EDAP TMS
ANNUAL REPORT
2012

HIFU
High Intensity Focused Ultrasound

ESWL
Extracorporeal Shockwave Lithotripsy

www.edap-tms.com

edap tms

Bringing New Horizons to Therapy

Dear EDAP Shareholders

EDAP has achieved many significant milestones over the past year. Almost without exception, the economic circumstances in the countries we operate in remain challenging. Yet, through the tremendous energy and effort from all the EDAP teams around the world, we achieved significant growth in revenues in 2012, concluded the follow-up phase of our US clinical trial for Ablatherm-HIFU and refocused our activities on the US market by relocating our Chief Executive Officer to the United States.

2012 was a record breaking year for EDAP in lithotripsy sales. We attribute much of this success to our strategy of having a wide range of products that address most of market segments and enable greater market penetration. Specifically, 2012 was a great year for our operations in Asia, and our activities gained significant traction in the Middle East.

We have been growing our lithotripsy business in the recent years because of our commitment and capacity for innovation. We have clearly demonstrated this over the past few years as we built a range of innovative products with our current range of lithotriptors including our Sonolith i move and Sonolith i-sys. They represent not only a very innovative offering on the market but also a wide range of options and solutions. This record of innovation, combined with an aggressive and effective market penetration strategy, has led to a record 2012 year for EDAP. As we continue to expand our presence around the world, we work at maintaining this trend.

Turning to our HIFU ("High Intensity Focused Ultrasound") division and our US ENLIGHT clinical trial, in 2012 we completed the 2-year patient follow-up phase and conducted in-depth analysis of the data and resulting statistics in order to provide the U.S. Food and Drug Administration ("FDA") with the most comprehensive data. On January 31, 2013, we submitted our Pre-Market Approval ("PMA") file to the FDA for our Ablatherm device 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. With this major milestone completed, we have now entered the substantive review phase for Ablatherm-HIFU. Since the start of our clinical trial, we have strived to maintain close communication with the FDA. We will continue to provide the agency with timely communications in order to support their review process.

We recently announced a new addition to our HIFU offering: a new robotic HIFU device for focal therapy of prostate cancer called Focal.One. Focal.One is the first device dedicated to the focal approach in prostate cancer therapy. We officially launched Focal.One at the 28th Annual European Urology Association (EAU) Congress in Milan, Italy, in March 2013 where we saw tremendous interest in the device. Focal.one, in combination with our existing Ablatherm device, provides the company with a full range of innovative HIFU offerings. This is in line with our global strategy of covering most segments of the markets within which we operate. It allows us to expand our business and answer the treatment needs of most types of urologists and patients with localized prostate cancer.

Finally, in 2012, we achieved major financial milestones by gradually streamlining our capital structure. We restructured and reduced the amount of outstanding bonds to $8 million. Also, we very recently launched a $ 12 million fund raise which will allow us to further strengthen our financial profile, as well to accelerate our investments in preparation for our market entry in the U.S. with Ablatherm-HIFU.

Sincerely,

Philippe Chauveau
Chairman of the Board
EDAP TMS S.A.
May 21, 2013

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

☒ ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(D) OF THE SECURITIES EXCHANGE ACT OF 1934
For the Fiscal Year Ended December 31, 2012

OR

☐ TRANSITION REPORT 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, 2012: 18,372,229 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 _____ No X_____

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__

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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®. 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 ''anticipate'' or 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
- 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 Warrants and New Debentures;
- our ability to repay our indebtedness when it comes due;
- 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, 2012, 2011 and 2010 and the selected income statement data for the years ended December 31, 2012, 2011 and 2010 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.

In thousands of euro, except per share data in euro	Year Ended and at December 31, 2012	2011	2010	2009	2008
INCOME STATEMENT DATA					
Total revenues	26,065	22,292	23,708	24,885	23,053
Total net sales	26,018	22,272	23,202	24,839	22,856
Gross profit	10,433	8,857	9,455	10,672	9,099
Operating expenses	(12,463)	(11,353)	(13,272)	(13,874)	(13,258)
Income (loss from operations)	(2,030)	(2,497)	(3,818)	(3,202)	(4,159)
Income (loss) before income taxes	(7,358)	(543)	(11,778)	(7,694)	1,648
Income tax (expense) benefit	(118)	(395)	(939)	(72)	(51)
Net income (loss)	(7,475)	(938)	(12,717)	(7,766)	1,597
Basic earnings (loss) per share	(0.43)	(0.07)	(0.98)	(0.74)	0.17
Diluted earnings (loss) per share	(0.43)	(0.07)	(0.98)	(0.74)	0.17
Dividends per share[(1)]	—	—	—	—	—
Basic weighted average shares outstanding	17,556,395	13,345,004	13,008,401	10,510,305	9,582,593
Diluted weighted average shares outstanding	17,556,395	13,345,004	13,008,401	10,510,305	9,582,593
BALANCE SHEET DATA					
Total current assets	24,729	25,032	29,865	33,248	35,786
Property and equipment, net	2,035	2,534	2,877	3,288	3,763
Total current liabilities	13,124	19,717	14,658	15,175	14,457
Total assets	30,444	32,238	35,938	40,378	43,863
Long-term debt, less current portion	6,585	720	10,075	10,138	9,500
Total shareholders' equity	8,161	8,714	8,900	12,579	17,191

(1) No dividends were paid with respect to fiscal years 2008 through 2011 and subject to approval of the annual shareholders' meeting to be held in 2013 the Company does not anticipate paying any dividend with respect to fiscal year 2012. 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
	€	€	€	€
2008	0.80	0.62	0.68	0.72
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

(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
	€	€	€	€
2012				
September	0.80	0.76	0.78	0.78
October	0.78	0.76	0.77	0.77
November	0.79	0.77	0.78	0.77
December	0.77	0.75	0.76	0.76
2013				
January	0.77	0.74	0.75	0.74
February	0.77	0.73	0.75	0.76
March, through March 22, 2013	0.78	0.76	0.77	0.77

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

On March 22, 2013, the Noon Buying Rate was U.S.$1.00 = 0.77€.

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 2010, 2011 and 2012, we had positive operating income in our Urology Devices and Services ("UDS") division, which however were not sufficient to offset the negative operating income in our HIFU division, nor the cost of the clincial 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, although total revenues have increased owing to increased sales volumes. 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 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. However, the Ablatherm is not 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. 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, our ongoing operations and repay our outstanding indebtedness.

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, 2012, we had €8.1 million cash and cash equivalents and short terms investments on hand and non-convertible debentures of $8.0 million of principal amount due June 30, 2014 (see Item 5 "Operating and Financial Review and Prospects'' for more information regarding the issuance of our outstanding debentures).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 will need to raise additional capital to repay our indebtedness when due or in the event of significant delays with the FDA PMA submission. If funding is not available on acceptable terms, or at all, we may need to delay the approval process, decrease our operating expenses or renegotiate with the holders of our outstanding debentures.

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 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 neeed to proceed with the substantive review. 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 granted a special temporary reimbursement for the use of our HIFU technology in the treatment of localized prostate cancer, under certain clinical conditions. French healthcare government authorities will review the clinical data gathered within the next five years in view of granting definitive reimbursement for HIFU. However, we cannot guarantee that such 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 2012, 2011 and 2010, 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-HIFU solution for the treatment of prostate cancer 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 submission and regulatory process to seek the FDA's approval on our Ablatherm-HIFU 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, 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 USHIFU, 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 Ltd, has developed a device using HIFU technology to treat uterine fibroids. Haifu, a Chinese company, is developing HIFU products addressing various types of cancers. Philips Healthcare 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''), formerly the Health Care Financing Administration (''HCFA''), 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 device 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 good manufacturing practices (''GMP'') 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 2012, approximately 79% of our total costs of sales and operating expenses were denominated in euro, while approximately 48% 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, 2012, 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 submission to the FDA for our Ablatherm through completion of the approval process, we will need to raise additional capital to repay our indebtedness when due or in the event of significant delays with the FDA PMA submission. If funding is not available on acceptable terms, or at all, we may need to delay the approval process, decrease our operating expenses or renegotiate with the holders of our outstanding debentures.

On January 19, 2012, we entered into a privately negotiated exchange agreement (the "Exchange Agreement") with all of the holders of our outstanding 9% Senior Convertible Debentures due October 29, 2012 and Warrant holders, whereby all October 2007 Convertible Debentures and Warrants were exchanged for $10.0 million of new non-convertible debentures (the "New Debentures"), 1,948,871 newly issued ordinary shares, 408,691 new warrants (the "January 2012 Warrants") and US$ 500,000 in cash. See Item 5 "Operating and Financial Review and Prospects'').

In accordance with the terms of the New Debentures, as from October 29, 2012, the holders of New Debentures can elect to receive interest payments in shares or in cash. The current economic and financial environment has adversely affected and may continue to affect our share price, thus we may be unable to make payment in shares without significantly diluting the interest of the existing shareholders. If we are unable to issue shares on reasonable terms or if holder of New Debentures so elect, we may need to make interest payments in cash, thus negatively affecting our working capital.

If any of the above materializes, it could have a material adverse effect on our business, financial condition and results of operations.

Risks relating to the outstanding warrants and New Debentures

We have a significant amount of indebtedness, consisting primarily of our New Debentures. We will need to raise additional funding before our New Debentures come due because we are unlikely to be able to generate sufficient cash flow from our operations to repay the principal on our indebtedness by that date. Further, if we are required for any reason to repay our outstanding New Debentures prior to their maturity date, we would be required to deplete our working capital or raise additional funds. Our failure to repay the New Debentures, if required, could result in legal action against us, which could require the sale of substantial assets.

The New Debentures are due and payable on June 30, 2014, unless reimbursed earlier. Our ability to make payments on, or to refinance or renegotiate our New Debentures, and to fund planned capital expenditures, research and development efforts, working capital, acquisitions and other general corporate purposes depends on our ability to generate cash in the future. We are unlikely to be able to generate sufficient cash flow from our operations to pay the principal on our New Debentures when due and as a result we may be required to renegotiate all or a portion of our indebtedness, including the New Debentures, on or before their maturity, sell assets, reduce or delay capital expenditures, including relating to regulatory approvals, decrease our operating expenses, seek to raise additional capital or take other similar actions. Renegotiating our indebtedness or raising additional capital may be difficult to accomplish on acceptable terms, if at all, and any issuance of equity or debt financings may contain terms that are not favorable to shareholders of the Company.

In addition, any event of default could require the early repayment of the New Debentures at the mandatory default amount, including all other amounts of interest, costs, expenses and liquidated damages due in respect of the defaulted New Debentures. If, prior to the maturity date, we are required to repay the outstanding New Debentures in full, we would be required to use our working capital and raise and/or borrow additional funds. Such additional funds may be difficult to obtain on acceptable terms, if at all.

If we were unable to repay the New Debentures when required, the New Debentures holders could commence legal action against us to recover the amounts due. Any such action would have a material adverse effect on our financial condition and results of operations and may limit or preclude us from advancing our product candidates through approvals or otherwise growing our business.

We may have to pay liquidated damages to the holders participating in the Exchange, which would increase our expenses and reduce our cash resources.

In connection with the issuance of New Debentures and January 2012 Warrants, we entered into a registration rights agreement (the "Registration Right Agreement"). Under the terms of the Registration Rights Agreement, subject to certain limited exceptions, if we fail to comply with certain provisions set forth in the Registration Rights Agreement, we will be required to pay the holders participating in the exchange, as liquidated damages, 1.0% of the aggregate balanced amount of October 2007 Convertible Debentures exchanged by each such holder in the Exchange Agreement for each 30-day period (or a pro rata portion thereof) during which such failure continues. There can be no assurance that the registration statement to which the Registration Rights Agreement relates will remain effective for the time periods necessary to avoid payment of liquidated damages. Any payment of liquidated damages would increase our expenses, reduce our cash resources and may limit or preclude us from advancing our product candidates through clinical trials or otherwise growing our business.

The issuance of ADSs upon exercise of outstanding warrants and in payment of interest on the New Debentures 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") will result in dilution of other shareholders since the selling shareholders may ultimately sell the full amount of ADSs issuable on exercise. Based on the total number of outstanding warrants as of April 2, 2013, up to 1,566,250 ADSs are issuable upon exercise, representing approximately 8.3% of our issued and outstanding share capital. In addition, interest on the New Debentures is payable, under certain circumstances, in ordinary shares or ADSs, under a formula which is tied to the trading price of our ADSs, and under which there is no upper limit of shares that may be required to be issued in payment of interest. 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 this 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. For more information regarding the March 2012 placement, see Item 10 "Material Contracts."

On June 25, 2012, our shareholders extended the validity of existing resolutions, and renewed the May 24, 2011 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.

Our total outstanding indebtedness may harm our financial condition and results of operations.

Our total consolidated long-term financial debt as of December 31, 2012 was €6.8 million and represented approximately 22% of our total assets, including the current portion of indebtedness of approximately €0.2 million as of that date. Our level of indebtedness could have important consequences on our future operations, including:

- Reducing the availability of our cash flow to fund working capital, capital expenditures and other general corporate purposes, and limiting our ability to obtain additional financing for these purposes; and
- Limiting our flexibility in planning for, or reacting to, and increasing our vulnerability to, changes in our business, the industry in which we operate and the general economy.

Provisions in the New Debentures could discourage an acquisition of us or an investment in us by a third party, even if the acquisition or investment would be favorable to investors.

If we are party to a "fundamental transaction" or "change of control" (as defined in the New Debenture) or agree to dispose of in excess of 40% of our assets, the holders have the right to require us to redeem the New Debentures at their election shortly after they are notified of such a change. Any redemption under these circumstances will be at a premium equal to the higher of 130% of the then-outstanding principal amount of the New Debenture, plus 100% of accrued and unpaid interest, and other amounts, costs, expenses and liquidated damages due in respect of the New Debentures.

In addition, under the terms of the New Debentures, for so long as the New Debentures are outstanding, in the event we issue any new securities or other indebtedness for cash in a transaction primarily for the purpose of raising capital, then we shall be required to apply 40% of the net proceeds to redeem the New Debentures for cash.

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 2012 was 58,241, the high and low bid price of our ADSs for the last two financial years ended on December 31, 2012 and December 31, 2011, was $ 2.85 and $5.68, and $ 1.43 and $1.37, 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 2011 was 33,082 as opposed to 58,241 for the same period of 2012. 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 25, 2012, our shareholders adopted resolutions allowing the Board of Directors to issue new shares in an aggregate maximum amount of 10 million shares. As of April 2, 2013, after taking into account the issuance of new shares following payments of quarterly interest paid in shares on October 1, 2012, the maximum number available to be issued is 9,885,044.

On December 19, 2012, our shareholders adopted resolutions allowing the issuance of stock options to subscribe to a maximum of 500,000 new shares to certain of our officers and employees under certain conditions, which the Board of Directors allocated in full on January 18, 2013.

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. In particular, in connection with the January 2012 Exchange Agreement, we undertook not to pay cash dividends on any of our equity securities as long as any New Debentures remain outstanding. 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;

- 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.; or

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.

Item 4. Information on the Company

We develop and market the Ablatherm® device, an advanced choice for High Intensity Focused Ultrasound (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-HIFU 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 we expect to submit for CE marking in the course of 2013. We also produce and commercialize medical equipment for treatment of urinary tract stones using Extra-corporeal Shockwave Lithotripsy ("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 – U.S.A, 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 piezo-electric 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 HIFU 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. This clearance is expected to enable us to maximize our opportunity to gain market share from our competitors in the United States.

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 US$ 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 August 17, 2012, we announced the completion of the two-year follow-up phase of all patients included in our ENLIGHT Ablatherm-HIFU multi-center U.S. Phase II/III clinical trial conducted under an Investigational Device Exemption (IDE) granted by the FDA, and started to compile the comprehensive Premarket Approval (PMA) file in view of FDA submission.

On January 31, 2013, we submitted our PMA application to the FDA for our Ablatherm-HIFU 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 neeed to proceed with the substantive review.

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 €5.6 million, €5.9 million and €6.9 for 2012, 2011 and 2010, 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 Ablatherm-HIFU device is not approved yet. Total net sales for the UDS division were €20.4 million (including €11.4 million in Asia and €9.0 million in Europe and the rest of the world), €16.4 million (including €7.6 million in Asia and €8.8 million in Europe and the rest of the world) and €16.3 million (including €7.8 million in Asia and €8.5 million in Europe and the rest of the world), each for 2012, 2011 and 2010, respectively.

See Note 27 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.

