EDAP TMS SA
Form 20-F
March 31, 2011

As filed with the Securities and Exchange Commission on March 31, 2011
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 20-F

ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF
THE SECURITIES EXCHANGE ACT OF 1934
__ REGISTRATION STATEMENT PURSUANT TO SECTION 12(B) OR (G) OF THE SECURITIES EXCHANGE ACT OF 1934,
OR
X ANNUAL REPORT PURSUANT TO SECTION 13 OR15(D) OF THE SECURITIES EXCHANGE ACT OF 1934
for the Fiscal Year Ended December 31, 2010
OR
__ TRANSITION REPORT PURSUANT TO SECTION 13 OR15(D) OF THE SECURITIES EXCHANGE ACT OF 1934
OR
__ SHELL COMPANY REPORT PURSUANT TO SECTION 13 OR15(D) OF THE SECURITIES EXCHANGE ACT OF 1934

0-29374
(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
(Name, Telephone, E-mail 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, 2010: 13,008,401 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" or "our" 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 European Monetary Union, including the Republic of France, and references to ''dollars,'' ''U.S. dollars'' or ''$'' are to th 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®, Praktis®, Sonolith®, Sonolith i-sys®, @-REGISTRY®. Registration of Sonolith i-move trademark is currently being processed. 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"), usually containing words such as ''believe,'' ''plan,'' ''intend,'' ''estimate,'' ''expect'' and ''anticipate'' or similar which reflect our views about future events and financial performance. Actual events or results may differ materially from those projected in such forward-looking statements as a result of various factors that may be beyond our control. These factors include, without limitation:

- the effects of intense competition in the markets in which we operate;
- the uncertainty of market acceptance for our HIFU devices;
- the clinical status of our HIFU devices;
- the uncertainty of reimbursement status of procedures performed with our products;
- the impact of government regulation, particularly relating to public healthcare systems and the commercial distribution of medical devices;
- the uncertainty in the U.S. FDA approval process, mostly changes in FDA recommendations and guidance;
- 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 October 2007 private placement;
- risks relating to ownership of our securities; and
- changes in the fair value of the convertible debentures and warrants issued in the October 2007 private placement.

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, 2008, 2009 and 2010 and the selected income statement data for the years ended December 31, 2008, 2009 and 2010 set forth below have been derived from our consolidated financial statements included in this annual report. The selected balance sheet data as of December 31, 2006 and the selected income statement data for the year ended December 31, 2006 have been derived from our audited consolidated financial statements as of and for the year ended December 31, 2006. These financial statements, together with our consolidated financial statements have been prepared in accordance with U.S. GAAP. To date, we have not been required, and presently are not required under French law, to prepare consolidated financial statements under French GAAP or IFRS, nor have we done so.

	Year Ended and at December 31,				
In thousands of euro, except per share data in euro	2006	2007	2008	2009	2010
INCOME STATEMENT DATA					
Total revenues	20,265	22,327	23,053	24,885	23,708
Total net sales	20,174	22,213	22,856	24,839	23,202
Gross profit	8,319	9,179	9,099	10,672	9,455
Operating expenses	(11,365)	(13,158)	(13,258)	(13,874)	(13,272)
Loss from operations	(3,047)	(3,979)	(4,159)	(3,202)	(3,818)
Income (loss) before income taxes	(3,328)	(5,461)	1,648	(7,694)	(11,778)
Income tax (expense) benefit	(103)	30	(51)	(72)	(939)
Net income (loss)	(3,431)	(5,430)	1,597	(7,766)	(12,717)
Basic earnings (loss) per share	(0.39)	(0.59)	0.17	(0.74)	(0.98)

Diluted earnings (loss) per share	(0.39)	(0.59)	0.17	(0.74)	(0.98)
Dividends per share(1)	—	—	—	—	—
Basic weighted average shares outstanding	8,817,007	9,200,757	9,582,593	10,510,305	13,008,401
Diluted weighted average shares outstanding	8,817,007	9,200,757	9,658,295	10,567,563	13,094,235
BALANCE SHEET DATA					
Total current assets	26,393	36,124	35,786	33,248	29,865
Property and equipment, net	3,211	4,179	3,763	3,288	2,877
Total current liabilities	10,926	12,884	14,457	15,175	14,658
Total assets	32,473	45,003	43,863	40,378	35,938
Long-term debt, less current portion	58	15,174	9,500	10,138	10,075
Total shareholders' equity	19,300	14,499	17,191	12,579	8,900

(1) No dividends were paid with respect to fiscal years 2006 through 2009 and subject to approval of the annual shareholders' meeting to be held in 2011 the Company does not anticipate paying any dividend with respect to fiscal year 2010. See Item 8, ''Financial Information — Dividends and Dividend Policy.''

Note: Certain prior years amounts have been reclassified to conform to the current year's presentation (See Item 5, "Operating Results—Research and Development, Patents and Licenses.'

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 €
2006	0.84	0.75	0.79	0.76
2007	0.78	0.67	0.73	0.68
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

(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.

	End of Month €	High €	Low €	Average €
2010				
September	0.74	0.79	0.73	0.76
October	0.72	0.73	0.71	0.72
November	0.77	0.77	0.70	0.73
December	0.75	0.76	0.75	0.76
2011				
January	0.73	0.78	0.73	0.75
February	0.73	0.74	0.72	0.73
March, through March 18, 2011	0.71	0.72	0.71	0.72

On March 18, 2011, the Noon Buying Rate was U.S.$1.00 = €0,71.

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

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

We depend on the success of our High Intensity Focused Ultrasound ("HIFU") technology for future revenue growth and net income. 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 remained stable owing to increased sales volumes. 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 in its commercialization phase 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 U.S. Food and Drug Administration ("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 and plan to complete the clinical trials in order to obtain FDA approval of the Ablatherm using the $17.4 million net proceeds of the October 2007 private placement. While we expect these funds to be sufficient to enable us to fund the clinical trials in their entirety, we cannot guarantee that the proceeds will in fact be enough to do so. We can also not guarantee that the FDA will accept the changes to the protocol that we may submit, based upon the December 11, 2009 panel recommendations and our ongoing discussions with the FDA. Finally, we cannot guarantee the successful completion of clinical trials nor can we guarantee that the FDA will grant approval to market a device even if clinical trials are conclusive and/or are successfully completed. 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."

Our clinical trials for products using HIFU technology may not be successful.

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. The results from preclinical testing and early clinical trials may not predict the results that will be obtained in large scale clinical trials, and there can be no assurance that our clinical trials will demonstrate that our products are safe, effective, and marketable. A number of companies have suffered significant setbacks in advanced clinical trials, even after promising results in earlier trials. Discussions with regulatory authorities to improve our clinical protocol may prove difficult and lengthy. We may face difficulties in recruiting patients in our study, hence hindering our progress and timing towards approval. 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. See Item 4, ''Information on the Company—High Intensity Focused Ultrasound Division—HIFU Division Clinical and Regulatory Status.''

We rely on scientific, technical and clinical data supplied by academics who work with us to evaluate and develop our devices. We cannot assure investors that there are no errors or omissions in such data that would adversely affect the development of our products.

The process of applying for regulatory approval is unpredictable, often lengthy and requires the expenditure of substantial resources. 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. We do not anticipate receiving FDA approval for any HIFU device, including the Ablatherm, for the coming years, if at all. 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.

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 may 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, French Healthcare Authorities recently 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 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. 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.

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 (see Item 8 – "significant changes as of March 31, 2011 with respect to recent events in Japan"). This has in the past resulted in significant variations in working capital requirements and operating cash flows. In 2010, 2009 and 2008, moreover, our operating cash flow was negative due to the cash requirements of operating activities, which we financed using cash and cash equivalents on hand. In addition, our 2010, 2009 and 2008 operating cash flow was negative due to the working-capital cash requirements, the 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 due to the sponsoring of the pre-market approval (''PMA'') trials for the FDA's approval of our Ablatherm-HIFU solution for the treatment of prostate cancer in the United States. Since we anticipate relying principally 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, and by the implementation of our U.S. clinical trials to seek the FDA's approval. In the future, our liquidity may be constrained and our cash flows may be uncertain, negative or significantly different from period to period. In 2006, we raised new equity funds via a $7.5 million private placement of ordinary shares in the form of ADSs, aimed at financing our new marketing and sales campaign to promote and develop the RPP business. Our future cash flow will be affected by the 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. In October 2007, we raised a $20 million in a private placement of convertible debentures (the "Convertible Debentures", as described in "Item 5 - Convertible Debentures"), aimed at financing our pre-market approval trial process to seek the FDA's approval on our Ablatherm-HIFU solution for the treatment of prostate cancer in the United States (our Ablatherm device, considered as a Class III device by the FDA, must receive pre-market approval by the FDA to ensure its safety and effectiveness). Our future cash flow will be affected by the expenses to fund the trials, while 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.

