EDAP TMS SA
Form 20-F
March 31, 2009
As filed with the Securities and Exchange Commission on March 31, 2009

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 20-F

ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF

THE SECURITIES EXCHANGE ACT OF 1934

For the Fiscal Year Ended December 31, 2008

0-29374

(Commission file number)

EDAP TMS S.A.

(Exact name of registrant as specified in its charter)

France

(Jurisdiction of incorporation or organization)

Parc d'Activites la Poudrette-Lamartine

4/6, rue du Dauphine

69120 Vaulx-en-Velin, France

(Address of principal executive offices)

Securities registered or to be registered pursuant to Section 12(b) of the Act:

Title of each class	Name of each exchange on which registered
American Depositary Shares, each representing One Ordinary Share	**NASDAQ Global Market**
Ordinary Shares, nominal value €0.13 per share	**NASDAQ Global Market**

Securities registered or to be registered pursuant to Section 12(g) of the Act:

None

Securities for which there is a reporting obligation pursuant to Section 15(d) of the Act: None

Outstanding shares of each of the issuer's classes of capital or common stock as of December 31, 2008: **9,582,593 Ordinary Shares**

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act.

Yes _____ No ____X____

If this report is an annual or transition report, indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934.

Yes _____ No ____X____

Indicate by check mark whether the registrant: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports) and (2) has been subject to such filing requirements for the past 90 days.

Yes ____X____ No _____

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, or a non-accelerated filer. See definition of “accelerated filer and large accelerated filer” in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer _____ Accelerated filer _____ Non-accelerated filed _____x_____

Indicate by check mark which basis of accounting the registrant has used to prepare the financial statements included in this filing:

U.S. GAAP _X_ International Financial Reporting Standards as issued by the International Accounting Standards Board __ Other

If "Other" has been checked in response to the previous question indicate by check mark which financial statement item the registrant has elected to follow. Item 17_____ Item 18_____

If this is an annual report, indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act).

Yes _____ No ____X____

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PRESENTATION OF FINANCIAL AND OTHER INFORMATION

Unless the context otherwise requires, references herein to “we,” “us” or “our” are to EDAP TMS S.A. and its consolidated subsidiaries and references herein to the “Company,” “EDAP” or “EDAP TMS” are to EDAP TMS S.A.

We prepare our consolidated financial statements in conformity with United States generally accepted accounting principles (‘‘U.S. GAAP’’). In this Annual Report, references to ‘‘euro’’ or ‘‘€’’ are to the legal currency of the countries of the European Monetary Union, including the Republic of France, and references to ‘‘dollars,’’ ‘‘U.S. dollars’’ or ‘‘$’’ are to the legal currency of the United States of America. Solely for the convenience of the reader, this Annual Report contains translations of certain euro amounts into dollars at specified rates. These translations should not be construed as representations that the euro amounts actually represent such dollar amounts or could be converted into dollars at those rates. Unless otherwise stated, the translations of euro into dollars have been made at the rate of U.S.$1.00 = €0.7184, the rate derived from the noon buying rate in The City of New York for cable transfers in euro as certified for customs purposes by the Federal Reserve Bank of New York (the ‘‘Noon Buying Rate’’) on December 31, 2008. See Item 3, ‘‘Key Information—Exchange Rates’’ for information regarding certain currency exchange rates and Item 11, ‘‘Quantitative and Qualitative Disclosures about Market Risk’’ for a discussion of the effects of fluctuations in currency exchange rates on the Company.

The following are registered trademarks of the Company in the United States: EDAP TMS, EDAP, Technomed, Ablatherm, Ablasonic, Ablapak, Praktis, Pulsolith, Sonolith. This Annual Report also makes references to trade names and trademarks of companies other than the Company.