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 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. As of December 31, 2012, the HIFU division had an installed base of 92 Ablatherm machines worldwide and 282 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 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-HIFU device. To that end, on January 31, 2013, we filed a PMA with the FDA and 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. 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 2012, the HIFU division maintained expenses at levels similar to 2011 on research and development ("R&D") projects to develop HIFU applications beyond prostate cancer. The division is considering sustaining R&D spending in 2013 and future years to strengthen its technological leadership in HIFU and expand its application beyond urology.

HIFU Products

Currently, the only commercial product of the company utilizing HIFU technology is the Ablatherm, 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. 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 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 area has been treated, while controlling and imaging the treatment in real time due to its integrated imaging system. Cell destruction by HIFU is accomplished by a combination of thermal and cavitation effects caused by focused application of piezoelectric-generated high-intensity ultrasound. The procedure is performed under general or spinal anesthesia.

On March 14, 2013, we presented to our distributors and the urology community Focal.One, 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 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. The Focal.One device is under CE Marking review for European market clearance.

HIFU Division Patents and Intellectual Property

As of December 31, 2012, the HIFU division's patent portfolio contained 36 patents consisting of 17 in the United States, 17 in the European Union and Japan and 2 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 2012, five patents covering obsolete technologies were abandoned or reach their term. One patent covering a very innovative HIFU transducer design, particularly well-suited for liver and pancreas applications, was delivered in Europe. Six additional patents covering certain other aspects of our HIFU technology in the European Union and Japan (4), the United States (1), and the rest of the world (1) are also under review. These patents relate to a new transducer design for both HIFU and high intensity collimated ultrasound ("HICU") technologies.

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 an 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 HIFU CE marking addressing brachytherapy failures. Extension was accepted in February 2012.

In 2007, a new clinical trial using Ablatherm-HIFU 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 two years, more investigational centers have been included in the study and, currently twenty 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.

In September 2010, a new clinical trial was started in France and Norway to validate the new strategy of Hemiablation 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 study is expected to be completed by December 2013. 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).

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.

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. 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-HIFU 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-HIFU, 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-HIFU results have been published in 70 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 the beginning of 2013, two long-term studies presenting results obtained over a period of 14 years on 538 patients and 15 years on 704 patients were published, showing excellent disease free survival results in primary patients (Ganzer & al. BJU, January 2013, and Thuroff & al. Journal of Endourology, February 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 HIFU. 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 covering 5,662 primary patients, and an abstract covering 929 patients treated with Ablatherm HIFU after radiorecurrence with 7 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. The PSA test measures the blood level of a protein, the PSA, which is produced only by the prostate. 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 licencee, 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 tumors, including USHIFU, which markets a device called the Sonablate SB500 for the treatment of localized prostate cancer. Insightec, an Israeli company majority owned by General Electric and Elbit Medical Imaging, has developed a device using HIFU technology to treat uterine fibroids. Haifu, a Chinese company developing HIFU products is addressing various cancers. Philips Healthcare is also developing HIFU devices addressing uterine fibroids, breast tumors and drug delivery activated by HIFU.

See Item 3, "Risk Factors – Risks Relating to Competition."

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

HIFU Division Sales and Distribution of Products

The HIFU division markets and sells its products through our own direct marketing and sales organization as well as through selected third-party distributors and agents in several countries. Using our direct subsidiaries or representative offices network, the HIFU division maintains direct marketing and sales forces in France, Germany, Russia and Italy, which currently represent its largest HIFU markets. Additionally, the HIFU division markets and sells its products through our distribution platform in 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 €20.5 million to our consolidated net sales during the fiscal year ended December 31, 2012.

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 688 ESWL lithotripters worldwide to this date and actively maintained or otherwise serviced 531 installed lithotripters as of December 31, 2012.

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 piezo-electric elements of the LT02, a machine we discontinued manufacturing in 2002) and the electrodes of the Sonolith line, which need to be replaced approximately every ten treatments, respectively. These parts incorporate key proprietary technologies, and the UDS division has retained sole marketing rights for these parts.

Product	Procedure	Development Stage	Clinical and Regulatory Status
Sonolith i-move	Electroconductive treatment of urinary stones	Commercial Production	Approved for distribution: European Union South Korea South-East Asia Peru Colombia Venezuela Japan United States Taiwan Singapore Costa Rica
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 which 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 3D virtual system that uses Infrared stereovision technology to guide the treatment robotically.

UDS Division Patents and Intellectual Property

As of December 31, 2012, the UDS division's patent portfolio contained eight patents consisting of one in the United States, five in the European Union and Japan and two in Israel and the rest of the world. They belong to four groups of patents covering key technologies relating to ESWL systems and associated software capabilities.

In 2012, three patents covering technologies embeded in our new lithotripter Sonolith i-move were delivered in France. Nine additional patents, two in the United States, and seven in the European Union and in Japan are also in the examination process. These patents concern the Sonolith i-sys lithotripter technology and our newly introduced Sonolith i-move device.

The UDS division's patents cover both piezoelectricity and electroconductivity technologies associated to ESWL treatment head, electrodes and localization systems. The UDS division's ongoing research and development 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 and Singapore. 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 and Malaysia and 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 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), Atlanta (U.S.A), 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 good manufacturing practices (GMP), 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. 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 pre-market approval (''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 Investigational Device Exemption ("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 Ablatherm device, a Class III device, has not yet been approved by FDA and 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, 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, 2012, 2011 and 2010 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 usually provide a minimum of one-year warranty upon installation. We accrue the estimated warranty costs at the time of sale.

Sales of RPP Treatments and leases:

Revenues related to the sale of Ablatherm treatments invoiced on a ‘‘Revenue-Per-Procedure’’ (‘‘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;
- 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.

Convertible Debentures

On October 29, 2007, the Company raised $20 million in non-secured, Convertible Debentures with detachable warrants. At the inception date, the Company elected to measure the instrument and its 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 are recorded as a liability, with subsequent changes in fair value recorded in financial income and expenses. The Company used a Black & Scholes valuation model to measure the fair value of the 2007 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 Debentures due June 30, 2014 and new warrants (the ‘2012 Exchange Offer Warrants’). The Company closed the Exchange on January 25, 2012. See Notes 1-21, 14 and 19 to the consolidated financial statements.

Warrants

As part of the October 2007 $20 million issuance of the Convertible Debentures, we issued warrants to both the investors in the Convertible Debentures and to the bank that assisted us as placement agent (together, the “2007 Warrants”). Warrants granted to the placement agent were cancelled in December 2010 as a result of the placement agent’s exchange of its warrants against a certain number of ADSs. In accordance with ASC 815, the 2007 Warrants

were classified as a liability because the Company would have been required to settle them on a net cash basis upon the occurrence of certain events outside the control of the Company. We accounted for the 2007 Warrants based on their fair value at inception date, with subsequent changes in fair value recorded as financial earnings (or loss) at each balance sheet date. We used a Black & Scholes pricing model to determine the fair value of the 2007 Warrants. The application of the model to the 2007 Warrants required the use of subjective assumptions, including historical share price volatility, the expected life of the 2007 Warrants, our risk-free interest rate, and the liquidity discount factor. A change in one or more of these assumptions would have resulted in a material change to the estimated fair value of the warrants issued to the investors. Pursuant to the January 2012 Exchange Agreement, the 2007 Warrants were cancelled on January 19, 2012 and January 2012 Warrants have been issued, all 408,691 January 2012 Warrants were exercised on January 16, 2013. In the March 2012 Placement, the Company also issued the March 2012 Warrants. See "— Convertible Debentures" above and Notes 1-21, 14, 16 and 19 to our consolidated financial statements.

Debentures

Pursuant to Option B of the January 2012 Exchange Agreement, certain holders of an aggregate principal amount of $10 million of Convertible Debentures and warrants to purchase up to 840,000 ordinary shares agreed to exchange their outstanding securities for an aggregate principal amount of $10 million of 9% non-convertible Senior New Debentures due June 30, 2014 (and January 2012 warrants to purchase up to 408,691 newly issued ordinary shares and 1,926,685 newly issued ordinary shares).

On May 9, 2012, the Company used $2.0 million of the net proceeds from the March 2012 Placement to partially reimburse the 2012 New Debentures, thus reducing their outstanding amount to $8.0 million.

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 treatment procedures and from the leasing of Ablatherm machines. We provide Ablatherms 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 an Ablatherm. 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 Ablatherms by hospitals and clinics in the long term. This activity has already increased significantly in the past years and now accounts for approximately half of the net sales of the HIFU division.

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

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 45% of our total consolidated revenue in 2012. Net sales of goods in Asia represented approximately 57% of such sales in 2012 and consisted primarily of sales of ESWL lithotripters and consumables. Net sales of spare parts, supplies and services in Asia represented approximately 42% of such sales in 2012 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 2012, approximately 79% of our costs of sales and research and development, selling, marketing and general and administrative expenses were denominated in euro, while approximately 48% 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 €2.7 million, €2.4 million, and €3.3 million in 2012, 2011 and 2010, respectively, representing approximately 10.2%, 10.9% and 14.1% of total revenues in 2012, 2011 and 2010, respectively. Consolidated research and development expenses included R&D government grants and tax credits of €1.0 million, €0.4 million and €0.7 million in 2012, 2011 and 2010, respectively. Excluding R&D government grants and tax credits, consolidated research and development expenses amounted to €3.7 million, €2.9 million and €4.0 million in 2012, 2011 and 2010, respectively, representing approximately 14.0%, 12.8% and 16.7% of total revenues in 2012, 2011 and 2010, respectively. Research and development costs in 2012, 2011 and 2010 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 4.2% of total revenues in 2012). Beginning in 2013, 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 €6.6 million in 2012, €5.9 million in 2011 and €6.7 million in 2010. Selling and marketing expenses included allowances for doubtful accounts of €0.5 million in 2012, €0.2 million in 2011 and €0.2 million in 2010. The €0.7 million or 12.7% increase in selling and marketing expenses from 2011 to 2012 was primarily a result of the expansion of selling and marketing efforts to address new markets, mostly in the United States, the Middle East and Eastern Europe. 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.

Over the past several years, we have experienced declining sale prices in the market for ESWL lithotripters. In 2012, 2011 and 2010, however, our ESWL sales have been growing as a result of 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 unit sale prices for ESWL lithotripters worldwide to continue to decline and 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, 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, 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 €579 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. See Note 14-3 to our consolidated financial statements.

Fiscal Year Ended December 31, 2011 Compared to Fiscal Year Ended December 31, 2010

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)	2011	2010
Total revenues	22.3	23.7
Total net sales	22.3	23.2
Of which HIFU	5.9	6.9
Of which UDS	16.4	16.3
Total cost of sales	(13.4)	(14.3)
Gross profit	8.9	9.5
Gross profit as a percentage of total net sales	39.8%	40.8%
Total operating expenses	(11.4)	(13.3)
Loss from operations	(2.5)	(3.8)
Net income (loss)	(0.9)	(12.7)

Total revenues

Our total revenues decreased 6.0% from €23.7 million in 2010 to €22.3 million in 2011, principally due to decreased HIFU sales that could not be offset by the increase in lithotripsy sales.

HIFU division. The HIFU division's total revenues decreased 14.6% to €5.9 million in 2011 as compared to €6.9 million in 2010.

The HIFU division's net sales of medical devices decreased 37.8% to €0.8 million in 2011, with three Ablatherm units sold, as compared with €1.2 million and four Ablatherm units sold in 2010.

Net sales of RPP treatments decreased 9.0% to €3.2 million in 2011.

Net sales of consumables decreased 5.6% to €0.7 million in 2011 and net sales of HIFU-related spare parts, supplies, leasing and services decreased 14.1% to €1.3 million in 2011.

Other HIFU-related revenues increase to €20 thousand in 2011 from €6 thousand in 2010.

UDS division. The UDS division's total revenues decreased 2.5% from €16.8 million in 2010 to €16.4 million in 2011, mostly due to the €0.5 million one-off revenue in 2010 related to a French government grant, while total net sales increased 0.5% to €16.4 million in 2011.

The UDS division's net sales of medical devices decreased 4.1% from €9.6 million in 2010 to €9.2 million in 2011 with 40 devices sold in 2011 compared to 45 units sold in 2010. Equipment sales in 2011 benefited from an increase in the average selling price due to a favorable product mix.

Net sales of UDS-related spare parts, supplies, leasing and services increased 7.2% from €6.7 million in 2010 to €7.2 million in 2011, primarily related to the revenues derived from the installed base (disposables and maintenance contracts).

There was no other UDS-related revenue in 2011, as compared to €500 thousand in 2010 related to a one-off French government grant as part of a small businesses aid program.

Cost of sales.

Cost of sales decreased from €14.3 million in 2010 to €13.4 million in 2011, and represented 60.3% as a percentage of net sales in 2011, down from 61.4% as a percentage of net sales in 2010.

Operating expenses.

Operating expenses decreased 14.5%, or €2.0 million, from €13.3 million in 2010 to €11.4 million in 2011. Operating expenses included R&D grants and tax credits of €415 thousand and €690 thousand in 2011 and 2010, respectively. The decrease was attributable to the reduction of the costs of the FDA PMA trials, as well as a global cost reduction program in marketing, sales and G&A expenses.

The costs associated with the FDA PMA trial decreased 59.9% at €0.8 million in 2011 compared to €1.9 million in 2010, reflecting the follow-up phase of the trials during the full year 2011, after the completion in June 2010 of the most active, recruitment and treatment phase.

Marketing and sales expenses decreased €0.9 million, or 14.2%, mostly due to reductions in expenses related to conferences and symposiums.

Research and development expenses decreased 25.5% at €2.4 million in 2011 from €3.3 million in 2010 and comprised R&D grants and tax credits of €415 thousand and €690 thousand in 2011 and 2010, respectively, and costs of the FDA PMA trials of €0.8 million and €1.9 million in 2011 and 2010, respectively.

General and administrative expenses and depreciation decreased 6.9% from €3.3 million in 2010 to €3.0 million in 2011.

Operating loss.

As a result of the factors discussed above, we recorded a consolidated operating loss of €2.5 million in 2011, as compared to a consolidated operating loss of €3.8 million in 2010.

We realized an operating loss in the HIFU division of €0.3 million in 2011, compared to an operating loss of €0.6 million in 2010 and an operating profit in the UDS division of €0.1 million in 2011, as compared to €0.1 million in 2010.

Financial (expense) income, net. Net financial income was €1.5 million in 2011, including a €2.4 million income due to the adjustment of the convertible debt to fair value, compared with a loss of €8.8 million in 2010, including a €6.0 million expense due to the adjustment of the convertible debt to fair value.

Foreign currency exchange gains (loss), net. In 2011, we recorded a net foreign currency exchange gain of €0.5 million, mainly due to the variation of the euro against the U.S. dollar and the Japanese yen, compared to a gain of €0.9 million in 2010.

Other income (expense), net. Other income(expense) in 2011 was a loss of €50 thousand.

Income taxes. Income tax was an expense of €0.4 million in 2011, compared to an expense of €0.9 million in 2010. Income tax expense in 2010 comprised the reimbursement of a €0.8 million state aid received by the EDAP-TMS France in 1994. See Note 20-5 of the consolidated financial statements.

Net income / (loss)

We realized a consolidated net loss of €0.9 million in 2011 compared with a consolidated net loss of €12.7 million in 2010. The €13.2 million variation in net income(loss) was primarily due to the €2.4 million positive impact from the variation in the convertible debt 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, 2012.

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 will need to raise additional capital to repay our New Debentures when due or in the event of significant

delays with the FDA PMA submission. 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, our ongoing operations and repay our outstanding indebtedness." Furthermore, failure to meet our obligations arising out of the January 2012 Exchange Agreement would cause us to incur substantial penalties in the form of liquidated damages and could, over the passage of time, lead to an event of default under the New Debentures. Payment of liquidated damages or mandatory default amount will have a material adverse effect on our financial condition and results of operation. See Item 3, "Key Information—Risk Factors—Risks Relating to the outstanding warrants and New Debentures."