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 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. In 2008, we had negative operating income in our UDS division, reflecting sharp price competition in this business together with non-optimal manufacturing costs on our newly developed Sonolith I-sys product range. In 2009, we had positive operating income in both HIFU and Urology Devices and Services (“UDS”) divisions which however were not sufficient to offset the cost of the Ablatherm-HIFU FDA PMA trials and the cost of our corporate activities thus resulting in a consolidated operating loss. In 2010, we had negative operating income in our HIFU division, reflecting a slowdown in HIFU activity which was not sufficient to offset the fixed costs of the division. 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.’’

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 Focus Surgery, Inc. (''Focus Surgery''), which has developed a device called the Sonablate SB500 for the treatment of localized prostate cancer. Misonix, Inc., USHIFU and International HIFU are also involved in marketing and distribution of the Sonablate. 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. In some cases, we also form cooperative arrangements with other companies. For example, on April 25, 2007, we signed an exclusive distribution agreement with China Medical Technologies ("Chinamed"), a Chinese company, to distribute their HIFU devices in the European Union and Russia once their devices are approved for use in those jurisdictions. Prior to this agreement, Chinamed had been developing HIFU products for various types of cancer tumors, but only marketing its HIFU products in China. In September 21, 2007, we entered into a Consulting Agreement with Chinamed, now Haifuning HIFU Technology (Beijing) Co. Ltd ("Haifuning") pursuant to which we will assist them in obtaining market approvals in Europe for their HIFU products, for other pathologies than prostate cancer. 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.

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.

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, in the United States. In particular, our Ablatherm device is under clinical trials in the U.S. and, following the December 11, 2009 panel experts recommendations and our discussions with the FDA, we thoroughly evaluated all options based on inputs from our clinical and regulatory advisors. 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 2-year follow-up phase. Clinical outcomes from these patients combined with our European long-term database will form the foundation of a submission to the FDA which we expect to occur in 2012. Consequently, we may not be able to follow the FDA recommendations with regards to our prospective study and its cryoablation comparative arm and to conduct our trials within the timeframe and budget we initially expected. Moreover, regulatory approval to market a product, if granted, may include limitations on the indicated uses for which it 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.”

Additional statutes or regulations that affect our business could also be adopted and could impose substantial additional costs or otherwise 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 countries 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, therefore, will 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. 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, could have a material adverse effect on our business, financial condition and results of operations.

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.

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 2010, approximately 66% of our total operating expenses were denominated in euro, while approximately 41% of our sales were denominated in currencies other than euro (primarily the U.S. dollar and the Japanese yen). Our operating profitability could be materially adversely affected by large fluctuations in the rate of exchange between the euro and other currencies. For instance, a decrease in the value of the U.S. dollar or the Japanese yen against the euro would have a negative effect on our revenues, which may not be offset by an equal reduction in operating expenses and would therefore negatively impact operating profitability. From time to time we enter into foreign exchange forward sale contracts to hedge against fluctuations in the exchange rates of the principal foreign currencies in which our receivables are denominated (in particular, the U.S. dollar and the Japanese yen), but there can be no assurance that such hedging activities will limit the effect of movements in exchange rates on our results of operations. As of December 31, 2010, 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.

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.

In accordance with the terms of our Convertible Debentures, we have the option to pay interest on the Convertible Debentures in shares. 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, we may need to make interest payments in cash, thus negatively affecting our working capital.

Further, the volatility in our share price due to the current economic and financial environment has had a direct impact on the valuation of the Convertible Debentures and warrants (the "Warrants" as defined in Item 5 – "Warrants" below) issued in the October 2007 private placement, which in turn could have a material adverse impact on our financial conditions. See "Risks Relating to the October 2007 Private Placement— Changes in the fair value of the Convertible Debentures and warrants issued in the October 2007 private placement at each balance sheet date could have a significant impact on our financial condition and results of operations."

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 October 2007 Private Placement

If we fail to maintain the registration of our securities, we will be subject to substantial penalties.

Pursuant to the terms of the registration rights agreement we entered into in connection with the October 2007 private placement, we secured the registration of a portion of the securities deliverable upon conversion of the Convertible Debentures and in payment of interest under the Convertible Debentures as well as the securities deliverable upon exercise of the warrants. If we fail to maintain the effectiveness of any registration statement as required under the registration rights agreement, we are subject to significant penalties, including payment of liquidated damages. Failure to meet these obligations will cause us to incur substantial penalties in the form of liquidated damages and could, given the passage of time, lead to an event of default under the Convertible Debentures. Payment of liquidated damages or mandatory default amount will have a material adverse effect on our financial condition and results of operation and our ability to continue as a going concern.

If we are required for any reason to repay our outstanding Convertible Debentures, we would be required to deplete our working capital or raise additional funds. Our failure to repay the Convertible Debentures, if required, could result in legal action against us, which could require the sale of substantial assets.

The Convertible Debentures are due and payable on October 30, 2012, unless sooner converted into ordinary shares. Any event of default could require the early repayment of the Convertible Debentures at the mandatory default amount, including all other amounts of interest, costs, expenses and liquidated damages due in respect of the defaulted Convertible Debentures. If, prior to the maturity date, we are required to repay the outstanding Convertible Debentures in full, we would be required to use our working capital and raise additional funds. If we were unable to repay the Convertible Debentures when required, the Convertible 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.

The issuance of shares upon conversion of the Convertible Debentures, exchange offer, exercise of outstanding Warrants and payment of interests on the Convertible Debentures will cause immediate and substantial dilution to our existing shareholders.

The issuance of ordinary shares upon conversion of the Convertible Debentures and exercise of the Warrants will result in substantial dilution to the interests of other shareholders since the selling shareholders may ultimately convert and sell the full amount issuable on conversion. Based on the conversion price of the Convertible Debentures and the exercise price of the Warrants at the closing of the October 2007 private placement, taking into account the December 2010 exchange offer extended to all Convertible Debentures and Warrants holders, up to 2,480,173 shares are issuable upon conversion and exercise, representing approximately 19% of our issued and outstanding share capital. In addition, interest on the Convertible Debentures is payable, under certain circumstances, in ordinary shares, 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 under our election to pay interest in ordinary shares. Although no single selling shareholder may convert its Convertible Debentures and/or exercise its Warrants if such conversion or exercise would cause it to own more than 4.99% of our outstanding ordinary, this restriction does not prevent each selling shareholder from converting and/or exercising a portion of its holdings, selling those securities and then converting the rest of its holdings. In this way, each selling shareholder could sell more than this limit while never holding more than this limit.

On June 24, 2010, our shareholders adopted several new resolutions and extended the validity of existing ones, allowing the Board of Directors to renegotiate our indebtedness with the maximum flexibility while remaining within the limit of the dilution already approved by shareholders, hence authorizing the issuance of a maximum of 6,512,370 new shares.

Based on these resolutions and in view of our debt restructuring and new projects financing, we filed a FormF-3 registration statement with the SEC on October 6, 2010 to register ordinary shares and warrants for a maximum amount of $9 million. Such registration statement was declared effective by the SEC on October 20, 2010.

Finally, pursuant to shareholders' authorization and upon the Board of Directors delegation, the management extended an offer to all Convertible Debentures and Warrant holders to exchange all of their Convertible Debentures and warrants for ADRs in order to redeem part of our outstanding convertible debt. On December 29, 30 and 31, 2010, we entered into specific exchange agreements (the "Exchange Agreements") with some of the debenture and warrant holders. Pursuant to these Exchange Agreements, we issued 1,441,743 new ordinary shares in the form of ADRs in exchange for 4,558 Convertible Debentures and 986,965 Warrants, reducing the nominal amount of our outstanding convertible debt to $10.5 million. In the future, we may extend other exchange offers to remaining Convertible Debentures and Warrant holders, or seek to negotiate new terms to further redeem our indebtedness; however, there is no certainty that we will be able to do so.

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We may not be authorized to issue enough ordinary shares or be able to fulfill the conditions precedent to pay interest on the Convertible Debentures in the form of ordinary shares, and if we fail to do so after we have notified the Convertible Debentures holders of our intention to do so, an event of default under the Convertible Debentures could occur.

As noted above, interest on the Convertible Debentures is payable, under certain circumstances, in ordinary shares, under a formula which is tied to the trading price of our ADSs. In order to pay interest in this manner, we need to notify our debenture holders at least 21 trading days prior to the relevant interest payment date and fulfil certain conditions during that notice period, up to and including the date interest is paid. Any such notice is irrevocable. Interest paid in ordinary shares is paid at the "interest conversion rate", which is based on the trading price of our ADSs during the notice period, after our irrevocable notice has been given. In the event our share price were to fall during the notice period, we would have to deliver a higher number of shares than we may have originally planned at the time we gave the irrevocable notice. In the event the number of shares we are required to deliver exceeds the number of shares we are then authorized by our shareholders to issue, we may not be able to deliver all of the interest shares then due. Additionally, if, on the day we pay interest, we do not fulfill the relevant conditions, we are not permitted to pay interest in the form of ordinary shares. In the event we are not able to deliver shares for any reason, we will be subject to late fees and our debenture holders may decline to receive interest paid in cash. In the event they do not accept payment in cash, we would not be able to make a complete interest payment or any interest payment at all, which will result in an event of default under the Convertible Debentures. An event of default with respect to the Convertible Debentures would have a material adverse effect on our financial conditions and results of operations.

