EDAP TMS SA
Form F-3
October 06, 2010
As filed with the Securities and Exchange Commission on October 6, 2010
Registration No. 333-

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

# FORM F-3
REGISTRATION STATEMENT
UNDER
THE SECURITIES ACT OF 1933

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

Not Applicable
(Translation of Registrant's name into English)

| France | Not applicable |
|---|---|
| (State or Other Jurisdiction of Incorporation or Organization) | (I.R.S. Employer Identification No.) |

Parc d'Activités la Poudrette-Lamartine
4, rue du Dauphiné
69120 Vaulx-en-Velin, France
+33 (0) 4 7215 3150
(Address and telephone number of Registrant's principal executive offices)

Corporation Service Company
2711 Centerville Road, Suite 400, Wilmington, DE 19808, USA – Tel: +1 800 927 9800
(Name, address and telephone number of agent for service)
Copies to:

| Blandine Confort | Linda Hesse |
|---|---|
| EDAP TMS S.A. | JONES DAY |
| 4, rue du Dauphiné | 2 rue Saint-Florentin |
| 69120 Vaulx-en-Velin, France | 75001 Paris, France |
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Approximate date of commencement of proposed sale to the public: From time to time after the effective date of this Registration Statement as determined by market conditions.
If the only securities being registered on this Form are being offered pursuant to dividend or interest reinvestment plans, please check the following box. ¨
If any of the securities being registered on this Form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933, check the following box. x
If this Form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, please check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. ¨
If this Form is filed as a post-effective amendment filed pursuant to Rule 462(c) under the Securities Act, please check the following box and list the Securities Act registration statement number of the earlier effective registration

statement for the same offering. ¨

If this Form is a registration statement pursuant to General Instruction I.C. or a post-effective amendment thereto that shall become effective upon filing with the Commission pursuant to Rule 462(e) under the Securities Act, check the following box. ¨

If this Form is a post-effective amendment to a registration statement filed pursuant to General Instruction I.C. filed to register additional securities or additional classes of securities pursuant to Rule 413(b) under the Securities Act, check the following box. ¨

CALCULATION OF REGISTRATION FEE

| Title of Each Class Of Securities to be Registered | Amount to be registered(1)(2) | Proposed maximum aggregate offering price(2)(3) | Amount of registration fee |
|---|---|---|---|
| Ordinary shares, with a nominal value €0.13 per share(4) | | | |
| Warrants(5) | | | |
| Total | US$ 9,000,000 | US$ 9,000,000 | US$641.70(6) |

(1) There are being registered under this Registration Statement such indeterminate number of ordinary shares and warrants as shall have an aggregate initial offering price not to exceed US$9,000,000. Any securities registered by this Registration Statement may be sold separately or as units with other securities registered under this Registration Statement. The proposed maximum initial offering price per security will be determined, from time to time, by the registrant in connection with the sale of the securities under this Registration Statement.

(2) In United States dollars or the equivalent thereof as converted from euros.

(3) Estimated solely for the purpose of calculating the registration fee pursuant to Rule 457(o) under the Securities Act based on the average of the high and low prices of our American Depositary Shares, each representing one ordinary share, on The NASDAQ Global Market on October 1, 2010.

(4) Ordinary shares may be in the form of American Depositary Shares evidenced by American Depositary Receipts. American Depositary Shares evidenced by American Depositary Receipts issuable on deposit of the ordinary shares registered hereby have been registered under a separate registration statement on Form F-6/A (File No. 333-7314). Each American Depositary Share represents the right to receive one ordinary share.

(5) Also includes an indeterminate number of ordinary shares (i) as may be issuable or deliverable upon exercise of warrants, and (ii) as may be required for delivery upon exercise of any warrants as a result of anti-dilution provisions.

(6) Calculated in accordance with Rule 457(o).

The Registrant hereby amends this Registration Statement on such date or dates as may be necessary to delay its effective date until the Registrant shall file a further amendment which specifically states that this Registration Statement shall thereafter become effective in accordance with Section 8(a) of the Securities Act of 1933 or until the Registration Statement shall become effective on such date as the Securities and Exchange Commission, acting pursuant to said Section 8(a), may determine.

The information in this prospectus is not complete and may be changed. We may not sell these securities or accept an offer to buy these securities until the registration statement filed with the Securities and Exchange Commission is effective. This prospectus is not an offer to sell these securities, and it is not soliciting offers to buy these securities in any state where such offer or sale is not permitted.

EDAP TMS S.A.

SUBJECT TO COMPLETION, DATED OCTOBER 6, 2010

PROSPECTUS
US$9,000,000
ORDINARY SHARES,
WARRANTS TO PURCHASE ORDINARY SHARES

EDAP TMS S.A.