(in thousands of euros)	**2012**	**2011**	**2010**
Net cash generated/(used) in operating activities	(162)	(737)	(3,818)
Net cash generated/(used) in investing activities	234	(612)	(685)
Net cash generated/(used) in financing activities	1,342	(327)	652
Net effect of exchange rate changes	727	(789)	(369)
Net increase/(decrease) in cash and cash equivalents	2,141	(2,469)	(4,221)
Cash and cash equivalents at the beginning of the year	4,900	7,369	11,590
Cash and cash equivalents at the end of the year	7,041	4,900	7,369
Total cash and cash equivalents, and short-term investments at the end of the year	**8,077**	**6,472**	**8,888**

Our cash position as of December 31, 2012, 2011 and 2010, was €8.1 million (including €1.0 million of short-term treasury investments), €6.5 million (including €1.6 million of short-term treasury investments) and €8.9 million (including €1.5 million of short-term treasury investments), respectively. We experienced positive cash flows of €2.1 million in 2012 and negative cash flows of €2.5 million and €4.2 million in 2011 and 2010, respectively. 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 2011, our negative cash flow situation was primarily due to the lack of additional external financing and the negative cash flows from operations. However, our cash needs were reduced when compared to the previous year thanks to cost reduction programs and improvements in working capital needs. In 2010, our negative cash flow situation was primarily due to the lack of significant additional external financing and the negative cash flows from operations.

In 2012, net cash used in operating activities was €162 thousand compared with net cash used in operating activities of €0.7 million in 2011 and €3.8 million in 2010, respectively.

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

- a net loss of €7.5 million;
- elimination of €5.4 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 receivable of €2.5 million;
- an increase in other receivables of €0.1 million;
- an increase in inventories of €0.5 million;
- a decrease in payables of €27 thousand;
- a decrease in prepaid expenses of €0.2 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 €0.8 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 €0.4 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 2010, net cash used in operating activities reflected principally:

- a net loss of €12.7 million;
- elimination of €8.3 million of net expenses without effects on cash, including €1.2 million of depreciation and amortization and a loss of €6.1 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 €0.1 million;
- a decrease in other receivables of €0.1 million;
- an increase in inventories of €0.4 million;
- an increase in payables of €0.2 million;
- a decrease in prepaid expenses of €0.9 million; and
- a decrease in accrued expenses of €0.2 million.

In 2012, net cash generated in investing activities was €234 thousand compared with net cash used of €612 thousand in investing activities in 2011 and €685 thousand in 2010.

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.

Net cash used in investing activities of €685 thousand in 2010 reflected investments of €0.2 million in capitalized assets produced by the Company, mostly lithotripsy machines used for commercial demonstrations and training, an investment of €0.4 million in property and equipment, net proceeds from sales of leased-back assets of €0.3 million and acquisition of short-term investments for €0.4 million.

In 2012, net cash generated in financing activities was €1.3 million compared with net cash used in financing activities of €328 thousand in 2011, and net cash generated of €652 thousand in 2010.

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.

Net cash provided by financing activities of €685 thousand in 2010 reflected principally the €9.0 million increase in capital related to the issuance of new shares, a long-term debt increase of €0.6 million through the Japanese and Italian subsidiaries, repayment of long term borrowing for €7.4 million, repayment of capital lease obligations totaling €0.8 million and an increase of €0.6 million in bank overdrafts.

Our future cash flow may also be affected by the expansion of our RPP business. Our marketing strategy consists of leasing our medical devices on a monthly, quarterly or yearly basis, rather than selling them directly to end-users. We make certain devices available to hospitals and clinics free of charge, charging instead on the basis of each procedure that was performed. Relative to the sale of devices, this business model initially generates smaller, but more predictable cash flows. We may continue to expand the RPP business model in the near future. See Item 4 "- HIFU Division Business Overview".

Historically, cash flows have been partially supported by capital raisings, including the October 2007 private placement of $20 million aggregate principal amount of our 9% Senior Convertible Debentures due 2012 and Warrants which resulted in net proceeds of approximately $17.4 million. In January 2012, we entered into an Exchange Agreement with all of the holders of our outstanding 9% Senior Convertible Debentures due October 29, 2012 and Warrant holders, whereby all October 2007 Convertible Debentures and Warrants were exchanged for $10 million of New Debentures due on June 30, 2014, 1,948,871 newly issued ordinary shares, 408,691 January 2012 Warrants and US$500,000 in cash. Furthermore, 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 March 28, 2012, we used our October 2011 Form F-3 registration statement to issue 2,812,500 ordinary shares in the form of ADSs to certain institutional investors in a registered direct placement, with warrants attached that allow investors to purchase up to 1,406,250 shares in the form of ADSs, which resulted in net proceeds of approximately $4.8 million. We also issued warrants to purchase up to 168,750 shares to the placement agent, Rodman & Renshaw LLC.

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, 2012, 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, 2012 (in thousands of euro, excluding interest expenses)

	Payments Due by Period				
	Total	**Less than 1 year**	**1-3 years**	**4-5 years**	**More than 5 years**
Short-Term Debt	2,095	2,095	—	—	—
Long-Term Debt	6,792	207	4,618	1,919	47
Capital Lease Obligations	953	459	358	132	4
Operating Leases	1,584	421	594	569	—
Interest on Debentures	819	546	273	-	—

New Accounting Pronouncements

In September 2011, the FASB issued ASU 2011-08, "Testing Goodwill for Impairment" ("ASU 2011-08"). ASU 2011-08 allows a company to first assess qualitative factors to determine whether it is more-likely-than-not that the fair value of a reporting unit is less than its carrying amount as a basis for determining whether it is necessary to perform the two-step goodwill impairment test. The more-likely-than-not threshold is defined as having a likelihood of more than 50 percent. The provisions of ASU 2011-08 are effective for annual and interim goodwill impairment tests performed for fiscal years beginning after December 15, 2011 with early adoption permitted. The adoption of ASU 2011-08 did not impact the company's consolidated financial statements.

In June 2011, the FASB issued ASU 2011-05, "Presentation of Comprehensive Income" ("ASU 2011-05"). ASU 2011-05 requires, in part, that companies present the total of comprehensive income, the components of net income and the components of other comprehensive income either in a single continuous statement of comprehensive income or in two separate but consecutive statements. The provisions of ASU 2011-05 are effective for fiscal years, and interim periods within those years, beginning after December 15, 2011. The adoption of ASU 2011-05 did not impact the company's consolidated financial statements.

Research and Development, Patents and Licenses

See "—Operating Results—Overview" and Item 4, ''Information on the Company—High Intensity Focused Ultrasound 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 €256 thousand in 2012, € 411 thousand in 2011 and €327 thousand in 2010 and were classified as a reduction of research and development expenses.

Off-Balance Sheet Arrangements

At December 31, 2012, 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 2, 2013. 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 € 0.6 million.

Name	Position
Marc Oczachowski Age : 43	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 47	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. With the exception of Mr. Marc Oczachowski, none of the directors have service contracts with the Company or any of its subsidiaries providing for benefits upon termination of employment. With the exception of Mr. Marc Oczachowski, all of the Board members are independent within the meaning of NASDAQ Marketplace Rule 5605(2).

Philippe Chauveau Age: 77 Mandate: 6 years Appointment : Apr. 8, 1997 (renewed) Expiration: 2014	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 worldwide. He is also personal executive coach to senior research leaders at Hoffmann LaRoche. 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: 71 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 mergers and acquisitions 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 has an MBA from Harvard Business School.
Argil Wheelock Age: 65 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 subsidiary of Endopharmaceuticals, a NASDAQ 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: 63 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.
Marc Oczachowski Age: 43 Mandate: 6 years Appointment : June 25, 2012 Expiration: 2018	Marc Oczachowski was elected as a member of the Company’s Board of Directors on June 25, 2012, for a term of six years, expiring in 2018. Marc Oczachowski is President of EDAP-TMS France, President of EDAP Technomed, Inc., a director of EDAP Technomed Co. Ltd and President of EDAP Technomed Srl.

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 2012 was approximately €683 thousand including performance bonuses of €193 thousand and benefits in kind of €28 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 2012. 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. Mr. Marc Oczachowski, as Chief Executive Officer of the Company, is not considered as independent and therefore is not a member of the Audit Committee. 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, 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

As of December 31, 2010, we employed 151 individuals on a full-time basis, as follows:

	Sales & Marketing	Manufac-turing	Service	Research & Dvpt	Regula-tory	Clinical Affairs	Adminis-trative	Total
France	16	31	19	11	4	2	14	97
Italy	3	0	0	0	0	0	2	5
Germany	5	0	2	0	0	0	2	9
Japan	13	0	13	0	1	0	3	30
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	41	31	36	11	5	3	24	151

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

Share Ownership

As of April 2, 2013, the total number of shares issued was 19,171,198 with 381,528 shares held as treasury stocks, thus bringing the total number of shares outstanding to 18,789,670.

As of April 2, 2013, the Board of Directors and the Senior Executive Officers of the Company held a total of 51,123 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 2, 2013, Senior Executive Officers held an aggregate of 465,338 options to purchase or to subscribe ordinary shares, with a weighted average exercise price of €2.65 per share. Of these options, 30,000 expire on February 24, 2014, 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 2, 2013, we had sponsored four stock purchase and subscription option plans open to employees of EDAP TMS group.

On January 29, 2004, the shareholders authorized the Board of Directors to grant up to 240,000 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 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, 2012, 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

As of December 31, 2012, a summary of stock option activity to purchase or to subscribe to Shares under these plans is as follows:

	2012		2011		2010	
	Options	Weighted average exercise price (€)	Options	Weighted average exercise price (€)	Options	Weighted average exercise price (€)
Outstanding on January 1,	830,025	3.23	906,775	3.19	656,013	3.57
Granted	-	-	-	-	325,012	2.23
Exercised	-	-	-	-	(18,000)	2.15
Forfeited	(15,750)	3.17	(51,750)	3,03	(56,250)	2.45
Expired	(3,425)	2.02	(25,000)	2,08	-	-
Outstanding on December 31,	810,850	3.18	830,025	3,23	906,775	3.19
Exercisable on December 31,	675,844	3.38	621,516	3.50	486,446	3.52
Shares purchase options available for grant on December 31	83,428		72,003		16,003	

The following table summarizes information about options to purchase existing Shares held by the Company, or to subscribe to new Shares, at December 31, 2012:

	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	4,8	3.99	416,838	3.99
2.60	124,000	1.2	2.60	124,000	2.60
2.38	174,100	7.5	2.38	87,050	2,38
1.88	95,912	7.5	1.88	47,956	1.88
1.88 to 3.99	810,850	5.2	3.18	675,844	3.38

On January 18, 2013, the Board of Directors granted 500,000 options to subscribe to 500,000 new shares to certain officers and employees of the Company, with an exercice price of 1.91 euro and expiring on January 17, 2023.

Item 7. Major Shareholders and Related Party Transactions

Major Shareholders (as of April 2, 2013)

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, 2012	% of share capital on Dec. 31, 2012	# of shares held on Dec.31, 2011	% of share capital on Dec. 31, 2011	of shares held on Dec.31, 2010	% of share capital on Dec. 31, 2010
PSM Vermogenswerwaltung GmbH ..	1,609,959	8.58	420,897	3.07	320,897	2.40
Bruce & Co. Inc.....	1,565,494	8.35	795,155	5.79	647,993	4.84
Mr. Jonathan Schwartz	817,137	4.36	928,644	6.77	462,366	3.45

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 2, 2013, 19,171,198 Shares were issued, including 18,789,670 outstanding and 381,528 treasury Shares. At March 22, 2013, there were 19,115,848ADSs, 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 €61 thousand, €60 thousand and €59 thousand for 2012, 2011 and 2010 respectively. . As of December 31, 2012, payables to Dae You amounted to €44 thousand and as of December 31, 2011, our payables to them amounted to €39 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 €371 thousand, €768 thousand and €315 thousand in 2012, 2011 and 2010 respectively. As of December 31, 2012, receivables (‘Net trade accounts and notes receivable’) amounted to €350 thousand. As of December 31, 2011, receivables from Dae You amounted to €95 thousand.

Interests of Experts and Counsel

N/A

Item 8. Financial Information

Consolidated Financial Statements

See Item 18, ‘‘Financial Statements.’’

Export Sales

As of December 31, 2012, total consolidated export net sales, which we define as sales made outside of France, were €21.9 million, which represented 84% 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 2012 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 2012 we invoiced EUR 7,838.60 of 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 2006 through 2012, and we do not anticipate paying any dividends for the foreseeable future. In particular, under the terms of the New Debentures, we agreed not to pay cash dividends on any of our equity securities as long as any of the New Debentures remain outstanding. 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 2, 2013

a) On January 16, 2013, Liberty Harbor Master Fund exercised its 408,691 January 2012 Warrants. On January 18, 2013, the Board of Directors convened, acted the receipt of EUR 53,129.83 corresponding to exercise of the Warrants and issued 408,691 new ADSs to Liberty Harbor Master Fund.

b) On January 31, 2013, we submitted our PMA application to the U.S. (FDA) for our Ablatherm-HIFU 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, the U.S. FDA provided a positive administrative acceptance review notification for the 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.

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 2008 through 2012, the reported high and low sales prices of the ADSs on NASDAQ.

	NASDAQ	
	High	**Low**
	$	
2012	2.85	1.43
2011	5.68	1.37
2010	6.97	1.89
2009	5.95	0.96
2008	5.12	1.05

The following tables set forth, for the years 2011 and 2012, and through March 22, 2013, the reported high and low sales prices of the ADSs on NASDAQ for each full financial quarter:

	NASDAQ	
	High	**Low**
	$	
2013:		
Through March 22, 2013	4.94	1.98
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
2011:		
First Quarter	5.68	3.22
Second Quarter	4.74	3.04
Third Quarter	4.35	1.50
Fourth Quarter	2.25	1.37

The following table sets forth, for the most recent six months (from September 2012 through March 22, 2013), the reported high and low sale prices of the ADSs on NASDAQ for each month:

	NASDAQ	
	High	**Low**
2012:	**$**	
September	1.88	1.63
October	1.99	1.65
November	1.87	1.64
December	2.35	1.43
2013:		
January	3.05	1.98
February	4.64	2.72
March (through March 22, 2013)	4.94	3.85

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 316488204 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 February 2013 to act the recent increase in share capital related to the issuance of additional shares in February 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 five members, four 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, Mr. Marc Oczachowski was 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 2017. 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 stock option. 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 an 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 January 25, 2012, we issued $10 million aggregate principal amount of New Debentures and January 2012 Warrants to purchase up to 408,691 newly issued ordinary shares at an exercise price equal to the par value per share.

Interest on the New Debentures will accrue at a rate of 9% per annum, payable quarterly as follows: commencing on the issuance date until October 29, 2012, interest may be paid, at our election, in cash or, subject to the satisfaction of certain conditions, in newly issued ordinary shares; and commencing on October 30, 2012 until repaid in full, interest may be paid, at the election of the holder, in cash or, subject to the satisfaction of certain conditions, in newly issued ordinary shares. The New Debentures may be redeemed at our option, in whole or in part, at any time and from time to time; provided, that in the event we issue securities or other indebtedness for cash in a transaction primarily for the purpose of raising capital at any time while the New Debentures remain outstanding, then we are required to apply 40% of the net proceeds of any such issuance to redeem the New Debentures for cash. Upon the occurrence of an "Event of Default" (as defined in the New Debentures), the outstanding principal amount plus accrued but unpaid interest and any other amounts owing under the New Debentures will become immediately due and payable in the amount of (i) 130% of the outstanding principal plus (ii) 100% of accrued but unpaid interest and any other amounts owing under the New Debentures. The New Debentures also contain customary restrictive covenants which can be waived with the consent of holders of two thirds of the outstanding principal amount of the New Debentures, such as limitations on our ability to incur certain indebtedness, enter into, incur or suffer to exist certain liens, amend its charter documents in a manner adverse to holders of the New Debentures, pay dividends on its equity securities or enter into related party transactions. A copy of the form of the New Debentures was furnished to the SEC on our report on Form 6-K dated January 27, 2012. The foregoing description is qualified in its entirety by reference to the full text of such exhibit.

The January 2012 Warrants were exercised in full on January 16, 2013 and consequently, no January 2012 Warrants are currently outstanding. A copy of the form of the January 2012 Warrants was furnished to the SEC on our report on Form 6-K dated January 27, 2012. The foregoing description is qualified in its entirety by reference to the full text of the exhibit attached hereto.

We also entered into a registration rights agreement on January 25, 2012 (the "Registration Rights Agreement") with the holders of the New Debentures and the January 2012 Warrants. Pursuant to the Registration Rights Agreement, we agreed to file a registration statement with the Securities and Exchange Commission within 30 days of closing the Exchange (the "Filing Deadline") to register the ordinary shares issuable upon exercise of the January 2012 Warrants and payable as interest at the election of the holders on the New Debentures. Such registration statement was declared effective by the SEC on May 16, 2012. A copy of the form of the Registration Rights Agreement was furnished to the SEC on our report on Form 6-K dated January 27, 2012. The foregoing description is qualified in its entirety by reference to the full text of the exhibit attached hereto.