Our increased leverage as a result of the sale of the Convertible Debentures and Warrants in the October 2007 private placement may harm our financial condition and results of operations.

Our total consolidated long-term financial debt as of December 31, 2010 was €10.4 million and represented approximately 29% of our total assets, including the current portion of indebtedness of approximately €0.322 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 Convertible Debentures could discourage an acquisition of us or an investment in us by a third party, even if the acquisition or investment would be favourable to investors.

The Convertible Debentures prohibit us from engaging in certain transactions, each known as a "fundamental transaction", including any merger, the sale of all of our assets or a tender offer under which our shareholders are permitted to exchange their shares for cash, securities or property, unless the successor entity agrees to comply with the requirement to provide our debenture holders, upon conversion, with the same property provided to our existing shareholders under the terms of the fundamental transaction. In addition, if we are party to a "fundamental transaction" or "change of control" (as defined in the debenture) or agree to dispose of in excess of 40% of our assets, the holders have the right to require us to redeem the Convertible 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 debenture or the outstanding principal amount of the debenture, plus all accrued and unpaid interest, divided by the conversion price then in effect, multiplied by the VWAP (as defined in the debenture) then in effect.

In addition, under the terms of the securities purchase agreement we entered into in the October 2007 private placement, for so long as the Convertible Debentures are outstanding, we are required to offer the investors who purchased Convertible Debentures and Warrants in the October 2007 private placement the right to participate in certain types of financings we arrange in the future, up to 50% of the value of such financing. We must provide this opportunity unless the offering is an underwritten public offering or an “exempt issuance”. Exempt issuances include securities issued to our employees under plans, subject to certain volume limits, and securities issued pursuant to strategic transactions with persons who are engaged in a business synergistic with ours. However, securities issued to persons who are not engaged in a synergistic business, such as a financial investor, are not exempt issuances.

The restrictions on the types of transactions we can engage in and the participation rights we may have to offer in future financings may result in discouraging third parties from engaging in these types of transactions with us, even if such transactions would be beneficial to us and our shareholders.

Changes in the fair value of the Convertible Debentures and Warrants issued in the October 2007 private placement at each balance sheet date could have a significant impact on our financial condition and results of operations.

We use various market parameters to evaluate the fair value of the Convertible Debentures and Warrants issued in the October 2007 private placement at each balance sheet date which could have a significant impact on our financial condition and results of operation as a result of changes in these market parameters. The following market parameters are most likely to change at each balance sheet date and the following paragraphs describe how hypothetical increases or decreases in those market parameters would have affected the U.S. Dollar fair value of the Convertible Debentures and Warrants as of December 31, 2010:

- stock volatility: as of December 31, 2010 and every other market parameter being equal, an increase in the stock volatility of 5 percentage points would have resulted in an increase of 1% in the fair value of the Convertible Debentures and Warrants, and a decrease in the stock volatility of 5 percentage points would have resulted in a decrease of 1% in the fair value of the Convertible Debentures and Warrants.

- the stock value: as of December 31, 2010 and every other market parameter being equal, an increase in the stock value of 10% would have resulted in an increase of 5% in the fair value of the Convertible Debentures and Warrants, and a decrease in the stock value of 10% would have resulted in a decrease of 5% in the fair value of the Convertible Debentures and Warrants.

- the risk free interest rate: as of December 31, 2010 and every other market parameter being equal, an increase in the risk free interest rate of 1 percentage point would have resulted in a decrease of 0.5% in the fair value of the Convertible Debentures and Warrants, and a decrease in the risk free interest rate of 1 percentage point would have resulted in an increase of 0.2% in the fair value of the Convertible Debentures and Warrants.

- credit spread: as of December 31, 2010 and every other market parameter being equal, an increase in the credit spread of 1 percentage point would have resulted in a decrease of 1% in the fair value of the Convertible Debentures and Warrants, and a decrease in the credit spread of 1 percentage point would have resulted in an increase of 0.7% in the fair value of the Convertible Debentures and Warrants.

- liquidity discount factor: as of December 31, 2010 and every other market parameter being equal, an increase in the liquidity discount factor of 5 percentage points would have resulted in a decrease of 3% in the fair value of the Convertible Debentures and Warrants, and a decrease in the liquidity discount factor of 5 percentage points would have resulted in an increase of 3% in the fair value of the Convertible Debentures and Warrants.

- combined sensitivity to market parameters: as of December 31, 2010, a 5 percentage point increase in stock volatility together with a 10% increase in the stock value, a 1 percentage point decrease in the risk free interest rate, a 1 percentage point decrease in the credit spread and a 5 percentage point decrease in the liquidity discount factor would have resulted in an increase of 11% in the fair value of the Convertible Debentures and Warrants; conversely, a 5 percentage point decrease in the stock volatility together with a 10% decrease in the stock value, a 1 percentage point increase in the risk free interest rate, a 1 percentage point increase in the credit spread and a 5 percentage point increase in the liquidity discount factor would have resulted in a decrease of 10% in the fair value of the Convertible Debentures and Warrants.

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 2010 was 528,234, the high and low bid price of our ADSs for the last two financial years ended on December 31, 2010 and December 31, 2009, was $ 6.97 and $ 5.95, and $ 1.89 and $0.96, 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 2009 was 61,795 as opposed to 528,234 for the same period of 2010. 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 set forth above, on June 24, 2010, shareholders adopted resolutions allowing the Board of Directors to issue new shares when renegotiating our indebtedness, only within the maximum 6,512,370 additional share limit already authorized by the shareholders, such limit is to be considered taking into account as of March 18, 2011, the conversions of Convertible Debentures and payments of quarterly interests paid in shares, hence reducing the maximum number authorized to be issued to 4,575,966. 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 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 non-U.S. 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 not paid any dividend on our shares for the past five years and do not anticipate paying any dividends for the foreseeable future. In particular, in connection with the October 2007 private placement, we agreed not to pay cash dividends on any of our equity securities. 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 within the United States against us and our non-U.S. resident directors and officers;

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- effect service of process within the United States against us and our non-U.S. resident directors and officers;
- 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
- bring an original action in a French court to enforce liabilities based upon the U.S. federal securities laws against us and our non-U.S. resident directors and officers.

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

Holders of ADSs do not have the same rights as shareholders and accordingly, cannot exercise rights of shareholders against us. The Bank of New York, 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 favour 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. 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 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. NATIXIS PRAMEX INTERNATIONAL Corp, 1251 Ave of the Americas – 34th floor, New York, NY 10020 – U.S.A, is our new agent for service of process in the United States as from January 1, 2010, replacing Mr. Lee Sanderson.

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 purchased most of the assets of Technomed International S.A. (''Technomed'') out of liquidation. Technomed was established in 1985 and launched an electrohydraulic lithotripter (using electric shocks produced by an electrode within a hydraulic system) in 1986 and the Prostatron, a medical device using TransUrethral Microwave Thermotherapy ("TUMT") for the minimally invasive treatment of benign prostate hyperplasia ("BPH") in the European Union in 1990. The assets we acquired in Technomed's liquidation included the ownership of, and full distribution rights to, the Prostatron, the Sonolith series of lithotripters (Sonolith Praktis, Sonolith Vision and Sonolith Isys) and the Ablatherm HIFU device.

In October 2000, we sold our Prostatron business to Urologix Inc. for consideration consisting of approximately $12 million in common stock and warrants to purchase additional shares of common stock and $8 million in cash.

In July 2002, we reorganized our management structure and created two separate operating divisions, the HIFU division and the UDS division. The implementation of the new corporate structure consolidated our management structure from a two-tiered management system with a Supervisory Board and a Management Board into a single Board of Directors with the consolidated management responsibilities of the two-tiered system.

On February 25, 2004, we finalized a distribution agreement (the "Distribution Agreement"), with a subsidiary of HealthTronics Surgical Services, Inc. ("HealthTronics"), under which HealthTronics agreed to distribute our lithotripters in the United States. Under the Distribution Agreement, 1,000,000 warrants were allocated to HealthTronics, which were to be exercised upon the completion of certain milestones linked to the grant of the Ablatherm pre-market approval and certain minimum sales of lithotripters in the United States. On December 29, 2005, we amended the Distribution Agreement after HealthTronics decided to focus all of its efforts on implementing Ablatherm clinical trials in the United States to gain FDA approval and to cease pursuing distribution of our lithotripters in the United States. In connection with this amendment, 200,000 warrants, of the 1,000,000 warrants that had been issued to HealthTronics, were cancelled since their exercise was directly linked to future purchases of our lithotripters.

On August 3, 2006, we closed a private placement of 961,676 ordinary shares in the form of ADSs, resulting in net proceeds of approximately $7.5 million. These funds were and are being used to fund additional marketing efforts to

accelerate the adoption of Ablatherm-HIFU in key European markets.

On November 10, 2006, HealthTronics informed us that they intended to cease conducting clinical trials and pursuing the Ablatherm PMA approval from the FDA.

