

EDAP TMS SA  
Form 424B3  
December 18, 2007  
Filed pursuant to Rule 424(b)(3)

Registration No. 333-147762

## **EDAP TMS S.A.**

### **Up to 2,993,184 Ordinary Shares in the form of**

#### **Ordinary Shares or American Depositary Shares**

The selling shareholders, may offer and sell from time to time an aggregate of up to 2,993,184 of our ordinary shares, nominal value 0.13 each. The shares covered by this prospectus consist of shares of our common stock issuable upon the conversion of our \$20 million aggregate principal amount 9% Senior Debentures due 2012, which we refer to as the Debentures, and shares of our common stock issuable as payment of interest on the Debentures. We sold the Debentures in a private placement transaction on October 31, 2007, which we refer to as the October 2007 private placement.

The selling shareholders may offer and sell the shares 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 are being registered for sale pursuant to an agreement 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. We may however receive proceeds in the event that some or all of the warrants issued to the selling shareholders in the October 2007 private placement, which we refer to as the Warrants, or the warrants issued to our placement agent are exercised for cash instead of via their cashless exercise procedure.

This offering is not being underwritten. The selling shareholders may sell the Securities being offered by it 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 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 December 14, 2007 was \$5.34.

**Investing in our Securities involves risks. See Risk Factors beginning on page 5.**

**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 December 18, 2007



**TABLE OF CONTENTS**

	<b>Page</b>
ABOUT THIS PROSPECTUS	1
SUMMARY	2
RISK FACTORS	4
WHERE YOU CAN FIND MORE INFORMATION ABOUT US	15
FORWARD LOOKING STATEMENTS	16
USE OF PROCEEDS	18
CAPITALIZATION AND INDEBTEDNESS	19
THE OFFERING	25
SELLING SHAREHOLDER	27
DESCRIPTION OF AMERICAN DEPOSITARY RECEIPTS	29
PLAN OF DISTRIBUTION	38
EXPENSES	41
ENFORCEABILITY OF CIVIL LIABILITIES	41
LEGAL MATTERS	42
EXPERTS	42

## ABOUT THIS PROSPECTUS

This prospectus relates to the sale of up to 2,993,184 of our ordinary shares by, the selling shareholders, either in the form of shares or ADSs. The Debentures and Warrants convertible into or exercisable for, respectively, the ordinary shares registered under the registration statement of which this prospectus forms a part were issued to the selling shareholders in the October 2007 private placement, which completed on October 31, 2007. In connection with the private placement, we granted the selling shareholder registration rights with respect to the issuable shares. See The October 2007 Private Placement.

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,<sup>®</sup> an advanced and clinically proven choice for High Intensity Focused Ultrasound ( 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.

### Recent Developments

#### *The October 2007 Private Placement*

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

**The Offering**

Company	EDAP TMS S.A.
---------	---------------

## Edgar Filing: EDAP TMS SA - Form 424B3

Selling Shareholder      The selling shareholders identified under   Selling Shareholders .

## Edgar Filing: EDAP TMS SA - Form 424B3

Securities Offered	Up to 2,993,184 ordinary shares, nominal value 0.13 per share, either in the form of shares or ADSs.
--------------------	--



## Edgar Filing: EDAP TMS SA - Form 424B3

### 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.

## Edgar Filing: EDAP TMS SA - Form 424B3

### Offer price

The selling shareholders may sell the Securities being offered by it 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 at prices and at terms that may be at fixed, prevailing market or negotiated prices that may vary. See Plan of Distribution .

## Edgar Filing: EDAP TMS SA - Form 424B3

### Use of proceeds

We will not receive any proceeds from the offering of the Securities by the selling shareholders. The Warrants may be exercised for cash or, under certain circumstances, via a cashless exercise procedure. If all of the Warrants issued under the October 2007 private placement are fully exercised for cash, including the warrants issued to our placement agent, we will receive approximately \$12.8 million in cash from those warrant holders. We will use any proceeds received from the exercise of Warrants for the purposes agreed to under the terms of the October 2007 private placement.

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 in this prospectus, including the following risk factors.