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.

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 20% or more of a listed 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, 2013.

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 new rules relating to trusts, in particular a specific new 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 January 11, 2013, EDAP is not included in such list as a company whose market capitalization exceeds 1 billion euros as of December 1, 2012 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 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 2012 taxable year. In addition, we do not anticipate it becoming a PFIC for the 2013 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

Newly enacted legislation requires certain U.S. holders that are individuals, estates or trusts 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 2012, and also does not anticipate becoming a PFIC with respect to the year 2013. 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

N/A

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

N/A

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, 2012, 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 2012, approximately 79% of our total costs of sales and operating expenses were denominated in euro. During the same period, approximately 48% 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, 2012 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 €99,000 for the year ended December 31, 2012, compared to a decrease of approximately €107,000 for the year ended December 31, 2011. 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, 2012 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 €0.497 million, €0.728 million and €0.675 million of our outstanding indebtedness at December 31, 2012, 2011 and 2010, respectively, were denominated in Japanese yen. Approximately €6.2 million, €7.3 million and €9.4 million of our outstanding indebtedness at December 31, 2012, 2011, and 2010, respectively, were denominated in U.S. dollars. See "Risk Factors— Risks relating to the outstanding warrants and New Debentures." In addition, we had approximately €0.6 million, €3.1 million and €4.9 million of cash denominated in U.S. dollars at December 31, 2012, 2011 and 2010, respectively, and €0.9 million, €0.5 million and €0.7 million of cash denominated in Japanese yen at December 31, 2012, 2011 and 2010, 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, 2012 to March 22, 2013, the following amounts were paid by the Depositary to the Company: $90,000.00 and $ 12,216.60 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, 2012. 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, 2012 based upon the framework as set forth by the Committee of Sponsoring Organizations of the Treadway Commission (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, 2012.

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 financial year.

Nature of the Fees	**2012[(1)] (in €)**	**2011[(2)] (in €)**
Audit fees	120,000	189,720
Audit-related fees		680
Tax fees		1,850
All other fees	8,800	
Total	**128,800**	**192,250**

(1) Including "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.
(2) For the fiscal year 2011, our external auditors were Ernst & Young Audit. See Item 16F "Change in Registrant's Certifying Accountant"

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 2012, 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

Under French Law, auditors are appointed for a term of six years. Ernst & Young Audit's mandate expired at the end of General Meeting of shareholders held on June 25, 2012 approving the financial statements for the fiscal year ended December 31, 2011. At such meeting, the shareholders, acting on the Board of Directors' proposal, voted not to renew the mandate of Ernst & Young Audit as our Registered Public Accounting Firm.

There were no (1) disagreements (as such term is defined in Item 16F(a)(1)(iv) of the Form 20-F) between the Company and Ernst & Young Audit on any matter of accounting principles or practices, financial statement disclosure, or auditing scope or procedure, which disagreements, if not resolved to the satisfaction of Ernst & Young Audit, would have caused Ernst & Young Audit to make reference to the subject matter of disagreement in connection with their report or (2) reportable events as such term is defined in Item 16F(a)(1)(v) of the Form 20-F. As part of the standard renewal process and in order to optimize audit and audit-related expenses, the Company's Management and the Board of Directors consulted Ernst & Young Audit and other audit firms and finally opted for PricewaterhouseCoopers Audit.

The Company has provided the foregoing disclosures to Ernst & Young Audit and requested that it furnish to the Company a letter addressed to the SEC stating whether or not it agrees with the statements made by the Company in response to this Item 16F. A copy of such letter, dated April 2, 2013, is attached hereto as Exhibit 15.2 to this annual report.

At the June 25, 2012 General Meeting of shareholders, PricewaterhouseCoopers Audit was appointed for a period of six fiscal years to be terminated at the end of the General Meeting to be called in 2018 in order to approve the financial statements of the Company for the fiscal year ending December 31, 2017.

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 Description

Number:

1.1 By-laws (*statuts*) of EDAP TMS S.A. as amended as of February 27, 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)]

8.1 List of subsidiaries of EDAP TMS S.A. as of April 2, 2013.

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.

15.3 Letter from Ernst & Young Audit to the SEC regarding Item 16F.

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 2, 2013

/s/ Marc Oczachowski
Marc Oczachowski
Chief Executive Officer

Dated: April 2, 2013

/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, 2012, 2011 and 2010

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 sheet and the related consolidated statement of income, of comprehensive income, of shareholders' equity and of cash flows present fairly, in all material respects, the financial position of EDAP TMS S.A. and its subsidiaries at December 31, 2012, and the results of their operations and their cash flows for the year ended December 31, 2012 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 audit provides a reasonable basis for our opinion.

Lyon, France, April 2, 2013

PricewaterhouseCoopers Audit

Represented by
/s/ Nicolas Brunetaud
Nicolas Brunetaud

Report of Independent Registered Public Accounting Firm

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

We have audited the accompanying consolidated balance sheets of EDAP TMS S.A. and subsidiaries as of December 31, 2010 and 2011, and the related consolidated statements of income, comprehensive income, changes in shareholders' equity and cash flows for the three years ended December 31, 2011. These consolidated financial statements are the responsibility of EDAP TMS's management. Our responsibility is to express an opinion on these consolidated financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the 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 audits 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 audits provide a reasonable basis for our opinion.

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of EDAP TMS S.A. and subsidiaries at December 31, 2010 and 2011, and the consolidated results of its operations and its cash flows for the three years 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, 2012 and 2011
(in thousands of euros unless otherwise noted)

ASSETS	Notes	2012	2011
Current assets			
Cash and cash equivalents	2	7,041	4,900
Current portion of net trade accounts and notes receivable	3	11,148	13,273
Other receivables	4	842	720
Inventories	5	4,263	3,920
Deferred tax assets	20-3	32	26
Other assets, current portion	6	367	621
Short-term investment	2	1,036	1,572
Total current assets		24,729	25,032
Property and equipment, net	7	2,035	2,534
Intangible assets, net	8	71	68
Goodwill	8	2,412	2,412
Deposits and other non-current assets		396	484
Net Trade accounts and notes receivable, non current	3	801	1,708
Total assets		30,444	32,238
LIABILITIES AND SHAREHOLDERS' EQUITY			
Current liabilities			
Trade accounts and notes payable	9	6,336	6,295
Deferred revenues, current portion	10	885	418
Social security and other payroll withholdings taxes		729	767
Employee absences compensation		473	444
Income taxes payable		12	31
Other accrued liabilities	11	1,928	1,988
Short-term borrowings	13	2,095	1,700
Current portion of capital lease obligations	12	459	557
Current portion of long-term debt	14-1	207	238
Convertible debentures carried at fair value	14-2	-	7,085
Financial instruments carried at fair value	14-3	-	195
Total current liabilities		13,124	19,717
Deferred revenues, non current	10	79	258
Capital lease obligations, non current	12	494	695
Non Convertible debentures	14-2	4,416	-
Financial instruments carried at fair value	14-3	1,754	-
Long-term debt, non current	14-1	415	720
Other long-term liabilities	15	1,999	2,135
Total liabilities		22,282	23,525
Shareholders' equity			
Common stock, €0.13 par value; 18,753,757 shares issued and 18,372,229 shares outstanding; 13,726,532 shares issued and 13,345,004 shares outstanding; at December 31, 2012 and 2011, respectively		2,438	1,784
Additional paid-in capital		45,791	39,784
Retained earnings		(35,569)	(28,093)
Cumulative other comprehensive loss		(3,327)	(3,590)
Treasury stock, at cost; 381,528 at December 31, 2012 and 2011, respectively	16	(1,172)	(1,172)
Total shareholders' equity	16	8,161	8,714
Total liabilities and shareholders' equity		30,444	32,238

EDAP TMS S.A. AND SUBSIDIARIES

CONSOLIDATED STATEMENTS OF INCOME
For the years ended December 31, 2012, 2011 and 2010
(in thousands of euros unless otherwise noted)

	Notes	2012	2011	2010
Sales of goods		17,009	12,399	13,135
Sales of RPPs & leases		3,988	4,508	4,689
Sales of spare parts and services		5,021	5,365	5,378
Total sales		26,018	22,272	23,202
Other revenues	17	47	20	506
Total revenues		26,065	22,292	23,708
Cost of goods		(9,735)	(7,365)	(7,656)
Cost of RPPs & leases		(2,329)	(2,240)	(2,641)
Cost of spare parts and services		(3,568)	(3,830)	(3,956)
Total cost of sales		(15,632)	(13,435)	(14,253)
Gross profit		10,433	8,857	9,455
Research and development expenses	18	(2,659)	(2,436)	(3,268)
Selling and marketing expenses		(6,620)	(5,874)	(6,684)
General and administrative expenses		(3,185)	(3,044)	(3,320)
Loss from operations		(2,030)	(2,497)	(3,818)
Financial (expense) income, net	19	(4,594)	1,522	(8,844)
Foreign currency exchange gain (loss), net		(733)	482	884
Other income (expense), net		-	(50)	-
Income (loss) before taxes		(7,358)	(543)	(11,778)
Income tax (expense) benefit	20	(118)	(395)	(939)
Net income (loss)		(7,475)	(938)	(12,717)
Basic income (loss) per share	21	(0.43)	(0.07)	(0.98)
Diluted income (loss) per share	21	(0.43)	(0.07)	(0.98)
Basic Weighted average shares outstanding	21	17,556,395	13,345,004	13,008,401
Diluted Weighted average shares outstanding	21	17,556,395	13,345,004	13,008,401

The accompanying notes are an integral part of the consolidated financial statements.

EDAP TMS S.A. AND SUBSIDIARIES

CONSOLIDATED STATEMENTS OF COMPREHENSIVE INCOME
For the years ended December 31, 2012, 2011 and 2010
(in thousands of euros unless otherwise noted)

	2012	2011	2010
Net income (loss)	(7,475)	(938)	(12,717)
Other comprehensive loss:			
Foreign currency translation adjustments	315	(274)	(93)
Provision for retirement indemnities	(52)	70	(162)
Comprehensive income (loss), net of tax	(7,213)	(1,143)	(12,972)

The accompanying notes are an integral part of the consolidated financial statements.

EDAP TMS S.A. AND SUBSIDIARIES

CONSOLIDATED STATEMENTS OF SHAREHOLDERS' EQUITY
For the years ended December 31, 2012, 2011 and 2010
(in thousands of euros unless otherwise noted)

	Number of Shares	Common Stock	Additional paid-in Capital	Retained Earnings	Cumulative Other Comprehensive Income (loss)	Treasury Stock	Total
Balance as of January 1, 2010	10,510,305	1,418	29,961	(14,436)	(3,131)	(1,233)	12,579
Net loss				(12,717)			(12,717)
Translation adjustment					(93)		(93)
Warrants and stock options granted	18,000		265			62	327
Capital increase	2,480,096	322	8,644				8,966
Provision for retirement indemnities					(162)		(162)
Balance as of December 31, 2010	13,008,401	1,740	38,870	(27,154)	(3,386)	(1,172)	8,900
Net loss				(938)			(938)
Translation adjustment					(274)		(274)
Warrants and stock options granted	336,603		199				199
Capital increase		44	714				758
Provision for retirement indemnities					70		70
Balance as of December 31, 2011	13,345,004	1,784	39,784	(28,093)	(3,590)	(1,172)	8,714
Net loss				(7,475)			(7,475)
Translation adjustment					315		315
Warrants and stock options granted			881				881
Capital increase	5,027,225	654	5,126				5,780
Provision for retirement indemnities					(52)		(52)
Balance as of December 31, 2012	18,372,229	2,438	45,791	(35,569)	(3,327)	(1,172)	8,161

The accompanying notes are an integral part of the consolidated financial statements.

EDAP TMS S.A. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF CASH FLOWS
For the years ended December 31, 2012, 2011 and 2010
(in thousands of euros unless otherwise noted).

	2012	2011	2010
Cash flows from operating activities			
Net income (loss)	(7,475)	(938)	(12,717)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization	931	1,413	1,233
Change in fair value	3,915	(2,435)	6,053
Other Non-cash compensation	243	370	489
Change in allowances for doubtful accounts & slow-moving inventories	153	457	186
Change in long-term provisions	(51)	431	(21)
Net capital loss on disposals of assets	290	355	78
Deferred tax expense (benefit)	(52)	293	180
Operating cash flow	(2,046)	(54)	(4,519)
Increase/Decrease in operating assets and liabilities:			
Decrease (Increase) in trade accounts and notes and other receivables	2,507	(172)	146
Decrease (Increase) in inventories	(497)	(436)	(355)
Decrease (Increase) in other assets	75	259	940
(Decrease) Increase in trade accounts and notes payable	(91)	508	192
(Decrease) Increase in accrued expenses, other current liabilities	(110)	(842)	(223)
Net increase (decrease) in operating assets and liabilities	1,884	(683)	700
Net cash used in operating activities	**(162)**	**(737)**	**(3,818)**
Cash flows from investing activities:			
Additions to capitalized assets produced by the Company	(334)	(756)	(244)
Net proceeds from sale of leased back assets	299	304	283
Acquisitions of property and equipment	(272)	(103)	(352)
Acquisitions of intangible assets	(44)	(11)	(13)
Acquisitions of short term investments, net	-	0	(406)
Net proceeds from sale of short term investments, net	536	-	-
Net proceeds from sale of assets	0	0	39
Increase (decrease) in deposits and guarantees, net	50	(47)	8
Net cash generated by (used in) investing activities	**234**	**(612)**	**(685)**
Cash flow from financing activities:			
Proceeds from capital increase	1,898	758	8,966
Proceeds from long term borrowings, net of financing costs	1,821	210	598
Repayment of long term borrowings	(2,176)	(299)	(7,424)
Repayment of obligations under capital leases	(595)	(701)	(843)
Increase (decrease) in bank overdrafts and short-term borrowings	395	(295)	(644)
Net cash generated by (used in) financing activities	**1,342**	**(328)**	**652**
Net effect of exchange rate changes on cash and cash equivalents	727	(789)	(369)
Net increase (decrease) in cash and cash equivalents	**2,141**	**(2,469)**	**(4,221)**
Cash and cash equivalents at beginning of year	4,900	7,369	11,590
Cash and cash equivalents at end of year	**7,041**	**4,900**	**7,369**

The accompanying notes are an integral part of the consolidated financial statements.

1—SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

1-1 Nature of operations

EDAP TMS S.A. and its subsidiaries (‘‘the Company’’) are engaged in the development, production, marketing, distribution and maintenance of a portfolio of minimally-invasive medical devices for the treatment of urological diseases. The Company currently produces devices for treating stones of the urinary tract and localized prostate cancer. Net sales consist primarily of direct sales to hospitals and clinics in France and Europe, export sales to third-party distributors and agents, and export sales through subsidiaries based in Germany, Italy and Asia.

The Company purchases the majority of the components used in its products from a number of suppliers but for some components, relies on a single source. Delay would be caused if the supply of these components or other components was interrupted and these delays could be extended in certain situations where a component substitution may require regulatory approval. Failure to obtain adequate supplies of these components in a timely manner could have a material adverse effect on the Company’s business, financial position and results of operation.

1-2 Management estimates

The preparation of financial statements in conformity with U.S. generally accepted accounting principles (‘‘U.S. GAAP’’) requires management to make estimates and assumptions, such as business plans, that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. Actual results could differ from those estimates.

1-3 Consolidation

The accompanying consolidated financial statements include the accounts of EDAP TMS S.A. and all its domestic and foreign owned subsidiaries, which include EDAP TMS France SAS, EDAP Technomed Inc., Edap Technomed Sdn Bhd, Edap Technomed Italia S.R.L, EDAP Technomed Co. Ltd. and EDAP TMS Gmbh. Edap Technomed Sdn Bhd was incorporated in early 1997. Edap Technomed Co. Ltd. was created in late 1996. EDAP TMS Gmbh was created in July 2006. EDAP SA, a subsidiary incorporating HIFU activities merged all of its activity into EDAP TMS France SAS in 2008. All intercompany transactions and balances are eliminated in consolidation

1-4 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. The Company provides training and provides a minimum of one-year warranty upon installation. The Company accrues for the warranty costs at the time of sale. Revenues related to disposables are recognized when goods are delivered.

Sales of RPPs and leases:

Revenues related to the sale of Ablatherm treatments invoiced on a ‘‘Revenue-Per-Procedure’’ (‘‘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.

1-5 Shipping and handling costs

The Company recognizes revenue from the shipping and handling of its products as a component of revenue. Shipping and handling costs are recorded as a component of cost of sales.