On April 3, 2007, we executed an Agreement and Release whereby HealthTronics agreed to transfer the Ablatherm FDA study to us. The Agreement and Release was amended on July 9, 2007. Under this Agreement and Release, HealthTronics agreed to pay us $600,000 under certain conditions linked to the registration of 200,000 shares it acquired under exercise of a portion of the 800,000 remaining warrants it had acquired pursuant to the Distribution Agreement. On September 29, 2009, HealthTronics's commitment to pay us $600,000, related to the April 3 and July 9, 2007 Agreement and Release, was waived in compensation of a royalty-free, sublicense granted to us allowing us to use certain HealthTronics's patents in the lithotripsy field.

On October 31, 2007, we completed a private placement of $20 million principal amount of 9% Senior Convertible Debentures due 2012. In addition, the purchasers of the Convertible Debentures and our placement agent (the "Placement Agent") received warrants to purchase our ordinary shares for an average exercise price of $6.68 per share which expire in 2013. The October 2007 private placement resulted in net proceeds of approximately $17.4 million. We agreed to use the proceeds of the private placement to finance costs associated with the regulatory approval for the commercialization of Ablatherm HIFU in the United States (including related clinical trials) and for general and administrative expenses.

In 2007, following the termination of the Distribution Agreement signed with HealthTronics, EDAP Technomed Inc, our Delaware registered fully owned subsidiary, regained the sponsorship of our Ablatherm IDE study and has pursued our clinical trials in the United States since then. Therefore, a portion of the proceeds resulting from our October 2007 private placement were transferred to EDAP Technomed Inc. to finance our U.S. Ablatherm-HIFU clinical trials.

Effective January 1, 2008, to clarify and simplify our French organizational structure, we merged the two operational French entities EDAP SA and Technomed Medical Systems SA into a single entity named EDAP TMS France S.A. (formerly Technomed Medical Systems SA), which is wholly owned by EDAP TMS SA, the holding company.

On October 30, 2009, our shareholders adopted several resolutions allowing the Board of Directors to renegotiate our indebtedness with the maximum flexibility while staying within the limit of the dilution already authorized by shareholders on October 30, 2007 and Februay 26, 2009. On November 16, 2009, pursuant to the shareholders' authorization, the Board of Directors issued a Supplement to the current Convertible Debentures allowing bondholders to convert their Convertible Debentures earlier, with a lower exercise price and including by the payment of an accelerated interest premium, payable in shares, within the already authorized dilution limits. This Supplement was unanimously approved on December 3, 2009 by the general meeting of bondholders. It expired on December 2, 2010.

On March 10, April 23 and November 16, 2010, one holder of Convertible Debentures elected to convert a total of 2,050 Convertible Debentures, representing a total value of $2.1 million. Under the terms of the Convertible Debentures and the above Supplement, 440,206 new shares were issued. Following this conversion, our total aggregate amount of our outstanding convertible debenture was reduced to $15.1 million.

On June 24, 2010, our shareholders adopted several new resolutions and extended the validity of existing ones, allowing the Board of Directors to renegotiate our indebtedness while remaining within the limit of the dilution already authorized by shareholders.

On October 6, 2010, based on the above mentioned resolutions and in view of debt restructuring and new projects financing, we filed a Form-F3 registration statement with the SEC to register ordinary shares and warrants for a maximum amount of $9 million. Such registration statement was declared effective by the SEC on October 20, 2010.

On December 29, 30 and 31, 2010, pursuant to the above mentioned shareholders' authorizations, the Management, upon the Board of Directors delegation, extended an offer to all senior debenture and warrant holders to exchange all of their Convertible Debentures and Warrants against ADRs in order to redeem part of our outstanding convertible

debt and entered into the Exchange Agreements with some of the Convertible Debentures and Warrants holders. Pursuant to the Exchange Agreements, we issued 1,441,743 new ordinary shares in the form of ADRs in exchange for 4,558 Convertible Debentures and 986,965 Warrants, reducing the nominal amount of our outstanding convertible debt to $10.5 million.

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 €6.9 million, €9.6 million and €9.1 million for 2010, 2009 and 2008, respectively (all in Europe and the rest of the world, outside 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 €16.3 million (including €7.8 million in Asia and €8.5 million in Europe and the rest of the world), €15.2 million (including €6.8 million in Asia and €8.4 million in Europe and the rest of the world) and €13.8 million (including €6.1 million in Asia and €7.7 million in Europe and the rest of the world), each for 2010, 2009 and 2008, 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. The HIFU division had total revenues of €6.9 million during the fiscal year ended December 31, 2010.

Our HIFU business is quite seasonal and generally linked to lengthly 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 and Russia. Clinical trials in the United States are underway. The HIFU division had an installed base of 86 Ablatherm machines worldwide (with an additional 8 used for clinical studies and other research and training purposes) and 265 trained clinical sites were using this technology as of December 31, 2010.

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 trend. 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. In addition to that current operational basis, we are seeking FDA approval to enter the U.S. market with our Ablatherm-HIFU device. 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.'' The HIFU division maintained expenses at levels similar to 2009 on research and development ("R&D") projects in 2010 to develop HIFU applications beyond prostate cancer. The division is considering sustaining R&D spending in 2011 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 and Russia. Clinical trials are underway in the United States. 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.

HIFU Division Patents and Intellectual Property

As of December 31, 2010, the HIFU division's patent portfolio contained 48 patents consisting of 19 in the United States, 23 in the European Union and Japan and 6 in Israel and the rest of the world. They belong to 22 groups of patents covering key technologies related to therapeutic ultrasound principles, systems and associated software.

During 2010, one patent expired in the United States and four patents covering obsolete technologies were abandoned (one in Canada, two in Israel and one in Japan). One patent covering the Ablatherm disposable has been delivered in Japan. One patent covering a specific transducer and probe design dedicated to thyroid or others extracorporeal treatments has been approved in the United States. In accordance to our decision to extend our patent portfolio to China, a patent covering our integrated imaging technology used on the Ablatherm HIFU probe has been delivered in China. Finally a new patent covering a specific transducer design for liver cancer treatment using HIFU technology has been delivered in France.

Nine additional patents covering certain other aspects of our HIFU technology in the European Union and Japan (6), the United States (2), and the rest of the world (1) are also under review. These patents relate to 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. This license agreement allows 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 this application. We own no interest in Theraclion.

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 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 (hormonotherapy, 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 new 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. Patients are still being enrolled.

In 2006, a clinical trial was launched to evaluate new Ablatherm treatment options allowing the treatment of larger prostates. This clinical study was completed in 2007 and a new software improving the device specifications was released at the end of 2007.

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. The objective of this trial is to demonstrate the existence, in vivo, of the enhancement of HIFU treatment effect by a concomitant chemotherapy with docetaxel. This adjuvant should give a better control of the local cancer in this population of patients, and so, in term, obtain a better control of the cancer illness. Patient enrolment is still in progress.

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 echography can diagnose early cancer recurrences. This trial has been extended by an amendment allowing for 15 additional patients. Patient enrolment was completed in January 2011.

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.

Clinical and Regulatory Status in the United States

In February 2004, we entered into the Distribution Agreement with HealthTronics. The terms of the Distribution Agreement granted HealthTronics the right to pursue market approval from the FDA for the Ablatherm. Under the terms of the Distribution Agreement, HealthTronics would be granted exclusive distribution rights for the Ablatherm in the United States. In November 2006, HealthTronics informed us that they intended to discontinue Ablatherm FDA

trials. On April 3, 2007, we executed an Agreement and Release whereby HealthTronics agreed to transfer the Ablatherm FDA study to us. See Item 4, “Information on the Company – History and Development of the Company.”

On June 29, 2007, the FDA officially approved the transfer of the study to EDAP Technomed Inc. and the trials resumed as per the approved protocol. In October 2007, we completed a private placement raising net proceeds of $17.4 million allowing us to finance and conduct the U.S. trials for the expected period of time.

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

On December 11, 2009, a Gastroenterology and Urology Devices Panel of the Medical Devices Advisory Committee (the "Panel") was convened by the FDA. The Panel 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 on January 28, 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.

Given the very challenging recommendations of the FDA with regards to our prospective study and its cryoablation comparative arm, there is a risk that we may not be able to follow FDA recommendations or to conduct our trials in the timeframe we initially expected and within an acceptable budget. In this respect, following the December 11, 2009 Panel experts recommendations and our discussions with the FDA, we thoroughly evaluated all options based on inputs 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 2-years follow-up phase. Clinical outcomes from these patients combined with our strong European long-term database will form the foundation of a submission to the FDA which we expect to occur in 2012. See Item 5, "Operating and Financial Review and Prospects – Liquidity and Capital Resources" and 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 might 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 Chineses 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.

HIFU Clinical Data

As of December 31, 2010, our clinical Ablatherm-HIFU results has been published in 42 peer-reviewed renowned journals. The first clinical paper reporting long term results using Ablatherm-HIFU was published in November 2007. The results of the study confirm the efficacy of HIFU in patients with localized prostate cancer. In 2010, the results of a major multicentric study on 803 patients have been published showing a local control of the disease in 77.9% of the patients.

