to the FDA's questions. As per the standard FDA review timeframe, the next step is a panel meeting of experts expected to be held in the next four to six months.. For more information, 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. See ''—HIFU Products.'' In 2013, the HIFU division maintained expenses at levels similar to 2012 on research and development ("R&D") projects to develop HIFU applications beyond prostate cancer. The division is considering maintaining similar levels of R&D spendings in 2014 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. 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. 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 with the reviewing team. Since then we have been providing all the requested additional information on our PMA file and on March 19, 2014, we completed our set of answers to the FDA's questions. As per the standard FDA review timeframe, the next step is a panel meeting of experts expected to be held in the next four to six months. The Ablatherm consists of a treatment module, 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 transducer automatically moves and fires at each predefined lesion until the entire targeted area has been treated, while controlling and imaging the treatment in real time due to its integrated imaging system.

- The Focal One is a new 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 Saudi Arabia. We are also working at obtaining clearance in other parts of the world.

HIFU Division Patents and Intellectual Property

As of December 31, 2013, the HIFU division's patent portfolio contained 36 patents consisting of 16 in the United States, 18 in the European Union and Japan and two in Israel and the rest of the world. They belong to 18 groups of patents covering key technologies related to therapeutic ultrasound principles, systems and associated software.

During 2013, one U.S. patent covering the original design of the HIFU transducer for prostate application expired. One patent covering the HIFU transducer design was granted in Japan. Twelve additional patents covering certain other aspects of our HIFU technology in the European Union and Japan (six), the United States (three), and the rest of the world (three) 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. A new patent covering HIFU lesion imaging for liver treatment was also filed in 2013. 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, French authorities approved a new treatment protocol concerning the treatment of patients who failed radiotherapy. We obtained CE Marking, which currently allows us to market this Ablatherm treatment indication.

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 was started 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. Following results obtained with the Dynamic Focusing technology, it was 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.

Clinical and Regulatory Status in the United States

In 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.

A Gastroenterology and Urology Devices Panel of the Medical Devices Advisory Committee (the "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 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 Panel's recommendation for a prospective study and reiterated the 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 and entered into the required two year follow-up phase. 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 with the reviewing team. Since then we have been providing all the requested additional information on our PMA file and on March 19, 2014, we completed our set of answers to the FDA's questions. As per the standard FDA review timeframe, the next step is a panel meeting of experts expected to be held in the next four to six months.Given the very challenging recommendations of the FDA with regards to our prospective study and its cryoablation comparative arm, there is a risk that 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).

We have set up an extensive worldwide 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.

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 238,590, 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. 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, external beam radiotherapy 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 tumorsSee 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.

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 €19.0 million to our consolidated net sales during the fiscal year ended December 31, 2013.

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. The UDS division has sold 733 ESWL lithotripters worldwide to this date and actively maintained or otherwise serviced 566 installed lithotripters as of December 31, 2013.

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 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 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	Commercial	Approved for distribution:
	treatment of	Production	European Union
	urinary stones		South Korea
			South-East Asia
			Peru
			Colombia
			Venezuela
			Japan
			United States
			Taiwan
			Singapore

			Costa Rica
			Mexico
Sonolith i-sys	Electroconductive treatment of urinary stones	Commercial Production	Approved for distribution: European Union
			South Korea
			Canada
			United States
			Japan
			Australia
			Colombia
			Peru
			South-East Asia
			Argentina
			Venezuela
			Taiwan
			Mexico
			Costa Rica

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, 2013, the UDS division's patent portfolio contained nine patents consisting of one in the United States, six in the European Union and Japan and two in 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.

In 2013, one patent covering piezoelectric technologies was delivered in Japan. 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 and Mexico. 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 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 as the Company opened a 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.

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 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).

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. 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. However, our HIFU devices (Class III), Ablatherm or Focal One devices, have not yet been approved by FDA and Ablatherm is currently under PMA procedure. The regulatory pathway for placement in the U.S. market may include the pre-market notification or PMA routes.

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 December 2012, the FDA conducted an inspection of our manufacturing processes and facility, concluded that there were no deficiencies and consequently issued a No Action Indicated (“NAI”) report.

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, 2013, 2012 and 2011 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, 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 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 Ablatherm 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.

Leases and Sales and leaseback Transactions

In accordance with ASC 840 - Leases, we classify all leases at the inception date as either a capital lease or an operating lease. A lease is a capital lease if it meets any one of the following criteria; otherwise, it is an operating lease:

- Ownership is transferred to the lessee by the end of the lease term;
- The lease contains a bargain purchase option;

- The lease term is at least 75% of the property's estimated remaining economic life; or
- The present value of the minimum lease payments at the beginning of the lease term is 90% or more of the fair value of the leased property to the lessor at the inception date.

We enter into sale and leaseback transactions from time to time. In accordance with ASC 840 - Leases, any profit or loss on the sale is deferred and amortized prospectively over the term of the lease, in proportion to the leased asset if a capital lease, or in proportion to the related gross rental charged to expense over the lease term, if an operating lease.

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 (the "2007 Warrants"). At the inception date, the Company elected to measure the instrument and the embedded derivatives in their entirety at fair value, with changes in fair value reported in the income statement under financial income, in accordance with ASC 815. Thus, the convertible debentures together with their embedded derivatives were recorded as a liability, with subsequent changes in fair value recorded in financial income and expenses. The Company used a binomial valuation model to measure the fair value of all Investor Warrants as defined below and a binomial valuation model with a Company specific credit spread to measure the fair value of the convertible debentures.

On January 19, 2012, the Company entered into a privately negotiated Exchange Agreement with all holders of the then outstanding 2007 Convertible Debentures and 2007 Warrants. Pursuant to the terms of the Exchange Agreement, certain holders agreed to exchange their outstanding securities for newly issued ordinary shares and an amount in cash (the "Option A Holders"), while all other holders (the "Option B Holders") agreed to exchange their outstanding securities for new, non-convertible debentures due June 30, 2014 (the "2012 Non-convertible Debentures") and new warrants (the "2012 Exchange Offer Warrants"). The Company closed the Exchange on January 25, 2012. The 2012 Non-convertible Debentures were recorded as a liability at their fair value at inception and subsequently valued on an amortized cost basis with changes recorded as a financial expense. The 2012 Exchange Offer Warrants were recorded as equity instruments and the Company used a Black-Scholes pricing model to determine their value at inception. On June 14, 2013, the Company fully redeemed its outstanding 2012 Non-convertible Debentures. See Notes 1-21, 14, 16 and 19 to our consolidated financial statements..

Warrants:

The 2007 Warrants were issued to both the investors in the 2007 Convertible Debentures and to the bank that assisted the Company as the Placement Agent. The warrants issued to the investors in the convertible debentures (the " 2007 Investor Warrants") and the Placement Agent (the "2007 Placement Agent Warrants") were evaluated at issuance under FASB ASC 480-10-25, and ASC 815-40-15 and ASC 815-40-25 (formerly EITF 07-5 and 00-19, respectively) as freestanding instruments, as they were both legally detachable and separately exercisable from any other instruments. Based on this analysis, the 2007 Warrants were classified as a derivative liability because the Company may have been required to pay a net-cash settlement upon the occurrence of certain events outside the control of the Company. Specifically, Section 3(e) (Certain Adjustments-Fundamental Transaction) of the 2007 Warrants provided that under certain circumstances outside the control of the Company, the Company might be required, at the Holder's election, to pay an amount of cash equal to the value of the warrant as determined in accordance with the Black-Scholes option pricing model. As a result, the 2007 Warrants did not qualify for a scope exception from derivative accounting under ASC 815-10-15-74(a) as it was not always within the Company's control to settle the contract in its own shares and therefore did not meet the guidance of ASC 815-40-25.

The valuation model of the 2007 Investor Warrants used a binomial valuation model at inception to capture the complexity of the instruments. For subsequent years, the Company used a Black-Scholes valuation model with changes in fair value recorded as a financial expense or income. At December 31, 2012, all the 2007 Placement Agent Warrants had been exchanged for ADRs.

The 2012 Exchange Offer Warrants were issued to Option B Holders as part of the January 19, 2012 Exchange Agreement, closed on January 25, 2012. These Warrants (also legally detachable and separately exercisable) do not provide for any net cash settlement in any circumstances. Specifically, the Black-Scholes cash settlement provision has been eliminated in Section 3(e) of the 2012 Exchange Offer Warrants. Considering this and all the other relevant

features of the 2012 Exchange Offer Warrants, the Company determined that the Warrants, which require settlement in shares, should be recognized as equity instruments. More specifically, the shares underlying the 2012 Exchange Offer Warrants were a fixed number of shares that were not redeemable outside of the Company's control, and therefore the guidance of ASC 480-10-25 did not apply. Further, the 2012 Exchange Offer Warrants qualified for a scope exception from derivative accounting under ASC 815-10-15-74(a) as the New Warrants are both indexed to the Company's own stock and can be classified in stockholders' equity in the statement of financial position. See Notes 1-21, 14 and 19 to our consolidated financial statements.

The Company used the Black-Scholes pricing model to value the 2012 Exchange Offer Warrants at inception.

On March 28, 2012, pursuant to a securities purchase agreement dated March 22, 2012, as amended, the Company issued new ordinary shares in the form of ADSs to selected institutional investors in a registered direct placement (the "March 2012 Placement") with warrants attached (the "March 2012 Investor Warrants"). The Company also issued warrants to the placement agent, Rodman & Renshaw LLC (the "March 2012 Placement Agent Warrants" and together with the March 2012 Investor Warrants, the "March 2012 Warrants"). The Company has accounted for the March 2012 Warrants as a liability and reflected this analysis in the Company's financial statements filed for the year 2012.

The Company used the Black-Scholes pricing model to value the March 2012 Warrants at inception, with changes in fair value recorded as a financial expense or income.

On May 28, 2013, pursuant to a securities purchase agreement dated May 20, 2013, as amended, the Company issued new ordinary shares in the form of ADSs to selected institutional investors in a registered direct placement (the "May 2013 Placement") with warrants attached (the "May 2013 Investor Warrants"). The Company also issued warrants to the placement agent, H.C. Wainwright & Co., LLC (the "May 2013 Placement Agent Warrants" and together with the May 2013 Investor Warrants, the "May 2013 Warrants"). As the May 2013 Warrants comprised the same structure and provisions as the March 2012 Warrants, including an exercise price determined in U.S. dollars while the functional currency of the Company is the euro, the Company determined that the May 2013 Warrants should be accounted for as a liability.

The Company used the Black-Scholes pricing model to value the May 2013 Warrants at inception, with changes in fair value recorded as a financial expense or income.

Accounts Receivable

We generate most of our revenues and corresponding accounts receivable from sales of medical equipment, spare parts, maintenance and service to public and private hospitals and physicians worldwide. We perform initial credit evaluations of our customers and adjust credit terms based upon customers' creditworthiness as determined by such things as their payment history, credit ratings and our historical experiences.

Allowance for Doubtful Accounts

We evaluate the collectability of our accounts receivable based on the individual circumstances of each customer on a quarterly basis. In circumstances where we are aware of a specific customer's inability to meet its financial obligations to us (e.g., bankruptcy filings, substantial downgrading of credit scores), we record a specific reserve for bad debts against amounts due to reduce the net recognized receivable to the amount we reasonably believe we will collect. If circumstances change (i.e. higher than expected defaults or an unexpected material adverse change in a major customer's ability to meet its financial obligations to us), our estimates of the recoverability of amounts due to us could be reduced by a material amount.

Operating Results

Overview

Total revenues include sales of our medical devices and sales of disposables ("sales of goods"), sales of RPPs and leases, and sales of spare parts and services, all net of commissions, as well as other revenues.

Sales of goods have historically been comprised of net sales of medical devices (ESWL lithotripters and Ablatherms) and net sales of disposables (mostly Ablapaks in the HIFU division and electrodes in the UDS division). The sale price of our medical devices is subject to variation based on a number of factors, including market competition, warranties and payment terms. Consequently, a particular sale of a medical device may, depending on its terms, result in significant fluctuations in the average unit sale price of the product for a given period, which may not be indicative of a market trend.

Sales of RPP and leases include the revenues from the sale of Ablatherm and Focal One treatment procedures and from the leasing of Ablatherm and Focal One machines. We provide Ablatherm and Focal One machines to clinics and hospitals for free for a limited period, rather than selling the devices. These hospitals and clinics perform treatments using the devices and pay us on the basis of the number of individual treatments provided. With this business model, the hospital or clinic does not make an initial investment until the increase in patient demand justifies the purchase of a HIFU machine. As a consequence, we are able to make Ablatherm treatments available to a larger number of hospitals and clinics, which we believe should serve to create more long-term interest in the product.

Compared to the sale of devices, this business model initially generates a smaller, although more predictable stream of revenue and, if successful, should lead to more purchases of Ablatherm and Focal One machines by hospitals and clinics in the long term.

Sales of spare parts and services include revenues arising from maintenance services furnished by us for the installed base of ESWL lithotripters and HIFU devices.

We derive a significant portion of both net sales of medical devices and consumables and net sales of spare parts and services from our operations in Asia, through our wholly-owned subsidiaries or representative offices in Japan (Edap Technomed Co. Ltd), Malaysia (Edap Technomed Sdh Bhd) and South Korea (Edap Technomed Korea). Revenue derived from our operations in Asia represented approximately 35% of our total consolidated revenue in 2013. Net sales of goods in Asia represented approximately 42% of such sales in 2013 and consisted primarily of sales of ESWL lithotripters and consumables. Net sales of spare parts, supplies and services in Asia represented approximately 39% of such sales in 2013 and related primarily to ESWL lithotripters, reflecting the fact that approximately 49% of the installed base of our ESWL lithotripters that we actively maintain or otherwise serve are located in Asia.

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 revenues. In 2013, approximately 81% of our costs of sales and research and development, selling, marketing and general and administrative expenses were denominated in euro, while approximately 41% of our sales were denominated in currencies other than euro (primarily the U.S. Dollar and Japanese yen). Our operating profitability could be materially affected by large fluctuations in the rate of exchange between the euro and such other currencies. To minimize our exposure to exchange rate risks, we sometimes use certain financial instruments for hedging purposes. See Item 3, ‘‘Key Information—Risk Factors—We sell our products in many parts of the world and, as a result, our business is affected by fluctuations in currency exchange rates’’ and Item 11, ‘‘Quantitative and Qualitative Disclosures About Market Risk’’ for a description of the impact of foreign currency fluctuations on our business and results of operations.

Reserves for slow-moving and obsolete inventory are determined based upon quarterly reviews of all inventory items. Items which are not expected to be sold or used in production, based on management’s analysis, are written down to their net realizable value, which is their fair market value or zero in the case of spare parts or disposable parts for devices that are no longer in commercial production.

Consolidated research and development expenses include all costs related to the development of new technologies and products and the enhancement of existing products, including the costs of organizing clinical trials and of obtaining patents and regulatory approvals. We do not capitalize any of our research and development expenses, except for the expenses relating to the production of machines to be used in clinical trials and that have alternative future uses as equipment or components for future research projects.

