

EDAP TMS SA
Form 424B3
September 05, 2006
Filed pursuant to Rule 424(b)(3)
Registration No. 333-136811

EDAP TMS S.A.

Up to 961,676 American Depositary Shares
representing up to 961,676 Ordinary Shares

The selling shareholders may offer and sell from time to time an aggregate of up to 961,676 of our ordinary shares, nominal value 0.13, either in the form of shares or American Depositary Shares, also known as ADSs. The ADSs are evidenced by American Depositary Receipts, or ADRs, and each ADS represents one of our ordinary shares. We refer to our shares offered hereunder, whether in the form of shares or ADSs, as Securities. These Securities were acquired by the selling shareholders pursuant to a private placement between us and the selling shareholders and are being registered for sale pursuant to agreements between the selling shareholders and us. All of the Securities listed in this prospectus are being sold by the selling shareholders named in this prospectus or any permitted transferees, pledges, donees or successors-in-interest. We will not receive any proceeds from the sale of Securities being offered in this prospectus.

This offering is not being underwritten. The selling shareholders may sell the Securities being offered by them from time to time on the NASDAQ Global Market, or on any other exchange, market or trading facility on which the Securities are traded or in private transactions, and on terms that may be at fixed, prevailing market or negotiated prices that may vary. The selling shareholders will pay all selling commissions and other offering related fees and expenses, if any, applicable to the sale of the Securities, although we will pay the expenses of registration of the Securities. For additional information on the methods of sale, you should refer to the section entitled Plan of Distribution.

Our ADSs are listed on the NASDAQ Global Market under the symbol EDAP. The last reported sale price of our ADSs on the NASDAQ Global Market on September 1, 2006 was \$7.36.

Investing in our Securities involves risks. See Risk Factors beginning on page 4.

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 September 5, 2006

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ABOUT THIS PROSPECTUS

This prospectus relates to the sale of up to 961,676 of our ordinary shares by persons who are shareholders of EDAP, either in the form of shares or ADSs, which were issued to the selling shareholders in a private placement. In connection with the private placement, we granted the acquiring investors registration rights.

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" 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 the 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.

SUMMARY

The following summary highlights information contained elsewhere in this prospectus. This summary is not complete and does not contain all of the information that may be important to you. You should read the entire prospectus, and any supplement hereto, including the financial statements and related notes and any other information incorporated by reference herein, before making an investment decision.

The Company

We develop and market Ablatherm[®], an advanced and clinically proven 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 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 and also 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 Extra-corporeal 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.

Recent Developments

On July 1, 2006, we launched a subsidiary in Germany under the GmbH structure to further efforts to market Ablatherm-HIFU units in that country. The subsidiary will be headquartered in Flensburg.

On August 3, 2006, we completed the private placement of 961,676 ordinary shares in the form of American Depositary Shares, resulting in net proceeds of approximately \$6.5 million. We expect to use proceeds from the offering to promote the use of Ablatherm-HIFU units among physicians and patients located in key countries in Europe.

The Offering

Company

EDAP TMS S.A.

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Selling Shareholders

The selling shareholders identified under Selling Shareholders.

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Securities Offered

Up to 961,676 ordinary shares, nominal value 0.13 per share, either in the form of shares or ADSs.

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ADSs

Each ADS represents the right to receive one ordinary share. The ADSs are evidenced by American Depositary Receipts, or ADRs, executed and delivered by The Bank of New York, as depositary.

Offer price

The selling shareholders may sell the Securities being offered by them from time to time on the NASDAQ Global Market, or any other exchange, market or trading facility on which the Securities are traded or in private transactions, and on terms that may be at fixed, prevailing market or negotiated prices that may vary. See Plan of Distribution.

Use of proceeds

We will not receive any proceeds from the offering of the Securities by the selling shareholders.

Listing and trading

The ADSs are listed and traded on the NASDAQ Global Market.

Symbol of the ADSs on the NASDAQ
Global Market

EDAP.

Risk Factors

For a discussion of some of the factors that you should carefully consider in connection with an investment in the Securities, see Risk Factors.

