

# EDAP TMS

## 2008 Annual Report

### America

Argentina  
Brazil  
Canada  
Chile  
Equator  
Mexico  
USA

### Europe

Belgium  
France  
Germany  
Italy  
Netherlands  
Norway  
Portugal  
Russia  
Spain  
Switzerland  
United Kingdom

### Middle East

Iran  
Yemen  
Oman  
Qatar  
Saudi Arabia  
Syria  
Turkey  
United Arab Emirates

### Africa

Algeria  
Morocco  
South Africa

### Extreme Orient

India  
Indonesia  
Japan  
Malaysia  
Philippines  
South Korea

### Oceania

Australia  
New Zealand

*Leader in Therapeutic Ultrasound*



edap tms

Bringing New Horizons to Therapy

## To our Shareholders:

EDAP finished 2008 with a record fourth quarter driven by higher lithotripsy and Ablatherm® HIFU sales.

The introduction of Sonolith® I-sys, our high-end ESWL device, has led to lithotripsy sales growth and raised visibility for our entire product portfolio among both urologists and patients. By year-end 2008 we had significantly increased our Ablatherm® HIFU RPP (revenue per procedure) through our RPP marketing action program, providing customers with a flexible sales offering to complement our current business model. Through quicker, easier, and expanded access to Ablatherm® HIFU, we have broadened our RPP customer base and driven further market penetration in Europe.

In addition to our RPP initiatives, we are actively pursuing aggressive sales and marketing strategies that position our Ablatherm HIFU technology as a minimally invasive treatment alternative for localized prostate cancer. A large number of European urologists have accepted HIFU as a standard of care for patients who are not suitable for surgery, have failed radiotherapy or wish to avoid side effects associated with more invasive therapies. By attending international and local congresses, supporting existing user sites, maintaining HIFU user networks and communicating via specialized media channels, we are dedicated to building awareness of HIFU's benefits in both patient and urologist communities.

While expanding our Ablatherm® HIFU business within Europe, we remain dedicated to expansion into the United States. We have made significant efforts to increase patient enrollment in our ongoing US ENLIGHT clinical trial. Recently, the FDA gave us permission to implement protocol amendments aimed at broadening inclusion criteria and adding participating sites, which will accelerate patient screening and enrollment. Pending the successful completion and positive outcome of the study, our priority is to pursue regulatory approval and commercialization of Ablatherm® HIFU for U.S. patients with localized prostate cancer.

In today's economic environment where the ability to raise capital is difficult, EDAP is fortunate to have a robust cash position of EUR 15.0 million (USD 20.8 million) on December 31, 2008. We are well funded to pursue our business operations while advancing our US ENLIGHT clinical trial. We also plan to continue prudent cash management to enable the execution of our long term growth strategy. The Board of Directors and management remain conservative and focused on controlling our expenses and investments outside our business expansion strategy.

During these times, we have the best interest of our shareholders in mind as we govern our daily business operations.

Best regards,



**Marc Oczachowski**  
**Chief Executive Officer**  
May 10<sup>th</sup>, 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:

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

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 filer  X

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

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

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

Item 17 \_\_\_\_\_ Item 18 \_\_\_\_\_

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

Yes \_\_\_\_\_ No  X

---

[THIS PAGE INTENTIONALLY LEFT BLANK]