Consolidated research and development expenses, as described above amounted to €2.6 million, €2.7 million, and €2.4 million in 2013, 2012 and 2011, respectively, representing approximately 10.8%, 10.2% and 10.9% of total revenues in 2013, 2012 and 2011, respectively. Consolidated research and development expenses included R&D government grants and tax credits of €1.1 million, €1.0 million and €0.4 million in 2013, 2012 and 2011, respectively. Excluding R&D government grants and tax credits, consolidated research and development expenses amounted to €3.7million, €3.7 million and €2.9 million in 2013, 2012 and 2011, respectively, representing approximately 15.4%, 14.0% and 12.8% of total revenues in 2013, 2012 and 2011, respectively. Research and development costs in 2013, 2012 and 2011 were mainly related to clinical expenses for the Phase II/III PMA trials in the United States to expand our leadership in HIFU for prostate cancer (the cost of which represented 4.0% of total revenues in 2013). Beginning in 2014, management expects the budget for research and development expenses in Europe (excluding the conduct of FDA clinical trials in the United States) to level off at approximately 10% of total revenues, which we expect will allow us to maintain our strategy to launch new clinical studies (thus strengthening our clinical credibility), to continue to focus our efforts on obtaining regulatory approvals and reimbursement in key countries, to continue to develop our HIFU and ESWL product range and to fund projects to expand the use of HIFU beyond the treatment of prostate cancer.

Consolidated selling and marketing expenses amounted to €6.3 million in 2013, €6.6 million in 2012 and €5.9 million in 2011. Selling and marketing expenses included allowances for doubtful accounts of €0.2 million in 2013, €0.5 million in 2012 and €0.2 million in 2011. The €0.3million or 5.1% decrease in selling and marketing expenses from 2012 to 2013 was primarily a result of lower depreciations on receivable accounts and the favorable impact of the U.S. Dollar and Japanese Yen exchange rate variations against the Euro. Management expects marketing and sales efforts to stay at significant levels in the future to consolidate the Ablatherm and Focal One HIFU technology's status as a standard of care for prostate cancer in Europe, and to sustain its worldwide market position in lithotripsy, including in the United States where the Company's full range of lithotripsy products is now approved.

In 2013, 2012 and 2011, our ESWL sales activity benefited from constant product innovation and the success of our Sonolith i-sys device launched in 2007 and our Sonolith i-move device launched in 2010, together with a sustained commercial effort which allowed us to capture market share in both the European, Asian and U.S. markets. We believe that the market for ESWL lithotripters is now mature and has become primarily a replacement and maintenance market, with intense competition. As a result, we expect total market volumes to remain stable at current levels in the foreseeable future.

We believe that our results of operations in the near future will be affected by our ability to grow our sales volumes both in the prostate cancer and the lithotripsy markets, along with our ability to control expenses in connection with the development, marketing and commercial launch of HIFU applications, including the Ablatherm, and the continuation of the regulatory process for Ablatherm in the United States. See ‘‘—Liquidity and Capital Resources.’’

Fiscal Year Ended December 31, 2013 Compared to Fiscal Year Ended December 31, 2012

We report our segment information on a “net contribution” basis, so that each segment’s results comprise the elimination of our intra-group revenues and expenses and thus reflect the true contribution to consolidated results of the segment. See Note 26 to our consolidated financial statements.

(in millions of euros)	2013	2012
Total revenues	24.1	26.1
Total net sales	24.1	26.0
Of which HIFU	5.1	5.6
Of which UDS	19.0	20.4
Total cost of sales	(14.8)	(15.6)
Gross profit	9.3	10.4
Gross profit as a percentage of total net sales	38.7%	40.1%
Total operating expenses	(12.1)	(12.5)
Income (loss) from operations	(2.8)	(2.0)
Net income (loss)	(5.0)	(7.5)

Total revenues

Our total revenues decreased 7.6% from €26.1 million in 2012 to €24.1 million in 2013, principally due to the negative exchange rate impact of the Japanese Yen against the Euro and decreased lithotripsy machines sales.

HIFU division. The HIFU division’s total revenues decreased 8.9% to €5.1 million in 2013 as compared to €5.6 million in 2012.

The HIFU division’s net sales of medical devices decreased 11.4% to €1.1 million in 2013, with two Ablatherm units and one Focal One unit sold, as compared to €1.3 million and four Ablatherm units sold in 2012.

Net sales of RPP treatments decreased 14.3% to €2.3 million in 2013.

Net sales of consumables and net sales of HIFU-related spare parts, supplies, leasing and services decreased from €1.0 million in 2012 to €0.6 million in 2013.

Other HIFU-related revenues decreased to €15 thousand in 2013 from €47 thousand in 2012.

UDS division. The UDS division’s total revenues decreased 7.2% from €20.4 million in 2012 to €19.0 million in 2013, mostly due to the negative exchange rate impact of the Japanese Yen against the Euro and decreased lithotripsy machine sales.

The UDS division’s net sales of medical devices decreased 14.5% from €12.8 million in 2012 to €11.0 million in 2013 with 45 devices sold in 2013 compared to 52 units sold in 2012.

Net sales of UDS-related spare parts, supplies, RPP, leasing and services increased 4.9% from €7.6 million in 2012 to €8.0 million in 2013, as a result of the increased installed base of lithotripsy machines.

Cost of sales.

Cost of sales decreased from €15.6 million in 2012 to €14.8 million in 2013, and represented 61.3% as a percentage of net sales in 2013, up from 60.1% as a percentage of net sales in 2012.

Operating expenses.

Operating expenses decreased 3.1%, or €0.4 million, from €12.5 million in 2012 to €12.1 million in 2013. Operating expenses included R&D grants and tax credits of €1,12 million and €995 thousand in 2013 and 2012, respectively. The decrease in operating expenses included a favorable exchange rate impact of €0.7 million. The costs associated with the FDA PMA trial was stable at €1.1 million in 2013 and reflected the administrative and file completion work with the FDA after the submission of the clinical file in January 2013.

Marketing and sales expenses decreased €0.3 million, or 5.2%, mostly due to reduced depreciations on client receivables, while we continued our strategic focus on the U.S. market.

Research and development expenses decreased 2.4% at €2.6 million in 2013 from €2.7 million in 2012, and comprised R&D grants and tax credits of €1,12 million and €995 thousand in 2013 and 2012, respectively, and costs of the FDA PMA trials of €1.0 million in 2013 and 2012.

General and administrative expenses were stable at €3.2 million in 2013 and 2012.

Operating loss.

As a result of the factors discussed above, we recorded a consolidated operating loss of €2.8 million in 2013, as compared to a consolidated operating loss of €2.0 million in 2012.

We realized an operating loss in the HIFU division of €0.7 million in 2013, stable from 2012 and an operating profit in the UDS division of €0.5 million in 2013, as compared to €1.2 million in 2012.

Financial (expense) income, net. Net financial expense was €0.9 million in 2013, including a €0.6 million of fair value adjustments on the outstanding notes and warrants and €0.3 million relating to interest expense, compared with a net financial expense of €4.6 million in 2012, including a €2.3 million expense due to fair value adjustments.

Foreign currency exchange gains (loss), net. In 2013, we recorded a net foreign currency exchange loss of €1.2 million, mainly due to the variation of the Euro against the U.S. Dollar and the Japanese Yen, compared to a loss of €0.7 million in 2012.

Other income (expense), net. There was no other income (expense) in 2013 and 2012.

Income taxes. Income tax was an expense of €0.1 million in 2013 and 2012.

Net income / (loss)

As a result of the above, we realized a consolidated net loss of €5.0 million in 2013 compared with a consolidated net loss of €7.5 million in 2012.

Fiscal Year Ended December 31, 2012 Compared to Fiscal Year Ended December 31, 2011

We report our segment information on a “net contribution” basis, so that each segment’s results comprise the elimination of our intra-group revenues and expenses and thus reflect the true contribution to consolidated results of the segment. See Note 27 to our consolidated financial statements.

(in millions of euros)	2012	2011

Total revenues	26.1		22.3	
Total net sales	26.0		22.3	
Of which HIFU	5.6		5.9	
Of which UDS	20.4		16.4	
Total cost of sales	(15.6	)	(13.4	)
Gross profit	10.4		8.9	
Gross profit as a percentage of total net sales	40.1	%	39.8	%
Total operating expenses	(12.5	)	(11.4	)
Income (loss) from operations	(2.0	)	(2.5	)
Net income (loss)	(7.5	)	(0.9	)

Total revenues

Our total revenues increased 16.9% from €22.3 million in 2011 to €26.1 million in 2012, principally due to increased lithotripsy machines sales.

HIFU division. The HIFU division's total revenues decreased 4.3% to €5.6 million in 2012 as compared to €5.9 million in 2011.

The HIFU division's net sales of medical devices increased 67.5% to €1.3 million in 2012, with four Ablatherm units sold, as compared with €0.8 million and three Ablatherm units sold in 2011.

Net sales of RPP treatments decreased 15.3% to €2.7 million in 2012

Net sales of consumables decreased 9.7% to €0.6 million in 2012 and net sales of HIFU-related spare parts, supplies, leasing and services decreased 18.9% to €1.0 million in 2012.

Other HIFU-related revenues increased to €47 thousand in 2012 from €20 thousand in 2011 and were related to the payment by Theraclion of licence related amounts.

UDS division. The UDS division's total revenues increased 24.5% from €16.4 million in 2011 to €20.4 million in 2012, mostly due to the increase in lithotripsy machine sales.

The UDS division's net sales of medical devices increased 39.1% from €9.2 million in 2011 to €12.8 million in 2012 with 52 devices sold in 2012 compared to 40 units sold in 2011.

Net sales of UDS-related spare parts, supplies, RPP, leasing and services increased 5.9% from €7.2 million in 2011 to €7.6 million in 2012, primarily related to the revenues derived from the installed base (disposables and maintenance contracts).

Cost of sales.

Cost of sales increased from €13.4 million in 2011 to €15.6 million in 2012, and represented 60.1% as a percentage of net sales in 2012, down from 60.3% as a percentage of net sales in 2011.

Operating expenses.

Operating expenses increased 9.8%, or €1.1 million, from €11.4 million in 2011 to €12.5 million in 2012. Operating expenses included R&D grants and tax credits of €995 thousand and €415 thousand in 2012 and 2011, respectively. The increase in operating expenses was mostly attributable to the increased activity on the FDA PMA trials and to the strategic focus on the U.S. market and the related expansion of sales and marketing efforts.

The costs associated with the FDA PMA trial increased 40.8% at €1.1 million in 2012 compared to €0.8 million in 2011, reflecting the increased activity on the trial to gather clinical data after the completion of the follow-up phase and prepare the clinical and technical file that was submitted to the FDA in January 2013.

Marketing and sales expenses increased €0.7 million, or 12.7%, mostly due to the strategic focus on the U.S. market and the related expansion of the U.S. sales team and marketing initiatives.

Research and development expenses increased 9.1% at €2.7 million in 2012 from €2.4 million in 2011, and comprised R&D grants and tax credits of €995 thousand and €415 thousand in 2012 and 2011, respectively, and costs of the FDA

PMA trials of €1.1 million and €0.8 million in 2012 and 2011, respectively.

General and administrative expenses and depreciation increased 4.6% from €3.0 million in 2011 to €3.2 million in 2012.

Operating loss.

As a result of the factors discussed above, we recorded a consolidated operating loss of €2.0 million in 2012, as compared to a consolidated operating loss of €2.5 million in 2011.

We realized an operating loss in the HIFU division of €0.7 million in 2012, compared to an operating loss of €0.3 million in 2011 and an operating profit in the UDS division of €1.2 million in 2012, as compared to €0.1 million in 2011.

Financial (expense) income, net. Net financial expense was €4.6 million in 2012, including a €2.3 million due to the January 2012 Exchange Agreement impact and €2.1 million relating to interest expense , compared with a net financial income of €1.5 million in 2011, including a €2.4 million income due to the adjustment of the convertible debt to fair value.

Foreign currency exchange gains (loss), net. In 2012, we recorded a net foreign currency exchange loss of €0.7 million, mainly due to the variation of the euro against the U.S. dollar and the Japanese yen, compared to a gain of €0.5 million in 2011.

Other income (expense), net. There was no other income (expense) in 2012, as compared with a loss of €50 thousand in 2011.

Income taxes. Income tax was an expense of €0.1 million in 2012, compared to an expense of €0.4 million in 2011.

Net income / (loss)

We realized a consolidated net loss of €7.5 million in 2012 compared with a consolidated net loss of €0.9 million in 2011. The €6.5 million variation in net loss was primarily due to the €6.4 million variation in the convertible debt adjustments to fair value.

Effect of Inflation

Management believes that the impact of inflation was not material to our net sales or loss from operations in the three years ended December 31, 2013.

Liquidity and Capital Resources

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. Seasonal demand has historically resulted in significant annual and quarterly fluctuations in trade and other receivables and inventories, and therefore led to significant variations in working capital requirements and operating cash flows that were not necessarily indicative of changes in our business. We believe our working capital is sufficient for our present working capital requirements although we have in the past experienced negative cash flows and associated risks to liquidity, and may in the future experience the same. Our negative cash flow situation is described in more detail below.

We anticipate that cash flow in future periods will be derived mainly from ongoing operations and any capital raising the Company may potentially undertake. As of the date of this annual report we do not employ any off-balance sheet financing. Because we anticipate relying principally on cash and cash equivalent balances 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 due to operating difficulties or adverse market conditions, would reduce the availability of funds to us. Additionally, we may need to raise additional capital in the event of significant delays in the FDA PMA approval. See Item 3, “Key Information—Risk Factors—We may not have sufficient funds to fund the PMA submission to the FDA for our Ablatherm device through completion of the approval process and our ongoing operations.”

(in thousands of euros)	2013	2012	2011
Net cash generated/(used) in operating activities	(2,495)	(162)	(737)
Net cash generated/(used) in investing activities	(589)	234	(612)
Net cash generated/(used) in financing activities	1,937	1,342	(328)
Net effect of exchange rate changes	788	727	(789)
Net increase/(decrease) in cash and cash equivalents	(360)	2,141	(2,469)
Cash and cash equivalents at the beginning of the year	7,041	4,900	7,369
Cash and cash equivalents at the end of the year	6,681	7,041	4,900
Total cash and cash equivalents, and short-term investments at the end of the year	7,681	8,077	6,472

37

Our cash position as of December 31, 2013, 2012 and 2011, was €7.7 million (including €1.0 million of short-term treasury investments), €8.1 million (including €1.0 million of short-term treasury investments) and €6.5 million (including €1.6 million of short-term treasury investments), respectively. We experienced negative cash flows of €0.4 million in 2013, positive cash flows of €2.1 million in 2012 and negative cash flows of €2.5 million in 2011.

In 2013, our negative cash flow was primarily due the cash utilization from our operating activities and was mitigated by the net €2.5 million cash infusion after the May 2013 $12 million fund raising and the $8 million repayment in June 2013 of the then outstanding 2012 Non-convertible Debentures. In 2012, our positive cash flow was primarily due to the $5.6 million gross proceeds of the March 2012 Placement and the related $2.5 million reduction in long-term financial debt

In 2013, net cash used in operating activities was €2.5 million compared with net cash used in operating activities of €162 thousand in 2012 and 0.7 million in 2011, respectively.