RISK FACTORS

We wish to caution you that the following important factors, and those important factors described in other reports submitted to, or filed with, the Securities and Exchange Commission, among other factors, could affect our actual results and could cause our actual results to differ materially from those expressed in any forward-looking statements made by us or on our behalf. In particular, as we are a non-U.S. company, there are risks associated with investing in our ADSs that are not typical for investments in the shares of U.S. companies. Prior to making an investment decision, you should carefully consider all of the information contained or incorporated by reference in this prospectus and any prospectus supplement, including the following risk factors.

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 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. The Ablatherm is not approved for commercial distribution in the United States and none of the Company's other HIFU products (excluding Ablatherm) have obtained approval for commercial distribution anywhere in the world. 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. To assist in the successful completion of clinical trials to obtain FDA approval for the Ablatherm, we partnered with HealthTronics Surgical Services, Inc. (HealthTronics) and signed a Distribution Agreement in February 2004 for assistance in the approval process for re-submission of an IDE to the FDA. Trials in the United States started in May 2006, with several centers fully approved and currently enrolling patients. The identification of HealthTronics as our U.S. partner does not guarantee the successful completion of clinical trials nor does it guarantee that the FDA will grant approval to market a device even if clinical trials are successfully completed. See Uncertainty Relating to Clinical Trials; Clinical Status of Certain Products Using HIFU Technology and 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/A for the 2005 financial year, which is incorporated by reference in this prospectus.

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 conduct clinical trials. Our U.S. partner HealthTronics may decide to cease its cooperation with us under the Distribution Agreement. 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/A for the 2005 financial year, which is incorporated by reference in this prospectus.

We rely on scientific, technical and clinical data supplied by academics that work with us to evaluate and develop our devices. We cannot assure you that there are no errors or omissions in such data that would adversely affect the development of such 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, through our U.S. partner HealthTronics, do not anticipate receiving FDA approval for any HIFU device, including the 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 partial reimbursements in Italy, Germany and 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 2005, 2004 and 2003, moreover, our 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 2005 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. 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 potential continued expansion of the leasing of our products, or the 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. In the future, our liquidity may be constrained and our cash flows may be uncertain, negative or significantly different from period to period. In 2003, we performed an extensive review of our business and adopted measures designed to address cash flow problems in the near term. There is no assurance, however, that these problems will not recur in the medium to long term.

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 2005 and 2004, we had positive operating income in both of our operating divisions (HIFU division and UDS division), reflecting efforts to restructure our operations in late 2003 and in control costs and operating losses in our holding company (holding expenses). We cannot assure you, however, 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/A for the 2005 financial year, which is incorporated by reference in this prospectus.

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 are working with HIFU for the minimally invasive treatment of tumors, including 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 UKHIFU are also involved in the manufacturing, 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. 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, recently signed a development partnership agreement with Siemens Medical Solutions to offer a HIFU device coupled with an IRM imaging system. Finally, Chinamed, a Chinese company, is also developing HIFU products for various types of cancer tumors, but the company is only marketing its HIFU products in China. 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/A for the 2005 financial year, which is incorporated by reference in this prospectus.

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 you 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. 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** in our annual report on Form 20-F/A for the 2005 financial year, which is incorporated by reference in this prospectus.

It is also possible that additional statutes or regulations that affect our business will 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, formerly the Health Care Financing Administration, 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 single 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 are reimbursed in the European Union, in Japan and in the United States. However, a decision to modify reimbursement policies for these procedures could have a material adverse effect on our business, financial conditions and results of operations. Procedures performed with our Ablatherm device are not reimbursed in the United States or in any of the European Union countries with the exception of Italy, Germany and the UK, where it is partially reimbursed. We cannot assure you that additional reimbursement approvals will be obtained. 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 mandated by the FDA and European Union standards for quality assurance and manufacturing process control. 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 single suppliers that for events beyond our control may fail to deliver sufficient supplies to us, which would interrupt our production processes.

We purchase the majority of the components used in our products from a number of suppliers, but rely on a single supplier for several 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, marketing and efforts with respect to the affected products would be delayed. These delays could be extensive, especially in situations where a component substitution would require regulatory approval. 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 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, may be highly uncertain. The medical device industry has been characterized by extensive litigation regarding patents and other intellectual property rights. Our products, including our HIFU devices, may be subject to litigation involving claims of patent infringement or violation of other intellectual property rights of third parties. The defense and prosecution of intellectual property suits, patent opposition proceedings and related legal and administrative proceedings are both costly and time consuming and may result in a significant diversion of effort and resources by our technical and management personnel. An adverse determination in any such litigation or proceeding to which we become a party could: subject us to significant liability to third parties; require us to seek licenses from third parties and pay ongoing royalties; require us to redesign certain products; or subject us to injunctions preventing the manufacture, use or sale of these 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/A for the 2005 financial year, which is incorporated by reference in this prospectus.