1-6 Cash equivalents and short term investments

Cash equivalents are cash investments which are highly liquid and have initial maturities of 90 days or less.

Cash investments with a maturity higher than 90 days are considered as short-term investments.

1-7 Accounts Receivables

Accounts receivables are stated at cost net of allowances for doubtful accounts. The Company makes judgments as to its ability to collect outstanding receivables and provides allowances for the portion of receivables when collection becomes doubtful. Provision is made based upon a specific review of all significant outstanding invoices. These estimates are based on our bad debt write-off experience, analysis of credit information, specific identification of probable bad debt based on our collection efforts, aging of accounts receivables and other known factors.

1-8 Inventories

Inventories are valued at the lower of manufacturing cost, which is principally comprised of components and labor costs, or market (net realizable value). Cost is determined on a first-in, first-out basis for components and spare parts and by specific identification for finished goods (medical devices). The Company establishes reserves for inventory estimated to be obsolete, unmarketable or slow moving, first based on a detailed comparison between quantity in inventory and historical consumption and then based on case-by-case analysis of the difference between the cost of inventory and the related estimated market value.

1-9 Property and equipment

Property and equipment is stated at historical cost. Depreciation and amortization of property and equipment are calculated using the straight-line method over the estimated useful life of the related assets, as follows:

Leasehold improvements	10 years or lease term if shorter
Equipment	3-10 years
Furniture, fixtures, fittings and other	2-10 years

Equipment includes industrial equipment and research equipment that has alternative future uses. Equipment also includes devices that are manufactured by the Company and leased to customers through operating leases related to Revenue-Per-Procedure transactions and devices subject to sale and leaseback transactions. This equipment is depreciated over a period of seven years.

1-10 Long-lived assets

The Company reviews the carrying value of its long-lived assets, including fixed assets and intangible assets, for impairment whenever events or changes in circumstances indicate that the carrying amount of such assets may not be fully recoverable. Recoverability of long-lived assets is assessed by a comparison of the carrying amount of the assets (or the Group of assets, including the asset in question, that represents the lowest level of separately-identifiable cash flows) to the total estimated undiscounted cash flows expected to be generated by the asset or group of assets. If the future net undiscounted cash flows is less than the carrying amount of the asset or group of assets, the asset or group of assets is considered impaired and an expense is recognized equal to the amount required to reduce the carrying amount of the asset or group of assets to its then fair value. Fair value is determined by discounting the cash flows expected to be generated by the assets, when the quoted market prices are not available for the long-lived assets. Estimated future cash flows are based on assumptions and are subject to risk and uncertainty.

1-11 Goodwill and intangible assets

Goodwill represents the excess of purchase price over the fair value of identifiable net assets of businesses acquired. Goodwill is not amortized but instead tested annually for impairment or more frequently when events or change in circumstances indicate that the assets might be impaired by comparing the carrying value to the fair value of the reporting units to which it is assigned. Under ASC 350, “Goodwill and other intangible assets”, the impairment test is performed in two steps. The first step compares the fair value of the reporting unit with its carrying amount, including goodwill. If the fair value of the reporting unit is less than its carrying amount, a second step is performed to measure the amount of impairment loss. The second step allocates the fair value of the reporting unit to the Company’s tangible and intangible assets and liabilities. This derives an implied fair value for the reporting unit’s goodwill. If the carrying amount of the reporting units goodwill exceeds the implied fair value of that goodwill, an impairment loss is recognized equal to that excess. For the purpose of any impairment test, the Company relies upon projections of future undiscounted cash flows and takes into account assumptions regarding the evolution of the market and its ability to successfully develop and commercialize its products.

Changes in market conditions could have a major impact on the valuation of these assets and could result in additional impairment losses.

Intangible assets consist primarily of purchased patents relating to lithotripters, purchased licenses, a purchased trade name and a purchased trademark. The basis for valuation of these assets is their historical acquisition cost. Amortization of intangible assets is calculated by the straight-line method over the shorter of the contractual or estimated useful life of the assets, as follows:

Patents	5 years
Licenses	5 years
Trade name and trademark	7 years

1-12 Treasury Stocks

Treasury stock purchases are accounted for at cost. The sale of treasury stocks is accounted for using the first in first out method. Gains on the sale or retirement of treasury stocks are accounted for as additional paid-in capital whereas losses on the sale or retirement of treasury stock are recorded as additional paid-in capital to the extent that previous net gains from sale or retirement of treasury stocks are included therein; otherwise the losses shall be recorded to accumulated benefit (deficit) account. Gains or losses from the sale or retirement of treasury stock do not affect reported results of operations.

1-13 Warranty expenses

The Company provides customers with a warranty for each product sold and accrues warranty expense at time of sale based upon historical claims experience. Standard warranty period may vary from 1 year to 5 years depending on the market. Actual warranty costs incurred are charged against the accrual when paid and are classified in cost of sales in the statement of income. Warranty expense amounted to €469 thousand, €362 thousand and €555 thousand for the years ended December 31, 2012, 2011 and 2010 respectively.

1-14 Income taxes

The Company accounts for income taxes in accordance with ASC 740, ‘‘Accounting for Income Taxes’’ Under ASC 740, deferred tax assets and liabilities are determined based on differences between the financial reporting and tax basis of assets and liabilities and are measured by applying enacted tax rates and laws to taxable years in which such differences are expected to reverse. A valuation allowance is established if, based on the weight of available evidence, it is more likely than not that some portion, or all of the deferred tax assets, will not be realized. In accordance with ASC740, no provision has been made for income or withholding taxes on undistributed earnings of foreign subsidiaries, such undistributed earnings being permanently reinvested.

As of January 1, 2007, the Company adopted FIN48 (now ASC 740) “Accounting for uncertainty in income tax”. Under ASC740, the measurement of a tax position that meets the more-likely-that-not recognition threshold must take into consideration the amounts and probabilities of the outcomes that could be realized upon ultimate settlement using the facts, circumstances and information available at the reporting date.

1-15 Research and development costs

Research and development costs are recorded as an expense in the period in which they are incurred.

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 and is not contingent on future taxable income. As such, the Company considers the research tax credits as a grant, offsetting operating expenses.

The research tax credit amounted to €256 thousand, €411 thousand and €327 thousand for the years ended December 31 2012, 2011 and 2010 respectively.

1-16 Advertising costs

Advertising costs are recorded as an expense in the period in which they are incurred. Advertising costs amounted to €374 thousand, €652 thousand and €920 thousand for the years ended December 31, 2012, 2011 and 2010 respectively.

1-17 Foreign currency translation and transactions

Translation of the financial statements of consolidated companies

The reporting currency of EDAP TMS S.A. for all years presented is the euro (€). The functional currency of each subsidiary is its local currency. In accordance with ASC 830, all accounts in the financial statements are translated into euro from the functional currency at exchange rate as follows:

- assets and liabilities are translated at year-end exchange rates;
- shareholders' equity is translated at historical exchange rates (as of the date of contribution);
- statement of income items are translated at average exchange rates for the year; and
- translation gains and losses are recorded in a separate component of shareholders' equity.

Foreign currencies transactions

Transactions involving foreign currencies are translated into the functional currency using the exchange rate prevailing at the time of the transactions. Receivables and payables denominated in foreign currencies are translated at year-end exchange rates. The resulting unrealized exchange gains and losses are carried to the statement of income.

1-18 Earnings per share

Basic earnings per share is computed by dividing income available to common shareholders by the weighted average number of shares of common stock outstanding for the period. Diluted earnings per share reflects potential dilution that could occur if securities or other contracts to issue common stock were exercised or converted into common stock or resulted in the issuance of common stock that then shared in the earnings of the Company. The dilutive effects of the Company's common stock options and warrants is determined using the treasury stock method to measure the number of shares that are assumed to have been repurchased using the average market price during the period, which is converted from U.S. dollars at the average exchange rate for the period.

1-19 Derivative instruments

ASC 815 requires the Company to recognize all of its derivative instruments as either assets or liabilities in the statement of financial position at fair value. The accounting for changes in the fair value (i.e., gains or losses) of a derivative instrument depends on whether it has been designated and qualifies as part of a hedging relationship and further, on the type of hedging relationship. For those derivative instruments that are designated and qualify as hedging instruments, the Company must classify the hedging instrument, based upon the exposure being hedged, as fair value hedge, cash flow hedge or a hedge of a net investment in a foreign operation.

Gains and losses from derivative instruments are recorded in the income statement.

(in thousands of euros unless otherwise noted, except per share data)

1-20 Employee stock option plans

At December 31, 2012, the Company had three stock-based employee compensation plans. The Company adopted ASC 718, "Share-Based Payment", effective January 1, 2006. ASC 718 requires the recognition of fair value of stock compensation as an expense in the calculation of net income (loss).

The fair value of each stock option granted during the year is estimated on the date of grant using the Black-Scholes option pricing model with the following assumptions:

	Year Ended December 31,		
	2012[(1)]	**2011**[(1)]	**2010**
Weighted-average expected life (years)	—	—	6.25
Expected volatility rates	—	—	87%
Expected dividend yield	—	—	—
Risk-free interest rate	—	—	2.32%
Weighted-average exercise price (€)	—	—	2.23
Weighted-average fair value of options granted during the year (€)	—	—	1.45

(1) The Company did not make any grants during the years ended December 31, 2012 and 2011.

1-21 Convertible debentures and detachable warrants

Convertible 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'). See Note 14 of the 2011 Annual Report on Form 20-F for further discussion. 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 the 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 New Debentures') and new warrants (the '2012 Exchange Offer Warrants'). The Company closed the Exchange on January 25, 2012. The 2012 New Debentures were recorded as a liability at their fair value at inception and subsequently valued on an amortized cost basis. 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. See Note 14, 16 and 20 for further discussion.

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. See Note 14 of the 2011 Annual Report on Form 20-F for further discussion. 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 the 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 against 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.The Company determined that the Warrants, which require settlement in shares, should be recognized as equity instruments See Note 16.6 for further discussion.

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"). Pursuant to guidance of ASC 815-40-15-7(i), the Company determined that the March 2012 Warrants could not be considered as being indexed to the Company's own stock, on the basis that the exercise price of the March 2012 Warrants is determined in U.S. dollars while the functional currency of the Company is the Euro. Therefore, the Company determined that the March 2012 Warrants should be accounted for as a liability.

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.

(in thousands of euros unless otherwise noted, except per share data)

1-22 Leases and Sales and leaseback transactions

In accordance with ASC 840, Accounting for Leases, the Company classifies 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;
- 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.

The Company enters into sale and leaseback transactions from time to time. In accordance with ASC 840, 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.

1-23 New accounting pronouncements

In September 2011, the FASB issued ASU 2011-08, "Testing Goodwill for Impairment" ("ASU 2011-08"). ASU 2011-08 allows a company to first assess qualitative factors to determine whether it is more-likely-than-not that the fair value of a reporting unit is less than its carrying amount as a basis for determining whether it is necessary to perform the two-step goodwill impairment test. The more-likely-than-not threshold is defined as having a likelihood of more than 50 percent. The provisions of ASU 2011-08 are effective for annual and interim goodwill impairment tests performed for fiscal years beginning after December 15, 2011 with early adoption permitted. The adoption of ASU 2011-08 did not impact the company's consolidated financial statements.

In June 2011, the FASB issued ASU 2011-05, "Presentation of Comprehensive Income" ("ASU 2011-05"). ASU 2011-05 requires, in part, that companies present the total of comprehensive income, the components of net income and the components of other comprehensive income either in a single continuous statement of comprehensive income or in two separate but consecutive statements. The provisions of ASU 2011-05 are effective for fiscal years, and interim periods within those years, beginning after December 15, 2011. The adoption of ASU 2011-05 did not impact the company's consolidated financial statements.

2—CASH EQUIVALENTS AND SHORT TERM INVESTMENTS

Cash and cash equivalents and short term investments are comprised of the following:

	December 31,	
	2012	**2011**
Total cash and cash equivalents	7,041	4,900
Short term investments	1,036	1,572
Total cash and cash equivalents, and short term investments	8,077	6,472

Short term investments are comprised of money market funds. The aggregate fair value of the short term investments is consistent with their book value. In 2012 and 2011, short term investments comprise €1.0 million pledged in favour of the bank as a collateral to a €1.0 million short term loan. See Note 13.

(in thousands of euros unless otherwise noted, except per share data)

3—TRADE ACCOUNTS AND NOTES RECEIVABLE, NET

Trade accounts and notes receivable consist of the following:

	December 31,	
	2012	2011
Trade accounts receivable	12,938	15,570
Notes receivable	613	684
Less: allowance for doubtful accounts	(1,602)	(1,272)
Total	11,949	14,981
Less current portion	(11,148)	(13,273)
Total long-term portion	801	1,708

Notes receivable usually represent commercial bills of exchange (drafts) with initial maturities of 90 days or less.

Bad debt expenses amount to €516 thousand, €191 thousand and €200 thousand, for the years ended December 31, 2012, 2011, and 2010.

Long term portion consists mainly of capital leases of medical devices. Future minimum lease payments to be received over the five coming years are as follows:

	December 31, 2012
2013	841
2014	401
2015	169
2016	60
2017	5
Total minimum lease payments	1,477

4—OTHER RECEIVABLES

Other receivables consist of the following:

	December 31,	
	2012	2011
Value-added taxes receivable	427	220
Research and development tax credit receivable from the French State	256	426
Research and development subsidies receivable from the French State	90	-
Personnel advances	35	37
Others	34	37
Total	842	720

(in thousands of euros unless otherwise noted, except per share data)

5—INVENTORIES

Inventories consist of the following:

	December 31,	
	2012	2011
Components, spare parts	4,032	3,657
Work-in-progress	566	573
Finished goods	600	856
Total gross inventories	5,198	5,086
Less: provision for slow-moving inventory	(934)	(1,167)
Total	4,263	3,920

The provision for slow moving inventory relates to components and spare parts. The allowance for slow moving inventory, the changes in which are classified within cost of sales, amounted to an income of €186 thousand for the year ended December 31, 2012 and an expense of €428 thousand and €184 thousand for the years ended December 31, 2011 and 2010, respectively.

6—OTHER ASSETS

Other assets consist of the following:

	December 31,	
	2012	2011
Deferred financing costs , current portion	-	31
Other prepaid expenses, current portion	367	590
Total	367	621

7—PROPERTY AND EQUIPMENT, NET

Property and equipment consist of the following:

	December 31,	
	2012	2011
Equipment	8,097	8,286
Furniture, fixture, and fittings and other	2,921	2,785
Total gross value	11,018	11,071
Less: accumulated depreciation and amortization	(8,984)	(8,536)
Total	2,035	2,534

Depreciation and amortization expense related to property and equipment amounted to €802 thousand, to €870 thousand and €950 thousand for the years ended December 31, 2012, 2011 and 2010, respectively.

Capitalized costs on equipment held under capital leases of €3,639 thousand and €3,426 thousand and are included in property and equipment at December 31, 2012 and 2011, respectively. Accumulated amortization of these assets leased to third parties was €2,646 thousand and €2,454 thousand, at December 31, 2012 and 2011, respectively. Amortization expense on assets held under capital leases is included in total amortization expense and amounted to €331 thousand, €333 thousand and €333 thousand for the years ended December 31, 2012, 2011 and 2010, respectively.

(in thousands of euros unless otherwise noted, except per share data)

8—GOODWILL AND INTANGIBLE ASSETS

As discussed in Note 1-11, the Company adopted ASC 350, ‘‘Goodwill and Other Intangible Assets’’, on January 1, 2002. ASC 350 requires that goodwill and other intangible assets that have indefinite lives not be amortized but instead be tested at least annually for impairment, or more frequently when events or change in circumstances indicate that the asset might be impaired, by comparing the carrying value to the fair value of the reporting unit to which they are assigned. The Company considers its ASC 280 operating segment — High Intensity Focused Ultrasound (HIFU) and Urology Devices and Services (UDS) — to be its reporting units for purposes of testing for impairment. Goodwill amounts to €1,767 thousand for the UDS division and to €645 thousand for the HIFU division, at December 31, 2012.

The Company completed the required annual impairment test in the fourth quarter of 2012. To determine the fair value of the Company’s reporting units, the Company used the discounted cash flow approach for each of the two reportable units. The main assumptions used are the following: (i) a five-year business plan approved by management, (ii) a discount rate of 15% for HIFU, 10% for UDS, (iii) a residual value specific to each segment. In both cases, the fair value of the reporting unit was in excess of the reporting unit's book value, which resulted in no goodwill impairment.