In 2013, net cash used in operating activities reflected principally:

- a net loss of €5.0 million;
- elimination of €1.8 million of net expenses without effects on cash, including €1.2 million of depreciation and amortization and a loss of €0.7 million due to fair value variations of financial instruments;
- a decrease in trade accounts receivables of €3.2 million;
- an increase in other receivables of €0.7 million;
- an increase in inventories of €1.0 million;
- a decrease in payables of €0.8 million;
- a decrease in prepaid expenses of €24 thousand; and
- a decrease in accrued expenses of €44 thousand.

In 2012, net cash used in operating activities reflected principally:

- a net loss of €7.5 million;
- elimination of €5.3 million of net expenses without effects on cash, including €0.9 million of depreciation and amortization and a loss of €4.1 million due to variation of the fair value of financial instruments (October 2007 Convertible Debentures and 2007 and 2012 Warrants);
- a decrease in trade accounts receivables of €2.5 million;
- an increase in other receivables of €0.1 million;
- an increase in inventories of €0.3 million;
- a decrease in payables of €0.1 million;
- a decrease in prepaid expenses of €0.1 million; and

- a decrease in accrued expenses of €0.1 million.

In 2011, net cash used in operating activities reflected principally:

- a net loss of €0.9 million;

- elimination of €0.7 million of net expenses without effects on cash, including €1.4 million of depreciation and amortization and a gain of €2.4 million due to variation of the fair value of financial instruments (October 2007 Convertible Debentures and 2007 Warrants);

- a decrease in trade accounts receivable of €0.4 million;

- an increase in other receivables of €0.6 million;

- an increase in inventories of €0.3 million;

- an increase in payables of €0.5 million;

- an increase in prepaid expenses of €0.3 million; and

- a decrease in accrued expenses of €0.8 million.

In 2013, net cash used in investing activities was €589 thousand compared with net cash generated of €234 thousand in investing activities in 2012 and net cash used of €612 thousand in 2011.

Net cash used in investing activities of €589 thousand in 2013 reflected investments of €0.5 million in capitalized assets produced by the Company, mostly for commercial demonstrations and training, an investment of €0.2 million in property and equipment, net proceeds from sales of leased-back assets of €0.1 million and net proceeds from sales of short-term treasury investments of €36 thousand.

Net cash generated in investing activities of €234 thousand in 2012 reflected investments of €0.3 million in capitalized assets produced by the Company, mostly lithotripsy and laser machines used for commercial demonstrations and training, an investment of €0.3 million in property and equipment, net proceeds from sales of leased-back assets of €0.3 million and net proceeds from sales of short-term treasury investments of €0.5 million.

Net cash used in investing activities of €612 thousand in 2011 reflected investments of €0.8 million in capitalized assets produced by the Company, mostly lithotripsy machines used for commercial demonstrations and training, an investment of €0.1 million in property and equipment, net proceeds from sales of leased-back assets of €0.3 million.

In 2013, net cash generated in financing activities was €1.9 million compared with net cash generated in financing activities of €1.3 million in 2012, and net cash used of €328 thousand in 2011.

Net cash generated in financing activities of €1.9 million in 2013 reflected principally the €8.6 million net proceeds from the May 2013 Placement, repayment of long term borrowings, including the $8 million outstanding 2012 Non-convertible Debentures for €6.2 million, repayment of capital lease obligations totaling €0.6 million and an increase of €0.1 million in bank overdrafts.

Net cash generated in financing activities of €1.3 million in 2012 reflected principally the €3.7 million net proceeds from the issuance of ordinary shares and warrants as part of the March 2012 Placement, repayment of long term borrowing for €2.2 million, repayment of capital lease obligations totaling €0.6 million and an increase of €0.4 million in bank overdrafts.

Net cash used in financing activities of €328 thousand in 2011 reflected principally the €0.8 million increase in capital related to the issuance of new shares, a long-term debt increase of €0.2 million through the Japanese subsidiary, repayment of long term borrowing for €0.3 million, repayment of capital lease obligations totaling €0.7 million and a decrease of €0.3 million in bank overdrafts.

Our policy is that our treasury department should maintain liquidity with the use of short-term borrowings and the minimal use of long-term borrowings. The treasury department currently adheres to this objective by using fixed-rate debt, which normally consists of long-term borrowing from a Japanese bank and with certain long-term borrowings consisting of sale and leaseback equipment financing. Currently the majority of our short-term debt is based on an annual variable rate: Euribor+0.5 and Eonia+0.5. We maintain bank accounts for each of our subsidiaries in the local currencies of each subsidiary. The primary currencies in which we maintain balances are the euro, the U.S. dollar and the Japanese yen. To minimize our exposure to exchange rate risks, we may use certain financial instruments for hedging purposes from time to time. As of December 31, 2013, there were no outstanding hedging instruments. See Notes 13 and 14 to the consolidated financial statements for further information on our borrowings.

Contractual Obligations and Commercial Commitments as of December 31, 2013 (in thousands of euro)

		Payments Due by Period			
	Total	Less than 1 year	1-3 years	4-5 years	More than 5 years
Short-Term Debt	2,208	2,208	—	—	—
Long-Term Debt	3,768	90	426	3,252	—
Capital Lease Obligations	562	184	296	83	—
Operating Leases	1,621	449	779	393	—

Interest	51	23	24	4	—

39

New Accounting Pronouncements

In February 2013, the FASB issued ASU 2013-02, "Comprehensive Income" ("ASU 2013-02"). ASU 2013-02 requires an entity to provide information about the amounts reclassified out of accumulated other comprehensive income by component. These disclosures may be presented on the face of the consolidated financial statements or in the notes thereto. ASU 2013-02 is effective for reporting periods beginning after December 15, 2012. The adoption of ASU 2013-02 had no effect on the consolidated financial position, results of operations or cash flows of the Company.

In July 2013, the FASB issued ASU 2013-11, “Presentation of an Unrecognized Tax Benefit When a Net Operating Loss Carryforward, a Similar Tax Loss, or a Tax Credit Carryforward Exists” (“ASU 2013-11”). ASU No. 2013-11 provides explicit guidance on the financial statement presentation of an unrecognized tax benefit when a net operating loss carryforward, a similar tax loss, or a tax credit carryforward exists. This guidance is effective for the Company’s interim and annual periods beginning December 15, 2014. The Company does not believe the adoption of this guidance will have a material impact on its consolidated financial statements.

Research and Development, Patents and Licenses

See “—Operating Results—Overview” and Item 4, ‘‘Information on the Company—High Intensity Focused Ultrasou Division—HIFU Division Patents and Intellectual Property’’ and ‘‘Information on the Company—Urology and Services Division—UDS Division Patents and Intellectual Property.’’

The French government provides tax credits to companies for innovative research and development. This tax credit is calculated based on a percentage of eligible research and development costs and it can be refundable in cash.

In 2009, the Company reviewed the presentation of its research tax credit and elected to change for the preferred classification as permitted under ASC 250-10.

Research tax credit amounted to €561 thousand in 2013, €256 thousand in 2012 and € 411 thousand in 2011 and were classified as a reduction of research and development expenses.

Off-Balance Sheet Arrangements

At December 31, 2013, we had no off-balance sheet arrangements.

Item 6. Directors, Senior Management and Employees

Senior Executive Officers

The following table sets forth the name, age and position of each of our Senior Executive Officers as of April 3, 2014. The Chief Executive Officer and the Chief Financial Officer listed below have entered into employment contracts with us or our subsidiaries (which permit the employee to resign subject to varying notice periods). In addition, in case of a change of control of the Company, or of a termination of their employment contract by the Company without cause, the Senior Executive Officers are entitled to receive severance packages totaling approximately € 0.8 million.

Name	Position
Marc Oczachowski Age: 44	Chief Executive Officer of EDAP TMS S.A. President of EDAP TMS France SAS and EDAP Technomed, Inc. Marc Oczachowski joined the Company in May 1997 as Area Sales Manager, based in Lyon, France. From March 2001 to January 2004, he held management positions as General Manager of EDAP Technomed Malaysia. He was appointed Chief Operating Officer of EDAP TMS in November 2004 and became Chief Executive Officer of the Company on March 31, 2007. He relocated to Austin, Texas, on July 1, 2012 to manage U.S. operations. Previously he worked for Sodem Systems, which manufactures orthopedic power tools, as Area Sales Manager. He is a graduate of Institut Commercial de Lyon, France.
Eric Soyer Age: 48	Chief Financial Officer of EDAP TMS S.A. Managing Director of EDAP TMS France SAS Eric Soyer joined the Company in December 2006. He was appointed Managing Director of the French operations on June 15, 2012. He was previously CFO of Medica, a €270 million French company operating 108 nursing home and post-care clinics throughout France and Italy. Prior to that he was CFO and a Managing Director of April Group, an insurance services company listed on Euronext Paris, with 22 subsidiaries in France, the UK, Spain, Germany and Italy. He has international experience as a controller and cost accountant for Michelin Group in France, the United States and Africa. Eric Soyer has a BA degree from Clermont Graduate School of Management, an MBA degree from the University of Kansas and an Executive MBA degree from the HEC Paris School of Management.

Board of Directors

The following table sets forth the names and backgrounds of the members of the Board of Directors. None of the directors have service contracts with the Company or any of its subsidiaries providing for benefits upon termination of employment.All of the Board members are independent within the meaning of NASDAQ Marketplace Rule 5605(2). All four Board of Directors mandates terminate on June 2014 at the Assembly Meeting of Shareholders approving the 2013 accounts where renewal of the mandates for a six year period will be submitted to shareholders' approval.

Philippe Chauveau Age: 78 Mandate: 6 years Appointment: Apr. 8, 1997	In 1997, Philippe Chauveau was named chairman of EDAP TMS S.A.'s Supervisory Board. In 2002, the Company's two-tiered board structure was replaced by a single Board of Directors with Philippe Chauveau serving as Chairman and CEO until 2004 when he was succeeded as CEO. From 2000 to 2007, Philippe Chauveau served as founding Chairman of the Board of Scynexis Inc., funded by private equity, which is an innovative drug discovery company based in the United States, partnering with major pharmaceutical companies

(renewed) Expiration: 2014	worldwide. He was Vice-President of research and development at AT&T Bell Labs and has also served as Chairman of Apple Computer Europe, preceded by increasing marketing roles in ITT and in Procter & Gamble. He has an Honours Degree from Trinity College Dublin with a B.A. and a Bsc.

Pierre Beysson Age: 72 Mandate: 6 years Appointment : Sept. 27, 2002 (renewed) Expiration: 2014	Pierre Beysson was appointed as a member of the Board of Directors in September 2002. Pierre Beysson was then the Chief Financial Officer of Compagnie des Wagons-Lits ("CWL"), the on-board train service division of Accor, a French multinational Hotel and Business Services Group. In this capacity, he sat on a number of boards of companies related to the Accor Group. He is now a consultant. Before his assignment at CWL, Pierre Beysson held a number of senior financial positions with Nixdorf Computers, Trane (Air Conditioning), AM International (Office Equipment) and FMC (Petroleum Equipment). Pierre Beysson was trained as a CPA, has auditing experience and holds an MBA from Harvard Business School.
Argil Wheelock Age: 66 Mandate: 6 years Appointment : June 25, 2009 Expiration: 2014	Dr. Argil Wheelock was elected as a member of the Company's Board of Directors in June 2009. Dr. Wheelock, a U.S. board certified urologist, is currently Chief of Urology at Erlanger Medical Center, a tertiary care and teaching hospital in Chattanooga, Tennessee. He is Chief Medical Advisor to HealthTronics Inc., a privately held company. HealthTronics is a leading U.S. provider of urological services and products. From 1996 to 2005, Dr. Wheelock served as Chairman and CEO of HealthTronics, a publicly traded NASDAQ company where he was a founder. He has built a successful track record introducing new medical devices to the U.S. and navigating the FDA approval process. He is widely known among the U.S. urological community for bringing clinical benefits to patients and economic value to urology practices. Dr. Wheelock graduated from the University of Tennessee College of Medicine and completed urological training at Mount Sinai Hospital in New York City.
Rob Michiels Age: 64 Mandate: 6 years Appointment : July 16, 2009 Expiration: 2014	Rob Michiels was elected as a member of the Company's Board of Directors in July 2009. He is a 30-year U.S. veteran of the medical device industry. He currently serves as chief executive officer (CEO) of CardiAQ Valve Technologies, a venture funded start-up developing Transcatheter Mitral Valve Implantation. He previously served as chief operating officer (COO) of CoreValve; and as President and COO of InterVentional Technologies. He helped drive both companies from cardiovascular start-ups to established market leaders, using new and innovative technologies which have strong synergies to the HIFU story. Rob Michiels is a director of CardiAQ Valve Technologies and of Embolization Prevention Technologies, both privately held companies. Rob Michiels is a founding partner of CONSILIUM, a medical device market research company active in identifying, funding and greenhousing start-up technologies. Fluent in English, French and Dutch languages, he holds a bachelor's degree in economics from Antwerp University in Belgium and a Masters in business administration (MBA) from Indiana University.

Compensation

Aggregate compensation paid or accrued for services in all capacities by the Company and its subsidiaries to Senior Executive Officers and to the Board of Directors as a group for the fiscal year 2013 was approximately €741 thousand including performance bonuses of €123 thousand and benefits in kind of €48 thousand (benefits in kind comprise car allowances for senior management and housing and school allowances for expatriate senior management). No amount was set aside or accrued by us to provide pension, retirement or similar benefits for Senior Executive Officers and to the Board of Directors as a group in respect of the year 2013. For information regarding compensation paid in the form of stock options, see " Share Ownership" and " Options to Purchase or Subscribe for Securities."

Compensation Committee

Compensation Committee is comprised of the following members: Mr. Philippe Chauveau, Mr. Pierre Beysson, Dr. Argil Wheelock and Mr. Rob Michiels. The Committee gathers once a year to review the compensation of our Chief Executive Officer, as per the approved charter of the Compensation Committee, and to propose any changes to compensation paid to the Board of Directors, provided that the majority of independent members participate in the votes for Management compensations.

Audit Committee

The Board of Directors' Audit Committee comprises all four independent members of the Board: Mr. Pierre Beysson, acting as Head of the Audit Committee, Mr. Philippe Chauveau, Dr. Argil Wheelock and Mr. Rob Michiels. The purpose of the Audit Committee, in accordance with its annually approved charter, is to:

- Provide assistance to the Board of Directors in fulfilling their oversight responsibility to the shareholders, potential shareholders, the investment community and others relating to: the integrity of our financial statements, our compliance with legal and regulatory requirements, our accounting practices and financial reporting processes, the effectiveness of our disclosure controls and procedures and internal control over financial reporting, the independent auditor's qualifications and independence, and the performance of our internal audit function and independent auditors.

- Prepare the Audit Committee report, the Audit Committee may request any officer or employee of the Company or our outside counsel or independent auditor to attend a meeting of the Audit Committee or to meet with any members of, or consultants to, the Audit Committee.