FORWARD-LOOKING INFORMATION

This report includes certain forward-looking statements, usually containing words such as ‘‘believe,’’ ‘‘plan,’’ ‘‘intend,’’ ‘‘estimate,’’ ‘‘expect’’ and ‘‘anti or similar expressions, which reflect our views about future events and financial performance. Actual events or results may differ materially from those projected in such forward-looking statements as a result of various factors that may be beyond our control. These factors include, without limitation:

- the effects of intense competition in the markets in which we operate;
- the uncertainty of market acceptance for our HIFU devices;
- the 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 suppliers;
- any event or other occurrence that would interrupt operations at our primary production facility,
- reliance on patents, licenses and key proprietary technologies;
- product liability risk;
- risk of exchange rate fluctuations, particularly between the euro and the U.S. dollar and between the euro and the Japanese yen;
- fluctuations in results of operations due to the cyclical nature of demand for medical devices;
- risks associated to the current uncertain worldwide economic and financial environment;
- risks associated with the October 2007 private placement;
- risks relating to ownership of our securities; and
- changes in the fair value of the debentures and warrants issued in the October 2007 private placement.

You should also consider the information contained in Item 3, ‘‘Key Information—Risk Factors’’ and Item 5, ‘‘Operating and Financial Review and Prospects,’’ as well as the information contained in our periodic filings with the Securities and Exchange Commission (including our reports on Form 6-K) for further discussion of the risks and uncertainties that may cause such differences to occur.

PART I

Item 1. Identity of Directors, Senior Management and Advisors

Not applicable.

Item 2. Offer Statistics and Expected Timetable

Not applicable.

Item 3. Key Information

Selected Financial Data

The following table sets forth selected consolidated financial data for the periods indicated. This information is qualified by and should be read in conjunction with the Consolidated Financial Statements and the Notes thereto included in Part III of this annual report, as well as Item 5, ''Operating and Financial Review and Prospects.'' The selected balance sheet data as of December 31, 2006, 2007 and 2008 and the selected income statement data for the years ended December 31, 2006, 2007 and 2008 set forth below have been derived from our Consolidated Financial Statements included in this annual report. The selected balance sheet data as of December 31, 2004 and 2005 and the selected income statement data for the year ended December 31, 2004 and 2005 have been derived from our audited consolidated financial statements as of and for the years ended December 31, 2004 and 2005. These financial statements, together with our Consolidated Financial Statements have been prepared in accordance with U.S. GAAP. To date, we have not been required, and presently are not required under French law, to prepare consolidated financial statements under French GAAP or IFRS, nor have we done so.

	Year Ended and at December 31,				
In thousands of euro, except per share data in euro	**2004**	**2005**	**2006**	**2007**	**2008**
INCOME STATEMENT DATA					
Total revenues	22,163	20,810	20,265	22,327	23,053
Total net sales	21,955	20,717	20,174	22,213	22,856
Gross profit	8,487	8,497	8,319	9,179	9,099
Operating expenses	(9,317)	(9,820)	(11,413)	(13,268)	(13,802)
Loss from operations	(830)	(1,323)	(3,094)	(4,089)	(4,703)
Income (loss) before income taxes	(871)	(961)	(3,375)	(5,571)	1,105
Income tax (expense) benefit	(278)	(104)	(56)	140	492
Net income (loss)	(1,149)	(1,065)	(3,431)	(5,430)	1,597
Basic earnings (loss) per share	(0.15)	(0.14)	(0.39)	(0.59)	0.17
Diluted earnings (loss) per share	(0.15)	(0.14)	(0.39)	(0.59)	0.17
Dividends per share[(1)]	—	—	—	—	
Basic weighted average shares outstanding	7,781,731	7,782,731	8,817,007	9,200,757	9,582,593
Diluted weighted average shares outstanding	7,781,731	7,782,731	8,817,007	9,200,757	9,658,295
BALANCE SHEET DATA					
Total current assets	22,041	22,777	26,393	36,124	35,786
Property and equipment, net	2,807	3,130	3,211	4,179	3,763
Total current liabilities	8,272	9,874	10,926	12,884	14,457
Total assets	27,901	28,796	32,473	45,003	43,863
Long-term debt, less current portion	—	55	58	15,174	10,318
Total shareholders' equity	17,964	17,372	19,300	14,499	16,374

(1) No dividends were paid with respect to fiscal years 2004 through 2007 and subject to approval of the annual shareholders' meeting to be held in June 2009, the Company does not anticipate paying any dividend with respect to fiscal year 2008. See Item 8, ''Financial Information — Dividends and Dividend Policy.''