From time to time, we may offer up to $9,000,000 of any combination of the securities described in this prospectus, either individually or in units.

This prospectus provides a general description of the securities we may offer. Each time we sell securities, we will provide specific terms of the securities offered in a supplement to this prospectus. We may also authorize one or more free writing prospectuses to be provided to you in connection with these offerings. The prospectus supplement and any related free writing prospectus may also add, update or change information contained in this prospectus. You should carefully read this prospectus, the applicable prospectus supplement and any related free writing prospectus, as well as any documents incorporated by reference before you invest in any securities. This prospectus may not be used to consummate a sale of securities unless accompanied by the applicable prospectus supplement.

Our ordinary shares, in ADS form, are listed on The NASDAQ Global Market under the symbol “EDAP”. On October 4, 2010, the last reported sale price for our ADSs was $2.33 per share. The applicable prospectus supplement will contain information, where applicable, as to any other listing on The NASDAQ Global Market or any securities market or other exchange of the securities, if any, covered by the prospectus supplement. There is currently no market through which the warrants may be sold and purchasers may not be able to resell warrants purchased under this prospectus. This may affect the pricing of any warrants in the secondary market, the transparency and availability of trading prices, the liquidity of the warrants, and the extent of issuer regulation. See the “Risk Factors section of the applicable prospectus supplement.”

We will sell these securities directly to investors, through agents designated from time to time or to or through underwriters or dealers. For additional information on the methods of sale, you should refer to the section entitled “Plan of Distribution” in this prospectus. If any underwriters are involved in the sale of any securities with respect to which this prospectus is being delivered, the names of such underwriters and any applicable commissions or discounts will be set forth in a prospectus supplement. The price to the public of such securities and the net proceeds we expect to receive from such sale will also be set forth in a prospectus supplement.

Investing in our Securities involves risks. See "Risk Factors" beginning on page 3.

Owning securities may subject you to tax consequences both in France and in the United States. This prospectus and any applicable prospectus supplement may not describe these tax consequences fully. You should read the tax discussion in this prospectus and any applicable prospectus supplement. Your ability to enforce civil liabilities under U.S. federal securities laws may be affected adversely by the fact that we are incorporated under the laws of France, many of our officers and directs and experts named in this prospectus are residents of France or elsewhere outside of the United States, and a substantial portion of our assets and the assets of such persons are located outside the United States. See "Enforcement of Civil Liabilities."

NEITHER THE SECURITIES AND EXCHANGE COMMISSION NOR ANY OTHER REGULATORY BODY HAS APPROVED OR DISAPPROVED OF THESE SECURITIES OR PASSED UPON THE ADEQUACY OR ACCURACY OF THIS PROSPECTUS. ANY REPRESENTATION TO THE CONTRARY IS A CRIMINAL OFFENSE.

Prospectus dated _____, 2010

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## ABOUT THIS PROSPECTUS

This prospectus relates to the sale of up to US$9,000,000 of our ordinary shares, either in the form of ordinary shares or American Depositary Shares, or warrants.

We may add, update or change in a prospectus supplement any of the information contained in this prospectus or in documents we have incorporated by reference into this prospectus. To the extent that any statement that we make in a prospectus supplement is inconsistent with statements made in this prospectus, the statements made in this prospectus will be deemed modified or superseded by those made in a prospectus supplement.

You should carefully read both this prospectus and any prospectus supplement, together with additional information described under the heading "Where You Can Find More Information About Us." "Documents Incorporated By Reference" and "Risk Factors" before you invest in our securities.

All references in this prospectus to the "Company," "EDAP" or "EDAP TMS" are to EDAP TMS S.A. All references to "we," "us" and "our" are to EDAP TMS S.A. and its subsidiaries collectively, unless the context otherwise requires.

In this prospectus and any prospectus supplement, "U.S. dollar" or "$" refers to U.S. currency and "euro" or "€" refers to th currency established for participating member states of the European Union as of the beginning of stage three of the European Monetary Union on January 1, 1999.

EDAP TMS

We develop and market Ablatherm® an advanced and clinically proven choice for High Intensity Focused Ultrasound, or HIFU, treatment of organ-confined prostate cancer. HIFU treatment is shown to be a minimally invasive and effective treatment option with a low occurrence of side effects. Ablatherm-HIFU is generally recommended for patients with organ-confined prostate cancer (stages T1-T2) who are not candidates for surgery or who prefer an alternative option, and is also recommended for patients who have failed a radiotherapy treatment. We are also developing this HIFU technology for the treatment of certain other types of tumors. In addition, we produce and commercialize medical equipment for treatment of urinary tract stones using Extracorporeal Shockwave Lithotripsy.