A one percentage point increase in the HIFU discount rate assumed in the impairment testing would not lead the Company to record an impairment charge. Similarly, a one percentage point increase in the UDS discount rate assumed in the impairment testing would not lead the Company to record an impairment charge. A zero growth rate in the Company’s UDS business plan would not lead the Company to record any impairment charge. A 10% growth rate in the Company’s HIFU business plan would not lead the Company to record any impairment charge.

Intangible assets consist of the following:

	December 31,	
	2012	2011
Licenses	453	412
Trade name and trademark	658	723
Patents	412	412
Organization costs	363	363
Total gross value	1,886	1,910
Less: accumulated amortization	(1,814)	(1,843)
Total	71	68

Amortization expenses related to intangible assets amounted to €36 thousand, €14 thousand and €36 thousand, for the years ended December 31, 2012, 2011 and 2010, respectively.

For the two coming years, the annual estimated amortization expense for intangible assets will be approximately €30 thousand.

(in thousands of euros unless otherwise noted, except per share data)

9—TRADE ACCOUNTS AND NOTES PAYABLE

Trade accounts and notes payable consist of the following:

	December 31,	
	2012	2011
Trade accounts payable	5,820	5,725
Notes payable	516	570
Total	6,336	6,295

Trade accounts payable usually represent invoices with a due date of 90 days or less and invoices to be received.

Notes payable represent commercial bills of exchange (drafts) with initial maturities of 90 days or less.

10—DEFERRED REVENUES

Deferred revenues consist of the following:

	December 31,	
	2012	2011
Deferred revenues on maintenance contracts	600	329
Deferred revenue on RPP	50	24
Deferred revenue on sale of devices	304	284
Deferral of the gain on sale-lease-back transactions	9	39
Total	964	676
Less long term portion	(79)	(258)
Current portion	885	418

11—OTHER ACCRUED LIABILITIES

Other accrued liabilities consist of the following:

	December 31,	
	2012	2011
Current portion of provision for warranty costs	666	651
Value added tax payable	326	342
Accruals for social expenses	386	278
Conditional government subsidies	341	519
Retirement indemnities	39	94
Accrued interests	139	183
Others	373	262
Total	2,270	2,329
Less non current portion of Conditional government subsidies	(341)	(341)
Current portion	1,928	1,988

Conditional government subsidies are granted by French government to finance R&D project developments and are subject to reimbursement conditional to development milestones.

(in thousands of euros unless otherwise noted, except per share data)

Changes in the provision for warranty costs are as follows:

	December 31,	
	2012	2011
Beginning of year	1,287	1,402
Amount used during the year	(694)	(477)
New warranty expenses	469	362
End of year	1,062	1,287
Less current portion	(666)	(651)
Long term portion	396	636

12—LEASE OBLIGATIONS

12-1 Capital leases

The Company leases certain of its equipment under capital leases. At December 31, 2012, this equipment consists of medical devices for an amount of €778 thousand and vehicles for an amount of €175 thousand. Future minimum lease payments under capital leases for the years ending December 31, 2012 are as follows:

	December 31, 2012
2013	495
2014	212
2015	177
2016	99
2017	39
Thereafter	4
Total minimum lease payments	1,026
Less: amount representing interest	(72)
Present value of minimum lease payments	953
Less: current portion	(459)
Long-term portion	494

Interest paid under capital lease obligations was €53 thousand, €81 thousand, and €115 thousand for the years ended December 31, 2012, 2011, and 2010, respectively.

12-2 Operating leases

As of December 31, 2012, operating leases having initial or remaining non-cancelable lease terms greater than one year consist of one lease for the facilities of TMS S.A. in Vaulx-en-Velin, France and several leases for facilities in Japan. The French lease contract signed on November 2011 has a lease term of nine years expiring at the option of the lessee at the end of a first fixed six-year period, then a three-year period, through 2019 (i.e. in 2017 and 2019).

(in thousands of euros unless otherwise noted, except per share data)

Future minimum lease payments for these operating leases consist of the following amounts, unless leases are otherwise cancelled by the lessees:

	France	Japan
2013	297	124
2014	297	-
2015	297	-
2016	297	-
2017	272	-
Total	1,460	124

Total rent expenses under operating leases amounted to €772 thousand, €751 thousand and €790 thousand for the years ended December 31, 2012, 2011 and 2010, respectively. These total rent expenses include the above-mentioned operating leases, but also lease expenses related to subsidiaries office rentals, office equipment and car rentals.

13—SHORT-TERM BORROWINGS

As of December 31, 2012, short-term borrowings consist mainly of €1,093 thousand of account receivables factored and for which the Company is supporting the collection risk and a loan in euro amounting to €1,000 thousand with the following conditions:

	Amount	Maturation	Interest rate
EDAP-TMS France SAS	1,000	October 19, 2013	Euribor + 0,5%

As of December 31, 2011, short-term borrowings consist mainly of €685 thousand of account receivables factored and for which the Company is supporting the collection risk and a loan in euro amounting to €1,000 thousand with the following conditions:

	Amount	Maturation	Interest rate
EDAP-TMS France SAS	1,000	January 20, 2012	Euribor + 0,5%

(in thousands of euros unless otherwise noted, except per share data)

14—LONG TERM DEBT, DEBENTURES AND FINANCIAL INSTRUMENTS CARRIED AT FAIR VALUE

14-1 Long-term debt:

	December 31,	
	2012	**2011**
Japanese yen term loan	497	728
Italy term loan	114	215
Malaysia term loan	11	15
Total long term debt	622	958
Less current portion	(207)	(238)
Total long-term portion	415	720

As of December 31, 2012, long-term debt in Japan consists of 3 loans in Yen with the following conditions:

	Initial Amount	Maturation	Interest rate
EDAP Technomed Co. Ltd	10,000,000	March 31, 2015	0.10%
	55,000,000	June 30, 2018	1.80%
	10,000,000	June 30, 2018	0.10%

The 10,000,000 JPY loan initially maturing on July 17, 2014 was repaid earlier in 2012.

As of December 31, 2011, long-term debt in Japan consists of 4 loans in Yen with the following conditions:

	Initial Amount	Maturation	Interest rate
EDAP Technomed Co. Ltd	10,000,000	July 17, 2014	2.00%
	10,000,000	March 31, 2015	0.10%
	55,000,000	June 30, 2018	1.80%
	10,000,000	June 30, 2018	0.10%

As of December 31, 2012, long-term debt in Italy consists of a loan in euro of an initial amount of €404 thousand with an interest rate at Euribor + 1.9% due to mature on February 28, 2014.

(in thousands of euros unless otherwise noted, except per share data)

14-2 Debentures:

	December 31,	
	2012	2011
Convertible debentures		7,085
Non Convertible debentures	4,416	
Total	4,416	7,085
Less current portion	-	(7,085)
Total long-term portion	4,416	-

As of December 31, 2012, Debentures consist of the $8.0 million of principal amount of the 9% non convertible New Debentures resulting from the January 2012 Exchange Agreement. New Debentures are evaluated at amortized cost, using an effective interest rate of 35%.

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 Investor Warrants. Pursuant to the terms of the Exchange Agreement:

- certain holders of an aggregate principal amount of $500,000 of Existing Debentures and Existing Warrants to purchase up to 42,000 ordinary shares agreed to exchange their outstanding securities for 22,186 newly issued ordinary shares, in the form of ADRs, and $500,000 in cash; and
- certain holders of an aggregate principal amount of $10 million of Convertible Debentures and warrants to purchase up to 840,000 ordinary shares agreed to exchange their outstanding securities for an aggregate principal amount of $10 million of 9% non-convertible Senior New Debentures due June 30, 2014 and January 2012 warrants to purchase up to 408,691 newly issued ordinary shares at an exercise price equal to the par value per share (the "January 2012 Warrants"), and 1,926,685 newly issued ordinary shares, in the form of restricted ADRs (collectively, the "Exchange").

Under the Exchange Agreement, the Company undertakes that in the event the Company raises capital then the Company shall be required to apply 40% of the net proceeds to redeem the New Debentures in whole or in part. The Exchange Agreement provides also for certain cases of early redemption at the election of the Holders of the New Debentures such as a change of control transaction or other types of fundamental transactions.

Under the Exchange Agreement, the Company also commits to certain covenants including not to pay cash dividends or distribution on any equity securities of the Company as long as any of the New Debentures remain outstanding.

On January 25, 2012, the Company closed the Exchange and all of the 2007 Convertible Debentures and the 2007 Investor Warrants were exchanged for the 2012 New Debentures of principal amount of $10 million, 1,948,871 newly issued ordinary shares, in the form of ADRs, the 2012 Exchange Offer Warrants and $500,000 in cash.

On May 9, 2012, the Company used $2.0 million of the net proceeds from the March 2012 Placement to partially reimburse the 2012 New Debentures, thus reducing their outstanding principal amount to $8.0 million.

The Company considered guidance contained in ASC 405-20 – Extinguishments of Liabilities, ASC 470-50 – Debt Modifications and Extinguishment and ASC 470-60 – Troubled Debt Restructuring, for the general concepts on debt modifications and restructurings. As a result, the Company determined that the Debt Extinguishment model should apply to account for the Exchange.

See below: Summary of the variations in the fair-value of the Debentures and financial instruments.

(in thousands of euros unless otherwise noted, except per share data)

14-3 Financial instruments carried at fair value:

	December 31,	
	2012	**2011**
Investor Warrants	1,571	195
Placement Agent Warrants	183	-
Total	1,754	195
Less current portion	-	(195)
Total long-term portion	1,754	-

On March 28, 2012, pursuant to a securities purchase agreement dated March 22, 2012, as amended, the Company issued 2,812,500 ordinary shares in the form of ADSs to selected institutional investors in a registered direct placement (the "March 2012 Placement"), at a price of $2.00 per share, with warrants attached (the "March 2012 Investor Warrants"). The March 2012 Investor Warrants allow investors to purchase up to 1,406,250 shares in the form of ADSs at an exercise price of $2.75. The March 2012 Investor Warrants are exercisable immediately and expire on March 28, 2017. The Company also issued warrants to purchase up to 168,750 shares in the form of ADSs to the placement agent, Rodman & Renshaw LLC, with an exercise price of $2.50 (the "March 2012 Placement Agent Warrants" and together with the Investor Warrants, the "March 2012 Warrants"). The March 2012 Placement Agent Warrants are exercisable from September 24, 2012 and expire on October 21, 2016. Total gross proceeds for the placement amounted to $5.625 million.

The Company determined that the March 2012 Warrants to purchase up to 1,575,000 new ordinary shares of the Company (1,406,250 shares underlying the March 2012 Investor Warrants and 168,750 shares underlying the March 2012 Placement Agent Warrants) should be accounted for as a liability.

See below: Summary of the variations in the fair-value of the Debentures and financial instruments.

Fair Value of 2007 Investor Warrants:

The valuation model of the Investor Warrants uses a Black –Scholes model.

As of December 31, 2011, the Black-Scholes valuation model used the following main assumptions and parameters:

- Share price at closing date: $1.69
- Strike price of warrants: $6.87
- Risk free interest rate at 6 years: 0.23%
- Share price volatility: 121%
- Liquidity discount factor: 42.66%

As of December 31, 2012, all the 2007 investor warrants have been cancelled pursuant to the January 2012 Exchange Agreement.

On that basis, the unit fair value of the Investor Warrants was $0.29 per warrant as of December 31, 2011. The total fair value for the remaining 882,000 issued Investor warrants was $0.253 million at December 31, 2011.

Fair Value of the 2007 Convertible Debentures:

The total fair value of the convertible debt is the aggregate of the fair value of the underlying debt host instrument and the fair value of the embedded derivative.

The estimate of the fair value of the underlying debt component is obtained by using the actual interest spread the Company would have had to pay if a straight, unsecured, debt had been raised, with no additional remuneration to lenders in the form of conversion options or warrants. Before and at inception date, the Company conducted an analysis of the terms on a non-convertible, unsecured, conventional debt. Based on this analysis, a rate of 30% has been used to assess the fair value of the debt host, which represents an interest spread of 26% over the risk-free interest rate at inception date. The present value of the debt host using an effective interest rate of 30% was $10.330 million.

At December 31, 2011 the fair value has been measured considering any changes required in underlying assumptions, and mostly the risk free interest rate and the credit spread. With the support of third-party experts, the Company determined that the spread to be used over the risk-free rate was 34.72%, in line with the increase in risk-aversion on financial markets. The present value of the debt host at December 31, 2011 was $8.998 million taking into account the remaining 10,500 debentures.

The valuation model of the conversion option uses a binomial valuation model to capture the complexity of the instrument, and notably the continuous possibility of an arbitrage between holding common shares versus interest bearing bonds.

As of October 29, 2007, the binomial model used the following main assumptions and parameters:

- Share price at inception date: $5.95
- Strike price of Convertible Debentures: $6.57
- Risk free interest rate at 5 years: 4.04%
- Share price volatility: 45%
- Liquidity discount factor: 26.91%
-

As of December 31, 2011, the binomial model uses the following main assumptions and parameters:

- Share price at closing date: $1.69
- Strike price of Convertible Debentures: $6.57
- Risk free interest rate at 5 years: 0.10%
- Share price volatility: 121%
- Liquidity discount factor: 42.66%

At inception, the Company used a 30-day volatility to fit the monthly arbitration step of its binomial valuation model. At December 31, 2008, given the peculiar market conditions and the erratic changes in stock volatility, the Company, in agreement with third-party experts, determined that a share price volatility based on the residual lifetime of the convertible instruments would be more relevant and should then be used for assessing the fair value of the instruments. Share price volatility was determined using the historical volatility methodology.

On that basis, the fair value of the conversion option was $5.780 million ($7.909 million before liquidity discount) at inception date and $168 thousand ($294 thousand before liquidity discount) as of December 31, 2011.

On January 25,, 2012, all Convertible Debentures have been exchanged for non-convertible 2012 New Debentures in the January 2012 Exchange Agreement. See Notes 14-2 and 14-3 and Note 19.

Fair Value of the March 2012 Investor Warrants:

The valuation model of the Investor Warrants uses a Black-Scholes model.

At inception date, the Black-Scholes valuation model used the following main assumptions and parameters:

- Share price at closing date: $1.95
- Strike price of warrants: $2.75
- Risk free interest rate at 5 years: 1.05%
- Share price volatility: 120%

As of December 31, 2012, the Black-Scholes valuation model used the following main assumptions and parameters:

- Share price at closing date: $2.04
- Strike price of warrants: $2.75
- Risk free interest rate at 5 years: 0.59%
- Share price volatility: 113%

On that basis, the unit fair value of the Investor Warrants was $1.55 per warrant at inception date, and $1.47 per warrant as of December 31, 2012. The total fair value for the 1,406,250 issued Investor warrants was $2.173 million at inception date and $2.073 million as of December 31, 2012.

Fair Value of the March 2012 Placement Agent Warrants:

The valuation model of the Placement Agent Warrants uses a Black-Scholes model.

At inception date, the Black-Scholes valuation model used the following main assumptions and parameters:

- Share price at closing date: $1.95
- Strike price of warrants: $2.5
- Risk free interest rate at 4.5 years: 0.92%
- Share price volatility: 120%

As of December 31, 2012, the Black-Scholes valuation model used the following main assumptions and parameters:

- Share price at closing date: $2.04
- Strike price of warrants: $2.5
- Risk free interest rate at 4.5 years: 0.50%
- Share price volatility: 113%

On that basis, the unit fair value of the Placement Agent Warrants was $1.52 per warrant at inception date, and $1.43 per warrant as of December 31, 2012. The total fair value for the 168,750 issued Placement Agent warrants was $0.256 million at inception date and $0.242 million as of December 31, 2012.

Summary of the variations in the fair-value of the Debentures and financial instruments:

All amounts in thousands Euros unless otherwise stated	As of Dec. 31, 2012	Impact of the January 2012 Exchange Agreement			Impact of the March 2012 Placement		Fair-value adjustments & amortized costs		USD/EUR Exch. impact	As of Dec. 31, 2011
		Cash	Exchange	Debt Issuance Costs	Reimbursement of non-Convertible Debentures	Equity Classification of Warrants	FV adjustments	Amortization costs		
Outstanding nominal amount in thousand US Dollar	8,000	(500)			(2,000)					10,500
Convertible Debentures carried at fair value	-	(385)	(6,948)				282		(34)	7,085
Non Convertible Debentures	4,416		4,883	(171)	(1,526)			1,292	(62)	
TOTAL Debentures	**4,416**	**(385)**	**(2,065)**	**(171)**	**(1,526)**		**282**	**1,292**	**(96)**	**7,085**
Investor Warrants 2007			(373)				178			195
Investor Warrants 2012	1,571					1,629	(75)		17	-
Placement Agent Warrants	183					192	(11)		2	-
Total Financial instruments carried at fair value	**1,754**		**(373)**			**1,821**	**92**		**19**	**195**
TOTAL =	**6,170**	**(385)**	**(2,437)**	**(171)**	**(1,526)**	**1,821**	**374**	**1,292**	**(78)**	**7,280**

The January 2012 Exchange Offer resulted in a loss of €2,250 thousand as detailed below.