### Risks Relating to the October 2007 Private Placement

***If we fail to register the resale of Securities by the applicable deadlines and maintain such registration, we will be subject to substantial penalties.***

Under the terms of the registration rights agreement we entered into in connection with the October 2007 private placement, we agreed to secure the registration of a portion of the Securities deliverable upon conversion of the Debentures and in payment of interest under the Debentures by certain dates. In addition, we agreed to secure the registration of the remaining Securities deliverable on conversion of the Debentures and all of the Securities deliverable upon exercise of the Warrants by certain dates. If we fail to achieve effectiveness by the required dates, or maintain the effectiveness of the registration statements required under this registration rights agreement, we are subject to significant penalties, including payment of liquidated damages. See The October 2007 Private Placement. Because of the SEC's recent interpretation of Rule 415, we cannot guarantee we will successfully secure effectiveness of the registration statements or, if it is secured, that we will be able to maintain such effectiveness. Failure to meet these obligations will cause us to incur substantial penalties in the form of liquidated damages and could, given the passage of time, lead to an event of default under the debentures. Payment of liquidated damages or mandatory default amount will have a material adverse effect on our financial condition and results of operation.

***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. We expect that the full amount of the Debentures will be converted into ordinary shares in accordance with the terms of the 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 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 and exercise of outstanding Warrants 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 4,913,102, including 188,965 shares issuable to our placement agent of our ordinary shares are issuable upon conversion and exercise, representing approximately 53% 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 ADRs, 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.

***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 to 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 ADRs. 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 ADRs during the notice period, after our irrevocable notice has been given. In the event our share price were to fall during the notice period, we would have to deliver a higher number of shares than we may have originally planned at the time we gave the irrevocable notice. In the event the number of shares we are required to deliver exceeds the number of shares we are then authorized by our shareholders to issue, we may not be able to deliver all of the interest shares then due. Additionally, if, on the day we pay interest, we do not fulfill the relevant conditions, we are not permitted to pay interest in the form of ordinary shares. In the event we are not able to deliver shares for any reasons, 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.

***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 September 30, 2007 was 1.689 million (approximately \$2.402 million) and represented approximately 8% of our total capitalization, including the current portion of indebtedness of approximately 0.537 million (approximately \$0.764 million), as of that date. We incurred an additional \$20 million in indebtedness in connection with the October 2007 private placement. 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 you.***

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. Securities issued to our employees under plans, subject to certain volume limits, will be an exempt issuance, as will 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 operate to discourage third parties from engaging in these transactions with us, even if those transactions would be beneficial to us and our shareholders.

### **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 ( HIFU ) technology for future revenue growth and net income. Our Extracorporeal Shockwave Lithotripsy ( ESWL ) line of products competes in a mature market that has experienced declining unit sales prices in recent years, although total revenues have remained stable owing to increased sales volumes. In particular, we are dependent on the successful development and commercialization of other product lines, such as medical devices based on HIFU, particularly the Ablatherm, to generate significant additional revenues and achieve and sustain profitability in the future. The Ablatherm is in its commercialization phase in the European Union, Canada and other countries. However, the Ablatherm is not approved for commercial distribution in the United States. In December 2001, our request for an additional Investigational Device Exemption ( IDE ) from the U.S. Food and Drug Administration ( FDA ) to conduct clinical trials in the United States for the Ablatherm as a primary therapy was rejected. We plan to resume and complete the clinical trials necessary to obtain FDA approval of the Ablatherm now that we have completed the October 2007 private placement, which resulted in net proceeds of approximately \$17.4 million. While we expect these funds to be sufficient to enable us to fund the clinical trials in their entirety, we cannot guarantee that the proceeds will in fact be enough to do so. Also, 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 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 2006 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. We may not have the necessary resources to pursue the trials. See 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 2006 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 our products.

The process of applying for regulatory approval is unpredictable, often lengthy and requires the expenditure of substantial resources. Our HIFU devices that have not received regulatory approval may not prove to be effective or safe in clinical trials or may not be approved by the appropriate regulatory authorities. We do not anticipate receiving FDA approval for any HIFU device, including the Ablatherm, for 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 United Kingdom, 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 2006, 2005 and 2004, 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 2006 and 2005 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. 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. In the future, our liquidity may be constrained and our cash flows may be uncertain, negative or significantly different from period to period. In 2006, we raised new equity

funds via a \$7.5 million Private Investment in Public Equity, aimed at financing our new marketing and sales campaign to promote and develop the revenue-per-procedure business in key European countries. 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.

***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 to control costs and operating losses in our holding company (holding expenses). In 2006, however, we had negative operating income in both of our operating divisions (HIFU division and UDS division), reflecting the clinical, marketing and sales efforts in the HIFU division to develop HIFU's status as a standard of care, and the R&D and regulatory efforts in the UDS division to develop a new, high-range lithotripter. We cannot assure you that we will realize sufficient revenue to become profitable in the future. See Item 5, Operating and Financial Review and Prospects included in our annual report on Form 20-F for the 2006 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, signed a development partnership agreement with Siemens Medical Solutions to offer a HIFU device coupled with IRM imaging system. Finally, Chinamed (China Medical Technology), 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 (HIFU) Division HIFU Competition and Item 4, Information on the Company Urology Devices and Services (UDS) Division, each included in our annual report on Form 20-F for the 2006 financial year, which is incorporated by reference in this prospectus. On April 25, 2007, we signed an exclusive distribution agreement with Chinamed to distribute their HIFU devices in the European Union and Russia once their devices are approved for use in those jurisdictions and on September 21, 2007, we signed a Consulting Agreement with them, pursuant to which we will assist them in obtaining market approvals in Europe for their HIFU products.