Our principal executive offices are located at Parc d'Activites la Poudrette- Lamartine, 4, rue du Dauphiné, 69120 Vaulx-en-Velin, France and our telephone number is +33 (0) 4 72 15 31 50.

## RISK FACTORS

An investment in our securities involves a high degree of risk. The prospectus supplement applicable to each offering of our securities will contain a discussion of the risks applicable to an investment in our securities. Prior to making a decision about investing in our securities, you should carefully consider the specific factors discussed under the heading "Risk Factors" in the applicable prospectus supplement, together with all of the other information contained or incorporated by reference in the prospectus supplement or appearing or incorporated by reference in this prospectus. You should also consider the risks, uncertainties and assumptions discussed under Item 1A, "Risk Factors," in our Annual Report on Form 20-F for the fiscal year ended December 31, 2009 which are incorporated herein by reference. These risk factors may be amended, supplemented or superseded from time to time by other reports we file with the Securities and Exchange Commission in the future. The risks and uncertainties we have described are not the only ones we face. Additional risks and uncertainties not presently known to us or that we currently deem immaterial may also affect our operations.

### Risks Relating to Our Business

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

We depend on the success of our High Intensity Focused Ultrasound, or HIFU, technology for future revenue growth and net income. Our Extracorporeal Shockwave Lithotripsy, or 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 Ablatherm, to generate significant additional revenues and achieve and sustain profitability in the future. Ablatherm is in its commercialization phase in the European Union, Canada and other countries. However, Ablatherm is not approved for commercial distribution in the United States. In December 2001, our request for an additional Investigational Device Exemption,or IDE, from the U.S. Food and Drug Administration, or FDA, to conduct clinical trials in the United States for 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 Ablatherm using the $17.4 million net proceeds of the October 2007 private placement. 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—High Intensity Focused Ultrasound ("HIFU") Division—HIFU Division Clinical and Regulatory Status" in our Annual Report on Form 20-F for the fiscal year ended December 31, 2009.

#### 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. 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'' in our Annual Report on Form 20-F for the fiscal year ended December 31, 2009.

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 Ablatherm, for several 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 UK, and evidence of the cost effectiveness of a therapy as compared to existing therapies. Acceptance by patients depends in part on physician recommendations, as well as other factors, including the degree of invasiveness and 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 cyclical demand for medical devices, and the resulting annual and quarterly fluctuations in trade and other receivables and inventories. This has in the past resulted in significant variations in working capital requirements and operating cash flows. In 2007, 2008 and 2009, 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 2007, 2008 and 2009 operating cash flow was negative due to 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 model, and, in 2007, due to the sponsoring of the pre-market approval, or 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 revenue-per-procedure basis), since each of these activities generates smaller immediate revenues than device sales, and by the implementation of our US 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. 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. Our future cash flow will be affected by the increased 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 2007, we had negative operating income in our UDS division, reflecting the research and development and regulatory efforts in the UDS division to develop a new, high-range lithotripter, and in connection with our FDA PMA trials, reflecting the regulatory and clinical efforts to resume and conduct our Ablatherm-HIFU PMA trials. Total costs were equal to total revenues for our HIFU division in 2007, due to the increase in revenues and margin on HIFU equipment and RPP treatment sales. In 2008, we again 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 our HIFU and 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. 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’’ in our Annual Report on Form 20-F for the fiscal year ended December 31, 2009.

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 US HIFU, or USHIFU, which has developed a device called the Sonablate SB500 for the treatment of localized prostate cancer. Insightec, an Israeli company owned mainly by General Electric and Elbit Medical Imaging Ltd, has developed a device using HIFU technology to treat uterine fibroids. St. Jude Medical Inc. has developed a device using HIFU to treat atrial fibrillation. Haifu, a Chinese company developing HIFU products addressing various types of cancers, signed a development partnership agreement with Siemens Medical Solutions to offer a HIFU device coupled with IRM imaging system. 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, or 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 (Bejing) Co. Ltd (“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—High Intensity Focused Ultrasound Division— HIFU Competition’’ and Item 4,

‘‘Information on the Company—Urology Devices and Services Division” in our Annual Report on Form 20-F for the fiscal year ended December 31, 2009.

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 currently under clinical trials in the US, we terminated patient enrollment and entered into the follow-up phase. We may not be able 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” in our Annual Report on Form 20-F for the fiscal year ended December 31, 2009.

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, or CMS, formerly the Health Care Financing Administration, or 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 and the UK, where procedures are partially reimbursed by either public healthcare systems or private insurers. We cannot assure investors that additional reimbursement approvals will be obtained in the near future. If reimbursement for our products is unavailable, limited in scope or amount or if pricing is set at unsatisfactory levels, our business could be materially harmed.

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

Our manufacturing operations must comply with regulations established by regulatory agencies in the United States, the European Union and other countries, and in particular with the 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’’ in our Annual Report on Form 20-F for the fiscal year ended December 31, 2009.