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EXCHANGE RATES

Fluctuations in the exchange rate between the euro and the dollar will affect the dollar amounts received by owners of American Depositary Shares (''ADSs'') representing ordinary shares of the Company (''Shares'') on conversion by the Depositary of dividends, if any, paid on the Shares in the form of ADSs. Moreover, such fluctuations may affect the dollar price of our ADSs on NASDAQ.

The following table sets forth, for each of the years indicated, the high, low, average and year-end Noon Buying Rates expressed in euro per $1.00.

Year ended December 31,	**High**	**Low**	**Average[(1)]**	**End of Year**
	€	**€**	**€**	**€**
2004	0.85	0.73	0.80	0.74
2005	0.86	0.74	0.81	0.84
2006	0.84	0.75	0.79	0.76
2007	0.78	0.67	0.73	0.68
2008	0.80	0.62	0.68	0.72

(1) The average of the Noon Buying Rates on the last business day of each month during the year indicated. See ''Presentation of Financial and Other Information'' elsewhere in this annual report.

The following table sets forth, for each of the previous six months, the high and low Noon Buying

Rates expressed in euro per $1.00.

	End of Month	**High**	**Low**	**Average**
	€	**€**	**€**	**€**
2008				
September	0.71	0.72	0.68	0.70
October	0.79	0.80	0.71	0.75
November	0.79	0.80	0.77	0.78
December	0.72	0.79	0.70	0.74
2009				
January	0.78	0.78	0.72	0.76
February	0.79	0.79	0.77	0.78

March, through March 20, 2009	0.74	0.80	0.73	0.78

On March 20, 2009, the Noon Buying Rate was U.S.$1.00 = €0.74.

RISK FACTORS

In addition to the other information contained in this annual report, the following risk factors should be carefully considered in evaluating us and our business. These statements are intended to highlight the material risk factors that may affect our business results.

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. After redesigning the clinical protocol, we resumed and plan to complete the clinical trials necessary to obtain FDA approval of the Ablatherm using the $17.4 million net proceeds of the October 2007 private placement. While we expect these funds to be sufficient to enable us to fund the clinical trials in their entirety, we cannot guarantee that the proceeds will in fact be enough to do so. 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."

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

Before obtaining regulatory approvals for the commercial sale of any of our devices under development, we must demonstrate through preclinical testing and clinical trials that the device is safe and effective for use in each indication. The results from preclinical testing and early clinical trials may not predict the results that will be obtained in large scale clinical trials, and there can be no assurance that our clinical trials will demonstrate that our products are safe, effective, and marketable. A number of companies have suffered significant setbacks in advanced clinical trials, even after promising results in earlier trials. We, the FDA or other regulatory authorities may suspend or terminate clinical trials at any time and regulating agencies such as the FDA may even refuse to grant exemptions to pursue clinical trials. See Item 4, ''Information on the Company—High Intensity Focused Ultrasound Division—HIFU Division Clinical and Regulatory Status.''

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

The process of applying for regulatory approval is unpredictable, often lengthy and requires the expenditure of substantial resources. Our HIFU devices that have not received regulatory approval may not prove to be effective or safe in clinical trials or may not be approved by the appropriate regulatory authorities. We do not anticipate receiving FDA approval for any HIFU device, including the Ablatherm, for several years, if at all. If our HIFU devices do not prove to be effective and safe in clinical trials to the satisfaction of the relevant regulatory authorities, our business, financial condition and results of operations could be materially adversely affected.

HIFU technology may not be accepted and adopted by the medical community.

Our HIFU devices represent new therapies for the conditions that they are designed to treat. Notwithstanding any positive clinical results that our HIFU devices may have achieved or may achieve in the future in terms of safety and effectiveness, and any marketing approvals that we may have obtained or may obtain in the future, there can be no assurance that such products will gain acceptance in the medical community. Physician acceptance depends, among other things, on adequate reimbursement from healthcare payers, which has not been provided for our HIFU products in any country, except for full public reimbursement in Germany and Italy and partial reimbursement from private insurers in the UK, and evidence of the cost effectiveness of a therapy as compared to existing therapies. Acceptance by patients depends in part on physician recommendations, as well as other factors, including the degree of invasiveness and the rate and severity of complications and other side effects associated with the therapy as compared to other therapies.