Employees

As of December 31, 2013, we employed 154 individuals on a full-time basis, as follows:

	Sales & Marketing	Manufac-turing	Service	Research & Dvpt	Regula-tory	Clinical Affairs	Adminis-trative	Total
France	13	33	17	13	4	2	12	94
Italy	3	0	0	0	0	0	2	5
Germany	4	0	2	0	0	0	2	8
Japan	13	0	14	0	2	0	3	32
Malaysia	2	0	2	0	0	0	2	6
South Korea	1	0	0	0	0	0	1	2
USA	2	0	2	0	0	1	2	7
Total	38	33	37	13	6	3	24	154

As of December 31, 2012, we employed 143 individuals on a full-time basis, as follows:

	Sales & Marketing	Manufac-turing	Service	Research & Dvpt	Regula-tory	Clinical Affairs	Adminis-trative	Total
France	13	28	16	13	2	2	13	87
Italy	3	0	0	0	0	0	2	5
Germany	4	0	2	0	0	0	2	8
Japan	13	0	13	0	2	0	3	31
Malaysia	2	0	2	0	0	0	2	6
South Korea	1	0	0	0	0	0	1	2
USA	2	0	0	0	0	1	1	4
Total	38	28	33	13	4	3	24	143

As of December 31, 2011, we employed 148 individuals on a full-time basis, as follows:

	Sales & Marketing	Manufac-turing	Service	Research & Dvpt	Regula-tory	Clinical Affairs	Adminis-trative	Total
France	15	31	14	12	4	2	14	92
Italy	3	0	0	0	0	0	2	5
Germany	5	0	2	0	0	0	1	8
Japan	16	0	13	0	1	0	3	33
Malaysia	2	0	2	0	0	0	2	6
South Korea	1	0	0	0	0	0	1	2
USA	1	0	0	0	0	1	0	2
Total	43	31	31	12	5	3	23	148

Management considers labor relations to be good. Employee benefits are in line with those specified by applicable government regulations.

Share Ownership

As of April 3, 2014, the total number of shares issued was 22,171,198 with 381,528 shares held as treasury stocks, thus bringing the total number of shares outstanding to 21,789,670.

As of April 3, 2014, the Board of Directors and the Senior Executive Officers of the Company held a total of 45,123 Shares. The Board of Directors and Senior Executive Officers beneficially own, in the aggregate less than 1% of the Company's shares.

As of April 3, 2014, Senior Executive Officers held an aggregate of 435,338 options to purchase or to subscribe ordinary shares, with a weighted average exercise price of €2.65 per share. Of these options, 155,338 expire on October 29, 2017, 50,000 expire on June 25, 2020 and 230,000 expire on January 18, 2023.

Options to Purchase or Subscribe for Securities

As of April 3, 2014, we had sponsored three stock purchase and subscription option plans open to employees of EDAP TMS group, one stock purchase option plan expired on February 24, 2014. .

On May 22, 2007, the shareholders authorized the Board of Directors to grant up to 600,000 options to subscribe to 600,000 new shares at a fixed price to be set by the Board of Directors.

On June 24, 2010, the shareholders authorized the Board of Directors to grant up to 229,100 options to purchase pre-existing shares at a fixed price to be set by the Board of Directors. All of the shares that may be purchased through the exercise of stock options are currently held as treasury stock.

On December 19, 2012, the shareholders authorized the Board of Directors to grant up to 500,000 options to subscribe to 500,000 new shares at a fixed price to be set by the Board of Directors.

On December 31, 2013, the expiration of our stock option contracts was as follows:

Date of expiration	Number of Options
February 24, 2014	124,000

October 29, 2017	416,838
June 25, 2020	270,012
January 18, 2023	500,000

As of December 31, 2013, a summary of stock option activity to purchase or to subscribe to Shares under these plans is as follows:

	2013		2012		2011	
	Options	Weighted average exercise price (€)	Options	Weighted average exercise price (€)	Options	Weighted average exercise price (€)
Outstanding on January 1,	810,850	3.18	830,025	3.23	906,775	3.19
Granted	500,000	1.91	-	-	-	-
Exercised	-	-	-	-	-	-
Forfeited	-	-	(15,750)	3.17	(51,750)	3.03
Expired	-	-	(3,425)	2.02	(25,000)	2.08
Outstanding on December 31,	1,310,850	2.70	810,850	3.18	830,025	3.23
Exercisable on December 31,	743,347	3.27	675,844	3.38	621,516	3.50
Shares purchase options available for grant on December 31	83,428		83,428		72,003	

The following table summarizes information about options to purchase existing Shares held by the Company, or to subscribe to new Shares, at December 31, 2013:

	Outstanding options			Exercisable options	
Exercise price (€)	Options	Weighted average remaining contractual life	Weighted average exercise price (€)	Options	Weighted average exercise price (€)
3.99	416,838	3.8	3.99	416,838	3.99
2.60	124,000	0.2	2.60	124,000	2.60
2.38	174,100	6.5	2.38	130,575	2.38
1.91	500,000	9.0	1.91	-	-
1.88	95,912	6.5	1.88	71,934	1.88
1.88 to 3.99	1,310,850	6.0	2.70	743,347	3.27

Item 7. Major Shareholders and Related Party Transactions

Major Shareholders

To our knowledge, we are not directly or indirectly owned or controlled by another corporation, by any foreign government, or by any other natural or legal person or persons acting severally or jointly.

To the best of our knowledge and on the basis of the notifications received or filed with the SEC, shareholders who are beneficial owners of more than 5% of our shares are as follows.

	# of shares held on Dec.31, 2013	% of share capital on Dec. 31, 2013	# of shares held on Dec.31, 2012	% of share capital on Dec. 31, 2012	# of shares held on Dec.31, 2011	% of share capital on Dec. 31, 2011
PSM Vermogenswerwaltung GmbH	1,718,904	7.75	1,609,959	8.58	420,897	3.07
Bruce & Co. Inc	1,565,494	7.06	1,565,494	8.35	795,155	5.79
Mr. Jonathan Schwartz	817,137	3.69	817,137	4.36	928,644	6.77

There are no arrangements known to us, the operation of which may at a later date result in a change of control of the Company. All shares issued by the Company have the same voting rights, except the treasury stocks held by the Company, which have no voting rights.

As of April 3 2014, 22,171,198 Shares were issued, including 21,789,670 outstanding and 381,528 treasury Shares. At March 21, 2014, there were 22,115,848 ADSs, each representing one Share, all of which were held of record by 26 registered holders in the United States (including The Depository Trust Company).

Related Party Transactions

The General Manager of the Company's Korean branch "EDAP-TMS Korea" is also Chairman of a Korean company named Dae You. EDAP-TMS Korea subcontracts to Dae You the service contract maintenance of our medical devices installed in Korea. The amounts invoiced by Dae You under this contract were €65 thousand, €61 thousand and €60 thousand for 2013, 2012 and 2011 respectively. As of December 31, 2013, payables to Dae You amounted to €66 thoushand and as of December 31, 2012, our payables to them amounted to €44 thousand.

Dae You has purchased medical devices from us, which it operates in partnership with hospitals or clinics. These purchases (‘Sales of goods’) amounted to €516 thousand, €371 thousand and €768 thousand in 2013, 2012 and 2011 respectively. As of December 31, 2013, receivables (‘Net trade accounts and notes receivable’) amounted to €423 thousand. As of December 31, 2012, receivables from Dae You amounted to €350 thousand.

Interests of Experts and Counsel

Not applicable.

Item 8. Financial Information

Consolidated Financial Statements

See Item 18, ‘‘Financial Statements.’’

Export Sales

As of December 31, 2013, total consolidated export net sales, which we define as sales made outside of France, were €19.5 million, which represented 81% of total net sales.

As part of our business, we are engaged in sales and marketing activities with hospital, clinics distributors or agents in countries on a worldwide basis where we can provide our minimally invasive therapeutic solutions to patients with prostate cancer or urinary stones. The following information complies with new sub-section “Disclosure of Certain Activities Relating to Iran” of the Section 13 of the U.S. Security Exchange Act of 1934: in 2013 we honored warranty contracts on previous sales of lithotripsy devices to three Iranian public hospitals in order to provide the hospitals with the necessary disposables and services to treat patients with kidney stones using our devices. As part of these warranty commitments, in 2013 we did not invoice any medical equipment to the hospitals. We intend to continue to honor previous warranty commitments and will provide the necessary parts and disposables to allow patients to be treated with our devices

Legal Proceedings

As of the date of this annual report, the Company is not involved in any material legal proceedings.

Dividends and Dividend Policy

The payment and amount of dividends depend on our earnings and financial condition and such other factors that our Board of Directors deems relevant. Dividends are subject to recommendation by the Board of Directors and a vote by the shareholders at the shareholders’ ordinary general meeting. Dividends, if any, would be paid in euro and, with respect to ADSs, would be converted at the then-prevailing exchange rate into U.S. dollars. Holders of ADSs will be entitled to receive payments in respect of dividends on the underlying Shares in accordance with the Deposit Agreement.

No dividends were paid with respect to fiscal years 2007 through 2013, and we do not anticipate paying any dividends for the foreseeable future. Thereafter, any declaration of dividends on our shares as well as the amount and payment will be determined by majority vote of the holders of our shares at an ordinary general meeting, following the recommendation of our Board of Directors. Such declaration 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 in its recommendation to shareholders.

Significant Changes as of April 3, 2014

Not applicable.

Item 9. The Offer and Listing

Description of Securities

The Shares are traded solely in the form of ADSs, each ADS representing one ordinary share. Each ADS may be evidenced by an American Depositary Receipt issued by The Bank of New York, our Depositary. The principal United States trading market for the ADSs, which is also the principal trading market for the ADSs overall, is the NASDAQ Global Market of the NASDAQ Stock Market, Inc. (‘‘NASDAQ”), on which the ADSs are quoted under the symbol ‘‘EDAP.’’

Trading Market

The following tables set forth, for the years 2009 through 2013, the reported high and low sales prices of the ADSs on NASDAQ.

	NASDAQ	
	High	Low
	$	
2013	4.94	1.98
2012	2.85	1.43
2011	5.68	1.37
2010	6.97	1.89
2009	5.95	0.96

The following tables set forth, for the years 2012 and 2013, and through March 21, 2014, the reported high and low sales prices of the ADSs on NASDAQ for each full financial quarter:

	NASDAQ	
	High	Low
	$	
2014:		
Through March 21, 2014	3.69	2.87
2013:		
First Quarter	4.94	1.98
Second Quarter	4.48	2.63
Third Quarter	2.96	2.38
Fourth Quarter	3.48	2.50
2012:		
First Quarter	2.85	1.61
Second Quarter	2.29	1.60
Third Quarter	2.20	1.60
Fourth Quarter	2.35	1.43

The following table sets forth, for the most recent six months (from September 2013 through March 21, 2014), the reported high and low sale prices of the ADSs on NASDAQ for each month:

	NASDAQ	
	High	Low
	$	
2013:		
September	2.70	2.40
October	3.48	2.50
November	2.86	2.52
December	3.12	2.71
2014:		
January	3.40	2.87
February	3.69	2.89
March (through March 21, 2014)	3.56	2.98

48

Item 10. Additional Information

Memorandum and Articles of Association

Set forth below is a brief summary of significant provisions of our by-laws (or statuts) and applicable French laws. This is not a complete description and is qualified in its entirety by reference to our by-laws, a translation of which is provided in Exhibit 1.1 to this annual report. Each time they are modified which can only occur with the approval of a two third majority of our the shareholders present or represented at a shareholders' meeting, we file copies of our statuts with, and such by-laws are publicly available from, the Registry of Commerce and Companies in Lyon, France, under number 316 488 204 RCS-LYON.

Our corporate affairs are governed by our by-laws and by Book II of the French Commercial Code, as amended.

Our by-laws were last updated in May 2013 to act the recent increase in share capital related to the issuance of additional shares in May 2013.

Corporate Purposes

Pursuant to Article 2 of the by-laws, the purposes of the Company are:

- investment, under whatever form, in all French or foreign groups, companies or businesses which currently exist or which may be created in the future, mainly through contribution, subscription or purchasing of stocks or shares, obligations or other securities, mergers, holding companies, groups, alliances or partnerships;
- management of such financial investments;
- direction, management, control and coordination of its subsidiaries and interests;
- provision of all administrative, financial, technical or other services; and
- generally, all transactions of whatever nature, financial, commercial, industrial, civil, relating to property and real estate which may be connected directly or indirectly, in whole or in part, to the Company's purposes or to any other similar or related purposes which may favor the extension or development of said purposes.

Board of Directors

The Board of Directors is currently composed of four members, all of them were appointed by the shareholders for a period of six years expiring on the date of the annual general shareholders' meeting approving the financial results for fiscal year 2013. See Item 6, ''Directors, Senior Management and Employees''. A director's term ends at the end of the ordinary general shareholders' meeting convened to vote upon the accounts of the then-preceding fiscal year and is held in the year during which the term of such director comes to an end. Directors may be re-elected; a director may also be dismissed at any time at the shareholders' meeting.

Each director must own at least one share during his/her term of office. If, at the time of his/her appointment, a director does not own the required number of shares or if during his/her term, he/she no longer owns the required number of shares, he/she is considered to have automatically resigned if he/she fails to comply with the shareholding requirement within three months.

An individual person may not be a member of more than five Boards of Directors or Supervisory Boards in corporations (société anonyme) registered in France; directorships in controlled companies (as defined by Section L.233-16 of the French Commercial Code) by the Company are not taken into account.

In case of the death or resignation of one or more directors, the Board of Directors may make provisional appointments to fill vacancies before the next general shareholders meetings. These provisional appointments must be

ratified by the next ordinary shareholders meeting. Even if a provisional appointment is not ratified, resolutions and acts previously approved by the Board of Directors nonetheless remain valid.

If the number of Directors falls below the compulsory legal minimum, the remaining directors must convene an ordinary general shareholders' meeting to reach a full Board of Directors.

Any director appointed in replacement of another director whose term has not expired remains in office only for the remaining duration of the term of his predecessor.

One of our employees may be appointed to serve as a director. His/her employment contract must include actual work obligations. In this case, he/she does not lose the benefit of his/her employment contract.

The number of directors have employment contracts with the Company may not exceed one third of the directors then in office and in any case, a maximum of five members.

Pursuant to our by-laws, a director may not be older that 80 years of age. If a director reaches this limit during his/her term, such director is automatically considered to have resigned at the next general shareholders meeting.

The Board of Directors determines the direction of our business and supervises its implementation. Within the limits set out by the corporate purposes and the powers expressly granted by law to the general shareholders' meeting, the Board of Directors may deliberate upon our operations and make any decisions in accordance with our business. However, a director must abstain from voting on matters in which the director has an interest. The resolutions passed in a meeting of the Board of Directors are valid only if a quorum of half of the Directors is reached. A director cannot borrow money from the Company.

French law provides that the functions of Chairman of the Board and Chief Executive Officer in a French société anonyme may be distinct and held by two separate individuals.

The Chairman of the Board

The Board of Directors must elect one of its members as Chairman of the Board of Directors, who must be an individual person. The Board of Directors determines the duration of the term of the Chairman, which cannot exceed that of his/her tenure as a director. The Board of Directors may dismiss the Chairman at any time. The Chairman's compensation is decided by the Board of Directors, upon recommendation of the Compensation Committee.

The Chairman represents the Board of Directors and organizes its work. The Chairman reports on the Board's to the general shareholders' meeting. The Chairman is responsible for ensuring the proper functioning of our governing bodies and that the Board members have the means to perform their duties.

Pursuant to Section 706-43 of the French Criminal Proceedings Code, the Chairman may validly delegate to any person he/she chooses the power to represent us in any criminal proceedings that we may face.