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 2009, approximately 70% of our total operating expenses were denominated in euro, while approximately 31% 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, 2009, 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, cyclicality 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 debentures, we have the option to pay interest on the 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 debentures and warrants 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 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” in our Annual Report on Form 20-F for the fiscal year ended December 31, 2009.

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 deliverable upon exercise of warrants issued in connection with our October 2007 Private Placement, 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 securities deliverable upon exercise of the warrants. If we fail to maintain the effectiveness of the registration statement as required under the registration rights agreement related to the sale of the warrants, we are subject to significant penalties, including payment of liquidated damages, which could amount to a substantial penalty. Payment of liquidated damages 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 debentures, we would be required to deplete our working capital or raise additional funds. Our failure to repay the debentures, if required, could result in legal action against us, which could require the sale of substantial assets.

The 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 debentures at the mandatory default amount, including all other amounts of interest, costs, expenses and liquidated damages due in respect of the defaulted debentures. If, prior to the maturity date, we are required to repay the debentures in full, we would be required to use our working capital and raise additional funds. If we were unable to repay the

debentures when required, the debenture 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 debentures, exercise of outstanding warrants and payment of interests on the debentures will cause immediate and substantial dilution to our existing shareholders.

The issuance of ordinary shares upon conversion of the 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 debentures and the exercise price of the warrants at the closing of the October 2007 private placement, up to 4,133,454, including 188,965 shares issuable to our placement agent of our ordinary shares, are issuable upon conversion and exercise, representing approximately 36% of our issued and outstanding share capital. In addition, interest on the 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 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.

Further, on February 26, 2009, our shareholders adopted a resolution authorizing the issuance of 3,000,000 new shares, representing 20% of our issued and outstanding share capital on a fully diluted basis. We planned to use these new shares exclusively to pay all of the interest payable under the debentures in shares.

On October 30, 2009, our shareholders adopted several resolutions allowing the Board of Directors to renegotiate our indebtedness with the maximum flexibility while remaining within the limit of the dilution already authorized by shareholders in October 2007 and February 2009. Pursuant to the shareholders' authorization, and in conformity with these resolutions, the Board of Directors issued on November 16, 2009 a Supplement to the current debentures allowing debenture holders to convert their debentures earlier, with a lower exercise price and including the payment of an accelerated interest premium, payable in shares, within the authorized dilution limits. All other terms of the debentures remained unchanged. This Supplement was unanimously approved by the debenture holders on December 3, 2009, convened in a General Meeting (Masse). However, there can be no guarantee that all debenture holders will opt for the early conversion option available to them in the November 16, 2009 Supplement to the current debentures and the Company may not therefore ensure that the dilution resulting from the conversion of the bonds will be limited to the 12-month period provided for such option.

Finally, on June 24, 2010, our shareholders adopted several resolutions extending the validity of certain resolutions adopted on October 30, 2009 and delegations granted to the Board of Directors to allow renegotiation with the OCRABSA holders the bond indebtedness of the Company and, if need be, to seize financing opportunities, within the dilution limit previously authorized). In addition, in accordance with French and international standards and in the interest of the Company, in the view of its development, the shareholders approved delegations to be given to the Board of Directors which would allow it to implement share capital increases, immediately or in the future, with or without preferential subscription rights, with the same objective of responding to opportunities which may present themselves to the Company and thus allow it to increase shareholder equity. These anticipated increases in capital,

will be implemented within the existing authorized dilution parameters that have already received shareholder approval.

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

As noted above, interest on the 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 fulfill 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 was 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 debentures. An event of default with respect to the debentures would have a material adverse effect on our financial conditions and results of operations. The terms and conditions of the debentures and warrants we issued in October 2007 are set forth in the respective instruments, the form of which were filed as Exhibit 1 to the Report of Foreign Private Issuer on Form 6-K furnished to the SEC on October 31, 2007. Such terms and conditions include anti-dilution provisions for the benefit of the holders of debentures and warrants in the event we issue new ordinary shares. Given the maximum number of shares that we can issue pursuant to the resolutions adopted by the shareholders' meeting of June 24, 2010, these anti-dilution provisions may need to be re-negotiated with the holders of debentures and warrants and amended upon any issuance by us of new ordinary shares.

Our increased leverage as a result of the sale of the 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 June 30, 2010 was €11.7 million and represented approximately 30% of our total assets, including the current portion of indebtedness of approximately €0.250 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 debentures could discourage an acquisition of us or an investment in us by a third party, even if the acquisition or investment would be favorable to investors.

The 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 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 debentures are outstanding, we are required to offer the investors who purchased 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 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 US Dollar fair value of the debentures and warrants as of June 30, 2010:

- stock volatility: as of June 30, 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 2% in the fair value of the convertible debentures and warrants.