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 patents being issued. We also cannot assure you 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 the our ability to make, use or sell certain products either in the United States or in foreign markets, including our HIFU devices.

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.

If the use of any of our products results in personal injury or death, we may face significant product liability claims. To date, we are a party to two product liability actions in the United States by patients claiming to have been injured in the course of a Prostatron procedure, for which we have retained liability following the sale of our Prostatron business in October 2000. See Item 5, Operating and Financial Review and Prospects Critical Accounting Policies Litigation and Item 8, Financial Information Legal Proceedings in our annual report on Form 20-F/A for the 2005 financial year, which is incorporated by reference in this prospectus, for more information about these actions. These product liability claims, if successful, could have a material adverse effect on our business, financial condition and results of operations.

We maintain separate product liability insurance policies for the United States and 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. Also, if any of our products prove to be defective, we may be required to recall or redesign the product. 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.

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 2005, approximately 76% of our selling and general and administrative expenses and approximately 93% of our research and development expenses were denominated in euro, while approximately 42% 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, 2005, we had three options to hedge against Japanese yen for a total nominal amount of JPY45 million (i.e., 331 thousand), in an amount of JPY15 million each, expiring on March, June and September 2006, respectively, and two options to hedge against U.S. dollars for a total nominal amount of US\$200 thousand (i.e., 160 thousand), in an amount of US\$100 thousand each, expiring on February and April 2006, respectively. As of March 31, 2006, we had three new foreign exchange sale contracts, one for the Japanese yen and two for U.S. dollars. 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, cyclicity 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.

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 July 2006 was 80,149, and the high and low bid price of our ADSs for the last two financial years ended on December 31, 2005 and December 31, 2004, has been \$5.68 and \$1.55, respectively, and the high and low bid price of our ADSs between January and July 2006 has been \$21.64 and \$5.30, 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. 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 stockholders.

We have issued 800,000 warrants to HealthTronics, which may be exercised by HealthTronics upon the completion of certain milestones in connection with its efforts to obtain a pre-market approval from the U.S. Food and Drug Administration for Ablatherm. Each warrant may be exercised for \$1.50 to acquire one ordinary share of the Company. 200,000 of these warrants are currently exercisable. In addition, 100,000 stock subscription options are currently exercisable and 552,900 shares may be granted to certain of our employees, depending on whether they achieve certain performance goals during the 2006-2007 period. 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 holders of our Securities, 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 you that we will make dividend payments in the future.

We have not paid any dividend on our shares since 1994, and do not anticipate paying any dividends for the foreseeable future. Declaration of dividends on the 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 Consolidated Financial Statements Dividends and Dividend Policy in our annual report on Form 20-F/A for the 2005 financial year, which is incorporated by reference in this prospectus.

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 ADRs have fewer rights than shareholders and have to act through the depositary to exercise those rights.

Holders of ADRs do not have the same rights as shareholders and accordingly cannot exercise rights of shareholders against us. The Bank of New York, as depositary, or the custodian, is the registered shareholder of the deposited shares underlying the ADSs, and therefore you will generally have to exercise your shareholder rights through The Bank of New York. In certain cases, we may not ask The Bank of New York to ask you for instructions as to how you wish the shares underlying the ADSs evidenced by your ADRs voted. The Bank of New York will not ask you for voting instructions in the absence of written instructions from us to do so. In the event that we did not so instruct The Bank of New York, you could still instruct The Bank of New York how to vote if you otherwise learn of our upcoming shareholders' meeting or vote by surrendering your ADSs, withdrawing your underlying shares, and then voting as ordinary shareholders. Even if we ask The Bank of New York to ask you for such instructions, it may not be possible for The Bank of New York to obtain these instructions from you in time for The Bank of New York to vote in accordance with such instructions. If The Bank of New York does not receive instructions from you, it may give a proxy to vote your underlying ordinary shares or other deposited securities to our designated representative. This means you may not be able to exercise your right to vote and there may be nothing you can do if your underlying ordinary shares or other deposited securities are not voted as you instructed.