As with any other Director, the Chairman may not be over eighty years old. In case the Chairman reaches this limit during his/her tenure, he/she will automatically be considered to have resigned. However, his/her tenure is extended until the next Board of Directors meeting, during which his/her successor will be appointed. Subject to the age limit provision, the Chairman of the Board may also be re-elected.

The Chief Executive Officer

We are managed by the Chairman of the Board of Directors or by an individual elected by the Board of Directors bearing the title of Chief Executive Officer. The choice between these two methods of management belongs to the Board of Directors and must be made as provided for by our by-laws. On March 31, 2008, the Board of Directors appointed Mr. Marc Oczachowski as Chief Executive Officer.

The Chief Executive Officer is vested with the powers to act under all circumstances on behalf of the Company, within the limits set out by the Company's corporate purposes, and subject to the powers expressly granted by law to the Board of Directors and the general shareholders' meeting.

The Chief Executive Officer represents the Company with respect to third parties. The Company is bound by any acts of the Chief Executive Officer even if they are contrary to corporate purposes, unless it is proven that the third party knew such act exceeded the Company's corporate purposes or could not ignore it in light of the circumstances. Publication of the by-laws alone is not sufficient evidence of such knowledge.

The Chief Executive Officer's compensation is set by the Board of Directors, upon recommendation of the Compensation Committee. The Chief Executive Officer can be terminated at any time by the Board of Directors. If such termination is found to be unjustified, damages may be allocated to the Chief Executive Officer, except when the Chief Executive Officer is also the Chairman of the Board.

The Chief Executive Officer may not hold another position as Chief Executive Officer or member of a Management Board in a corporation (société anonyme) registered in France except when (a) such company is controlled (as referred to in Section L.233-16 of the French Commercial Code) by the Company and (b) when this controlled company's shares are not traded on a regulated market.

Pursuant to our by-laws, the Chief Executive Officer may not be over seventy years old. In case the Chief Executive Officer reaches this limit during his/her office, he/she is automatically considered to have resigned. However, his/her tenure is extended until the next Board of Directors meeting, during which his/her successor must be appointed.

Dividend and Liquidation Rights (French Law)

Net income in each fiscal year, as increased or reduced, as the case may be, by any profit or loss of the Company carried forward from prior years, less any contributions to legal reserves, is available for distribution to our shareholders as dividends, subject to the requirements of French law and our by-laws.

Under French law and our by-laws, we are required to allocate 5% of our net profits in each fiscal year to a legal reserve fund until the amount in such reserve fund is equal to 10% of the nominal amount of the registered capital. The legal reserve is distributable only upon the liquidation of the Company.

Our shareholders may, upon recommendation of the Board of Directors, decide to allocate all or a part of distributable profits, if any, among special or general reserves, to carry them forward to the next fiscal year as retained earnings, or to allocate them to the shareholders as dividends.

Our by-laws provide that, if so agreed by the shareholders, reserves that are available for distribution under French law and our by-laws may be distributed as dividends, subject to certain limitations.

If we have made distributable profits since the end of the preceding fiscal year (as shown on an interim income statement certified by our statutory auditors), the Board of Directors has the authority under French law, without the approval of shareholders, to distribute interim dividends to the extent of such distributable profits. We have never paid interim dividends.

Under French law, dividends are distributed to shareholders pro rata according to their respective shareholdings. Dividends are payable to holders of shares outstanding on the date of the annual shareholders' meeting deciding the distribution of dividends, or in the case of interim dividends, on the date of the Board of Directors meeting approving the distribution of interim dividends. However, holders of newly issued shares may have their rights to dividends limited with respect to certain fiscal years. The actual dividend payment date is decided by the shareholders in an ordinary general meeting or by the Board of Directors in the absence of such a decision by the shareholders. The payment of the dividends must occur within nine months from the end of our fiscal year. Under French law, dividends not claimed within five years of the date of payment revert to the French State.

If the Company is liquidated, our assets remaining after payment of our debts, liquidation expenses and all of our remaining obligations will be distributed first to repay in full the nominal value of the shares, then the surplus, if any, will be distributed pro rata among the shareholders based on the nominal value of their shareholdings and subject to any special rights granted to holders of priority shares, if any. Shareholders are liable for corporate liabilities only up to the par value of the shares they hold and are not liable to further capital calls of the Company.

Changes in Share Capital (French Law)

Our share capital may be increased only with the approval of two thirds of the shareholders voting or represented at an extraordinary general meeting, following a recommendation of the Board of Directors. Increases in the share capital may be effected either by the issuance of additional shares (including the creation of a new class of shares) or by an increase in the nominal value of existing shares. Additional Shares may be issued for cash or for assets contributed in kind, upon the conversion of debt securities previously issued by the Company, by capitalization of reserves, or, subject to certain conditions, in satisfaction of indebtedness incurred by the Company. Dividends paid in the form of shares may be distributed in lieu of payment of cash dividends, as described above under ‘‘—Dividend and Liquidation Rights (French law).’’ French law permits different classes of shares to have liquidation, voting and dividend rights different from those of the outstanding ordinary shares, although we only have one class of shares.

Our share capital may be decreased only with the approval of two thirds of the shareholders voting or represented at an extraordinary general meeting. The share capital may be reduced either by decreasing the nominal value of the shares or by reducing the number of outstanding shares. The conditions under which the registered capital may be reduced will vary depending upon whether or not the reduction is attributable to losses incurred by the Company. The number of outstanding shares may be reduced either by an exchange of shares or by the repurchase and cancellation by us of our shares. Under French law, all the shareholders in each class of shares must be treated equally unless the inequality in treatment is accepted by the affected shareholder. If the reduction is not attributable to losses incurred by

us, each shareholder will be offered an opportunity to participate in such capital reduction and may decide whether or not to participate therein.

Repurchase of Shares (French Law)

Pursuant to French law, the Company may not acquire its own shares except (a) to reduce its share capital under certain circumstances with the approval of the shareholders at an extraordinary general meeting or (b) to provide shares for distribution to employees under a profit sharing or a stock option plan. However, the Company may not hold more than 10% of its shares then-issued. A subsidiary of the Company is prohibited by French law from holding shares of the Company and, in the event it becomes a shareholder of the Company, such shareholder must transfer all the shares of the Company that it holds.

Attendance and Voting at Shareholders' Meetings (French Law)

In accordance with French law, there are two types of general shareholders' meetings, ordinary and extraordinary. Ordinary general meetings are required for matters such as the election of directors, the appointment of statutory auditors, the approval of the report prepared by the Board of Directors and the annual accounts, the declaration of dividends and the issuance of (non-convertible) bonds.

Extraordinary general meetings are required for approval of matters such as amendments to the Company's by-laws, modification of shareholders' rights, approval of mergers, increases or decreases in share capital (including a waiver of preferential subscription rights), the creation of a new class of shares, the authorization of the issuance of investment certificates or securities convertible or exchangeable into shares and for the sale or transfer of substantially all of the Company's assets.

The Board of Directors is required to convene an annual ordinary general shareholders meeting, which must be held within six months of the end of our fiscal year, for approval of the annual accounts. Other ordinary or extraordinary meetings may be convened at any time during the year. Shareholders meetings may be convened by the Board of Directors or, if the Board of Directors fails to call such a meeting, by our statutory auditors or by a court-appointed agent. The court may be requested to appoint an agent either by one or more shareholders holding at least 5% of the our registered capital or by an interested party under certain circumstances, or, in case of an urgent matter, by the Work Council (Comité d'entreprise) representing the employees. The notice calling a meeting must state the agenda for such meeting.

French law provides that, at least 15 days before the date set for any general meeting on first notice, and at least ten days before the date set for any general meeting on second notice, notice of the meeting (avis de convocation) must be sent by mail to all holders of properly registered shares who have held such shares for more than one month before the date of the notice. A preliminary written notice (avis de réunion) must be sent to each shareholder who has requested to be notified in writing. Under French law, one or several shareholders together holding a specified percentage of shares may propose resolutions to be submitted for approval by the shareholders at the meeting. Upon our request, The Bank of New York Mellon will send to holders of ADSs notices of shareholders' meetings and other reports and communications that are made generally available to shareholders. The Works Council may also require the registration of resolution proposals on the agenda.

Attendance and exercise of voting rights at ordinary and extraordinary general meetings are subject to certain conditions. Shareholders deciding to exercise their voting rights must have their shares registered in their names in the shareholder registry maintained by or on behalf of the Company before the meeting. An ADS holder must timely and properly return its voting instruction card to the Depositary to exercise the voting rights relating to the shares represented by its ADSs. The Depositary will use its reasonable efforts to vote the underlying shares in the manner indicated by the ADS holder. In addition, if an ADS holder does not timely return a voting instruction card or the voting instruction card received is improperly completed or blank, that holder will be deemed to have given the Depositary a proxy to vote, and the Depositary will vote in favor of all proposals recommended by the Board of Directors and against all proposals that are not recommended by the Board of Directors.

All shareholders who have properly registered their shares have the right to participate in general meetings, either in person, by proxy, or by mail, and to vote according to the number of shares they hold. Each share confers on the shareholder the right to one vote. Under French law, an entity we control directly or indirectly is prohibited from holding shares in the Company and, in the event it becomes a shareholder, shares held by such entity would be deprived of voting rights. A proxy may be granted by a shareholder whose name is registered on our share registry to his or her spouse, to another shareholder or to a legal representative, in the case of a legal entity, or by sending a proxy in blank to the Company without nominating any representatives. In the latter case, the Chairman of the shareholders' meeting will vote such blank proxy in favor of all resolutions proposed by the Board of Directors and against all

others.

The presence in person or by proxy of shareholders having not less than 20% (in the case of an ordinary general meeting or an extraordinary general meeting deciding upon any capital increase by capitalization of reserves) or 25% (in the case of any other extraordinary general meeting) of the shares entitled to vote is necessary to reach a quorum. If a quorum is not reached at any meeting, the meeting is adjourned. Upon reconvening of an adjourned meeting, there is no quorum requirement in the case of an ordinary general meeting or an extraordinary general meeting deciding upon any capital increase by capitalization of reserves. The presence in person or by proxy of shareholders having not less than 20% of the Shares is necessary to reach a quorum in the case of any other type of extraordinary general meeting.

At an ordinary general meeting or an extraordinary general meeting deciding upon any capital increase by capitalization of reserves, a simple majority of the votes of the shareholders present or represented by proxy is required to approve a resolution. At any other extraordinary general meeting, two-thirds of the votes cast is required. However, a unanimous vote is required to increase liabilities of shareholders. Abstention from voting by those present or represented by proxy is viewed as a vote against the resolution submitted to a vote.

In addition to his/her rights to certain information regarding the Company, any shareholder may, during the two-week period preceding a shareholders' meeting, submit to the Board of Directors written questions relating to the agenda for the meeting. The Board of Directors must respond to such questions during the meeting.

Under French law, shareholders can nominate individuals for election to the Board of Directors at a shareholders' meeting. When the nomination is part of the agenda of the shareholders' meeting, the nomination must contain the name, age, professional references and professional activity of the nominee for the past five years, as well as the number of shares owned by such candidate, if any. In addition, if the agenda for the shareholders' meeting includes the election of members of the Board of Directors, any shareholder may require, during the meeting, the nomination of a candidate for election at the Board of Directors at the shareholders' meeting, even if such shareholder has not followed the nomination procedures. Under French law, shareholders cannot elect a new member of the Board of Directors at a general shareholders meeting if the agenda for the meeting does not include the election of a member of the Board of Directors, unless such nomination is necessary to fill a vacancy due to the previous resignation of a member.

As set forth in our by-laws, shareholders' meetings are held at our registered office of the Company or at any other locations specified in the written notice. We do not have staggered or cumulative voting arrangements for the election of Directors.

Preferential Subscription Rights (French Law)

Shareholders have preferential rights to subscribe for additional shares issued by the Company for cash on a pro rata basis (or any equity securities of the Company or other securities giving a right, directly or indirectly, to equity securities issued by the Company). Shareholders may waive their preferential rights, either individually or at an extraordinary general meeting under certain circumstances. Preferential subscription rights, if not previously waived, are transferable during the subscription period relating to a particular offering of shares. U.S. holders of ADSs may not be able to exercise preferential rights for Shares underlying their ADSs unless a registration statement under the Securities Act is effective with respect to such rights or an exemption from the registration requirement thereunder is available.

Form and Holding of Shares (French Law)

Form of Shares

Our by-laws provide that shares can only be held in registered form.

Holding of Shares

The shares are registered in the name of the respective owners thereof in the registry maintained by or on behalf of the Company.

Stock certificates evidencing shares, in a manner comparable to that in the United States, are not issued by French companies, but we may issue or cause to be issued confirmations of shareholdings registered in such registry to the persons in whose names the shares are registered. Pursuant to French law, such confirmations do not constitute documents of title and are not negotiable instruments.

Ownership of ADSs or Shares by Non-French Residents (French Law)

Under French law, there is no limitation on the right of non-French residents or non-French security holders to own, or where applicable, vote securities of a French company. A non-resident of France must file a déclaration administrative, or administrative notice, with French authorities in connection with the acquisition of a controlling

interest in any French company. Under existing administrative rulings, ownership, by a non-resident of France or a French corporation which is itself controlled by a foreign national, of 33.33% or more of a company's share capital or voting rights is regarded as a controlling interest, but a lower percentage may be held to be a controlling interest in certain circumstances (depending upon such factors as the acquiring party's intentions, its ability to elect directors or financial reliance by the French company on the acquiring party).

Certain Exemptions (French Law)

Under the U.S. securities laws, as a foreign private issuer, we are exempt from certain rules that apply to domestic U.S. issuers with equity securities registered under the U.S. Securities Exchange Act of 1934, including the proxy solicitation rules and the rules requiring disclosure of share ownership by directors, officers and certain shareholders. We are also exempt from certain of the current NASDAQ corporate governance requirements. For more information on these exemptions, see Item 16 G, ''Corporate Governance —Exemptions from Certain NASDAQ Corporate Governance Rules.''

Enforceability of Civil Liabilities (French Law)

We are a société anonyme, or limited liability corporation, organized under the laws of the Republic of France. The majority of our directors and executive officers reside in the Republic of France. All or a substantial portion of our assets and the assets of such persons are located outside the United States. As a result, it may not be possible for investors to effect service of process within the United States upon such persons or to enforce, either inside or outside the United States, judgments against such persons obtained in U.S. courts or to enforce in U.S. court judgments obtained against such persons in courts in jurisdictions outside the United States, in each case, in any action predicated upon the civil liability provisions of the federal securities laws of the United States. In an original action brought in France predicated solely upon the U.S. federal securities laws, French courts may not have the requisite jurisdiction to grant the remedies sought, and actions for enforcement in France of judgments of U.S. courts rendered against French persons referred to in the second sentence of this paragraph would require such French persons to waive their right under Article 15 of the French Civil Code to be sued in France only. We believe that no such French persons have waived such right with respect to actions predicated solely upon U.S. federal securities laws. In addition, actions in the United States under the U.S. federal securities laws could be affected under certain circumstances by the French law of July 16, 1980, which may preclude or restrict obtaining evidence in France or from French persons in connection with such actions.