- the stock value: as of June 30, 2010 and every other market parameter being equal, an increase in the stock value of 10% would have resulted in an increase of 2% 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 3% in the fair value of the convertible debentures and warrants.

- the risk free interest rate: as of June 30, 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 1% 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 1% in the fair value of the convertible debentures and warrants.

- credit spread: as of June 30, 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 1% in the fair value of the convertible debentures and warrants.

- liquidity discount factor: as of June 30, 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 1% 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 1% in the fair value of the convertible debentures and warrants.

- combined sensitivity to market parameters: as of June 30, 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 8% in the fair value of the 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 7% in the fair value of the 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 2009 was 61,795, the high and low bid price of our ADSs for the last two financial years ended on December 31, 2009 and December 31, 2008, was $ 5.95 and $5.12, and $0.96 and $1.05, respectively. The average daily trading volume of our ADSs in June 2010 was 84,248, the high and low bid price of our ADSs for the first six months of 2010 were $4.25 and $2.16.

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 2008 was 9,138 as opposed to 61,795 for the same period of 2009. 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 or in view of implementing share capital increases, only within the maximum 6,512,370 additional share limit already authorized by the shareholders, such limit to be considered taking into account the conversions of debentures and payments of quarterly interests paid in shares up to June 30, 2010. 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 Securities Exchange Act of 1934, as amended, or 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 four 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” in our Annual Report on Form 20-F for the fiscal year ended December 31, 2009.

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;
- 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

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

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

Under French law, shareholders have preferential rights to subscribe for cash issuances of new shares or other securities giving rights to acquire additional shares on a pro rata basis. U.S. holders of our securities may not be able to exercise preferential subscription rights for their shares unless a registration statement under the Securities Act is effective with respect to such rights or an exemption from the registration requirements imposed by the Securities Act is available. We may, from time to time, issue new shares or other securities giving rights to acquire additional shares (such as warrants) at a time when no registration statement is in effect and no Securities Act exemption is available. If so, U.S. holders of our securities will be unable to exercise their preferential rights and their interests will be diluted. We are under no obligation to file any registration statement in connection with any issuance of new shares or other securities.

For holders of ADSs, the Depositary may make these rights or other distributions available to holders after we instruct it to do so and provide it with evidence that it is legal to do so. If we fail to do this and the Depositary determines that it is impractical to sell the rights, it may allow these rights to lapse. In that case the holders of ADSs will receive no value for them.

Risks Related to the Issuance of Securities under this Prospectus

An active market may not develop for the warrants, which may hinder your ability to liquidate your investment.

Each issuance of warrants will be a new issue of securities with no established trading market, and we do not currently intend to list them on any securities exchange. A dealer may intend to make a market in the warrants after their issuance pursuant to this Prospectus; however, a dealer may not be obligated to do so and may discontinue such market-making at any time. As a result, we cannot assure you that an active trading market will develop for any series of the warrants. In addition, subsequent to their initial issuance, the warrants may trade at a discount to their initial offering price, depending upon the value of the underlying ordinary shares and upon our prospects or the prospects for companies in our industry generally and other factors, including those described herein.

A large number of ordinary shares may be issued and subsequently sold upon the exercise of the warrants. The sale or availability for sale of these warrants may depress the price of our ordinary shares.

The number of ordinary shares that will be initially issuable upon the exercise of warrants will be determined by the particular terms of each issue of warrants and will be described in the relevant prospectus supplement. To the extent that purchasers of warrants sell ordinary shares issued upon the exercise of the warrants, the market price of our ordinary shares may decrease due to the additional

selling pressure in the market. The risk of dilution from issuances of ordinary shares underlying the warrants may cause shareholders to sell their ordinary shares, which could further contribute to any decline in the ordinary share price.

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

Any downward pressure on the price of ordinary shares caused by the sale of ordinary shares issued upon the exercise of the warrants could encourage short sales by third parties. In a short sale, a prospective seller borrows ordinary shares from a shareholder or broker and sells the borrowed ordinary shares. The prospective seller hopes that the ordinary share price will decline, at which time the seller can purchase ordinary shares at a lower price for delivery back to the lender. The seller profits when the ordinary share price declines because it is purchasing Ordinary Shares at a price lower than the sale price of the borrowed ordinary shares. Such sales could place downward pressure on the price of our ordinary shares by increasing the number of ordinary shares being sold, which could further contribute to any decline in the market price of our ordinary shares.

We cannot predict the actual number of ordinary shares that we will issue upon the exercise of the warrants. The number of ordinary shares that we will issue under the warrants may depend on the market price of our ordinary shares.