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 of 1933, as amended, or 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 our shares in the form of ADSs, The Bank of New York may make these rights or other distributions available to you 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 Bank of New York determines that it is impractical to sell the rights, it may allow these rights to lapse. In that case you will receive no value for them.

If we fail to maintain the effectiveness of the registration statement for the applicable period, we may be subject to substantial penalties.

In connection with the private placement transaction in which we sold the Securities offered hereby to the selling shareholders, we have entered into registration rights agreements to register with the U.S. Securities and Exchange Commission the resale of those Securities.

Under the terms of the registration rights agreements, we are required to use our commercially reasonable efforts to keep the registration statement of which this prospectus is a part effective until the earlier of:

- such time as the Securities covered by the registration statement have been publicly sold by the selling shareholders; or
- the date that all Securities covered by the registration statement may be sold by non-affiliates pursuant to Rule 144(k) as determined by our counsel pursuant to a written opinion letter.

We may be subject to monthly cash penalties equal to one percent of up to the full purchase price of the Securities, or \$74,529.89, if the registration statement ceases to be effective for more than 30 consecutive days or more than an aggregate of 90 days in any 12-month period (assuming that all of the Securities remain entitled to registration hereunder pursuant to the terms of the relevant registration rights agreement). See The Offering.

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, NE, 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.

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 amended annual report on Form 20-F/A for the year ended December 31, 2005 (SEC File No. 000-29374);
- our reports furnished to the SEC on Form 6-K on July 6, 2006, July 27, 2006, August 3, 2006 and August 9, 2006 and on Form 6-K/A on August 18, 2006;
- any future reports on Form 6-K to the extent that we indicate they are incorporated by reference into this registration statement; and
- any future annual reports on Form 20-F that we may file with the SEC under the Exchange Act prior to the termination of the offering contemplated by this prospectus.

Documents on Display

You may request a copy of these documents at no cost to you by writing or telephoning us at our principal executive offices, located at Parc d'Activités la Poudrette- Lamartine, 4/6, rue du Dauphine, 69120 Vaulx-en-Velin, France, +33 (0) 4 78 26 40 46, 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 Securities 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.

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 contained 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 and technological advances in the industry;

the uncertainty of market acceptance for our HIFU devices and our revenue per procedure, or RPP, model;

the uncertainty of reimbursement status of procedures performed with our products;

the clinical status of our HIFU devices;

the impact of government regulation, particularly relating to public healthcare systems and the commercial distribution of medical devices;

dependence on our strategic partners and 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;

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risk of exchange rate fluctuations, particularly between the euro and the U.S. dollar and between the euro and the Japanese yen; and

fluctuations in results of operations due to the cyclical nature of demand for medical devices.

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/A for the 2005 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

The proceeds from the sale of Securities offered pursuant to this prospectus are solely for the account of the selling shareholders. Accordingly, we will receive no proceeds from the sale of the Securities.

CAPITALIZATION AND INDEBTEDNESS

The following table sets out our consolidated short-term debt and capitalization in accordance with U.S. GAAP as of June 30, 2006. Except as disclosed below, there have been no material changes to our consolidated capitalization since June 30, 2006. Because we will not be issuing shares or receiving proceeds in this offering, our capitalization table is not adjusted to reflect the offering. This table should be read in conjunction with our financial statements, which are incorporated by reference in this prospectus.

	(in thousands)	\$(¹)
Current portion of capital lease	434	554
Capital lease obligations, less current portion	492	629
Short-term debt, including current portion of long-term debt	995	1,271
Long-term debt, net of current portion of long-term debt	303	387
Shareholders' equity:		
Share capital (7,837,831 shares, nominal value 0.13 per share, authorized, issued and outstanding) ^{(2), (3)}	1,087	1,389
Additional paid-in capital ⁽³⁾	20,352	26,008
Retained earnings, including cumulative foreign translation adjustment	(4,204)	(5,372)
Deferred stock compensation	417	533
Treasury stock ⁽⁴⁾	(1,595)	(2,039)
Total shareholders' equity	16,057	