Material Contracts

On March 28, 2012, pursuant to a securities purchase agreement, we issued Investor Warrants which are exercisable immediately and will expire five years after the date of issuance. The Investor Warrants are exercisable, at the option of the holder, upon the surrender of the Investor Warrants to us and the payment in cash of the exercise price of $2.75 per ordinary share in the form of ADSs. We also issued Placement Agent Warrants with an exercise price of $2.50 per ordinary share in the form of ADSs. The Placement Agent Warrants are exercisable from September 24, 2012 and expire on October 21, 2016. With respect to both the Investor Warrants and the Placement Agent Warrants (together, the "March 2012 Warrants"), the exercise price is subject to appropriate adjustment in the event of stock dividends, stock splits, reorganizations or similar events affecting our ordinary shares. The holders of the March 2012 Warrants are entitled to 20 days' notice before the record date for certain distributions to holders of our ordinary shares. If certain "fundamental transactions" occur, such as a merger, consolidation, sale of substantially all of our assets, tender offer or exchange offer with respect to our ordinary shares or reclassification of our ordinary shares, the holders of the March 2012 Warrants will be entitled to receive thereafter in lieu of our ordinary shares, the consideration (if different from ordinary shares) that the holders of the March 2012 Warrants would have been entitled to receive upon the occurrence of the fundamental transaction as if the March 2012 Warrants had been exercised immediately before the fundamental transaction. If any holder of ordinary shares is given a choice of consideration to be received in the fundamental transaction, then the holders of the March 2012 Warrants shall be given the same choice upon the exercise of the March 2012 Warrants following the fundamental transaction. A copy of the form of Investor Warrant was furnished to the SEC on our report on Form 6-K dated March 28, 2012. The foregoing description is qualified in its entirety by reference to the full text of the Form 6-K.

On May 28, 2013, pursuant to a securities purchase agreement, we issued Investor Warrants which will expire on November 29, 2018. The Investor Warrants are exercisable, from November 29, 2013, at the option of the holder, upon the surrender of the Investor Warrants to us and the payment in cash of the exercise price of $4.25 per ordinary share in the form of ADSs. We also issued Placement Agent Warrants with an exercise price of $5.00 per ordinary share in the form of ADSs. The Placement Agent Warrants are exercisable from November 29, 2013 and expire on May 28, 2016. With respect to both the Investor Warrants and the Placement Agent Warrants (together, the "May 2013 Warrants"), the exercise price is subject to appropriate adjustment in the event of stock dividends, stock splits, reorganizations or similar events affecting our ordinary shares. The holders of the May 2013 Warrants are entitled to 20 days' notice before the record date for certain distributions to holders of our ordinary shares. If certain "fundamental transactions" occur, such as a merger, consolidation, sale of substantially all of our assets, tender offer or exchange

offer with respect to our ordinary shares or reclassification of our ordinary shares, the holders of the May 2013 Warrants will be entitled to receive thereafter in lieu of our ordinary shares, the consideration (if different from ordinary shares) that the holders of the May 2013 Warrants would have been entitled to receive upon the occurrence of the fundamental transaction as if the May 2013 Warrants had been exercised immediately before the fundamental transaction. If any holder of ordinary shares is given a choice of consideration to be received in the fundamental transaction, then the holders of the May 2013 Warrants shall be given the same choice upon the exercise of the May 2013 Warrants following the fundamental transaction. A copy of the form of Investor Warrant was furnished to the SEC on our report on Form 6-K dated May 28, 2013. The foregoing description is qualified in its entirety by reference to the full text of the Form 6-K.

Exchange Controls

Under current French foreign exchange control regulations, there are no limitations on the amount of cash payments that we may remit to residents of foreign countries. Laws and regulations concerning foreign exchange controls do require, however, that all payments or transfers of funds made by a French resident to a non-resident be handled by an accredited intermediary.

Under current French law, there is no limitation on the right of non-French residents or non-French security holders to own, or where applicable, vote securities of a French company. A non-resident of France must file a déclaration administrative, or administrative notice, with French authorities in connection with the acquisition of a controlling interest in any French company. Under existing administrative rulings, ownership by a non-resident of France or a French corporation which is itself controlled by a foreign national, of 331/3 % or more of a French company's share capital or voting rights is regarded as a controlling interest, but a lower percentage may be held to be a controlling interest in certain circumstances (depending upon such factors as the acquiring party's intentions, its ability to elect directors or financial reliance by the French company on the acquiring party).

Certain Income Tax Considerations

The following generally summarizes the material French and US tax consequences of purchasing, owning and disposing of Shares or ADS (the "Securities"). The statements set forth below are based on the applicable laws, treaties and administrative interpretations of France and the United States as of the date hereof, all of which are subject to change.

This discussion is intended only as a descriptive summary and does not purport to be a complete analysis or listing of all potential tax effects of the purchase, ownership or disposition of Securities. It does not constitute legal or tax advice.

Investors should consult their own tax advisors regarding the tax consequences of the purchase, ownership and disposition of Securities in light of their particular circumstances, including especially the laws of all jurisdictions in which they are resident for tax purposes.

French Taxation

The following summary of the French tax consequences of purchasing and disposing of Securities does not address the treatment of Securities that are held by a resident of France (except for purposes of describing related tax consequences for other holders) or in connection with a permanent establishment or fixed base through which a holder carries on business or performs personal services in France, or by a person that owns, directly or indirectly, 5% or more of the stock of the Company. Moreover, the following discussion of the tax treatment of dividends only deals with distributions made on or after January 1, 2014.

There are currently no procedures available for holders that are not U.S. residents to claim tax treaty benefits in respect of dividends received on Securities registered in the name of a nominee. Such holders should consult their own tax advisors about the consequences of owning and disposing of Securities.

French law provides for specific rules relating to trusts, in particular specific tax and filing requirements as well as modifications to wealth, estate and gift taxes as they apply to trusts. Given the complex nature of these new rules and the fact that their application varies depending on the status of the trust, the grantor, the beneficiary and the assets held in the trust, the following summary does not address the tax treatment of Securities held in a trust. If Securities are held in trust, the grantor, trustee and beneficiary are urged to consult their own tax adviser regarding the specific tax consequences of acquiring, owning and disposing of Securities.

Taxation of Dividends on Securities - Withholding Tax

Dividends paid by a French corporation, such as EDAP, to non-residents normally are subject to a 30% French withholding tax (reduced to 21% since January 1, 2012 when non-residents are individuals resident from one of the countries of the European Economic Area and 15% for distributions made to not-for-profit organizations with a head office in a Member State of the European Economic Area which would be subject to the tax regime set forth under article 206-5 of the French General Tax Code if their head office was located in France and which meet the criteria set forth in the administrative guidelines BOI-RPPM-RCM-30-30-10-70-20120912, n°130).

From January 1, 2012, dividends paid by a French corporation transferred to non-cooperative States or territories (Etat ou territoire non coopératif), within the meaning of Article 238-0 A of the French General Tax Code (a "Non-Cooperative State"), will be subject to French withholding tax at a rate of 75% irrespective of the tax residence of the beneficiary of the dividends, if the dividends are received in such States or territories (subject to certain exceptions and the more favorable provisions of an applicable double tax treaty, provided that the double tax treaty is found to apply and the relevant conditions are fulfilled). The list of Non-Cooperative States is published by ministerial executive order, which is updated on a yearly basis. However, non-resident holders that are entitled to and comply with the procedures for claiming benefits under an applicable tax treaty may be subject to a reduced rate (generally 15%) of French withholding tax. If a non-resident holder establishes its entitlement to treaty benefits prior to the payment of a dividend, then French tax generally will be withheld at the reduced rate provided under the treaty.

Taxation on Sale or Disposition of Securities

Generally, holders, who are not residents of France for tax purposes, will not be subject to any French income tax or capital gains tax upon the sale or the disposal of Securities unless:

- the holders have held more than 25% of EDAP dividend rights, known as ("droits aux bénéfices sociaux"), at any time during the preceding five years, either directly or indirectly, and, as relates to individuals, alone or with relatives; or

- the holders are established or domiciled in a Non-Cooperative State, in which case they will be subject to a 75% tax on your capital gain; or

- the holders transfer the Securities upon redemption or repurchase by EDAP in which case the proceeds may be partially or fully characterized as dividends under French domestic law and as a result, be subject to French dividend withholding tax.

If the holders are resident in a State with which France has signed a double tax treaty that contains more favorable provisions, the holders may be exempt from any French income or capital gains tax when they sell or dispose of any Securities even if one of the above statements applies to them.

Transfers of Securities issued by a listed French company such as EDAP will not be subject to French registration or stamp duty if such transfers are not evidenced by a written agreement (acte). However, if the transfer is evidenced by a written agreement executed either in France or outside France, the transfer of Securities will be subject to a registration duty of 0.1% assessed on the sale price.

Pursuant to Article 235 ter ZD of the French General Tax Code, purchases of shares or ADS are subject to a 0.2% French tax on financial transactions provided that EDAP's market capitalization exceeds 1 billion euros as of December 1 of the year preceding the taxation year. A list of companies whose market capitalization exceeds 1 billion euros as of December 1 of the year preceding the taxation year is published annually by the French state. Pursuant to a ministerial regulation (arrêté) dated December 27, 2013, EDAP is not included in such list as a company whose market capitalization exceeds 1 billion euros as of December 1, 2013 and therefore, purchases of EDAP's Securities are not subject to such tax.

Estate and Gift Tax

France imposes estate and gift tax on Securities of a French company that are acquired by inheritance or gift. The tax applies without regard to the tax residence of the transferor. However, France has entered into estate and gift tax treaties with a number of countries pursuant to which, assuming certain conditions are met, residents of the treaty country may be exempted from such tax or obtain a tax credit.

Wealth Tax

Individuals who are not residents of France for purposes of French taxation are not subject to a wealth tax ("impôt de solidarité sur la fortune") in France as a result of owning an interest in the share capital of a French corporation, provided that such ownership interest is, directly and indirectly, less than 10% of the corporation's share capital and does not enable the shareholder to exercise influence over the corporation. Double taxation treaties may provide for a more favorable tax treatment.

Taxation of U.S. Holders

Shares

The following is a summary of the material French and U.S. federal income tax consequences of the purchase, ownership and disposition of Securities by a holder that is a resident of the United States for purposes of the Convention between the Government of the United States of America and the Government of the French Republic for the Avoidance of Double Taxation and the Prevention of Fiscal Evasion with Respect to Taxes on Income and Capital of August 31, 1994, (the "Treaty"), which entered into force on December 30, 1995 (as amended by the protocol described below and any subsequent protocols), and the tax regulations issued by the French tax authorities, and are fully eligible for benefits under the Treaty (a "U.S. holder").

In particular, the United States and France signed a protocol on January 13, 2009, that entered into force on December 23, 2009 and make several significant changes to the Treaty, including changes to the "Limitation of Benefits" provision. U.S. holders are advised to consult their own tax advisors regarding the effect the protocol may have on their eligibility for Treaty benefits in light of their own particular circumstances.

A holder generally will be entitled to Treaty benefits in respect of Securities if he is concurrently:

- the beneficial owner of Securities (and the dividends paid with respect thereto);
- an individual resident of the United States, a U.S. corporation, or a partnership, estate or trust to the extent its income is subject to taxation in the United States in its hands or in the hands of its partners or beneficiaries;
- not also a resident of France for French tax purposes; and
- not subject to an anti-treaty shopping article that applies in limited circumstances.

Special rules apply to pension funds and certain other tax-exempt investors.

If a partnership holds Securities, the tax treatment of a partner generally will depend on the status of the partner and the activities of the partnership. If a U.S. holder is a partner in a partnership that holds Securities, the holder is urged to consult its own tax advisor regarding the specific tax consequences of owning and disposing of its Securities.

For U.S. federal income tax purposes, a U.S. holder's ownership of our ADSs will be treated as ownership of our underlying ordinary shares.

This summary does not deal with Securities that are not held as capital assets, and does not address the tax treatment of holders of ADSs that acquire them in "pre-release" transactions or holders that are subject to special rules, such as banks, insurance companies, dealers in securities or currencies, regulated investment companies, persons that elect mark-to-market treatment, persons holding Securities as a position in a synthetic security, straddle or conversion transaction, persons that own, directly or indirectly, 5% or more of our voting stock or 5% or more of our outstanding capital and persons whose functional currency is not the U.S. dollar.

This summary does not discuss the treatment of Securities that are held in connection with a permanent establishment or fixed base through which a holder carries on business or performs personal services in France. The summary is based on laws, treaties, regulatory interpretations and judicial decisions in effect on the date hereof, all of which are subject to change. Such changes could apply retroactively and could affect the consequences described below.

Holders should consult their own tax advisors regarding the U.S. tax consequences of the purchase, ownership and disposition of Securities in the light of their particular circumstances, including the effect of any state or local laws.

Dividends and Paying Agents

Generally, dividend distributions to non-residents of France are subject to French withholding tax at a 30% rate (reduced to 21% since January 1, 2012 when non-residents are individuals resident from one of the countries of the European Economic Area) or to 75% as from January, 1 2012 if paid in non-cooperative States or territories, as defined in Article 238-0 A of the French General Tax Code, irrespective of the tax residence of the beneficiary of the dividends if the dividends are received in such States or territories. Eligible U.S. holders providing evidence of the entitlement to Treaty benefits with respect to the dividend (art.30) under the ‘‘Limitation on Benefits’’ provision contained in the Treaty who are U.S. residents, as defined pursuant to the provisions of the Treaty and who receive dividends in non-cooperative States or territories, should not be subject to this 75% withholding tax rate.

Under the Treaty, the rate of French withholding tax on dividends paid to an eligible U.S. holder as defined pursuant to the provisions of the Treaty and whose ownership of Securities is not effectively connected with a permanent establishment or fixed base that such U.S. holder has in France is reduced to 15%, or to 5% if such U.S. holder is a corporation and owns directly or indirectly at least 10% of the share capital of the issuing company; such U.S. holder may claim a refund from the French tax authorities of the amount withheld in excess of the Treaty rates of 15% or 5%, if any. For U.S. holders that are not individuals, the requirements for eligibility for Treaty benefits, including the reduced 5% or 15% withholding tax rate, contained in the "Limitation on Benefits" provision of the Treaty are complicated, and certain technical changes were made to these requirements the protocol of January 13, 2009. U.S. holders are advised to consult their own tax advisers regarding their eligibility for Treaty benefits in light of their own particular circumstances.

French withholding tax will be withheld at the 5% or 15% Treaty rate if a U.S. holder has established before the date of payment that the holder is a resident of the United States under the Treaty by following the simplified procedure described below.

The gross amount of dividends that a U.S. holder receives (before the deduction of French withholding tax) generally will be subject to U.S. federal income taxation as ordinary dividend income to the extent paid or deemed paid out of the current or accumulated earnings and profits of the Company (as determined under U.S. federal income tax principles). Such dividends will not be eligible for the dividends received deduction generally allowed to U.S. corporations. To the extent that an amount received by a U.S. holder exceeds the allocable share of current and accumulated earnings and profits of the Company, such excess will be applied first to reduce such U.S. holder's tax basis in its Securities and then, to the extent it exceeds the U.S. holder's tax basis, it will constitute capital gain from a deemed sale or exchange of such Securities. As the Company does not maintain "earnings and profits" computations, holders should assume that all distributions constitute dividends.