The actual number of ordinary shares that we will issue upon the exercise of the warrants is uncertain and will be determined, or made determinable, by the particular terms of each issue of warrants and will be described in the relevant prospectus supplement. The number of ordinary shares issuable upon the exercise of the warrants may fluctuate based on the market price of our ordinary shares. Holders of warrants may receive more ordinary shares if our ordinary share price declines.

## WHERE YOU CAN FIND MORE INFORMATION ABOUT US

We file annual reports and special reports and other information with the Securities and Exchange Commission, or the SEC. However, as a foreign private issuer, we and our shareholders are exempt from some SEC reporting requirements, including proxy solicitation rules, short-swing insider profit disclosure rules of Section 16 of the Exchange Act with respect to our shares and the rules regarding the furnishing of quarterly reports to the SEC, which are required to be furnished only if required or otherwise provided in our home country domicile.

Our SEC filings are also available over the Internet at the SEC's website at http://www.sec.gov. The address of the SEC's Internet site is provided solely for the information of prospective investors and is not intended to be an active link. You may also read and copy any document we file at the SEC's public reference room at 100 F Street, N.E., Washington, DC 20549, USA. The public may obtain information on the operation of the SEC's public reference room by calling the SEC in the United States at 1-800-SEC-0330.

## DOCUMENTS INCORPORATED BY REFERENCE

The SEC allows us to "incorporate by reference" in this prospectus the information in the documents that we file with it, which means we can disclose important information to you by referring you to those documents. The information incorporated by reference is considered to be a part of this prospectus. We incorporate by reference in this prospectus the documents listed below:

- our annual report on Form 20-F for the year ended December 31, 2009 (SEC File No. 000-29374);
- and interim results as of June 30, 2010 filed on Form 6-K on September 30, 2010.

In addition, any reports on Form 6-K submitted to the SEC by us pursuant to the Exchange Act after the date of the initial registration statement and prior to effectiveness of the registration statement that we specifically identify in such forms as being incorporated by reference into the registration statement of which this prospectus forms a part and all subsequent annual reports on Form 20-F filed after the effective date of this registration statement and prior to the termination of this offering and any reports on Form 6-K subsequently submitted to the SEC or portions thereof that we specifically identify in such forms as being incorporated by reference into the registration statement of which this prospectus forms a part, shall be considered to be incorporated into this prospectus by reference and shall be considered a part of this prospectus from the date of filing or submission of such documents.

You may request a copy of the documents incorporated by reference herein at no cost to you by writing or telephoning us at our principal executive offices, located at 4, rue du Dauphine, Parc d'Activites la Poudrette-Lamartine, 69120 Vaulx-en-Velin, France, +033 (0) 4 7215 3150, attention: Blandine Confort.

Information in this prospectus may be modified by information included in subsequent Exchange Act filings that we incorporate by reference, the result of which is that only the information as modified will be part of this prospectus. Other information in this prospectus will not be affected by the replacement of this superseded information, nor will an investor's ability to rely on such superseded information be affected, to the extent such reliance occurs prior to the delivery of the superseding information.

Additional information regarding us may be obtained on our website, www.edap-tms.com, which is not intended to be an active link. Such information is not incorporated by reference into this prospectus.

You should rely only on the information that we incorporate by reference or provide in this prospectus and any accompanying prospectus supplement. We have not authorized anyone to provide you with different information. The selling shareholders are not making an offer of the Shares in any jurisdiction where the offer is not permitted. You should not assume that the information in this prospectus or any prospectus supplement is accurate as of any date other than the date on the front of the relevant documents.

## CURRENCY AND EXCHANGE RATES

All references to "€" are to euros and all references to "U.S. $" are to U.S. dollars. The following table sets forth the high and low exchange rates for one U.S. dollar expressed in euros, for the period indicated and, the average of such exchange rates, and the exchange rate at the end of such period, in each case, based upon the noon rates as quoted by the Federal Reserve Bank of New York (the "Noon Buying Rate").

| | Six Months Ended June 30, 2010 | Year Ended December 31, 2009 | 2008 | 2007 |
|---|---|---|---|---|
| High | 0.84 | 0.80 | 0.80 | 0.78 |
| Low | 0.69 | 0.66 | 0.62 | 0.67 |
| Rate at end of period | 0.81 | 0.70 | 0.72 | 0.68 |
| Average rate per period | 0.76 | 0.72 | 0.68 | 0.73 |

On October 1, 2010, the exchange rate for one US dollar expressed in euros based upon the Noon Buying Rate was €0.73.

## FORWARD–LOOKING STATEMENTS

The statements incorporated by reference or contained in this prospectus discuss our future expectations, contain projections of our results of operations or financial condition, and include other forward-looking information within the meaning of Section 27A of the Securities Act. Our actual results may differ materially from those expressed in forward-looking statements made or incorporated by reference in this prospectus.