---

---

## TABLE OF CONTENTS

	<b>Page</b>
Presentation of Financial and Other Information.....	1
Forward-looking Information .....	1
<b>PART I</b>	
<b>Item 1.</b> Identity of Directors, Senior Management and Advisors .....	2
<b>Item 2.</b> Offer Statistics and Expected Timetable.....	2
<b>Item 3.</b> Key Information.....	2
<b>Item 4.</b> Information on the Company .....	16
<b>Item 4A.</b> Unresolved Staff Comments .....	28
<b>Item 5.</b> Operating and Financial Review and Prospects.....	28
<b>Item 6.</b> Directors, Senior Management and Employees .....	41
<b>Item 7.</b> Major Shareholders and Related Party Transactions .....	46
<b>Item 8.</b> Financial Information .....	47
<b>Item 9.</b> The Offer and Listing.....	48
<b>Item 10.</b> Additional Information .....	49
<b>Item 11.</b> Quantitative and Qualitative Disclosures about Market Risk .....	62
<b>Item 12.</b> Description of Securities Other than Equity Securities.....	62
<b>PART II</b>	
<b>Item 13.</b> Defaults, Dividend Arrearages and Delinquencies .....	63
<b>Item 14.</b> Material Modifications to the Rights of Security Holders and Use of Proceeds.....	63
<b>Item 15.</b> Controls and Procedures .....	63
<b>Item 16A.</b> Audit Committee Financial Expert. ....	64
<b>Item 16B.</b> Code of Ethics .....	64
<b>Item 16C.</b> Principal Accounting Fees and Services .....	64
<b>Item 16D.</b> Exemptions from the Listing Standards for Audit Committees .....	65
<b>Item 16E.</b> Purchases of Equity Securities by the Issuer and Affiliated Purchasers.....	65
<b>Item 16F.</b> Change in Registrant’s Certifying Accountant.....	65
<b>Item 16G.</b> Corporate Governance .....	65
<b>PART III</b>	
<b>Item 17.</b> Financial Statements .....	66
<b>Item 18.</b> Financial Statements .....	66
<b>Item 19.</b> Exhibits .....	66

[THIS PAGE INTENTIONALLY LEFT BLANK]

## 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 “anticipate” 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
<b>INCOME STATEMENT DATA</b>					
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 <sup>(1)</sup> .....	—	—	—	—	—
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
<b>BALANCE SHEET DATA</b>					
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

<sup>(1)</sup> 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.”



## 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.

<u>Year ended December 31,</u>	<b>High</b>	<b>Low</b>	<b>Average<sup>(1)</sup></b>	<b>End of Year</b>
	€	€	€	€
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

<sup>(1)</sup> 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.

	<b>End of Month</b>	<b>High</b>	<b>Low</b>	<b>Average</b>
	€	€	€	€
<b>2008</b>				
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
<b>2009</b>				
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 liable following 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, 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.



***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 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 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;
- enforce U.S. court judgments based upon the civil liability provisions of the U.S. federal securities laws against us and our non-U.S. resident directors and officers in France; or
- bring an original action in a French court to enforce liabilities based upon the U.S. federal securities laws against us and our non-U.S. resident directors and officers.

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

Holders of ADSs do not have the same rights as shareholders and accordingly, cannot exercise rights of shareholders against us. The Bank of New York, as depositary (the "Depositary"), is the registered shareholder of the deposited shares underlying the ADSs, and therefore holders of ADSs will generally have to exercise the rights attached to those shares through the Depositary. We will use reasonable efforts to request that the Depositary notify the holders of ADSs of upcoming votes and ask for voting instructions from them. If a holder fails to return a voting instruction card to the Depositary by the date established by it for receipt of such voting instructions, or if the

Depository receives an improperly completed or blank voting instruction card, or if the voting instructions included in the voting instruction card are illegible or unclear, then such holder will be deemed to have instructed the Depository to vote its shares and the Depository shall vote such shares in favour of any resolution proposed or approved by our Board of Directors and against any resolution not so proposed or approved.

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

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

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



#### **Item 4. Information on the Company**

We develop and market the Ablatherm<sup>®</sup>, an advanced choice for High Intensity Focused Ultrasound (HIFU) treatment of localized prostate cancer. HIFU treatment is shown to be a minimally invasive and effective treatment option for localized prostate cancer with a low occurrence of side effects. Ablatherm-HIFU is generally recommended for patients with localized prostate cancer (stages T1-T2) who are not candidates for surgery or who prefer an alternative option. It is also used for patients who failed a radiotherapy treatment. In addition, we are developing HIFU technology for the treatment of certain other types of tumors. We also produce and commercialize medical equipment for treatment of urinary tract stones using Extra-corporeal Shockwave Lithotripsy (“ESWL”).