Subject to certain exceptions for short-term and hedged positions, the U.S. dollar amount of dividends received by an individual with respect to the Securities is currently subject to taxation at a maximum rate of 20% if the dividends are "qualified dividends." Dividends paid on the Securities will be treated as qualified dividends if (i) the issuer is eligible for the benefits of a comprehensive income tax treaty with the United States that the IRS has approved for the purposes of the qualified dividend rules and (ii) the Company was not, in the year prior to the year in which the dividend was paid, and is not, in the year in which the dividend is paid, a passive foreign investment company, or PFIC. The Treaty has been approved for the purposes of the qualified dividend rules. Based on our audited financial statements and relevant market and shareholder data, we do not believe we were a PFIC for U.S. federal income tax purposes with respect to our 2013 taxable year. In addition, we do not anticipate it becoming a PFIC for the 2014 taxable year (as described under "—Passive Foreign Investment Company Rules" below). Accordingly, dividends, if any, paid by us in 2013 to a U.S. holder would constitute "qualified dividends."

Holders of Securities should consult their own tax advisers regarding the availability of the reduced dividend tax rate in light of their own particular circumstances.

Dividends distributed with respect to the Securities generally will be treated as dividend income from sources outside of the United States, and generally will be treated as "passive category" (or, in the case of certain U.S. holders, "general category") income for U.S. foreign tax credit purposes. Subject to certain limitations, French income tax withheld in connection with any distribution with respect to the Securities may be claimed as a credit against the U.S. federal income tax liability of a U.S. holder if such U.S. holder elects for that year to credit all foreign income taxes. Alternatively, such French withholding tax may be taken as a deduction against taxable income. Foreign tax credits will not be allowed for withholding taxes imposed in respect of certain short-term or hedged positions in securities and may not be allowed in respect of certain arrangements in which a U.S. holder's expected economic profit is insubstantial. U.S. holders should consult their own tax advisors concerning the implications of these rules in light of their particular circumstances.

Dividends paid in euro will be included in the income of a U.S. holder in a U.S. dollar amount calculated by reference to the exchange rate in effect on the date of receipt by the holder (or, in the case of the ADSs, by the Depositary), regardless of whether the payment is in fact converted into U.S. dollars. If such a dividend is converted into U.S. dollars on the date of receipt, a U.S. holder generally should not be required to recognize foreign currency gain or loss in respect of the dividend income.

Capital Gains

Under the Treaty, a U.S. holder will not be subject to French tax on any gain derived from the sale or exchange of Securities, unless the gain is effectively connected with a permanent establishment or fixed base maintained by the holder in France.

For U.S. federal income tax purposes, gain or loss realized by a U.S. holder on the sale or other disposition of Securities will be capital gain or loss, and will be long-term capital gain or loss if the Securities were held for more than one year. The net amount of long-term capital gain recognized by an individual U.S. holder generally is subject to taxation at a maximum rate of 20%. U.S. holders' ability to offset capital losses against ordinary income is limited.

Additional Issues For U.S. Holders

Procedures for Claiming Treaty Benefits

Pursuant to French official administrative guidelines (BOFIP BOI-INT-DG-20-20-20-20-20120912), U.S. holders can either claim Treaty benefits under a simplified procedure or under the normal procedure. The procedure to be followed depends on whether the application for Treaty benefits is filed before or after the dividend payment.

Under the simplified procedure, in order to benefit from the lower rate of withholding tax applicable under the Treaty before the payment of the dividend, a U.S. holder must complete and deliver to the paying agent (through its account holder) a treaty form (Form 5000), to certify in particular that:

- the U.S. holder is beneficially entitled to the dividend;
- the U.S. holder is a U.S. resident within the meaning of the Treaty;
- the dividend is not derived from a permanent establishment or a fixed base that the U.S. holder has in France; and
- the dividend received is or will be reported to the tax authorities in the United States.

For partnerships or trusts, claims for Treaty benefits and related attestations are made by the partners, beneficiaries or grantors who also have to supply certain additional documentation.

In order to be eligible for Treaty benefits, pension funds and certain other tax-exempt U.S. holders must comply with the simplified procedure described above, though they may be required to supply additional documentation evidencing their entitlement to those benefits.

If Form 5000 is not filed prior to the dividend payment, a withholding tax will be levied at the 30% rate, and a holder would have to claim a refund for the excess under the normal procedure by filing both Form 5000 and Form 5001 no later than December 31 of the second calendar year following the year in which the dividend is paid.

Pension funds and certain other tax-exempt entities are subject to the same general filing requirements as other U.S. holders except that they may have to supply additional documentation evidencing their entitlement to these benefits.

Copies of Form 5000 and Form 5001 may be downloaded from the French tax authorities' website (www.impots.gouv.fr) and are also available from the U.S. Internal Revenue Service and from the Centre des Impôts des Non-Résidents in France (10 rue du Centre 93160, Noisy-le-Grand).

Medicare Tax

Certain U.S. holders that are individuals, estates or trusts are required to pay an additional 3.8% tax on, among other things, dividends on and capital gains from the sale or other disposition of stock for taxable years beginning after

December 31, 2012. U.S. holders that are individuals, estates or trusts should consult their tax advisors regarding the effect of this legislation on their ownership and disposition of the Securities.

Passive Foreign Investment Company Rules

Unfavorable U.S. tax rules or the PFIC rules, apply to companies that are considered PFICs. The Company will be classified as a PFIC in a particular taxable year if either (a) 75% or more of its gross income is treated as passive income for purposes of the PFIC rules; or (b) the average percentage of the value of its assets that produce or are held for the production of passive income is at least 50%.

As explained above, the Company believes that it was not a PFIC for U.S. tax purposes with respect to the year 2013, and also does not anticipate becoming a PFIC with respect to the year 2014. However, as discussed in Form 20-Fs filed by the Company with respect to certain prior years the Company believes that it was a PFIC in the past. Moreover, because the PFIC determination is made annually and is dependent upon a number of factors, some of which are beyond the Company's control (including whether the Company continues to earn substantial amounts of operating income as well as the market composition and value of the Company's assets), there can be no assurance that the Company will not become a PFIC in future years.

U.S. holders that held Securities at any time during the years when the Company was a PFIC and did not make certain U.S. tax elections (a "mark-to-market election" or a "QEF election") will be subject to adverse tax treatment. For instance, such holders will be subject to a special tax at ordinary income tax rates on certain dividends that the Company pays and on gains realized on the sale of Securities (“excess distributions”) in all subsequent years, even though the Company ceased to qualify as a PFIC. The amount of this tax will be increased by an interest charge to compensate for tax deferral, calculated as if the excess distributions had been earned ratably over the period the U.S. holder held its Securities. It may be possible, in certain circumstances, for a holder to avoid the application of the PFIC rules by making a "deemed sale" election for its taxable year that includes the last day of the Company’s last taxable year during which it qualified as a PFIC. The PFIC rules are extremely complex, and holders should consult their own tax advisers regarding the possible application of the PFIC rules to their Securities and the desirability and availability of a “deemed sale election.”

French Estate and Gift Tax

Under the estate and gift tax convention between the United States and France dated November 24, 1978 (as amended by the protocol signed on December 8, 2004), a transfer of Securities by gift or by reason of the death of a U.S. holder entitled to benefits under that convention generally will not be subject to French gift or inheritance tax, so long as the donor or transferor was not domiciled in France at the time of the transfer, and Securities were not used or held for use in the conduct of a business or profession through a permanent establishment or fixed base in France.

French Wealth Tax

The French wealth tax does not generally apply to Securities of a U.S. holder if the holder is a resident of the United States for purposes of the Treaty and does not own directly or indirectly a shareholding exceeding 25% of the financial rights of EDAP.

U.S. Information Reporting and Backup Withholding Rules

Payments of dividends and sales proceeds that are made within the United States or through certain U.S.-related financial intermediaries are subject to information reporting and may be subject to backup withholding unless the holder (i) is a corporation or other exempt recipient or (ii) provides a taxpayer identification number and certifies that no loss of exemption from backup withholding has occurred. Holders that are not U.S. persons generally are not subject to information reporting or backup withholding. However, such a holder may be required to provide a certification of its non- U.S. status in connection with payments received within the United States or through a U.S.-related financial intermediary.

Information with Respect to Foreign Financial Assets

In addition, U.S. holders that are individuals (and, to the extent provided in future regulations, entities) are subject to reporting obligations with respect to the shares, securities, debt instruments and other obligations of a French corporation if the aggregate value of such assets and certain other “specified foreign financial assets” exceeds $50,000. Significant penalties can apply if a U.S. holder fails to disclose its specified foreign financial assets.

U.S. holders should also consider their possible obligation to file a Form TD F 90-22.1—Foreign Bank and Financial Accounts Report as a result of holding the Securities. U.S. holders are urged to consult their tax advisors regarding these and any other reporting requirements that may apply with respect to their Securities.

The discussion above is a general summary. It does not cover all tax matters that may be important to you. You should consult your tax advisors regarding the application of the U.S. federal tax rules to your particular circumstances, as well as the state, local, non-U.S. and other tax consequences to you of the purchase, ownership and disposition of the Securities.

Statement by Experts

Not applicable.

Documents on Display

We file annual, periodic, and other reports and information with the SEC. These materials, including this annual report and the exhibits hereto, may be inspected and copied at the SEC's Public Reference Room at 100 F Street, N.E., Washington, D.C. 20549. The public may obtain information on the operation of the SEC's Public Reference Room by calling the SEC in the United States at +1 800 SEC 0330. Certain of our public filings are also available on the SEC's website at http://www.sec.gov (such documents are not incorporated by reference in this annual report).

Subsidiary Information

Not applicable.

Item 11. Quantitative and Qualitative Disclosures about Market Risk

We are exposed to market risk from changes in both foreign currency exchange rates and interest rates. We do not hold or issue derivative or other financial instruments. As of December 31, 2013, we had no outstanding foreign exchange sale or purchase contracts.

Exchange Rate Risk

Revenues and Expenses in Foreign Currencies

We are exposed to foreign currency exchange rate risk because a significant portion of our costs are denominated in currencies other than those in which we earn revenues. In 2013, approximately 81% of our total costs of sales and operating expenses were denominated in euro. During the same period, approximately 59% of our sales were denominated in euro, the rest being denominated primarily in U.S. dollars and Japanese yen.

A uniform 10% strengthening in the value of the euro as of December 31, 2013 relative to the U.S. dollar and the Japanese yen would have resulted in an increase in income before taxes and minority interests of approximately €112,000 for the year ended December 31, 2013, compared to an increase of approximately €99,000 for the year ended December 31, 2012. This calculation assumes that the U.S. dollar and Japanese yen exchange rates would have changed in the same direction relative to the euro In addition to the direct effect of changes in exchange rates quantified above, changes in exchange rates also affect the volume of sales.

We regularly assess the exposure of our receivables to fluctuations in the exchange rates of the principal foreign currencies in which our sales are denominated (in particular, the U.S. dollar and the Japanese yen) and, from time to time, hedge such exposure by entering into forward sale contracts for the amounts denominated in such currencies that we expect to receive from our local subsidiaries. As of December 31, 2013 we had no outstanding hedging instruments.

Financial Instruments and Indebtedness

Over the past three years, we also had exchange rate exposures with respect to indebtedness and assets denominated in Japanese yen and U.S. dollars. Approximately €0.312 million, €0.497 million and €0.728 million of our outstanding indebtedness at December 31, 2013, 2012 and 2011, respectively, were denominated in Japanese yen. Approximately €3.4 million, €6.2 million and €7.3 million of our outstanding indebtedness at December 31, 2013, 2012, and 2011,

respectively, were denominated in U.S. dollars. In addition, we had approximately €1.9 million, €0.6 million and €3.1 million of cash denominated in U.S. dollars at December 31, 2013, 2012 and 2011, respectively, and €0.7 million, €0.9 million and €0.5 million of cash denominated in Japanese yen at December 31, 2013, 2012 and 2011, respectively.

Item 12. Description of Securities Other than Equity Securities

American Depositary Shares

Fees Payable to ADS Holders

The Bank of New York Mellon, as the Company's Depositary, currently collects its fees for delivery and surrender of ADSs directly from investors depositing shares or surrendering ADSs for the purpose of withdrawal or from intermediaries acting for them. With respect to our New Debentures and the outstanding 2012 warrants, fees for delivery of ADS directly linked to a warrant exercise or the payment of quarterly interest shares are supported by the Company.

The Depositary may collect fees for making distributions to investors by deducting those fees from the amounts distributed or by selling a portion of distributable properly to pay the fees. The Depositary may collect its annual fee for Depositary services by deductions from cash distributions or by directly billing investors or by charging the book-entry system accounts of participants acting for them. The Depositary may generally refuse to provide fee-attracting services until fees for those services are paid.

Fees:	For:
$5.00 (or less) per 100 ADSs (or portion of 100 ADSs)	- Issuance of ADSs, including issuances resulting from a distribution of shares or rights or other property, - Cancellation of ADSs for the purpose of withdrawal, including if the deposit agreement terminates.
$0.2 (or less) per ADS	- Any cash distribution to ADS registered holders.
A fee equivalent to the fee that would be payable if securities distributed to you had been shares and the shares had been deposited to issuance of ADSs	- Distribution of securities distributed to holders of deposited securities which are distributed by the Depositary to ADS registered holders.
Registration or transfer fees	- Transfer and registration of shares on our share register to or from the name of the Depositary or its agent when you deposit or withdraw shares
Expenses of the Depositary	- Cable, telex and facsimile transmissions (when expressly provided in the deposit agreement) - Converting foreign currency to U.S. dollars

Taxes and other governmental charges the Depositary or the custodian have to pay on any ADS or share underlying an ADS, for example, stock transfer taxes, stamp duty or withholding taxes	-	As necessary
Any charges incurred by the Depositary or its agents for servicing the deposited securities	-	As necessary

Fees Payable to the Company by the Depositary

From January 1, 2013 to March 21, 2014, the following amounts were paid by the Depositary to the Company: $90,000.00 and $ 8,808.59 respectively for administration of ADR program and for expenses linked to the assistance in printing, mailing and distributing assembly meetings materials and proxies.

PART II

Item 13. Defaults, Dividend Arrearages and Delinquencies

None.

Item 14. Material Modifications to the Rights of Security Holders and Use of Proceeds

Not applicable.

Item 15. Controls and Procedures

Disclosure Controls and Procedures

Under the supervision and with the participation of the Company's management, including the Chief Executive Officer and Chief Financial Officer, the Company conducted an evaluation of the effectiveness of its disclosure controls and procedures (as such term is defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act), as of December 31, 2013. Based on this evaluation, the Company's Chief Executive Officer and Chief Financial Officer concluded that the Company's disclosure controls and procedures were effective as of such date. The Company's disclosure controls and procedures are designed to ensure that information required to be disclosed by us in the reports we file under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms and that such information is accumulated and communicated to management, including the Chief Executive Officer and Chief Financial Officer, to allow timely discussions regarding required disclosure.

Management's Report on Internal Control Over Financial Reporting

Management is responsible for establishing and maintaining adequate internal control over financial reporting. Internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles.