Forward-looking statements that express our beliefs, plans, objectives, assumptions or future events or performance may involve estimates, assumptions, risks and uncertainties. Therefore, our actual results and performance may differ materially from those expressed in the forward-looking statements. Forward-looking statements often, although not always, include words or phrases such as the following: “will likely result,” “are expected to,” “will continue,” “is anticipated,” “estimate,” “intends,” “plans,” “projection” and “outlook.” You should not unduly rely on forward-looking statements contain or incorporated by reference in this prospectus.

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 US 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 cyclical 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 debentures and warrants issued in the October 2007 private placement.

Readers should also consider the information contained in “Risk Factors” in this prospectus and Item 5, “Operating and Financial Review and Prospects,” in our annual report on Form 20-F for the 2009 financial year incorporated by reference in this prospectus, as well as the information contained in our periodic filings and submissions with the SEC (including our reports on Form 6-K).

Any forward-looking statement speaks only as of the date on which that statement is made. We will not update any forward-looking statement to reflect events or circumstances that occur after the date on which such statement is made.

## USE OF PROCEEDS

Except as described in any applicable prospectus supplement and in any free writing prospectuses in connection with a specific offering, we currently intend to use the net proceeds from the sale of the securities offered hereby for operating costs, capital expenditures and for general corporate purposes, including working capital. We may also use a portion of the net proceeds to invest in or acquire businesses or technologies that we believe are complementary to our own, although we have no current plans, commitments or agreements with respect to any acquisitions as of the date of this prospectus. We may use the net proceeds to repay part of our October 2007 convertible debt. As of June 30, 2010, $15,558,000 remains outstanding. The $15,558,000 is in the form of 15,558 debentures with a face value of $1,000 and each bond is convertible into 152 shares of ordinary shares at any time at the election of the holder, using a conversion price of $6.57, subject to standard anti-dilution adjustments. The debentures mature in two years (October 28, 2012) and bear an annual interest rate of 9% payable on a quarterly basis in cash or in ordinary shares at our option (decision made every quarter) with a 10% discount price over the average market price of our ordinary shares. Investors in the convertible debentures also received an aggregate number of 1,680,000 detachable warrants to purchase one share of common stock for each warrant. The warrants have a three-year term and an exercise price of $6.87, subject to standard anti-dilutive adjustments.

## CAPITALIZATION AND INDEBTEDNESS

The following table sets out, as of June 30, 2010, our consolidated short-term debt and capitalization in accordance with U.S. GAAP.

Except as disclosed below, there have been no material changes to our consolidated capitalization since June 30, 2010. This table should be read in conjunction with our financial statements, which are incorporated by reference in this prospectus.

| | € | $(1) |
|---|---|---|
| | Actual | |
| | (in thousands) | |
| Current portion of capital lease | 762 | 936 |
| Capital lease obligations, less current portion | 1,042 | 1,281 |
| Short-term debt, including current portion of long-term debt | 2,481 | 3,049 |
| Long-term debt(2) net of current portion of long-term debt | 11,417 | 14,032 |
| Shareholders' equity: | | |
| Share capital(3) (4) | 1,498 | 1,841 |
| Additional paid-in capital | 31,940 | 39,258 |
| Retained earnings, including cumulative foreign translation adjustment | (18,043 ) | (22,177 ) |
| Cumulative other comprehensive income | (3,730 ) | (4,585 ) |
| Treasury stock(5) | (1,233 ) | (1,516 ) |
| Total shareholders' equity | 10,431 | 12,821 |
| Total capitalization | 26,133 | 32,120 |

(1) Dollar amounts have been translated solely for the convenience of the reader at an exchange rate of €1 =$1.2291, the noon buying rate in The City of New York for cable transfers of euro as certified for customs purposes by the Federal Reserve Bank of New York on June 30, 2010.

(2) Long-term debt, actual as of June 30, 2010 and as adjusted, includes the fair value of the convertible debentures, warrants and embedded call option on the Company's stock all issued in the October 2007 private placement, net of issuance expenses of $2.6 million, and net of conversions that occurred since inception. At inception, the total nominal amount of convertible debentures was $20 million. Some debentures have been converted in August 2009, March 2010 and April 2010, the converted amounts being $2,892 thousand, $1,300 thousand and $250 thousand, respectively. Consequently, the outstanding nominal amount of the convertible debentures as of June 30, 2010 was $15.6 million with a fair value of €9.8 million (or $12.1 million). There has been no further conversion since July 1, 2010, to date.

(3) As of June 30, 2010, we had an issued share capital of 11,523,902 fully paid ordinary shares, including 399,528 shares held as treasury stock, each with a nominal value of €0.13 per share, resulting in outstanding share capital of 11,124,374.