#### **History and Development of the Company**

Founded in 1979, we originally specialized in the manufacturing and distribution of lithotripters (devices which use shockwaves to disintegrate urinary calculi) and produced the first piezo-electric lithotripter (using electric shocks produced by a piezo-component) in 1985. In 1994, we purchased most of the assets of Technomed International S.A. (“Technomed”) out of liquidation. Technomed was established in 1985 and launched an electrohydraulic lithotripter (using electric shocks produced by an electrode within a hydraulic system) in 1986 and the Prostatron, a medical device using TransUrethral Microwave Thermotherapy (TUMT) for the minimally invasive treatment of BPH in the European Union in 1990. The assets we acquired in Technomed’s liquidation included the ownership of, and full distribution rights to, the Prostatron, the Sonolith series of lithotripters (Sonolith Praktis, Sonolith Vision and Sonolith Isys) and the Ablatherm HIFU device.

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

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

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

On August 3, 2006, we closed a private placement of 961,676 ordinary shares in the form of American Depositary Shares, resulting in net proceeds of approximately \$7.5 million. These funds were and are being used to fund additional marketing efforts to accelerate the adoption of Ablatherm-HIFU in key European markets.

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

On April 3, 2007, we executed an Agreement and Release whereby HealthTronics agreed to transfer the Ablatherm FDA study to us. The Agreement and Release was amended on July 9, 2007. Under the Agreement and Release, as amended, HealthTronics exercised 200,000 warrants which had been granted under the Distribution Agreement to acquire 200,000 of our ordinary shares for an aggregate exercise price of \$300,000. The 600,000 remaining warrants granted under the Distribution Agreement were cancelled. Pursuant to a registration rights agreement, we also agreed to file a registration statement under the Securities Act to enable HealthTronics to resell its ordinary shares (in the form of ordinary shares or ADSs) in transactions that are registered under the Securities



Act. Under the Agreement and Release, HealthTronics agreed to pay us \$600,000 within five days of the earlier of (a) 60 days after the effective date of the resale registration statement (such sixty-day period being subject to extension in certain circumstances) and (b) the date that HealthTronics had sold all of our ordinary shares. Further, under the terms of the Agreement and Release, HealthTronics agreed to use its reasonably best efforts to resell its ordinary shares in accordance with a registration statement. Finally, pursuant to the Agreement and Release, HealthTronics transferred to us one Ablatherm device and six lithotripters that HealthTronics had previously acquired and returned to us two Ablatherm devices we owned. We filed a resale registration statement on Form F-3 on July 16, 2007 reflecting the terms of the amended Agreement and Release. We were unable, however, to resolve a comment from the SEC staff on the Form F-3 registration statement relating to the availability of Form F-3 for the resale of the ordinary shares held by HealthTronics. As a result, with HealthTronics concurring, we elected to withdraw the resale registration statement by letter dated September 18, 2007. In an e-mail communication to us, HealthTronics has confirmed to us that they intend to honor their obligations under the Agreement and Release and specifically to pay us the \$600,000 amount. The timing of that payment, however, is unclear. The shares held by HealthTronics may now be sold without registration under Rule 144 under the Securities Act, provided that the requirements of the rule for resales by non-affiliates are satisfied. We are pursuing discussions with HealthTronics regarding these matters. Given the contingent nature of the \$600,000 settlement, the amount has not been reflected in our financial statements for the year ended December 31, 2008.

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

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

Effective January 1, 2008, to clarify and simplify our French organizational structure, we merged the two operational French entities EDAP SA and Technomed Medical Systems SA into a single entity named EDAP TMS France S.A. (formerly Technomed Medical Systems SA), which is wholly owned by EDAP TMS SA, the holding company. The merger has not changed our business segments and we will continue to report on our two business activities as the HIFU division and UDS division, as described below.