The Company's internal controls over financial reporting include those policies and procedures that:

- Pertain to the maintenance of records that in reasonable detail accurately and fairly reflect the transactions and dispositions of the assets of the Company;

- Provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the Company are being made only in accordance with authorizations of the Company's management and directors; and

- Provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of the Company's assets that could have a material effect on the financial statements.

Because of inherent limitations, internal controls over financial reporting may not prevent or detect misstatements. Projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

Management assessed the effectiveness of internal control over financial reporting as of December 31, 2013 based upon the framework as set forth by the Committee of Sponsoring Organizations of the Treadway Commission (1992

COSO) in Internal Control-Integrated Framework. Based on the Management's assessment, management concluded that the Company's internal control over financial reporting was effective as of December 31, 2013. This annual report does not include an attestation report of the company's registered public accounting firm on the Company's internal control over financial reporting due to the Company's market capitalization remaining below $75 million at June 30, 2013.

Change in Internal Control over Financial Reporting

No change in the Company's internal control over financial reporting occurred as of the end of the period covered by this report that has materially affected, or is reasonably likely to materially affect the Company's internal control over financial reporting.

Item 16. [Reserved]

Item 16A. Audit Committee Financial Expert

Our Board of Directors has determined that the chair of the Board's Audit Committee, Mr. Pierre Beysson, an independent director, qualifies as an audit committee financial expert.

Item 16B. Code of Ethics

We have adopted a code of ethics applicable to our Chief Executive Officer, Chief Financial Officer, principal accounting officers and to any persons performing similar functions. The code of ethics is reviewed every year by the Board of Directors. In 2012, there were no waivers of its applicability. Our code of ethics has previously been filed with the SEC and we have made it available on our website at http://www.edap-tms.com. You may request a copy of our code of ethics free of charge upon request to Blandine Confort, Investor Relations Officer, at bconfort@edap-tms.com.

Item 16C. Principal Accountant Fees and Services

The ''Audit and Non-Audit Services Pre-Approval Policy'' was approved by our Audit Committee on December 22, 2003 (the "2003 Rules") and reviewed on November 20, 2012. This requires all services which are to be performed by our external auditors to be pre-approved. Pre-approval may be in the form of a general pre-approval or as pre-approval on a case-by-case basis. All services to be performed by the external auditors were subjected to the above policy and approved in advance. The Audit Committee has been regularly informed of the services and the fees to be paid. Our external auditors PricewaterhouseCoopers Audit ("PwC") billed the following services related to our 2012 and 2013 financial years.

Nature of the Fees	2013 (in €)	2012 (in €)
Audit fees	220,000	120,000
All other fees (1)	-	8,800
Total	220,000	128,800

(1) "Other fees" for 2012 paid to Ernst & Young Audit in relation with special reports issued for the 2011 annual general shareholders' meeting held on June 25, 2012 and with correspondence with the SEC related to its review of the 2011 annual report on Form 20-F.

Audit Fees

The following services were billed under the category ''audit services'': audit of financial statements and services performed in relation to legal obligations, including the formulation of audit opinions and reports, domestic and international legal audits and support in the preparation and auditing of the documents to be filed.

Audit-Related Fees

Audit-related services mainly consisted of services that are normally performed by the external auditor in connection with the auditing of the annual financial statements. Audit-related services also included advice on issues of accounting and reporting which were not classified as audit services, support with the interpretation and implementation of new accounting and reporting standards, auditing of employee benefit plans and support with the implementation of corporate control requirements for reporting.

Tax Fees

Tax services consisted of services relating to issues of domestic and international taxation (adherence to tax law, tax planning and tax consulting). Furthermore, services were commissioned for the review of tax returns, assistance with tax audits, as well as assistance relating to tax law.

All Other Fees
Other services mainly consisted for 2012 of amounts paid to Ernst & Young Audit in relation with special reports issued for the 2011 annual general shareholders' meeting held on June 25, 2012 and with correspondence with the SEC related to its review of the 2011 annual report on Form 20-F.

All these services were unrelated to the audits of our financial statements.

Item 16D. Exemptions from the Listing Standards for Audit Committees

Not applicable.

Item 16E. Purchases of Equity Securities by the Issuer and Affiliated Purchasers

In 2013, there was no other purchase of equity securities of the Company registered pursuant to Section 12 of the Exchange Act by the Company or by affiliated purchasers.

Item 16F. Change in Registrant's Certifying Accountant

Not applicable.

Item 16G. Corporate Governance Requirements

Exemptions from Certain NASDAQ Corporate Governance Rules

EDAP is incorporated under the laws of France, with securities listed on regulated public markets in the United States (NASDAQ). As a foreign private issuer listed on the NASDAQ, we are subject to the NASDAQ rules which provide for exemptions from the NASDAQ corporate governance requirements for a foreign private issuer when those standards are contrary to a law, rule or regulation of any public authority exercising jurisdiction over such issuer or contrary to generally accepted business practices in the issuer's country of domicile. We are thus exempt from compliance with certain corporate governance standard that are contrary to the French corporate law. These exemptions, and the practices followed by the Company, are described below.

We are exempt from NASDAQ's quorum requirements applicable to meetings of shareholders. In keeping with French law and generally accepted business practices in France, the presence in person or by proxy of shareholders having not less than 20% (in the case of an ordinary general meeting or an extraordinary general meeting deciding upon any capital increase by capitalization of reserves) or 25% (in the case of an extraordinary general meeting) of the shares is necessary for a quorum. If a quorum is not present at any meeting, the meeting is adjourned. Upon recommencement of an adjourned meeting, there is no quorum requirement in the case of an ordinary general meeting or an extraordinary general meeting deciding upon any capital increase by capitalization of reserves. The presence in person or by proxy of shareholders having not less than 20% of the Shares is necessary for a quorum in the case of any other type of extraordinary general meeting. We petitioned for this exemption because there are doubts as to whether it would be legally permissible for a French company to adopt in its by-laws quorum requirements that would be more stringent than those prescribed by French corporate law, and this would in any event be contrary to generally accepted business practice in France.

Item 16H. Mine Safety Disclosure

Not applicable.

PART III

Item 17. Financial Statements.

See Item 18, "Financial Statements."

Item 18. Financial Statements

The financial statements listed in the Index to Financial Statements are filed as a part of this annual report.

Item 19. Exhibits

The exhibits listed in the Index to Exhibits are filed or incorporated by reference as a part of this annual report.

INDEX TO EXHIBITS

Pursuant to the rules and regulations of the Securities and Exchange Commission, the Company has filed certain agreements as exhibits to this annual report on Form 20-F. These agreements may contain representations and warranties by the parties. These representations and warranties have been made solely for the benefit of the other party or parties to such agreements and (i) may be intended not as statements of fact, but rather as a way of allocating the risk to one of the parties to such agreements if those statements turn out to be inaccurate; (ii) may have been qualified by disclosures that were made to such other party or parties and that either have been reflected in the Company's filings or are not required to be disclosed in those filings; (iii) may apply materiality standards different from what may be viewed as material to investors; and (iv) were made only as of the date of such agreements or such other date(s) as may be specified in such agreements and are subject to more recent developments. Accordingly, these representations and warranties may not describe the Company's actual state of affairs at the date hereof.

Exhibit Number:	Description
1.1	By-laws (statuts) of EDAP TMS S.A. as amended as of May 28, 2013.
4.1	French version of Commercial Lease dated November 1, 2011 and Amendment No. 1 dated March 27, 2012, between Maison Antoine Baud and EDAP TMS France (incorporated herein by reference to Exhibit 4.1 to the Annual Report on Form 20-F filed on April 26, 2012)(1)
4.2	English language summary of Commercial Lease dated November 1, 2011 and Amendment No. 1 dated March 27, 2012, between Maison Antoine Baud and EDAP TMS France (incorporated herein by reference to Exhibit 4.2 to the Annual Report on Form 20-F filed on April 26, 2012) (1)
4.3	Form of Amended and Restated Depositary Agreement between EDAP TMS SA and The Bank of New York Mellon, as depositary (incorporated herein by reference to Exhibit 1.2 to Form F-6 dated September 15, 2011, SEC File No. 333-176843). (1)
4.4	Form of 9% Debenture due June 30, 2014 (incorporated herein by reference to Form 6-K dated January 27, 2012). (1)
4.5	Form of Ordinary Share Purchase Warrant (incorporated herein by reference to Form 6-K dated January 27, 2012). (1)
4.6	Form of Registration Rights Agreement dated as of January 19, 2012 (incorporated herein by reference to Form 6-K dated January 27, 2012). (1)
4.7	Form of Ordinary Share Purchase Warrant (incorporated herein by reference to Exhibit 4.1 to Form 6-K dated March 28, 2012). (1)
4.8	Form of Securities Purchase Agreement dated March 22, 2012 among EDAP TMS S.A. and each purchaser identified on the signature pages thereto (incorporated herein by reference to Exhibit 1.1 to Form 6-K dated March 28, 2012). (1)
4.9	Form of Ordinary Share Purchase Warrant (incorporated herein by reference to Exhibit 4.1 to Form 6-K dated May 28, 2013). (1)
4.10	Form of Securities Purchase Agreement dated March 23, 2013 among EDAP TMS S.A. and each purchaser identified on the signature pages thereto (incorporated herein by reference to Exhibit 1.1 to Form 6-K dated May 28, 2013). (1)
8.1	List of subsidiaries of EDAP TMS S.A. as of April 3, 2014.
12.1	Certification of Chief Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
12.2	Certification of Chief Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
13.1	Certification of Chief Executive Officer and Chief Financial Officer pursuant to Section 906 of the Sarbanes Oxley Act of 2002.
15.1	Consent of PricewaterhouseCoopers Audit.
15.2	Consent of Ernst & Young Audit.

101 Interactive Data File

(1) Previously filed.

SIGNATURES

The registrant hereby certifies that it meets all of the requirements for filing on Form 20-F and that it has duly caused and authorized the undersigned to sign this annual report on its behalf.

EDAP TMS S.A.

Dated: April 3, 2014

/s/ Marc Oczachowski
Marc Oczachowski
Chief Executive Officer

Dated: April 3, 2014

/s/ Eric Soyer
Eric Soyer
Chief Financial Officer

INDEX TO FINANCIAL STATEMENTS

Audited Consolidated Financial Statements for EDAP TMS S.A. and Subsidiaries for the Years Ended December 31, 2013, 2012 and 2011

Report of Independent Registered Public Accounting Firm

To the Board of Directors and Shareholders,
EDAP TMS S.A.
Vaulx-en-Velin

In our opinion, the accompanying consolidated balance sheets and the related consolidated statements of income, comprehensive income, shareholders' equity and cash flows present fairly, in all material respects, the financial position of EDAP TMS S.A. and its subsidiaries at December 31, 2013 and 2012, and the results of their operations and their cash flows for each of the two years in the period ended December 31, 2013 in conformity with accounting principles generally accepted in the United States of America. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits. We conducted our audits of these statements in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, and evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

Lyon, France, April 3, 2014

PricewaterhouseCoopers Audit

Represented by
/s/ Elisabeth L'hermite
Elisabeth L'hermite

Report of Independent Registered Public Accounting Firm

Board of Directors and Shareholders of EDAP TMS S.A.,

We have audited the accompanying consolidated statements of income, comprehensive income, shareholders' equity and cash flows of EDAP TMS S.A. for the year ended December 31, 2011. These consolidated statements are the responsibility of EDAP TMS's management. Our responsibility is to express an opinion on these consolidated statements based on our audits.

We conducted our audit in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. We were not engaged to perform an audit of the Company's internal control over financial reporting. Our audit included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion. An audit also includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, and evaluating the overall financial statement presentation. We believe that our audit provides a reasonable basis for our opinion.

In our opinion, the consolidated statements referred to above present fairly, in all material respects, the consolidated results of operations and cash flows of EDAP TMS S.A. for the year ended December 31, 2011, in conformity with U.S. generally accepted accounting principles.

ERNST & YOUNG Audit

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Represented by
/s/ Nicolas Sabran
Nicolas Sabran

April 26, 2012
Lyon, France

EDAP TMS S.A. AND SUBSIDIARIES
CONSOLIDATED BALANCE SHEETS
As of December 31, 2013 and 2012
(in thousands of euros unless otherwise noted)

ASSETS	Notes	2013	2012
Current assets			
Cash and cash equivalents	2	6,681	7,041
Current portion of net trade accounts and notes receivable	3	7,895	11,148
Other receivables	4	1,497	842
Inventories	5	4,698	4,263
Deferred tax assets	20-3	22	32
Other assets, current portion	6	331	367
Short-term investment	2	1,000	1,036
Total current assets		22,125	24,729
Property and equipment, net	7	1,655	2,035
Intangible assets, net	8	36	71
Goodwill	8	2,412	2,412
Deposits and other non-current assets		331	396
Net Trade accounts and notes receivable, non current	3	316	801
Total assets		26,874	30,444
LIABILITIES AND SHAREHOLDERS' EQUITY			
Current liabilities			
Trade accounts and notes payable	9	5,435	6,336
Deferred revenues, current portion	10	826	885
Social security and other payroll withholdings taxes		760	729
Employee absences compensation		506	473
Income taxes payable		10	12
Other accrued liabilities	11	1,570	1,928
Short-term borrowings	13	2,208	2,095
Current portion of capital lease obligations	12	184	459
Current portion of long-term debt	14-1	90	207
Total current liabilities		11,589	13,124
Deferred revenues, non current	10	47	79
Capital lease obligations, non current	12	378	494
Non Convertible debentures	14-2	-	4,416
Financial instruments carried at fair value	14-3	3,439	1,754
Long-term debt, non current	14-1	239	415
Other long-term liabilities	15	1,897	1,999
Total liabilities		17,589	22,282
Shareholders' equity			
Common stock, €0.13 par value; 22,171,198 shares issued and 21,789,670 shares outstanding; 18,753,757 shares issued and 18,372,229 shares outstanding; at December 31, 2013 and 2012, respectively		2,882	2,438
Additional paid-in capital		51,385	45,791
Retained earnings		(40,590)	(35,569)
Cumulative other comprehensive loss		(3,221)	(3,327)
Treasury stock, at cost; 381,528 at December 31, 2013 and 2012, respectively	16	(1,172)	(1,172)
Total shareholders' equity	16	9,284	8,161

Total liabilities and shareholders' equity	26,874	30,444

EDAP TMS S.A. AND SUBSIDIARIES

CONSOLIDATED STATEMENTS OF INCOME
For the years ended December 31, 2013, 2012 and 2011
(in thousands of euros except per share data and where otherwise noted)

	Notes	2013	2012	2011
Sales of goods		14,767	17,009	12,399
Sales of RPPs & leases		3,922	3,988	4,508
Sales of spare parts and services		5,375	5,021	5,365
Total sales		24,065	26,018	22,272
Other revenues	17	15	47	20
Total revenues		24,080	26,065	22,292
Cost of goods		(8,883)	(9,735)	(7,365)
Cost of RPPs & leases		(2,191)	(2,329)	(2,240)
Cost of spare parts and services		(3,686)	(3,568)	(3,830)
Total cost of sales		(14,761)	(15,632)	(13,435)
Gross profit		9,319	10,433	8,857
Research and development expenses	18	(2,595)	(2,659)	(2,436)
Selling and marketing expenses		(6,279)	(6,620)	(5,874)
General and administrative expenses		(3,200)	(3,185)	