(4) On July 1, 2010, we issued 160,463 new ordinary shares in payment of interest on the debentures.

(5) As of June 30, 2010, we held 399,528 of our ordinary shares as treasury stock, a portion of which was dedicated to serve stock purchase option plans as follows:

- 32,000 shares which may be purchased at a price of €2.08 per share and 3,425 shares which may be purchased at a price of €2.02 per share pursuant to the exercise of options that were granted in 2001 and in 2002 and are outstanding; and
- 135,000 shares which may be purchased at a price of €2.60 per share pursuant to the exercise of options that were granted in 2004.
- 229,100 shares which may be purchased at a price of €2.38 per share pursuant to the exercise of options that were granted in 2010.

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## THE SECURITIES WE MAY OFFER

We may offer our ordinary shares, either in the form of shares or American Depositary Shares, or warrants to purchase any of such securities, with a total value of up to $9,000,000 million from time to time under this prospectus, together with any applicable prospectus supplement and related free writing prospectus, at prices and on terms to be determined by market conditions at the time of offering. This prospectus provides you with a general description of the securities we may offer. Each time we offer a type or series of securities, we will provide a prospectus supplement that will describe the specific amounts, prices and other important terms of the securities.

A prospectus supplement and any related free writing prospectus that we may authorize to be provided to you may also add, update or change information contained in this prospectus or in documents we have incorporated by reference. However, no prospectus supplement or free writing prospectus will offer a security that is not registered and described in this prospectus at the time of the effectiveness of the registration statement of which this prospectus is a part.

We may sell the securities directly to or through underwriters, dealers or agents. We, and our underwriters or agents, reserve the right to accept or reject all or part of any proposed purchase of securities. If we do offer securities through underwriters or agents, we will include in the applicable prospectus supplement:

- The names of those underwriters or agents,
- Applicable fees, discounts and commissions to be paid to them,
- Details regarding over-allotment options, if any, and
- The net proceeds to us.

## DESCRIPTION OF ORDINARY SHARES

Issued capital

Share Capital structure

Information on our share capital is provided in “Item 10.—Additional Information” in our annual report on Form 20-F for the financial year ended December 31, 2009 incorporated by reference into this prospectus. Updated information on our share capital as of June 30, 2010 is provided in Note 7 of the form 6-K filed on September 30, 2010 with the SEC and incorporated by reference into this prospectus.

Number of shares issued

Updated information on the number of shares issued by us is provided in Notes7-1 of the form 6-K filed on September 30, 2010 with the SEC and incorporated by reference into this prospectus.

EDAP TMS S.A. shares have not been pledged as collateral in any way.

Capital authorized and not issued

The Shareholders’ Meeting of EDAP TMS S.A. held on June 24, 2010 authorized the Board of Directors to increase the share capital of EDAP TMS S.A., including in cases of tender or exchange offers, through the issuance of shares or other securities, for a maximum total amount of 846,608.10 euros.

Additional information on the current authorizations granted by the Shareholders' Meeting to the Board of Directors in respect of capital increases is provided in the Report of the Board of Directors to the Ordinary and Extraordinary General Meeting of June 24, 2010 and the Project of Resolutions to be submitted to the Ordinary and Extraordinary General Meeting of June 24, 2010 on Form 6-K filed on June 14, 2010 with the SEC.

The following table shows all the current authorizations granted by the Shareholders' Meeting to the Board of Directors in respect of capital increases, and the usage made of these powers during fiscal year 2010.

| NATURE OF AUTHORIZED OPERATION | Valid through | Maximum amount of capital increase (par value) (in euros) | Use of delegation over the year | Balance |
|---|---|---|---|---|
| Authorization to be granted to the Board of Directors to renegotiate the indebtedness of the Company and in particular to amend the terms of the convertible bonds with detachable warrants to purchase ordinary shares issued by the Company on October 29, 2007 (the "OCRABSA"), including by means of issuance of the implementation of any premium payable in shares issuance | 18 months | 846,608.10 | No | N/A |
| Issuance of shares, with cancellation of shareholders' preferential subscription rights, reserved for OCRABSA holders for payments in the form of shares related to the OCRABSA; | 18 months | 846,608.10 | No | N/A |
| Issuance of shares or other securities giving access to the Company's share capital, with cancellation of shareholders' preferential subscription rights in favor of OCRABSA holders to be offered in exchange for the OCRABSA in the context of a private exchange offer that may be initiated by the Company | 18 months | 846,608.10 | No | N/A |
| Issuance of shares or other securities giving access to the Company's share capital, with cancellation of shareholders' preferential subscription right in favor of OCRABSA holders who contractually waive their rights to conversion or reimbursement of all or part of their OCRABSA | | | | |