Our legal name is EDAP TMS S.A. and our commercial name is EDAP TMS. EDAP TMS S.A. was incorporated on December 3, 1979 as a *Société Anonyme* organized under the laws of the Republic of France for 60 years from the date of incorporation. Our principal executive offices are located at Parc d'Activités la Poudrette-Lamartine, 4/6, rue du Dauphiné, 69120 Vaulx-en-Velin, France and our telephone number is +33 (0) 4 72 15 31 50. Mr. Lee Sanderson, CPA, 945 Concord Street, Framingham, MA 01701, USA, is our agent for service of process in the United States.

### **Business Overview & Strategy**

Through our HIFU and UDS divisions we develop, produce and market minimally invasive medical devices, mainly for urological diseases. We believe that the creation of these two divisions has allowed us to expand our market share by optimizing worldwide distribution capabilities, all of which is coordinated through our subsidiaries.

EDAP TMS S.A. is a holding company and is responsible for providing common services to its subsidiaries, including preparation and consolidation of the financial statements for the group, complying with the

requirements of various regulatory agencies and maintaining the listing of its publicly held securities and, in conjunction with its Board of Directors, directing the overall strategy of our group.

Our HIFU and UDS divisions operate in Europe, the Americas, Asia and the rest of the world. Total net sales for the HIFU division (in net contributions to Group total sales) were €9.1 million, €9.3 million and €7.6 million for 2008, 2007, and 2006, respectively (all in Europe and the rest of the world, outside Asia and the United States). Total revenues for the UDS division were €13.8 million (including €6.1 million in Asia and €7.7 million in Europe and the rest of the world), €12.9 million (including €6.5 million in Asia and €6.4 million in Europe and the rest of the world) and €12.6 million (including €5.4 million in Asia and €7.2 million in Europe and the rest of the world), each for 2008, 2007, and 2006, respectively.

See Note 28 of the Notes to the Consolidated Financial Statements for a breakdown of total sales and revenue during the past three fiscal years by operating division.

### Organizational Structure

The following table sets forth the fully consolidated subsidiaries of the Company as of the date of this Annual Report:

Name of the Company	Jurisdiction of Establishment	Percentage Owned <sup>(1)</sup>
EDAP TMS France S.A.....	France	100%
EDAP Technomed Inc. ....	United States	100%
EDAP Technomed Co. Ltd.....	Japan	100%
EDAP Technomed Sdn Bhd.....	Malaysia	100%
EDAP Technomed Srl.....	Italy	100%
EDAP TMS GmbH.....	Germany	100%

(1) Percentage of equity capital owned by EDAP TMS S.A. directly or indirectly through subsidiaries.

### High Intensity Focused Ultrasound (“HIFU”) Division

The HIFU division is engaged in the development, manufacturing and marketing of medical devices based on HIFU technology for the minimally invasive treatment of urological and other clinical indications. The HIFU division had total revenues of €9.2 million during the fiscal year ended December 31, 2008.

#### *HIFU Division Business Overview*

The HIFU division currently develops, manufactures and markets devices for the minimally invasive destruction of certain types of localized tumors using HIFU technology. HIFU technology uses a high-intensity convergent ultrasound beam generated by high power transducers to produce heat. HIFU technology is intended to allow the surgeon to destroy a well-defined area of diseased tissue without damaging surrounding tissue and organs, thereby eliminating the need for incisions, transfusions and general anesthesia and associated complications. The Ablatherm is a HIFU-based device developed and marketed by the HIFU division for the treatment of organ-confined prostate cancer, referred to as T1-T2 stage. Ablatherm can be used for patients who are not candidates for surgery or who have failed a radiotherapy treatment. Ablatherm is approved for commercial distribution in the European Union, Canada, South Korea and Russia, and clinical trials in the United States have started. The HIFU division had an installed base of 75 Ablatherm machines worldwide (with an additional 8 used for clinical studies and other research and training purposes) and 213 trained clinical sites were using this technology as of December 31, 2008.