Our cash flow is highly dependent on demand for our products.

Our cash flow has historically been subject to significant fluctuations over the course of any given financial year due to cyclical demand for medical devices, and the resulting annual and quarterly fluctuations in trade and other receivables and inventories. This has in the past resulted in significant variations in working capital requirements and operating cash flows. In 2008, 2007 and 2006, 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 2008, 2007 and 2006 operating cash flow was negative due to the cash requirements of investing activity to expand our mobile activity and to expand the leasing of our products as part of our revenue-per-procedure model, and, in 2007, due to the sponsoring of the pre-market approval (‘‘PMA’’) trials for the FDA’s approval of our Ablatherm-HIFU solution for the treatment of prostate cancer in the United States. Since we anticipate relying principally on cash flow from operating activities to meet our liquidity requirements, a decrease in the demand for our products, or the inability of our customers to meet their financial obligations to us, would reduce the funds available to us. Our future cash flow may also be affected by the expected continued expansion of the leasing of our products, or the continued expansion of our mobile activity (which is invoiced on a revenue-per-procedure basis), since each of these activities generates smaller immediate revenues than device sales, and by the implementation of our US clinical trials to seek the FDA’s approval. In the future, our liquidity may be constrained and our cash flows may be uncertain, negative or significantly different from period to period. 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. Our future cash flow will be affected by the increased expenses in sales efforts as well as marketing and promotion tools, while there is no assurance that this will result in the increase in the demand for our products and services. In October 2007, we raised a $20 million convertible debt via a Private Investment in Public Equity, aimed at financing our pre-market approval trial process to seek the FDA’s approval on our Ablatherm-HIFU solution for the treatment of prostate cancer in the United States (our Ablatherm device, considered as a Class III device by the FDA, must receive pre-market approval by the FDA to ensure its safety and effectiveness). Our future cash flow will be affected by the increased expenses to fund the trials, while there is no assurance that our cash flow will in fact be enough to do so or that clinical trials will be successful or that the FDA will grant approval to market our device even if the trials are successfully completed.

We have a history of operating losses and it is uncertain when and if we will reach profitability.

We have incurred operating losses in each fiscal year since 1998 and may never achieve profitability. We expect that our marketing, selling and research and development expenses will increase as we attempt to develop and commercialize HIFU devices. We may not, however, generate a sufficient level of revenue to offset these expenses and may not be able to adjust spending in a timely manner to respond to any unanticipated decline in revenue. In 2006, we had negative operating income in both of our operating divisions (HIFU division and “Urology Device and Services” (“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

research and development ("R&D") and regulatory efforts in the UDS division to develop a new, high-range lithotripter. In 2007, we also had negative operating income in our UDS division, reflecting the R&D and regulatory efforts in the UDS division to develop a new, high-range lithotripter, and in connection with our FDA/PMA trials, reflecting the regulatory and clinical efforts to resume and conduct our Ablatherm-HIFU PMA trials. Total costs were equal to total revenues for our HIFU division in 2007, due to the increase in revenues and margin on HIFU equipment and RPP treatment sales. In 2008, we again had negative operating income in our UDS division, reflecting sharp price competition in this business together with non-optimal manufacturing costs on our newly developed Sonolith I-sys product range. We cannot assure investors that we will realize sufficient revenue to become profitable in the future. See Item 5, ''Operating and Financial Review and Prospects.''

Competition in the markets in which we operate is intense and is expected to increase in the future.

Competition in the markets in which we operate is intense and is expected to increase in the future. In each of our main businesses, we face competition both directly from other manufacturers of medical devices that apply the same technologies that we use, as well as indirectly from existing or emerging therapies for the treatment of urological disorders.