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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.

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 217,730, of which 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.

If the efficacy of HIFU therapy is established, the HIFU division believes that its application 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.

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 Ablatherm-HIFU device competes 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 Ablatherm-HIFU is 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) is providing 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 Focus Surgery, which has developed a device called the Sonablate SB500 for the treatment of localized prostate cancer. Misonix, USHIFU and International HIFU are also involved in the marketing and distribution of the Sonablate. 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..

We have also entered into cooperative arrangements with other companies. On April 25, 2007, we signed an exclusive distribution agreement with Chinamed to distribute their HIFU devices in the European Union and Russia once their devices are approved for use in those jurisdictions. Prior to this agreement, Chinamed had been developing HIFU products for various types of cancer tumors, but only marketing its HIFU products in China. On September 21, 2007, we entered into a Consulting Agreement with Chinamed, now Haifuning, pursuant to which we will assist them in obtaining market approvals in Europe for their HIFU products. See Item 4, ‘‘Information on the Company—HIFU Division— HIFU Competition’’ and ‘‘Information on the Company—UDS Division.’’. See Risk Factors – risks relating 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 €16.3 million to our consolidated net sales during the fiscal year ended December 31, 2010.

Our UDS business is quite seasonal and generally linked to lengthly 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 anaesthesia, and the resulting complications. The UDS division currently manufactures three models of lithotripters: the Sonolith Praktis, the Sonolith i-move and the Sonolith i-sys. The newly designed ESWL device: the Sonolith i-move is to gradually replace the Sonolith Praktis if and when the Sonolith i-move is approved in the United States and Japan. The UDS division has sold 600 ESWL lithotripters worldwide to this date and actively maintained or otherwise served 440 installed lithotripters as of December 31, 2010.

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. The UDS division through our Japanese and Italian subsidiaries also derives marginal revenues from the distribution of Prostatron parts and related services under the distribution agreement entered into with Urologix in October 2000.

UDS Division Business Strategy

The UDS division's business strategy 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. To achieve this strategic goal, the UDS division intends to capitalize and expand on its expertise as the manufacturer of minimally invasive devices such as its ESWL lithotripters. Until December 31, 2007, the UDS division manufactured the Ablatherm and the disposable Ablapack on behalf of the HIFU division; the HIFU division now manufactures its own products as part of EDAP TMS France. 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 and 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 (although the manufacturing of new machines was discontinued 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 Praktis	Electroconductive treatment of	Commercial Production	Approved for distribution: European Union

compact lithotripter	urinary stones	Japan
		United States
		Canada
		Russia
		South Korea
		Australia
		New Zealand
		Taiwan

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
Sonolith i-sys Praktis compact lithotripter	Electroconductive treatment of urinary stones	Commercial Production	Approved for distribution: European Union South Korea Canada United States Japan Australia Colombia Peru

The Sonolith Praktis, the Sonolith i-move and the Sonolith i-sys rely on an 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 Praktis, an electroconductive lithotripter designed for smaller clinics which is more compact than the Sonolith i-sys, which is more fully dedicated and integrated electroconductive lithotripters for larger hospitals and can be used as a urological workstation to perform endourological procedures. The Sonolith i-move, launched in 2010 to gradually replace the Sonolith Praktis in the clinics and small hospitals segment, 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 during the first few months of its commercial launch 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, 2010, the UDS division's patent portfolio contained nine patents consisting of two in the United States, four in the European Union and Japan and three 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.

During 2010, one patent covering the real time ultrasound imaging technology on our i-sys device has been granted in France.

Five additional patents, one in the United States, three the European Union and one in Japan are also in the examination process. These patents concern the i-sys lithotripter technology and our newly introduced 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, 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.

UDS Division Regulatory Status

The Sonolith Praktis is available for commercial distribution in the United States, Canada, the European Union, Russia, South Korea, Australia, New Zealand, Taiwan and Japan. The Sonolith i-move is available for commercial distribution in the European Union, South Korea, South-East Asia, Peru, Venezuela and Colombia. The Sonolith i-sys is available in the European Union, South Korea, Canada, United States, Peru, Colombia, Japan and Australia. The UDS division continues to provide disposables, replacement parts and services for the current installed base of LT02 machines, 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 nearly 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. See Item 4, "Information on the Company—History and Development of the Company."

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 products on behalf of Andromeda in Japan and 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 facility that is FDA-approved and 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. Up until December 31, 2007, the HIFU division subcontracted the manufacturing of its HIFU devices and accessories, including disposables. Each division now 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, 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 3,740 square meters and are leased to us under a renewable nine-year commercial lease agreement. 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.

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 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, the Ablatherm device, a Class III device, has not yet been approved by FDA; it is currently under IDE Study G050103.

The regulatory pathway for placement in the U.S. market may include the pre-market notification or PMA routes. Regardless of the regulatory route to market, FDA has mandated the submission of clinical evidence of safety and effectiveness.

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.

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, Labour 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 Prostatron 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, 2010, 2009 and 2008 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 one-year warranty upon installation. We accrue the estimated training and warranty costs at the time of sale. Revenues related to disposables are recognized when goods are delivered.

Sales of RPP Treatments and leases:

Revenues related to the sale of Ablatherm treatments invoiced on a RPP basis are recognized when the treatment procedure has been completed. If a contract of RPP includes a minimum number of treatments, the revenue is recognized on a linear basis over the contract period. For treatments in excess of minimum levels, the revenue is 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 linear 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 Warrants as defined below and a binomial valuation model with a Company specific credit spread to measure the fair value of the Convertible Debentures. See Item 3, “Key Information—Risk Factors—Changes in the fair value of the Convertible Debentures and warrants issued in the October 2007 private placement of each balance sheet date could have a significant impact on our financial condition and results of operations”, Notes 14 and 20 to the consolidated financial statements for a detailed description of the fair value calculations and see Note 1-21 to our 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 (the “Placement Agent”). Warrants granted to the Placement Agent (the “Placement Agent Warrants”) were cancelled last December 2010 when Placement Agent signed an Exchange Agreement with us to exchange its warrants against a certain number of ADRs. In accordance with ASC 815, the warrants issued to the investors in the Convertible Debentures (the “Investor Warrants” and together with the Placement Agent Warrants, the “Warrants”) are classified as a liability because the Company may be 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 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 use a Black & Scholes pricing model to determine the fair value of the Warrants. The application of the model to the Warrants requires the use of subjective assumptions, including historical share price volatility, the expected life of the Warrants, our risk-free interest rate, and the liquidity discount factor. A change in one or more of these assumptions could result in a material change to the estimated fair value of the Investor Warrants. See Item 3, “Key Information—Risk Factors—Changes in the fair value of the Convertible Debentures and warrants issued in the October 2007 private placement at each balance sheet date could have a significant impact on our financial condition and results of operations”, “— Convertible Debentures” above and Notes 14 and 20 to our consolidated financial statements.

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 collectibility 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 (Prostatrons, 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 competitive environment, 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.

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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 Prostatrons, 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 Korea (Edap Technomed Korea). Revenue derived from our operations in Asia represented approximately 36% of our total consolidated revenue in 2010. Net sales of goods in Asia represented approximately 45% of such sales in 2010 and consisted primarily of sales of ESWL lithotripters and consumables. Net sales of spare parts, supplies and services in Asia represented approximately 23% of such sales in 2010 and related primarily to ESWL lithotripters, reflecting the fact that approximately 51% of the installed base of our ESWL lithotripters that we actively maintain or otherwise serve are located in Asia (see Item 8 – “significant changes as of March 31, 2011 with respect to recent events in Japan”).

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 2010, approximately 66% of our research and development, selling, marketing and general and administrative expenses were denominated in euro, while approximately 41% of our sales were denominated in currencies other than euro (primarily the U.S. Dollar and Japanese yen). Our operating profitability could be materially affected by large fluctuations in the rate of exchange between the euro and such other currencies. To minimize our exposure to exchange rate risks, we sometimes use certain financial instruments for hedging purposes. See Item 3, ‘‘Key Information—Risk Factors—We sell our products in many parts of the world and, as a result, our business is affected by fluctuations in currency exchange rates’’ and Item 11, ‘‘Quantitative and Qualitative Disclosures About Market Risk’’ for a description of the impact of foreign currency fluctuations on our business and results of operations.