Extinguishment of Convertible Debentures and cancellation of 2007 Warrants and issuance of New Debentures – See Notes 14-2 & 14-3	2,437
Issuance of new shares and warrants – See Statements of Shareholders Equity (See Note 16-7)	(4,687)
Financial loss from the 2012 January Exchange Agreement	(2,250)

(in thousands of euros unless otherwise noted, except per share data)

Long-term debt, Debentures and Financial instruments carried at fair value at December 31, 2012 mature as follows:

2013	207
2014	4,527
2015	91
2016	266
2017	1,653
2018	47
Total	6,792

15—OTHER LONG-TERM LIABILITIES

Other long-term liabilities consist of the following:

	December 31,	
	2012	2011
Provision for retirement indemnities (Japan & France)	1,016	939
Provision for employee termination indemnities (Italy)	246	219
Provision for warranty costs, less current portion	396	636
Conditional government subsidies, less current portion	341	341
Total	1,999	2,135

Pension, post-retirement, and post-employment benefits for most of the Company's employees are sponsored by European governments. The Company's liability with respect to these plans is mostly limited to specific payroll deductions.

In addition to government-sponsored plans, subsidiaries in Japan and France have defined benefit retirement indemnity plans in place. The provision for retirement indemnities at December 31, 2012 represents an accrual for lump-sum retirement indemnity payments to be paid at the time an employee retires. The largest part of this liability relates to employees in France. This provision has been calculated taking into account the estimated payment at retirement (discounted to the current date), turnover and salary increases.

The provision is management best estimate based on the following assumptions as of year-end:

	Pension Benefits – France		
	2012	2011	2010
Discount rate	3.20%	4.70%	4.60%
Salary increase	2.50%	2.50%	2.50%
Retirement age	65	65	65
Average retirement remaining service period	24	25	25

	Pension Benefits – Japan		
	2012	2011	2010
Discount rate	1.60%	1.00%	1.00%
Salary increase	1.50%	1.50%	2.30%

In 2012, provision presentation according to ASC 715 in thousands of euros:

	France	Japan
Non current liabilities	517	498
Current liabilities	-	39
Accumulated other comprehensive income	(68)	(157)
Total	449	380

In 2011, provision presentation according to ASC 715 in thousands of euros:

	France	Japan
Non current liabilities	386	552
Current liabilities	-	94
Accumulated other comprehensive income	25	(199)
Total	411	447

The Company does not have a funded benefit plan. Detailed reconciliation of pension cost components (in thousands of euros) during fiscal year ending December 31, 2012:

France	**2012**	**2011**	**2010**
Change in benefit obligations			
Benefit obligations at beginning of year	386	371	262
Service cost	29	31	21
Interest cost	18	17	13
Plan amendments			31
Actuarial (gain) / loss	93	(33)	43
Benefits paid	(8)	-	-
Benefit obligations at end of year [(1)]	517	386	371
Unrecognized actuarial (gain) loss	38	(56)	(23)
Unrecognized prior service cost	30	31	31
Accrued pension cost	449	411	363

[(1)] The accumulated benefit obligation was €353 thousand and €264 thousand at December 31, 2012 and 2011 respectively.

(in thousands of euros unless otherwise noted, except per share data)

Japan	2012	2011	2010
Change in benefit obligations			
Benefit obligations at beginning of year	646	562	435
Service cost	61	68	50
Interest cost	6	6	6
Plan amendments	-	-	-
Termination benefits	-	-	-
Actuarial (gain) / loss	(6)	37	68
Benefits paid	(93)	-	(95)
Exchange rate impact	(76)	47	98
Benefit obligations at end of year[(1)]	538	646	562
Unrecognized actuarial (gain) loss	157	199	236
Unrecognized prior service cost	-	-	-
Accrued pension cost	380	447	326

(1) The accumulated benefit obligation was €474 thousand and €570 thousand at December 31, 2012 and 2011 respectively.

16—SHAREHOLDERS' EQUITY

16-1 Common stock

As of December 31, 2012, EDAP TMS S.A.'s common stock consisted of 18,753,757 issued shares, fully paid, and with a par value of €0.13 each. 18,372,229 of the shares were outstanding.

16-2 Pre-emptive subscription rights

Shareholders have preemptive rights to subscribe on a *pro rata* basis for additional shares issued by the Company for cash. Shareholders may waive such preemptive subscription rights at an extraordinary general meeting of shareholders under certain circumstances. Preemptive subscription rights, if not previously waived, are transferable during the subscription period relating to a particular offer of shares.

16-3 Dividend rights

Dividends may be distributed from the statutory retained earnings, subject to the requirements of French law and the Company's by-laws. The Company has not distributed any dividends since its inception as the result of an accumulated statutory deficit of €22,844 thousand. Dividend distributions, if any, will be made in euros. The Company has no plans to distribute dividends in the foreseeable future.

16-4 Treasury stock

As of December 31, 2012, the 381,528 shares of treasury stock consisted of (i) 190,238 shares acquired between August and December 1998 for €649 thousand, and (ii) 191,290 shares acquired in June and July 2001 for €523 thousand. All 381,528 shares of treasury stock have been acquired to cover outstanding stock options (see Note 16-5).

16-5 Stock-option plans

As of December 31, 2012, EDAP TMS S.A. sponsored three stock purchase and subscription option plans:

On January 29, 2004, the shareholders of EDAP TMS S.A. authorized the Board of Directors to grant up to 240,000 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. Under this plan, 124,000 options are still in force on December 31, 2012.

On May 22, 2007, the shareholders of EDAP TMS S.A. 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.

Conforming to this stock option plan, on October 29, 2007, the Board of Directors granted 504,088 options to subscribe to new Shares to certain employees of EDAP TMS. The exercise price was fixed at €3.99 per share. Options were to begin vesting one year after the date of grant and all options were fully vested as of October 29, 2011 (i.e., four years after the date of grant). Shares acquired pursuant to the options cannot be sold prior to four years from the date of grant. The options expire on October 29, 2017 (i.e., ten years after the date of grant) or when employment with the Company ceases, whichever occurs earlier. At December 31, 2007 the total fair value of the options granted under this plan was €1,731 thousand. This non-cash financial charge has been recognized in the Company's operating expenses over a period of 48 months, between October 2007 and October 2011. The impact on 2010 operating income, in accordance with ASC 718 was €167 thousand. The impact on 2011 operating income was €53 thousand and there was no more impact on 2012 operating income. Under this plan, 416,838 options are still in force on December 31, 2012.

Conforming to this stock option plan, on June 25, 2010, the Board of Directors granted the remaining 95,912 options to subscribe to new Shares to certain employees of EDAP TMS. The exercise price was fixed at €1.88 per share. Options were to begin vesting one year after the date of grant and will be fully vested as of June 25, 2014 (i.e., four years after the date of grant). Shares acquired pursuant to the options cannot be sold prior to four years from the date of grant. The options expire on June 25, 2020 (i.e., ten years after the date of grant) or when employment with the Company ceases, whichever occurs earlier. At June 25, 2010 the total fair value of the options granted under this plan was €143 thousand. This non-cash financial charge will be recognized in the Company's operating expenses over a period of 48 months; the impact on 2010 Operating Income was €39 thousand. The impact on 2011 operating income was €56 thousand. The impact on 2012 operating income was €30 thousand. Under this plan, 95,912 options are still in force on December 31, 2012.

(in thousands of euros unless otherwise noted, except per share data)

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. Conforming to this stock option plan, on June 25, 2010, the Board of Directors granted 229,100 options to purchase existing Shares to certain employees of EDAP TMS. The exercise price was fixed at €2.38 per share. Options were to begin vesting one year after the date of grant and will be fully vested as of June 25, 2014 (i.e., four years after the date of grant). Shares acquired pursuant to the options cannot be sold prior to four years from the date of grant. The options expire on June 25, 2020 (i.e., ten years after the date of grant) or when employment with the Company ceases, whichever occurs earlier. At June 24, 2010 the total fair value of the options granted under this plan was €328 thousand. This non-cash financial charge will be recognized in the Company's operating expenses over a period of 48 months; the impact on 2010 Operating Income was €82 thousand. The impact on 2011 operating income was €90 thousand. The impact on 2012 operating income was €47 thousand. Under this plan, 174,100 options are still in force on December 31, 2012.

As of December 31, 2012, a summary of stock option activity to purchase or to subscribe to Shares under these plans is as follows:

	2012		2011		2010	
	Options	Weighted average exercise price (€)	Options	Weighted average exercise price (€)	Options	Weighted average exercise price (€)
Outstanding on January 1,	830,025	3.23	906,775	3.19	656,013	3.57
Granted	-	-	-	-	325,012	2.23
Exercised	-	-	-	-	(18,000)	2.15
Forfeited	(15,750)	3.17	(51,750)	3.03	(56,250)	2.45
Expired	(3,425)	2.02	(25,000)	2.08	-	-
Outstanding on December 31,	810,850	3.18	830,025	3.23	906,775	3.19
Exercisable on December 31,	675,844	3.38	621,516	3.50	486,446	3.52
Share purchase options available for grant on December 31	83,428		72,003		16,003	

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 January 18, 2013, the Board of Directors granted 500,000 options to certain categories of employees.

(in thousands of euros unless otherwise noted, except per share data)

The following table summarizes information about options to purchase existing Shares held by the Company, or to subscribe to new Shares, at December 31, 2012:

	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	4,8	3.99	416,838	3.99
2.60	124,000	1.2	2.60	124,000	2.60
2.38	174,100	7.5	2.38	87,050	2,38
1.88	95,912	7.5	1.88	47,956	1.88
1.88 to 3.99	810,850	5.2	3.18	675,844	3.38

A summary of the status of the non-vested shares as of December 31, 2012, and changes during the year ended December, 2012, is presented below:

	Options	Weighted average Grant-Date Fair Value (€)
Non-vested at January 1, 2012	208,509	1.45
Granted	0	0
Vested	(67,503)	1.45
Forfeited	(6,000)	1.43
Non-vested at December 31, 2012	135,006	1.45

16-6 Warrants

On January 25, 2012, pursuant to the Exchange Agreement, we issued warrants (the "2012 Exchange Offer Warrants") to purchase 408,691 newly issued ordinary shares, to certain holders of the New Debentures, at an exercise price equal to the par value per share. The 2012 Exchange Offer Warrants are exercisable immediately and will expire on January 24, 2022. The fair value of the 2012 Exchange Offer Warrants at inception amounts to 805 K€.

At inception, the Black-Scholes valuation model used the following main assumptions and parameters:

- Share price at closing date: $2.59
- Strike price of warrants: €0.13
- Risk free interest rate at 10 years: 2.08%
- Share price volatility: 120%

On that basis, the unit fair value of the 2012 Exchange Offer Warrants was $2.56 per warrant at inception date. The total fair value for the 408,691 issued 2012 Exchange Offer Warrants was $1.047 million at inception date.

On January 16, 2013, the holders exercised in full the 408,691 2012 Exchange Offer Warrants.

(in thousands of euros unless otherwise noted, except per share data)

16- 7 Changes in warrants, stock options and capital increase

Warrants and stock options granted and Capital increase in 2012 comprised the following:

	Change in shareholders' equity resulting from the January 2012 Exchange Agreement	Other change in shareholders equity	**Total**
Warrants and stock options granted	805	76	881
Capital increase	3,882	1,898	5,780
Total Capital Increase	4,687	1,974	6,661

17—OTHER REVENUES

Other revenues consist of the following:

	2012	**2011**	**2010**
Grants and others	47	20	506
Total	47	20	506

In 2012 and 2011, other revenues mainly consist of sales of a license.

In 2010, other revenues consist mainly of €500 thousand of French Government grant as part of a small businesses aid program.

18—RESEARCH AND DEVELOPMENT EXPENSES

Research and development expenses consist of the following:

	2012	**2011**	**2010**
Gross research and development expenses	(3,654)	(2,851)	(3,958)
Research Tax Credit	256	411	327
Grants	739	4	363
Net Research and development expenses	(2,659)	(2,436)	(3,268)

In 2012, grants mainly consisted of European, national and regional grants for the development of innovative imaging solutions for the focal treatment of prostate cancer.

In 2010, grants mainly consisted of national grants for the development of the HIFU technology.

(in thousands of euros unless otherwise noted, except per share data)

19—FINANCIAL INCOME, NET

Interest (expense) income, net consists of the following:

	2012	2011	2010
Interest income	126	185	265
Interest expense	(2,065)	(875)	(2,136)
Depreciation of prepaid expenses on debt grant	(31)	(224)	(920)
Changes in fair value of the 2007 Convertible Debentures	(282)	1,301	(3,434)
Changes in fair value of the warrants	(92)	1,133	(2,618)
Impact from the January 2012 Exchange Agreement	(2,250)		
Total	(4,594)	1,522	(8,844)

In 2012, interest expense on the 2012 Non-convertible Debenture amounted to €1,895 thousand, of which €597 thousand expense for the payment of the 9% interest coupon.

Interest expense in 2011 comprised a €687 thousand expense for the payment of the 9% interest coupon on the Convertible Debentures and accelerated conversion.

Interest expense in 2010 comprised a €1,058 thousand expense for the payment of the 9% interest coupon on the Convertible Debentures and accelerated conversion.

The 2007 Convertible Debenture was recorded at fair value. As a result of the January 2012 Exchange Offer, the 2007 Convertible Debt was remeasured, which resulted in a loss of €2,250 thousand, as detailed in Notes 14-2 and 14-3.

20—INCOME TAXES

20-1 Loss before income taxes

Loss before income taxes is comprised of the following:	2012	2011	2010
France	(5,392)	1,192	(8,972)
EDAP Inc, U.S.A.	(1,739)	(1,146)	(2,143)
Other countries	(227)	(589)	(663)
Total	(7,358)	(543)	(11,778)

20-2 Income tax (expense)/ benefit

Income tax (expense)/benefit consists of the following:	2012	2011	2010
Current income tax expense:			
France	(102)	(95)	(818)
Other countries	(22)	(45)	(49)
Sub-total current income tax expense	(124)	(140)	(866)
Deferred income tax (expense) benefit:			
France	(2)	(0)	(13)
Other countries	8	(255)	(60)
Sub-total deferred income tax (expense) benefit	6	(255)	(73)
Total	(118)	(395)	(939)

(in thousands of euros unless otherwise noted, except per share data)

20-3 Deferred income taxes:

Deferred income taxes reflect the impact of temporary differences between the amounts of assets and liabilities reported for financial reporting purposes and such amounts as measured in accordance with tax laws. The tax effects of temporary differences which give rise to significant deferred tax assets (liabilities) are as follows:

	December 31,	
	2012	**2011**
Net operating loss carryforwards	19,563	17,426
Elimination of intercompany profit in inventory	119	223
Elimination of intercompany profit in fixed assets	122	193
Other items	689	808
Total deferred tax assets	20,493	18,650
Capital leases treated as operating leases for tax	(76)	(140)
Other items	(11)	(10)
Total deferred tax liabilities	(87)	(150)
Net deferred tax assets	20,406	18,500
Valuation allowance for deferred tax assets	(20,375)	(18,474)
Deferred tax assets (liabilities), net of allowance	32	26

Net operating loss carryforwards of €11,112 thousand, €1,600 thousand, €1,811 thousand, €397 thousand, €510 thousand and €42,488 thousand as of December 31, 2012 are available at EDAP Technomed Inc., EDAP-TMS France S.A.S., Edap Technomed Co Ltd Japan, Edap Technomed Sdn Bhd Malaysia, EDAP TMS GmbH and EDAP TMS S.A., respectively. These net operating losses generate deferred tax assets of €19,563 thousand. Realization of these assets is contingent on future taxable earnings in the applicable tax jurisdictions. As of December 31, 2012, €14,947 thousand out of these €19,563 thousand net operating loss carry-forwards have no expiration date. The remaining tax loss carry-forwards expire in years 2014 through 2032. In accordance with ASC 740, a valuation allowance is recorded as realization of those amounts is not considered probable.