We believe that because ESWL has long been the standard treatment for urinary tract calculus disease, competition in that market comes principally from current manufacturers of lithotripters, including Siemens, Storz and Dornier. In the markets that we target for our HIFU products, competition comes from new market entrants and alternative therapies, as well as from current manufacturers of medical devices. In the HIFU market our devices, in particular the Ablatherm, compete with all current treatments for localized tumors, including surgery, external beam radiotherapy, brachytherapy and cryotherapy. Other companies 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. In some cases, we also form cooperative arrangements with other companies. For example, on April 25, 2007, we signed an exclusive distribution agreement with China Medical Technologies ("Chinamed"), a Chinese company, to distribute their HIFU devices in the European Union and Russia once their devices are approved for use in those jurisdictions. Prior to this agreement, Chinamed had been developing HIFU products for various types of cancer tumors, but only marketing its HIFU products in China. In September 21, 2007, we entered into a Consulting Agreement with Chinamed, pursuant to which we will assist them in obtaining market approvals in Europe for their HIFU products. On December 31, 2008, the HIFU business of Chinamed was acquired by another Chinese company, Haifuning HIFU Technology (Beijing) Co. Ltd ("Haifuning"), which plans to pursue development of the HIFU technologies. Both the Distribution Agreement and the Consulting Agreement were assigned to Haifuning in connection with the acquisition. See Item 4, ''Information on the Company—High Intensity Focused Ultrasound Division— HIFU Competition'' and Item 4, ''Information on the Company—Urology Devices and Services Division.''

Many of our competitors have significantly greater financial, technical, research, marketing, sales, distribution and other resources than us and may have more experience in developing, manufacturing, marketing and supporting new medical devices. In addition, our future success will depend in large part on our ability to maintain a leading position in technological innovation, and we cannot assure investors that we will be able to develop new products or enhance our current ones to compete successfully with new or existing technologies. Rapid technological development by competitors may result in our products becoming obsolete before we recover a significant portion of the research, development and commercialization expenses incurred with respect to those products.

We also face competition for our maintenance and service contracts. Larger hospitals often utilize their in-house maintenance departments instead of contracting with equipment manufacturers like us to

maintain and repair their medical equipment. In addition, third-party medical equipment maintenance companies increasingly compete with equipment manufacturers by offering broad repair and maintenance service contracts to hospitals and clinics. This increased competition for medical devices and maintenance and service contracts could have a material adverse effect on our business, financial condition and results of operations.

We operate in a highly regulated industry and our future success depends on government regulatory approval of our products, which we may not receive or which may be delayed for a significant period of time.

Government regulation significantly impacts the development and marketing of our products, particularly in the United States. We are regulated in each of our major markets with respect to preclinical and clinical testing, manufacturing, labeling, distribution, sale, marketing, advertising and promotion of our products. To market and sell products still in the clinical trial stage, we are required to obtain approval or clearance from the relevant regulatory agencies, including the FDA in the United States. In particular, we are currently going through the FDA approval process for 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.’’

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. In contrast, 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 investors 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. There is a risk that we may not comply with all applicable standards and, therefore, will be unable to manufacture our products for commercial sale. Our manufacturing facilities are subject to inspection by regulatory authorities at any time. If any inspection by the regulatory authorities reveals deficiencies in manufacturing, we could be required to take immediate remedial actions, suspend production or close the current and future production facilities, which would disrupt our manufacturing processes. Accordingly, failure to comply with these regulations could have a material adverse effect on our business, financial condition and results of operations.

We depend on a single site to manufacture our products, and any interruption of operations could have a material adverse effect on our business.

Most of our manufacturing currently takes place in a single facility located in Vaulx-en-Velin, on the outskirts of Lyon, France. A significant interruption in the operations of our sole facility for any reason, such as fire, flood or other natural disaster or a failure to obtain or maintain required regulatory approvals, could have a material adverse effect on our business, financial condition and results of operations.

For certain components or services we depend on 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 Division—HIFU Division Patents and Intellectual Property'' and Item 4, ''Information on the Company—Urology Devices and Services Division—UDS Division Patents and Intellectual Property.''