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

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

Consolidated research and development expenses, as described above amounted to €3.3 million, €3.7 million and €3.7 million in 2010, 2009 and 2008, respectively, representing approximately 14.1%, 14.7% and 16.1% of total revenues in 2010, 2009 and 2008, respectively. Consolidated research and development expenses included R&D government

grants and tax credits of €0.5 million, €0.5 million and €0.5 million in 2010, 2009 and 2008, respectively – See Note 1-15 of the consolidated financial statements – Research and development costs. Excluding R&D government grants and tax credits, consolidated research and development expenses amounted to €3.8 million, €4.1 million and €4.3 million in 2010, 2009 and 2008, respectively, representing approximately 16.0%, 16.5% and 18.5% of total revenues in 2010, 2009 and 2008, respectively. Research and development costs in 2010 and 2009 were primarily 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 7% of total revenues in 2010). Beginning in 2011, 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 getting 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 €6.5 million in 2010, €6.1 million in 2009 and €5.7 million in 2008. Selling and marketing expenses included allowances for doubtful accounts of €0.2 million in 2010, €0.3 million in 2009, and included no allowance for doubtful accounts in 2008. The €0.4 million or 6.9% increase in selling and marketing expenses from 2009 to 2010 was primarily due to the €0.3 million increase in expenses to support sales efforts in the United States for the Lithotripsy division. Management expects marketing and sales efforts to stay at significant levels in the future to consolidate the Ablatherm-HIFU technology's status as a standard of care for prostate cancer in Europe, and to sustain its worldwide market position in Lithotripsy.

In 2010, 2009 and 2008, we did not record any non-recurring operating expense.

Over the past several years, we have experienced declining sale prices in the market for ESWL lithotripters. In 2010, 2009 and 2008, however, our ESWL sales had a significant increase as a result of the success of our Sonolith Isys device launched in 2007 and our Sonolith i-move device launched in 2010, and a sustained commercial effort which allowed us to capture market share in both the European and Asian 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 control expenses in connection with the development, marketing and commercial launch of HIFU applications, including the Ablatherm, and the funding of Ablatherm trials in the United States in order to continue the FDA process. See ''—Liquidity and Capital Resources.'' Increases, if any, in expenses may only be offset partially in the near future by revenues arising from sale of HIFU devices and treatments.

Fiscal Year Ended December 31, 2010 Compared to Fiscal Year Ended December 31, 2009

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)	2010		2009	
Total revenues	23.7		24.9	
Total net sales	23.2		24.8	
Of which HIFU	6.9		9.6	
Of which UDS	16.3		15.2	
Total cost of sales	(14.3	)	(14.2	)
Gross profit	9.5		10.7	
Gross profit as a percentage of total net sales	40.8	%	43.0	%
Operating expenses before FDA PMA	(11.3	)	(11.7	)
FDA PMA expenses	(1.9	)	(2.2	)
Total operating expenses	(13.3	)	(13.9	)
Operating loss before FDA PMA	(1.9	)	(1.0	)
Loss from operations	(3.8	)	(3.2	)
Net income (loss)	(12.7	)	(7.8	)

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Total revenues

Our total revenues decreased 4.7% from €24.9 million in 2009 to €23.7 million in 2010, principally due to decreased HIFU sales and the increase in lithotripsy equipment sales.

HIFU division. The HIFU division's total revenues decreased 28.4% to €6.9 million in 2010 as compared to €9.6 million in 2009.

The HIFU division's net sales of medical devices decreased 54.4% to €1.2 million in 2010, with four Ablatherm units sold, as compared €2.7 million and seven Ablatherm units sold in 2009.

Net sales of RPP treatments decreased 16.5% to €3.5 million in 2010, in the context of a depressed economic environment.

Net sales of consumables decreased 27.5% to €0.8 million in 2010, and net sales of HIFU-related spare parts, supplies, leasing and services decreased 18.1% from €1.8 million in 2009 to €1.5 million in 2010.

Other HIFU-related revenues were stable at €6 thousand in 2010 from €7 thousand in 2009.

UDS division. The UDS division's total revenues increased 10.2% from €15.3 million in 2009 to €16.8 million in 2010, mostly due to increased sales volumes in medical devices.

The UDS division's net sales of medical devices increased 11.1% from €8.6 million in 2009 to €9.6 million in 2010 with 45 devices sold in 2010 compared to 39 units sold in 2009. Equipement sales in 2010 benefited from a €0.9 million favorable currency exchange rate impact, mostly on the Japanese Yen, while the average sales price decreased as a result of the product mix with a greater number of smaller, modular machines.

Net sales of UDS-related spare parts, supplies, leasing and services increased 2.0% from €6.6 million in 2009 to €6.7 million in 2010, primarily related to the success of the RPP-type sales of lithotripsy treatments, mainly in France.

Other UDS-related revenue increased from €39 thousand in 2009 to €500 thousand in 2010, with a €0.5 million Government grant as part of a small businesses aid program.

Cost of sales.

Cost of sales was stable from €14.2 million in 2009 to €14.3 million in 2010, and represented 61.4% as a percentage of net sales in 2010, up from 57.2% as a percentage of net sales in 2009.

Operating expenses.

Operating expenses decreased 4.3%, or €0.6 million, from €13.9 million in 2009 to €13.3 million in 2010. Operating expenses included R&D grants and tax credits of €690 thousand and €452 thousand in 2010 and 2009, respectively. Without the effect of the FDA PMA trials, operating expenses decreased €0.3 million or 2.7%, mainly due to the €0.8 million decrease in R&D, marketing, G&A and depreciation expenses and despite the €0.5 million increase in selling expenses, mostly related to the inception of our commercial organization in the United States.

The costs associated with the FDA PMA trial decreased 12.8% at €1.9 million in 2010 compared to €2.2 million in 2009, as a result of the completion in June of the most active recruitment and treatment phase of the trial, and the entering in the second half of the year in the less costly patient follow-up phase.

Excluding the FDA PMA trials, marketing and sales expenses increased €0.4 million, or 6.9%, mostly due to the €88 thousand decrease in expenses related to congresses and exhibitions, and the €0.5 million increase in selling expenses, mostly related to the inception of our commercial organization in the United States.

Excluding the FDA PMA trials, research and development expenses decreased 16.7% at €1.5 million in 2010 from €1.8 million in 2009, and comprised R&D grants and tax credits of €690 thousand and €452 thousand in 2010 and 2009, respectively.

Excluding the FDA PMA trials, general and administrative expenses and depreciation decreased 11.4% from €3.8 million in 2009 to €3.3 million in 2010.

Operating loss.

As a result of the factors discussed above, we recorded a consolidated operating loss of €3.8 million in 2010, as compared to a consolidated operating loss of €3.2 million in 2009.

Excluding the expenses of the FDA PMA trials, the consolidated operating loss in 2010 was €1.9 million, an increase of €0.9 million when compared to the previous year.

We realized an operating loss in the HIFU division of €0.6 million in 2010, compared to an operating profit of €0.2 million in 2009 and an operating profit in the UDS division of €0.1 million in 2010, as compared to €0.2 million in 2009.

Financial (expense) income, net. Financial (expense) income net was 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, compared with a loss of €4.4 million in 2009, including a €2.7 million income due to the adjustment of the convertible debt to fair value.

Foreign currency exchange gains (loss), net. In 2010, we recorded a net foreign currency exchange gain of €0.9 million, mainly due to the variation of the euro against the U.S. dollar and the Japanese yen, compared to a loss of €0.1 million in 2009.

Other income (expense), net. No other income or expense in 2010 and 2009.

Income taxes. Income tax was an expense of €0.9 million in 2010, compared to an expense of €72 thousand in 2009. 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 21-5 of the consolidated financial statements.

Net income / (loss)

We realized a consolidated net loss of €12.7 million in 2010 compared with a consolidated net loss of €7.8 million in 2009. The €5.0 million variation in net loss was primarily due to the €9.4 million negative impact from the variation in the convertible debt fair value.

Fiscal Year Ended December 31, 2009 Compared to Fiscal Year Ended December 31, 2008

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)	2009(1)	2008(1)
Total revenues	24.9	23.1
Total net sales	24.8	22.9
Of which HIFU	9.6	9.1
Of which UDS	15.2	13.8
Total cost of sales	(14.2)	(14.0)
Gross profit	10.7	9.1
Gross profit as a percentage of total net sales	43.0%	39.8%
	(11.7)	(11.1)

Operating expenses before FDA PMA		
FDA PMA expenses	(2.2)	(2.2)
Total operating expenses	(13.9)	(13.3)
Operating loss before FDA PMA	(1.0)	(2.0)
Loss from operations	(3.2)	(4.2)
Net income (loss)	(7.8)	1.6

(1) Certain prior years amounts have been reclassified to conform to the current year's presentation (see Note 1-15 "Research and development costs" to our consolidated financial statements).

Total revenues

Our total revenues increased 7.9% from €23.1 million in 2008 to €24.9 million in 2009, principally due to increased HIFU-RPP sales and the increase in lithotripsy equipment sales.

HIFU division. The HIFU division's total revenues increased 4.7% at €9.6 million in 2009 as compared to €9.2 million in 2008. Sales of medical devices were stable, while sales of RPP treatments experienced solid growth.

The HIFU division's net sales of medical devices remained stable at €2.7 million in 2009, with seven Ablatherm units sold, as compared €2.7 million in 2008. In 2008, we also sold seven Ablatherm units. The average unit sales price also remained stable at €380 thousand in 2009 (down 1.1% from €384 thousand in 2008).

Net sales of RPP treatments increased 17.9% to €4.2 million in 2009, driven by the 24% growth in the number of treatments performed both on a mobile and fixed RPP basis.