20-4 Effective tax rate

A reconciliation of differences between the statutory French income tax rate and the Company's effective tax rate is as follows:

	2012	**2011**	**2010**
French statutory rate	33.3%	34.4%	33.8%
Income of foreign subsidiaries taxed at different tax rates	0.4%	12.6%	0.6%
Effect of net operating loss carry-forwards and valuation allowances	(37.6%)	(287.3%)	(28.3%)
Non taxable debt fair value variation	(1.1%)	154.1%	(17.4%)
Non deductible entertainment expenses	1.9%	9.5%	0.4%
Other	1.5%	4%	2.9%
Effective tax rate	(1.6%)	(72.7%)	(8.0%)

20-5 Uncertainty in Income Taxes

According to ASC 740, the Company reviewed the tax positions of each subsidiary. On December 31, 2012 there is no uncertainty in the Company's tax positions.

(in thousands of euros unless otherwise noted, except per share data)

In July 2010, the Company was requested by the French Tax Authorities to pay the amount of €772,822 to comply with the European Court of Justice ruling on fair competition and illegal state aids (C-214/07 "Commission of the European Communities vs. French Republic"). The amount was related to a state aid received by EDAP-TMS France in 1994 for the acquisition of the activities of Technomed International and included €374,156 of late interest. The Company reversed consequently the €50 thousand reserve that had been taken as of December 31, 2009.

In March 2011, the Company engaged in a contentious procedure against the French Tax Authorities to contest this position and ask for the recuperation of the paid amounts. As of December 31, 2012, this procedure was still ongoing.

As a result, the effect on the retained earnings is the following:

	Unrecognized tax benefits		
	2012	**2011**	**2010**
Balance as of January 1st,	-	-	(50)
Impact of tax positions taken during a prior period	-	-	-
Impact of tax positions taken during the current period	-	-	-
Impact of settlements with taxing authorities	-	-	50
Impact of a lapse of the applicable statute of limitations	-	-	-
Balance as of December 31st,	-	-	-

As the state aid received in 1994 was an income tax credit, the payment of €773 thousand has been recognized as an income tax in 2010. The tax years that remain subject to examination by major tax jurisdictions are 2010, 2011 and 2012.

(in thousands of euros unless otherwise noted, except per share data)

21—EARNINGS (LOSS) PER SHARE

A reconciliation of the numerators and denominators of the basic and diluted EPS calculations for the years ended December 31, 2012, 2011 and 2010 is as follows:

	For the year ended Dec. 31, 2012			For the year ended Dec. 31, 2011			For the year ended Dec. 31, 2010		
	Loss in euro (Numera-tor)	Shares Denominato r)	Per-Share Amount	Loss in euro Numerator)	Shares (Denomin-ator)	Per-Share Amount	Loss in euro (Numerator)	Shares (Denomin-ator)	Per-Share Amount
Basic EPS									
Income (loss) available to common Shareholders	(7,475,490)	17,556,395	(0.43)	(938,636)	13,345,004	(0.07)	(12,717,105)	13,008,401	(0.98)
Effect of dilutive securities:									
Stock options only in the money		-			-			-	
Diluted EPS									
Income (Loss) available to common shareholders, including assumed Conversions	(7,475,490)	17,556,395	(0.43)	(938,636)	13,345,004	(0.07)	(12,717,105)	13,008,401	(0.98)

The effects of dilutive securities, representing a number of shares of 388,256, 8,981 and 85,834 for the years ended December 31, 2012, 2011 and 2010 respectively, were excluded from the calculation of earnings per share as a net loss was reported in these periods.

22—COMMITMENTS AND CONTINGENCIES

22-1 Commitments

The Company currently has commitments regarding its operating leases as described in Note 12-2.

In connection with the issuance of New Debentures and January 2012 Warrants, the Company entered into a registration rights agreement (the "Registration Right Agreement"). Under the terms of the Registration Rights Agreement, subject to certain limited exceptions, if the Company fails to comply with certain provisions set forth in the Registration Rights Agreement, the Company will be required to pay the holders participating in the exchange, as liquidated damages, 1.0% of the aggregate balanced amount of October 2007 Convertible Debentures exchanged by each such holder in the Exchange Agreement for each 30-day period (or a pro rata portion thereof) during which such failure continues.

(in thousands of euros unless otherwise noted, except per share data)

22-2 Litigation

As of the date of these financial statements, the Company is not involved in any material legal proceedings.

22-3 Contingencies

The Company currently has contingencies relating to warranties provided to customers for products as described in Note 1-13 and Note 11.

23—FAIR VALUE OF FINANCIAL INSTRUMENTS

The following disclosure of the estimated fair value of financial instruments was made in accordance with the requirements of ASC 825 ‘‘Disclosure about fair value of financial instruments.’’ The estimated fair value amounts have been determined by the Company using available market information and appropriate valuation methodologies. The estimates of fair values of the Company’s financial instruments are compared below to the recorded amounts at December 31, 2012 and 2011.

	December 31,		December 31,	
	2012 Recorded Value	2012 Estimated Fair Value	2011 Recorded Value	2011 Estimated Fair Value
Assets:				
Cash and cash equivalents	7,041	7,041	4,900	4,900
Trade accounts and notes receivable, net	11,949	11,949	14,981	14,981
Short term investments	1,036	1,036	1,572	1,572
Liabilities:				
Short-term borrowings	2,095	2,095	1,700	1,700
Trade accounts payable	5,820	5,820	5,725	5,725
Notes payable	516	516	570	570
Debentures and other Long Term Debt	5,038	5,038	7,085	7,085
Investor Warrants	1,571	1,571	195	195
Placement Agent Warrants	183	183	-	-

The recorded amount of cash and cash equivalents, restricted short term investment, investments available for sale, trade accounts and notes receivable (drafts), short-term borrowings, and trade accounts and notes payable (drafts) are a reasonable estimate of their fair value due to the short-term maturities of these instruments.

(in thousands of euros unless otherwise noted, except per share data)

24—CONCENTRATION OF CREDIT RISK

Financial instruments, which potentially subject the Company to concentrations of credit risk, consist principally of cash and cash equivalents and trade accounts and notes receivable from customers, primarily located in France, Japan and the United States. The Company maintains cash deposits with major banks. Management periodically assesses the financial condition of these institutions and believes that any possible credit risk is limited. The Company has procedures in effect to monitor the creditworthiness of its customers. The Company obtains bank guarantees for first-time or infrequent customers, and in certain cases obtains insurance against the risk of a payment default by the customer. The Company reviewed individual customer balances considering current and historical loss experience and general economic conditions in determining the allowance for doubtful accounts receivable of €1.6 million and €1.3 million, for the years ended December 31, 2012, and 2011, respectively.

Ultimate losses may vary from the current estimates, and any adjustments are reported in earnings in the periods in which they become known.

In 2012, 2011 and 2010, the Company did not generate significant revenue with a single customer.

25—FOREIGN CURRENCY TRANSACTIONS

The Company generates a significant percentage of its revenues, and of its operating expenses, in currencies other than euro. The Company's operating profitability could be materially adversely affected by large fluctuations in the rate of exchange between the euro and such other currencies. The Company engages in foreign exchange hedging activities when it deems necessary, but there can be no assurance that hedging activities will be offset by the impact of movements in exchange rates on the Company's results of operations. As of December 31, 2012, there were no outstanding hedging instruments.

26—SEGMENT INFORMATION

In July 2002, the Company announced an organizational realignment that created two operating divisions within the Company. For reporting purposes, this organizational realignment created three reporting segments: the corporate activities of the holding Company, EDAP TMS S.A., the High Intensity Focused Ultrasound division and the Urological Devices and Services division. Then, in 2007, the Company created a new reporting segment dedicated to the FDA approval for Ablatherm-HIFU activity. The following tables set forth the key income statement figures, by segment for fiscal years 2012, 2011 and 2010 and the key balance sheet figures, by segment, for fiscal years 2012, 2011 and 2010.

The business in which the Company operates is the development and production of minimally invasive medical devices, primarily for the treatment of urological diseases. Substantially all revenues result from the sale of medical devices and their related license and royalty payments from third parties. The segments derive their revenues from this activity.

Segment operating profit or loss and segment assets are determined in accordance with the same policies as those described in the summary of significant accounting policies. Interest income and expense, current and deferred income taxes are not allocated to individual segments. A reconciliation of segment operating profit or loss to consolidated net loss is as follows:

	2012	2011	2010
Segment operating loss	(2,030)	(2,497)	(3,818)
Financial income (expense), net	(4,594)	1,522	(8,844)
Foreign Currency exchange (losses) gains, net	(733)	482	884
Other income (expense), net	-	(50)	-
Income tax (expense) credit	(118)	(395)	(939)
Consolidated net loss	(7,475)	(938)	(12,717)

(in thousands of euros unless otherwise noted, except per share data)

A summary of the Company's operations by segment is presented below for years ending December 31, 2012, 2011 and 2010:

	HIFU Division	UDS Division	EDAP TMS (Corporate)	FDA	Total consolidated
2012					
Sales of goods	1,884	15,126	-	-	17,009
Sales of RPPs & leases	2,695	1,293	-	-	3,988
Sales of spare parts and services	1,006	4,015	-	-	5,021
Total sales	5,585	20,433	-	-	26,018
Total net sales	5,585	20,433	-	-	26,018
External other revenues	47	-	-	-	47
Total revenues	5,632	20,433	-	-	26,065
Total COS	(2,909)	(12,723)	-	-	(15,632)
Gross margin	2,723	7,710	-	-	10,433
R&D	(920)	(746)	-	(992)	(2,659)
Selling and marketing expenses	(1,825)	(4,794)	-	-	(6,620)
G&A	(723)	(1,014)	(1,352)	(97)	(3,185)
Total expenses	(3,468)	(6,554)	(1,352)	(1,089)	(12,463)
Operating income (loss)	(746)	1,156	(1,352)	(1,089)	(2,030)
Total Assets	7,316	20,894	2,071	162	30,444
Capital expenditures	22	539	39	-	600
Long-lived assets	1,504	3,129	217	64	4,913
Goodwill	645	1,767	-	-	2,412

	HIFU Division	UDS Division	EDAP TMS (Corporate)	FDA	Total consolidated
2011					
Sales of goods	1,442	10,957	-	-	12,399
Sales of RPPs & leases	3,270	1,238	-	-	4,508
Sales of spare parts and services	1,153	4,212	-	-	5,365
Total sales	5,865	16,407	-	-	22,272
Total net sales	5,865	16,407	-	-	22,272
External other revenues	20	-	-	-	20
Total revenues	5,885	16,407	-	-	22,292
Total COS	(2,621)	(10,815)	-	-	(13,435)
Gross margin	3,264	5,592	-	-	8,857
R&D	(950)	(792)	-	(694)	(2,436)
Selling and marketing expenses	(1,968)	(3,865)	(41)	-	(5,874)
G&A	(604)	(813)	(1,547)	(79)	(3,044)
Total expenses	(3,521)	(5,471)	(1,588)	(773)	(11,353)
Operating income (loss)	(257)	122	(1,588)	(773)	(2,497)
Total Assets	7,677	21,309	2,984	268	32,238
Capital expenditures	84	760	27	-	871
Long-lived assets	1,948	3,391	150	9	5,498
Goodwill	645	1,767	-	-	2,412

(in thousands of euros unless otherwise noted, except per share data)

	HIFU Division	UDS Division	EDAP TMS (Corporate)	FDA	Total consolidated
2010					
Sales of goods	1,939	11,196	-	-	13,135
Sales of RPPs & leases	3,505	1,184	-	-	4,689
Sales of spare parts and services	1,438	3,940	-	-	5,378
Total sales	6,882	16,319	-	-	23,202
Total net sales	6,882	16,319	-	-	23,202
External other revenues	6	500	-	-	506
Total revenues	6,888	16,820	-	-	23,708
Total COS	(3,285)	(10,969)	-	-	(14,253)
Gross margin	3,604	5,851	-	-	9,455
R&D	(741)	(793)	-	(1,734)	(3,268)
Selling and marketing expenses	(2,741)	(3,943)	-	-	(6,684)
G&A	(766)	(1,024)	(1,338)	(193)	(3,320)
Total expenses	(4,247)	(5,760)	(1,338)	(1,927)	(13,272)
Operating income (loss)	(644)	91	(1,338)	(1,927)	(3,818)
Total Assets	9,344	20,803	5,474	317	35,938
Capital expenditures	116	411	73	-	600
Long-lived assets	2,341	3,310	175	59	5,886
Goodwill	645	1,767	-	-	2,412

27—VALUATION ACCOUNTS

	Allowance for doubtful accounts	Slow-moving inventory
Balance as of January 1, 2010	862	805
Charges to costs and expenses	200	184
Deductions: write-off and others	17	(118)
Balance as of December 31, 2010	1,079	871
Charges to costs and expenses	191	428
Deductions: write-off and others	2	(133)
Balance as of December 31, 2011	1,272	1,166
Charges to costs and expenses	516	124
Deductions: write-off and others	(186)	(356)
Balance as of December 31, 2012	1,602	934

(in thousands of euros unless otherwise noted, except per share data)

28—SUPPLEMENTAL DISCLOSURES OF CASH FLOW INFORMATION

Interest and income taxes paid are as follows:

	2012	2011	2010
Income taxes paid (refunds received)	143	143	942
Interest paid	401	38	66
Interest received	16	40	43

Non-cash transactions:	2012	2011	2010
Capital lease obligations incurred	137	29	73

29—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 €61 thousand, €60 thousand and €59 thousand for 2012, 2011 and 2010 respectively. . As of December 31, 2012, payables to Dae You amounted to €44 thousand and as of December 31, 2011, our payables to them amounted to €39 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 €371 thousand, €768 thousand and €315 thousand in 2012, 2011 and 2010 respectively. As of December 31, 2012, receivables (‘Net trade accounts and notes receivable’) amounted to €350 thousand. As of December 31, 2011, receivables from Dae You amounted to €95 thousand.

30—SUBSEQUENT SIGNIFICANT EVENTS

a) On January 16, 2013, Liberty Harbor Master Fund exercised its 408,691 January 2012 Warrants. On January 18, 2013, the Board of Directors convened, acted the receipt of EUR 53,129.83 corresponding to exercise of the Warrants and issued 408,691 new ADSs to Liberty Harbor Master Fund.

b) On January 31, 2013, we submitted our PMA application to the U.S. (FDA) for our Ablatherm-HIFU 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, the U.S. FDA provided a positive administrative acceptance review notification for the 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.

EDAP TMS SA
Senior Executive Officers

Philippe Chauveau
Chairman of the Board of Directors,

Marc Oczachowski
Chief Executive Officer

Eric Soyer
Chief Financial Officer

EDAP TMS
Board of Directors

Philippe Chauveau
Chairman

Pierre Beysson
Paris, France

Rob Michiels
Laguna Hills, CA, USA

Argil Wheelock
Chattanooga, TN, USA

EDAP TMS SA
Corporate Headquarters

Parc d'Activités
La Poudrette Lamartine
4, Rue du Dauphiné
F 69120 Vaulx-en-Velin
France
Tel : +33 (0)4 72 15 31 50
Fax : +33 (0)4 72 15 31 51
www.edap-tms.com
www.hifu-planet.com

Blandine Confort
Investor Relations
Tel: +33 (0)4 72 15 31 72
bconfort@edap-tms.com

EDAP TMS's subsidiaries
Officers

Marc Oczachowski
President
EDAP TMS France S.A.S.
EDAP Technomed Inc

Eric Soyer
General Manager
EDAP TMS France S.A.S.

Judith Johannsen
General Manager
EDAP TMS GmbH
Germany

Sergio Pontecorvi
General Manager
EDAP Technomed S.r.l.
Rome, Italy

Jean-François Bachelard
Asia Operations Supervisor
General Manager
EDAP Technomed Co. Ltd
Tokyo, Japan

Hervé de Soultrait
General Manager
EDAP Technomed (M) Sdn, Bhd
Kuala Lumpur, Malaysia

EDAP TMS's branches
Officers

Jean-François Bachelard
General Manager
EDAP
Moscow, Russia

Young Hwan Park
General Manager
EDAP TMS Korea
Seoul, Korea

Bringing New Horizons to Therapy

EDAP TMS - PA La Poudrette Lamartine - 4, rue du Dauphiné - 69120 Vaulx-en-Velin - FRANCE
Tel : +33 (0)4 72 15 31 50 - Fax : +33 (0)4 72 15 31 51 - www.edap-tms.com - contact@edap-tms.com

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