We own patents covering several of our technologies and have additional patent applications pending in the United States, the European Union, Japan and elsewhere. The process of seeking patent

protection can be long and expensive and there can be no assurance that our patent applications will result in the issuance of patents. We also cannot assure investors that our current or future patents are or will be sufficient to provide meaningful protection or commercial advantage to us. Our patents or patent applications could be challenged, invalidated or circumvented in the future. The failure to maintain or obtain necessary patents, licenses or other intellectual property rights from third parties on acceptable terms or the invalidation or cancellation of material patents could have a material adverse effect on our business, financial condition or results of operations. Litigation may be necessary to enforce patents issued to us or to determine the enforceability, scope and validity of the proprietary rights of others. Our competitors, many of which have substantial resources and have made substantial investments in competing technologies, may apply for and obtain patents that will interfere with our ability to make, use or sell certain products, including our HIFU devices, either in the United States or in foreign markets.

We also rely on trade secrets and proprietary know-how, which we seek to protect through non-disclosure agreements with employees, consultants and other parties. It is possible, however, that those non-disclosure agreements will be breached, that we will not have adequate remedies for any such breach, or that our trade secrets will become known to, or independently developed by, competitors. Litigation may be necessary to protect trade secrets or know-how owned by us. In addition, effective copyright and trade secret protection may be unavailable or limited in certain countries.

The occurrence of any of the foregoing could have a material adverse effect on our business, financial condition and result of operations.

We face a significant risk of exposure to product liability claims in the event that the use of our products results in personal injury or death.

If the use of any of our products results in personal injury or death, we may face significant product liability claims. For example, in 2000, a patient made a product liability claim against us in the United States, alleging that he was injured in the course of a Prostatron procedure, for which we remained liablefollowing the sale of our Prostatron business in October 2000. In February 2008, we reached a settlement for this claim in the amount of $15,000, which was fully covered by our Product Liability insurance. See Item 5, ‘‘Operating and Financial Review and Prospects—Critical Accounting Policies—Litigation’’ and Item 8, ‘‘Financial Information—Legal Proceedings’’ for more information about this action.

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 2008, approximately 66% of our total operating expenses were denominated in euro, while approximately 25% 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, 2008, we had

no outstanding hedging instruments. In addition, since any dividends that we may declare will be denominated in euro, exchange rate fluctuations will affect the U.S. dollar equivalent of any dividends received by holders of ADSs.

Our results of operations have fluctuated significantly from quarter to quarter in the past and may continue to do so in the future.

Our results of operations have fluctuated in the past and are expected to continue to fluctuate significantly from quarter to quarter depending upon numerous factors, including, but not limited to, the timing and results of clinical trials, changes in healthcare reimbursement policies, cyclicality of demand for our products, changes in pricing policies by us or our competitors, new product announcements by us or our competitors, customer order deferrals in anticipation of new or enhanced products offered by us or our competitors, product quality problems and exchange rate fluctuations. Furthermore, because our main products have relatively high unit prices, the amount and timing of individual orders can have a substantial effect on our results of operations in any given quarter.

Our results of operations and financial condition could be adversely affected by the adverse economic and financial developments.

The current economic and financial environment may affect the level of public and private spending in the healthcare sector generally. A cautious or negative business outlook may cause our customers to delay or cancel investment in medical equipment, which would adversely affect our revenues.

In addition, we rely on the credit market to secure dedicated lease financings to fund the development of our RPP activity. Due to the limited availability of lending in the current market environment, we may be unable to access sufficient lease financing. Without lease financing, we may be unable to continue the development of our RPP activity or we may need to fund such activity out of our existing working capital. Similarly, some of our clients rely on lease financing to finance their purchases of equipment. Limited availability of lease financing facilities may also affect their purchasing decisions and may adversely impact our equipment sales.

In accordance with the terms of our debentures, we have the option to pay interest on the debentures in shares. The current economic and financial environment may adversely affect our share price, thus we may be unable to make payment in shares without significantly diluting the interest of the existing shareholders. If we are unable to issue shares on reasonable terms, we may need to make interest payment in cash, thus negatively affecting our working capital.