In addition to developing, manufacturing and marketing HIFU devices, the HIFU division also generates revenues from leasing equipment, as well as from the sale of disposables, spare parts and maintenance services. Our HIFU mobile treatment option provides access to the HIFU devices without requiring hospitals and clinics to make an up-front investment in the equipment. Instead, hospitals and clinics perform treatments using these devices and

remunerate us on a revenue-per-procedure (“RPP”) basis (i.e., on the basis of the number of individual treatments provided). With this model, once the treatment is established in the medical community, a permanent installation may become more attractive, leading to the sale of the device in some of the larger locations. With the proceeds from the private placement in August 2006, we are pursuing our marketing reach and focusing on Ablatherm penetration under this model, in major European countries.

### ***HIFU Division Business Strategy***

The HIFU division’s business strategy is to capitalize on its expertise in HIFU and its position in urology to achieve long-term growth as a leader in the development, manufacturing, marketing and distribution of minimally invasive medical devices for urological and other indications, using HIFU technology, while preserving patient quality of life. The HIFU division believes that minimally invasive treatments using HIFU could provide an alternative to current invasive therapies on the basis of reduced cost and reduced morbidity for a number of different indications. The key elements of the HIFU division’s strategy to achieve that objective are:

- *Provide Minimally Invasive Solutions to Treat Prostate Cancer using HIFU.* Building upon our established position in the ESWL market, our HIFU division is striving to become the leading provider of our minimally invasive treatment option for prostate cancer. We believe that there is a large market opportunity with an increase in incidence linked to the aging male population, an increase in screening and recent campaigns to increase awareness. We also believe that HIFU could represent a credible alternative to surgery, external beam radiotherapy, brachytherapy and cryotherapy for the treatment of organ-confined prostate cancer without the cost, in-patient hospitalization and adverse side effects associated with those therapies. The HIFU division intends to achieve this through a direct sales network in key European countries and through selected distributors in other European countries and in Asia. The HIFU division has built a strong clinical credibility based on clinical articles published in peer-reviewed journals. We ensure effective patient and physician education through a focused communication program. In addition to that current operational basis, we are seeking FDA approval to enter the US market with our Ablatherm-HIFU device.
- *Achieve Long-Term Growth by Expanding HIFU Applications Beyond Prostate Cancer.* The HIFU division’s long-term growth strategy is to apply our HIFU technology toward the minimally invasive treatment of other medical conditions beyond prostate cancer. We believe that HIFU could represent an alternative to surgery and radiotherapy for the treatment of many tumors without the cost, in-patient hospitalization and adverse side effects associated with those therapies. The HIFU division is working on various other applications where HIFU could provide an alternative to current invasive therapies. See “—HIFU Products.” The HIFU division maintained expenses at similar levels to 2007 on R&D projects in 2008 to develop HIFU applications beyond prostate cancer. The division is considering sustaining R&D spending in 2009 and future years to strengthen its technological leadership in HIFU and expand its application beyond urology.

### ***HIFU Products***

Currently, the only commercial product utilizing HIFU technology is the Ablatherm, an ultrasound guided HIFU device for the treatment of organ-confined prostate cancer. The Ablatherm is cleared for distribution in the European Union, South Korea, Canada, Australia, South Africa, New Zealand, the Philippines, Mexico, Brazil and Russia. Clinical trials are underway in the United States. The Ablatherm consists of a treatment module, a control table with a computer and a computer screen, and a diagnostic ultrasound device connected to the treatment module. After insertion of an endorectal probe, the physician visualizes the prostate and defines the area to be treated. The computer automatically calculates the optimum treatment distribution of lesions. During the treatment, the transducer automatically moves and fires at each predefined lesion until the entire area has been treated, while controlling and imaging the treatment in real time due to its integrated imaging system. Cell destruction by HIFU is accomplished by a combination of thermal and cavitation effects caused by focused application of piezoelectric-generated high-intensity ultrasound. The procedure is generally performed under spinal anesthesia.