Net sales of consumables increased 3.5% at €1.0 million in 2009, and net sales of HIFU-related spare parts, supplies, leasing and services decreased 4.2% from €1.9 million in 2008 to €1.8 million in 2009.

Other HIFU-related revenue decreased from €138 thousand in 2008 to €7 thousand in 2009 and reflected the decrease in HIFU related consulting services. See Note 17 of the consolidated financial statements.

UDS division. The UDS division's total revenues increased 10.1% from €13.9 million in 2008 to €15.3 million in 2009, mostly due to increased sales volumes in medical devices.

The UDS division's net sales of medical devices increased 14.8% from €7.5 million in 2008 to €8.6 million in 2009 with 39 devices sold in 2009 compared to 49 units sold in 2008. Equipment sales in 2009 benefited from a favorable change in product mix, as a greater proportion of high-end Sonolith Isys machines were sold, thus driving the 45.0% increase in average sales price in 2009.

Net sales of UDS-related spare parts, supplies, leasing and services increased 5.0% from €6.3 million in 2008 to €6.6 million in 2009, primarily related to the success of the RPP-type sales of lithotripsy treatments, mainly in France.

Other UDS-related revenue decreased from €59 thousand in 2008 to €39 thousand in 2009.

Cost of sales.

Cost of sales increased 1.9% from €14.0 million in 2008 to €14.2 million in 2009, and represented 57.2% as a percentage of net sales in 2009, down from 61.1% as a percentage of net sales in 2008.

Operating expenses.

Operating expenses increased 4.6%, or €0.6 million, from €13.3 million in 2008 to €13.9 million in 2009. Operating expenses included R&D tax credits of €452 thousand and €544 thousand in 2009 and 2008, respectively, that were reclassified from income tax to pre-tax income see Note 1-14 of the consolidated financial statements - Summary of Significant Accounting Policies. Without the effect of the FDA PMA trials, operating expenses increased €0.6 million or 5.1%, mainly due to the €0.7 million increase in selling expenses.

The costs associated with the FDA PMA trial were stable at €2.2 million in 2009 compared to €2.2 million in 2008, and comprised mostly clinical and administrative expenses due to the ongoing PMA trials in the United States.

Excluding the FDA PMA trials, marketing and sales expenses increased €0.4 million, or 6.8%, mostly due to the strengthening of sales teams in Europe and Japan, and to new allowances for doubtful accounts of €0.3 million in 2009.

Excluding the FDA PMA trials, research and development expenses increased 4.4% at €2.3 million in 2009 from €2.2 million in 2008, and comprised R&D tax credits of €452 thousand and €544 thousand in 2009 and 2008, respectively.

Excluding the FDA PMA trials, general and administrative expenses decreased 9.2% from €3.8 million in 2008 to €3.4 million in 2009.

Operating loss.

As a result of the factors discussed above, we recorded a consolidated operating loss of €3.2 million in 2009, as compared to a consolidated operating loss of €4.2 million in 2008.

Excluding the expenses of the FDA PMA trials, the consolidated operating loss in 2009 was €1.0 million, an improvement of €1.0 million when compared to the previous year.

We realized an operating profit in the HIFU division of €0.2 million in 2009, compared to €0.7 million in 2008 and an operating profit in the UDS division of €0.2 million in 2009, as compared to an operating loss of €0.7 million in 2008.

Financial (expense) income, net. Financial (expense) income net was a loss of €4.4 million in 2009, including a €2.7 million expense due to the adjustment of the convertible debt to fair value, compared with a gain of €5.2 million in 2008, including a €6.7 million income due to the adjustment of the convertible debt to fair value.

Foreign currency exchange gains (loss), net. In 2009, we recorded a net foreign currency exchange loss of €0.1 million, mainly due to the weakening of the euro against the U.S. dollar and the Japanese yen, compared to a gain of €0.6 million in 2008.

Other income (expense), net. No other income or expense in 2009, compared to a loss of €1 thousand in 2008.

Income taxes. Income tax was an expense of €72 thousand in 2009, compared to an expense of €51 thousand in 2008. R&D tax credits of €452 thousand and €544 thousand in 2009 and 2008, respectively, are not included in the net amount of income taxes as they were reclassified from income tax to pre-tax income – see Note 1-14 of the consolidated financial statements - Summary of Significant Accounting and Note 21-2 of the consolidated financial statements.

Net income / (loss)

We realized a consolidated net loss of €7.8 million in 2009 compared with a consolidated net profit of €1.6 million in 2008. The €9.4 million variation in net income / (loss) was primarily due to the €9.4 million negative 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, 2010.

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 would 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, failure to meet our obligations arising out of the Convertible Debentures issued in the October 2007 private placement 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 Convertible 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 October 2007 Private Placement.”

(in thousands of euros)	2010	2009	2008
Net cash used in operating activities	(3,818)	(2,996)	(4,593)
Net cash used in investing activities	(685)	402	(712)
Net cash used in financing activities	652	323	296
Net effect of exchange rate changes	(369)	33	1,313
Net increase/(decrease) in cash and cash equivalents	(4,221)	(2,237)	(3,696)
Cash and cash equivalents at the beginning of the year	11,590	13,827	17,523
Cash and cash equivalents at the end of the year	7,369	11,590	13,827
Total cash and cash equivalents, and short-term investments at the end of the year	8,888	12,703	14,970

Our cash position as of December 31, 2010, 2009 and 2008, was €8.9 million (including €1.5 million of short-term treasury investments), €12.7 million (including €1.1 million of short-term treasury investments) and €15.0 million (including €1.1 million of short-term treasury investments), respectively. We experienced negative cash flows of €4.2 million, €2.3 million and €3.7 million in 2010, 2009 and 2008, respectively. 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 2009, our negative cash flow situation was primarily due to the lack of significant additional external financing, however, our cash needs were reduced when compared to the previous year due to cash improvements from the operating activities. In 2008, our negative cash flow situation was primarily due to the lack of external financing similar to the capital raising activities in 2007 and the negative cashflow operations.

In 2010, net cash used in operating activities was €3.7 million compared with net cash used in operating activities of €3.0 million in 2009 and €4.6 million in 2008, respectively.

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 (Convertible Debentures and 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 2009, net cash used in operating activities was €3.0 million compared with net cash used in operating activities of €4.6 million in 2008 and €2.7 million in 2007, respectively.

In 2009, net cash used in operating activities reflected principally:

- a net loss of €7.8 million;
- elimination of €5.1 million of net expenses without effects on cash, including €1.8 million of depreciation and amortization, €0.3 million of change in long-term provisions and a loss of €2.9 million due to variation of the fair value of financial instruments (Convertible Debentures and Warrants);
- an increase in trade accounts receivable of €0.5 million;
- a decrease in other receivables of €0.2 million

- an increase in inventories of €0.3 million;
- a decrease in payables of €0.3 million;
- a decrease in prepaid expenses of €0.5 million; and
- an increase in accrued expenses of €54 thousand.

In 2008, net cash used in operating activities reflected principally:

- a net profit of €1.6 million;
- elimination of €3.3 million of net expenses without effects on cash, including €1.8 million of depreciation and amortization and the €6.7 million profit due to changes in the fair value of financial instruments (Convertible Debentures and Warrants);
- an increase in trade accounts receivable of €3.5 million, mostly due to the exceptionally high level of sales in December 2008;
- an increase in inventories of €0.1 million;
- an increase in payables of €0.6 million; and
- an increase in accrued expenses and other current liabilities of €0.2 million.

In 2010, net cash used in investing activities was €685 thousand compared with net cash generated of €402 thousand in investing activities in 2009 and €712 thousand in 2008.

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.

Net cash generated in investing activities of €402 thousand in 2009 reflected investments of €0.4 million in capitalized assets produced by the Company, mostly HIFU devices used on the RPP basis, an investment of €0.4 million in property and equipment, and net proceeds from sales of leased-back assets of €1.1 million.

In 2008, net cash used in investing activities was €712 thousand, reflecting investments of €0.7 million in capitalized assets produced by the Company (mainly Ablatherm devices as a support of the RPP business model in HIFU), an investment of €0.4 million in property and equipment, and net proceeds from sales of leased-back assets of €1.1 million.

In 2010, net cash provided by financing activities was €652 thousand compared with net cash provided in financing activities of €323 thousand in 2009, and net cash generated of €296 thousand in 2008.

Net cash provided by financing activities of €0.65 million 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.

Net cash provided by financing activities of €0.3 million in 2009 reflected principally the €2.6 million increase in capital related to the issuance of new shares in payment of the interest coupons on the convertible debt and the U.S. $ 2.9 million partial conversion of the convertible debt, a long-term debt increase of €0.5 million through the Japanese subsidiary, repayment of long term borrowing for €2.2 million, repayment of capital lease obligations totaling €0.9 million, and an increase of €0.3 million in bank overdrafts.

In 2008, net cash provided by financing activities was €0.3 million, reflecting principally the €0.6 million increase in capital related to the issuance of new shares in payment of the interest coupons on the convertible debt, a long-term debt increase of €0.2 million through the Japanese subsidiary, repayment of long term borrowing for €0.1 million,

repayment of capital lease obligations totaling €0.6 million, and an increase of €0.2 million in bank overdrafts.