Further, the volatility in our share price due to the current economic and financial environment has had a direct impact on the valuation of the debentures and warrants issued in the October 2007 private placement, which in turn could have a material adverse impact on our financial conditions. See “Changes in the fair value of the debentures and warrants issued in the October 2007 private placement at each balance sheet date could have a significant impact on our financial condition and results of operations.”

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

Risks Relating to the October 2007 Private Placement

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

As per the terms of the registration rights agreement we entered into in connection with the October 2007 private placement, we secured the registration of a portion of the securities deliverable upon conversion of the debentures and in payment of interest under the debentures as well as the securities

deliverable upon exercise of the warrants. If we fail to maintain the effectiveness of the registration statements required under the registration rights agreement, we are subject to significant penalties, including payment of liquidated damages. Failure to meet these obligations will cause us to incur substantial penalties in the form of liquidated damages and could, given the passage of time, lead to an event of default under the debentures. Payment of liquidated damages or mandatory default amount will have a material adverse effect on our financial condition and results of operation and our ability to continue as a going concern.

If we are required for any reason to repay our outstanding 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, exercise of outstanding warrants and payment of interests on the debentures will cause immediate and substantial dilution to our existing shareholders.

The issuance of ordinary shares upon conversion of the debentures and exercise of the warrants will result in substantial dilution to the interests of other shareholders since the selling shareholders may ultimately convert and sell the full amount issuable on conversion. Based on the conversion price of the debentures and the exercise price of the warrants at the closing of the October 2007 private placement, up to 4,913,102, 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.

Further, on February 26, 2009, our shareholders adopted a resolution authorizing the issuance of 3,000,000 new shares, representing a 20% of our issued and outstanding share capital on a fully diluted basis. We plan to use these new shares exclusively to pay all of the interest payable under the debentures in shares on April 1, 2009 and each subsequent interest payment date, unless we notify holders of the debentures otherwise, in accordance with the terms of the debentures.

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

As noted above, interest on the debentures is payable, under certain circumstances, in ordinary shares, under a formula which is tied to the trading price of our 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 reason, we will be subject to late fees and our debenture holders may decline to receive interest paid in cash. In the event they do not accept payment in cash, we would not be able to make a complete interest payment or any interest payment at all, which will result in an event of default under the debentures. An event of default with respect to the debentures would have a material adverse effect on our financial conditions and results of operations.

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 December 31, 2008 was €9.6 million and represented approximately 22% of our total capitalization, including the current portion of indebtedness of approximately €0.079 million as of that date. Our level of indebtedness could have important consequences on our future operations, including:

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

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

The debentures prohibit us from engaging in certain transactions, each known as a "fundamental transaction", including any merger, the sale of all of our assets or a tender offer under which our shareholders are permitted to exchange their shares for cash, securities or property, unless the successor entity agrees to comply with the requirement to provide our debenture holders, upon conversion, with the same property provided to our existing shareholders under the terms of the fundamental transaction. In addition, if we are party to a "fundamental transaction" or "change of control" (as defined in the debenture) or agree to dispose of in excess of 40% of our assets, the holders have the right to require us to redeem the debentures at their election shortly after they are notified of such a change. Any redemption under these circumstances will be at a premium equal to the higher of 130% of the then-outstanding principal amount of the debenture or the outstanding principal amount of the debenture, plus all accrued and unpaid interest, divided by the conversion price then in effect, multiplied by the VWAP (as defined in the debenture) then in effect.

In addition, under the terms of the securities purchase agreement we entered into in the October 2007 private placement, for so long as the debentures are outstanding, we are required to offer the investors who purchased debentures and warrants in the October 2007 private placement the right to participate in certain types of financings we arrange in the future, up to 50% of the value of such financing. We must provide this opportunity unless the offering is an underwritten public offering or an "exempt issuance". 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.