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, sales, 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, we plan to go through the FDA approval process with our Ablatherm device. 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 included in our annual report on Form 20-F for the 2006 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 ( CMS ), formerly the Health Care Financing Administration ( HCFA ), for Medicare reimbursement, individual managed care organizations, private insurers and other payers. These decisions may be revised from time to time, which could affect reimbursement for procedures performed using our devices. Outside the United States, and in particular in the European Union and Japan, third-party reimbursement is generally conditioned upon decisions by national health authorities. In the European Union, there is no 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 ( GMP ) 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 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. 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 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 (HIFU) Division HIFU Division Patents and Intellectual Property and Item 4, Information on the Company Urology Devices and Services (UDS) Division UDS Division Patents and Intellectual Property, each included in our annual report on Form 20-F for the 2006 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 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, each included in our annual report on Form 20-F for the 2006 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 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. 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 2006, approximately 79% of our selling, marketing and general and administrative expenses and approximately 91% of our research and development expenses were denominated in euro, while approximately 32% 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 September 30, 2007, we had an outstanding hedging instrument on the Japanese Yen exchange rate. 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 October 2007 was 8,330, the high and low bid price of our ADSs for the last two financial years ended on December 31, 2006 and December 31, 2005, has been \$21.64 and \$5.12, and \$5.68 and \$3.10 respectively, and the high and low bid price of our ADSs between January and October 2007 has been \$9.40 and \$4.60, 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 existing shareholders.***

The extraordinary general meeting of our shareholders held on May 22, 2007 delegated to our Board of Directors the authority to issue up to 6,000,000 additional shares, either in the form of shares or through the issuance of securities exercisable for or convertible into our shares. We used this authorization to issue the Debentures and Warrants in the October 2007 private placement. These securities were issued without preferential subscription rights. See The issuance of shares upon conversion of the Debentures and exercise of outstanding Warrants will cause immediate and substantial dilution to our existing shareholders. above. In addition, 600,000 of the shares authorized at the May 22, 2007 shareholders meeting were allowed to be granted to certain of our employees through the issuance of subscription options. On October 29, 2007, 504,088 options to subscribe to 504,088 new shares were granted to certain employees. Finally, 237,340 new ordinary shares may be granted to certain of our employees if they achieve certain performance goals during the 2007-2008 period pursuant to the Shareholders authorization dated February 17, 2005. 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 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. 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 2006 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 register the resale of certain other securities by the applicable deadlines and maintain such registration, we may be subject to substantial penalties.***

Prior to the October 2007 private placement, we had two existing registration rights agreements in force with respect to our securities. Under the terms of those registration rights agreements, we are required to secure effectiveness of Securities Act registration statements and keep such registration statements effective for extended periods of time, including, depending on the relevant circumstances, until such time as all securities covered by those registration statements have been sold or for two years from the effectiveness of those registration statements. As of the date of this prospectus, we have not secured effectiveness of one of those registration statements. Further, we may be subject to monthly cash penalties if either of these registration statements ceases to be effective for more than 30 consecutive days or more than an aggregate of 90 days in any 12-month period.

## 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 annual report on Form 20-F for the year ended December 31, 2006 (SEC File No. 000-29374);

- our reports furnished to the SEC on Form 6-K on April 4, 2007, April 12, 2007, May 11, 2007, July 16, 2007, August 30, 2007, both reports furnished on October 31, 2007, November 6, 2007, November 26, 2007 (which includes certain recently published unaudited financial information) and November 30, 2007 (which includes unaudited financial information supplemental to the information furnished on November 26, 2007);

- 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 the documents incorporated by reference herein 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](http://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:

- our ability to secure and maintain effectiveness of the registration statements required under the terms of the October 2007 private placement;
- our ability to pay interest on the Debentures in the form of ordinary shares if we give notice that we will do so;
- 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;
- 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 for the 2006 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. The Warrants may be exercised for cash or, under certain circumstances, via a cashless exercise procedure. If all of the Warrants issued under the October 2007 private placement are fully exercised for cash, we will receive approximately \$12.8 million in cash from the Warrant holders. We will use any proceeds received from the exercise of Warrants for the purposes agreed to under the terms of the October 2007 private placement.