Our future cash flow may also be affected by the expansion of our mobile RPP business. In 1999, in an effort to increase the availability of our equipment, we implemented a new marketing strategy of leasing our medical devices on a monthly, quarterly or yearly basis, rather than selling them directly to end-users, and in 2002, we began to develop our mobile activity by making 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. The RPP model is now established in Europe as a growth and profitability model, and we will continue to expand this business model in the near future. See Item 4 - HIFU Division Business Overview. On October 31, 2007, we completed the private placement of $20 million aggregate principal amount of our 9% Senior Convertible Debentures due 2012. In addition, the purchasers of the Convertible Debentures and our Placement Agent received warrants to purchase our ordinary shares, which expire in 2013. The October 2007 private placement resulted in net proceeds of approximately $17.4 million. In August 2009, bonds for a total value of $2.9 million were converted, thus reducing the outstanding principal amount of the convertible debt from $20 million to $17.1 million. In March, April and November, 2010, additional Convertible Debentures were converted for a total value of $2.1 million, thus reducing the outstanding principal amount of the convertible debt from $17.1 million to $15.1 million. In December, 2010, certain bondholders and the Placement Agent accepted an offer to exchange all of their Convertible Debentures and warrants against ADRs; as a result, the outstanding principal amount of the convertible debt was further reduced by $4.6 million to $10.5 million and a total of 986,965 warrants were cancelled. The terms of the Convertible Debentures allow us to use the proceeds of the private placement to finance costs associated with the regulatory approval for the commercialization of Ablatherm HIFU in the United States (including related clinical trials) and for general and administrative expenses. The warrants may be exercised for cash or, under certain circumstances, through a cashless exercise procedure. If all of the outstanding warrants issued under the October 2007 private placement were fully exercised for cash, we would receive approximately $6.1 million in cash from those warrant holders. For more information on the terms of the Convertible Debentures and the use of proceeds relating to the issuance of the Convertible Debentures, see the Form of Securities Purchase Agreement dated as of October 29, 2007, included as Exhibit 4.5 to this annual report.

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, 2010, there were no outstanding hedging instruments.

Contractual Obligations and Commercial Commitments as of December 31, 2010 (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	2,031	2,031	—	—	—
Long-Term Debt	10,397	322	9,871	204	—
Capital Lease Obligations.	1,649	688	797	164	—
Operating Leases.	739	578	161	—	—

New Accounting Pronouncements

In October 2009, the Financial Accounting Standards Board issued new accounting guidance that requires entities to allocate revenue in multiple-element arrangements using estimated selling prices of the delivered goods and services based on a selling price hierarchy. This guidance eliminates the requirement to establish the fair value of undelivered products and services and instead provides for separate revenue recognition based upon management's estimate of the selling price for an undelivered item when there is no other means to determine the fair value of that undelivered item. This new approach is effective prospectively for multiple-element revenue arrangements entered into or materially modified in fiscal years beginning on or after June 15, 2010. The Company does not expect adoption to have a material impact on the Company's financial position or results of operations.

Research and Development, Patents and Licenses

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

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

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

Research tax credit amounted to €326 thousand in 2010 and €452 thousand in 2009 and were classified as a reduction of research and development expense. The 2008 research tax credit amounting to €544 thousand has also been reclassified from income tax to research and development expense.

Off-Balance Sheet Arrangements

At December 31, 2010, we have 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 March 31, 2011. 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 € 0.4 million.

Name	Age	Position
Marc Oczachowski		Chief Executive Officer of EDAP TMS S.A. and President of the HIFU Division and the UDS Division.
	Age : 41	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. 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		Chief Financial Officer of EDAP TMS S.A.
	Age 44	Eric Soyer joined the Company in December 2006. He was previously CFO of Medica, a €270 million French company operating 108 nursing home and post-care clinics throughout France and Italy. Prior to that he was CFO and a Managing Director of April Group, an insurance services company listed on Euronext Paris, with 22 subsidiaries in France, the UK, Spain, Germany and Italy. He has international experience as a controller and cost accountant for

Michelin Group in France, the United States and Africa. Eric Soyer has a BA degree from Clermont Graduate School of Management, an MBA degree from the University of Kansas and an Executive MBA degree from the HEC Paris School of Management.

Board of Directors

The following table sets forth the names and backgrounds of the members of the Board of Directors. None of the directors have service contracts with the Company or any of its subsidiaries providing for benefits upon termination of employment.

Philippe Chauveau Age: 75 Mandate: 6 years Appointment : Apr. 8, 1997 (renewed) Expiration : June 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. Additionally, he is involved in management development programs at Solvay Business School in Brussels, Belgium. 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: 69 Mandate: 6 years Appointment : Sept. 27, 2002 (renewed) Expiration : June 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: 63 Mandate: 6 years Appointment : June 25, 2009 Expiration : June 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: 61 Mandate: 6 years	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

Appointment : July 16, 2009 Expiration : June 2014	drive both companies from cardiovascular start-ups to established market leaders, using new and innovative technologies which have strong synergies to the HIFU story. Rob Michiels is a director of CardiAQ Valve Technologies and of Embolization Prevention Technologies, both privately held companies. Rob Michiels is a founding partner of CONSILIUM, a medical device market research company active in identifying, funding and greenhousing start-up technologies. Fluent in English, French and Dutch languages, he holds a bachelor's degree in economics from Antwerp University in Belgium and a Masters in business administration (MBA) from Indiana University.

Compensation and Options

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 2010 was approximately €0.505 million (including performance bonuses of €0.102 million). 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 2010.

Compensation Committee

The entire Board of Directors acts as a ‘‘Compensation Committee’’ which gathers once a year to review the compensation of our Senior Executive Officers, 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 members of the Board, each an independent director: Mr. Pierre Beysson, acting as Head of the Audit Committee, Mr. Philippe Chauveau, Dr. Argil Wheelock and Mr. Rob Michiels. The purpose of the Audit Committee, in accordance with its annually approved charter, is to:

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

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

Employees

As of December 31, 2008, we employed 149 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	13	96
Italy	3	0	0	0	0	0	2	5
Germany	4	0	2	0	0	0	2	8
Japan	9	0	15	0	2	0	3	29
Malaysia	2	0	3	0	0	0	2	7
South Korea	1	0	0	0	0	0	1	2
Russia	1	0	0	0	0	0	0	1
USA	0	0	0	0	0	1	0	1
Total	36	31	39	11	6	3	23	149

As of December 31, 2009, we employed 154 individuals on a full-time basis, as follows:

	Sales & Marketing	Manufac-turing	Service	Research & Dvpt	Regula-tory	Clinical Affairs	Adminis-trative	Total
France	16	30	19	13	4	2	15	99
Italy	3	0	0	0	0	0	2	5
Germany	5	0	2	0	0	0	2	9
Japan	12	0	13	0	2	0	3	30
Malaysia	2	0	3	0	0	0	3	8
South Korea	1	0	0	0	0	0	1	2
USA	0	0	0	0	0	1	0	1
Total	39	30	37	13	6	3	26	154

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 March 18, 2011, the total number of shares issued was 13,463,306 with 381,528 shares held as treasury stocks, thus bringing the total number of shares outstanding to 13,048,401.

As of March 18, 2011, the Board of Directors and the Senior Executive Officers of the Company held a total of 31,123 Shares. The Board of Directors and Senior Executive Officers beneficially own, in the aggregate less than 1% of the Company's shares.

As of March 18, 2011, Senior Executive Officers held an aggregate of 238,763 options to purchase or to subscribe to shares of our common stock, with a weighted average exercise price of €3.35 per share. Of these options, 3,425 expire on June 18, 2012, 30,000 expire on February 24, 2014, 155,338 expire on October 29, 2017 and 50,000 expire on June 25, 2020.

Options to Purchase or Subscribe for Securities

As of March 18, 2011, we had sponsored four stock purchase and subscription option plans open to employees of EDAP TMS group.

On June 12, 2001, the shareholders authorized the Board of Directors to grant up to 300,000 options to purchase pre-existing Shares, at a fixed exercise price to be set by the Supervisory Board.

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 and up to 105,328 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 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 31, 2010, the expiration of our stock option contracts was as follows:

Date of expiration	Number of Shares
September 25, 2011	25,000
June 18, 2012	3,425
February 24, 2014	124,000
October 29, 2017	445,338
June 25, 2020	309,012

As of December 31, 2010, a summary of stock option activity to purchase or to subscribe to Shares under these plans is as follows:

	2010		2009		2008	
	Options	Weighted average exercise price (€)	Options	Weighted average exercise price (€)	Options	Weighted average exercise price (€)
Outstanding on January 1,	656,013	3.57	706,725	3.51	781,625	3.51
Granted	325,012	2.23				
Exercised	(18,000)	2.15	(24,212)	2.07		
Forfeited	(56,250)	2.45	(26,500)	3.36	(34,000)	