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

We use various market parameters to evaluate the fair value of the convertible debentures and warrants issued in the October 2007 private placement at each balance sheet date which could have a significant impact on our financial condition and results of operation as a result of changes in these market parameters. The following market parameters are most likely to change at each balance sheet date and the following paragraphs describe how hypothetical increases or decreases in those market parameters would have affected the US Dollar fair value of the debentures and warrants as of December 31, 2008:

- stock volatility: as of December 31, 2008 and every other market parameter being equal, an increase in the stock volatility of 5 percentage points would have resulted in an increase of 2% in the fair value of the convertible debentures and warrants, and a decrease in the stock volatility of 5 percentage points would have resulted in a decrease of 2% in the fair value of the convertible debentures and warrants.

- the stock value: as of December 31, 2008 and every other market parameter being equal, an increase in the stock value of 10% would have resulted in an increase of 2% in the fair value of the convertible debentures and warrants, and a decrease in the stock value of 10% would have resulted in a decrease of 2% in the fair value of the convertible debentures and warrants.

- the risk free interest rate: as of December 31, 2008 and every other market parameter being equal, an increase in the risk free interest rate of 1 percentage point would have resulted in a decrease of 1% in the fair value of the convertible debentures and warrants, and a decrease in the risk free interest rate of 1 percentage point would have resulted in an increase of 2% in the fair value of the convertible debentures and warrants.

- credit spread: as of December 31, 2008 and every other market parameter being equal, an increase in the credit spread of 1 percentage point would have resulted in a decrease of 2% in the fair value of the convertible debentures and warrants, and a decrease in the credit spread of 1 percentage point would have resulted in an increase of 2% in the fair value of the convertible debentures and warrants.

- liquidity discount factor: as of December 31, 2008 and every other market parameter being equal, an increase in the liquidity discount factor of 5 percentage points would have resulted in a decrease of 1% in the fair value of the convertible debentures and warrants, and a decrease in the liquidity discount factor of 5 percentage points would have resulted in an increase of 1% in the fair value of the convertible debentures and warrants.

- combined sensitivity to market parameters: as of December 31, 2008, a 5 percentage point increase in stock volatility together with a 10% increase in the stock value, a 1 percentage point decrease in the risk free interest rate, a 1 percentage point decrease in the credit spread and a 5 percentage point decrease in the liquidity discount factor would have resulted in an increase of 9% in the fair value of the debentures and warrants; conversely, a 5 percentage point decrease in the stock volatility together with a 10% decrease in the stock value, a 1 percentage point increase in the risk free interest rate, a 1 percentage point increase in the credit spread and a 5 percentage point increase in the liquidity discount factor would have resulted in a decrease of 8% in the fair value of the debentures and warrants.

Risks Relating to Ownership of Securities

Our securities may be affected by volume fluctuations, and may fluctuate significantly in price.

Our ADSs are currently traded on the NASDAQ Global Market. The average daily trading volume of our ADSs in December 2008 was 9,138, the high and low bid price of our ADSs for the last two financial years ended on December 31, 2008 and December 31, 2007, was $ 5.12 and $9.40, and $ 1.05 and $4.25, respectively, and the high and low bid price of our ADSs during 2008 was $5.12 and $1.05, 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. 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, out of the 600,000 authorized. In July 2009, 11,775 new ordinary shares will be granted to certain of our employees upon achievement on certain performance goals during 2007 and 2008 pursuant to the Shareholders' authorization dated February 17, 2005. Finally, on February 26, 2009, the extraordinary general meeting of our shareholders delegated to our Board of Directors the authority to issue up to 3,000,000 additional shares for the purpose of paying all of the interest payable under the debentures in shares on April 1, 2009 and each subsequent interest payment date, unless we notify the holders of the debentures otherwise, in accordance with the terms of the debentures. 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 (the "Exchange Act"), relating to the solicitation of proxies for shareholder meetings. Although we are subject to the periodic reporting requirements of the Exchange Act, the periodic disclosure required of non-U.S. issuers under the Exchange Act is more limited than the periodic disclosure required of U.S. issuers. Therefore, there may be less publicly available information about us than is regularly published by or about other public companies in the United States.

We currently do not intend to pay dividends, and cannot assure shareholders that we will make dividend payments in the future.

We have not paid any dividend on our shares 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."

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;