### ***HIFU Division Patents and Intellectual Property***

As of December 31, 2008, the HIFU division's patent portfolio contained 57 patents consisting of 25 in the United States, 23 in the European Union and Japan and 9 in Israel and the rest of the world. They belong to 25 groups of patents covering key technologies related to therapeutic ultrasound principles, systems and associated software.

During 2008, 4 patents expired, 2 in the United States and 2 in the European Union. One patent covering new transducer design for High Intensity Contact Ultrasound applications ("HICU") has been granted in the European Union.

Twelve additional patents covering certain other aspects of our HIFU technology in the European Union (3), the United States (3), Japan (5) and the rest of the world (1) are also under review. These patents relate to new transducer design for both HIFU and HICU technologies. Taking into consideration the Chinese research and industry involvement in therapeutic ultrasound applications and business, we currently intend to extend this patent portfolio to China.

Our ongoing research and development objectives are to maintain our leadership position in the treatment of prostate cancer and to extend the HIFU technology to new applications and minimally invasive systems. These research projects are conducted in cooperation with the French National Institute for Health and Medical Research ("INSERM") which give rise in some cases to the filing, followed by the grant of co-owned patents. We have entered into various license agreements with INSERM whereby we commit to pay a fixed amount of royalties to INSERM based on the net revenues generated from the sales of HIFU devices using co-owned patents. Under these agreements, which last for the life of each co-owned patents we have the exclusive right to the commercial use of the co-owned patents, including the right to out-license such commercial rights.

In August 2004, we licensed our HIFU technology for the specific treatment of the "cervicofacial" lesions, including the thyroid, to Theraclion, a French company created by our former Director of research and development. This license agreement allows for the payment of certain royalties calculated on the basis of Theraclion's future sales of devices. We determined that we could not invest in these specific applications at that time and this license agreement therefore allows Theraclion to pursue the development of HIFU for this application. We own no interest in Theraclion.

Although we believe that our HIFU patents are valid and should be enforceable against third parties and that our patent applications should, if successfully pursued, result in the issuance of additional enforceable patents, there can be no assurance that any or all of these patents or patent applications will provide effective protection for the HIFU division's proprietary rights in such technology. HIFU devices, as they are currently or may in the future be designed, may also be subject to claims of infringement of patents owned by third parties, which could result in an adverse effect on our ability to market HIFU systems.

### ***HIFU Division Clinical and Regulatory Status***

The HIFU division has conducted an extensive clinical trial for the Ablatherm in the European Union. This trial, the European Multicentric Study, involved a total of 652 patients suffering from localized prostate cancer and included six sites in France, Germany and The Netherlands. The primary goals of the trial were to assess the safety and effectiveness of the Ablatherm.

The diagnosis of prostate cancer has two steps. The first one is the evaluation of the Prostate Specific Antigen (PSA), which although not specific to cancer tumors, measures the increase of cells' activity inside the prostate. The second is based on biopsies: a sextant biopsy is performed inside the prostate to reveal the presence of a tumor.

An interim analysis performed on the first 559 patients included 402 patients treated with the Ablatherm device as a first-line therapy. Of these patients, 81.4% had a normal PSA and 87.2% had negative biopsies at the last follow-up and were considered cancer free. The trials also included 157 patients who underwent an Ablatherm treatment as a salvage therapy after a previous failed therapy (hormonotherapy, radiation or prostatectomy). Of these patients, 80.7% and 67.9% had negative biopsies and normal PSA after treatment, respectively.

Based on these results, we obtained in May 1999 a CE Marking that allows us to market the Ablatherm in the European Union.

In June 2000, the HIFU division applied for an approval by the Japanese Ministry of Health for the Ablatherm to be marketed in Japan. We retrieved the application in 2005 to update it and review the process. The process of requesting approval to market the Ablatherm in Japan might be long and may never result in the approval to market the Ablatherm in Japan. See Item 3, “Key Information—Risk Factors—Our future revenue growth and income depend, among other things, on the success of our HIFU technology.”

In 2001, the French Urology Association (“AFU”) conducted an independent clinical trial to confirm the efficacy and safety results observed in the European Multicentric Study, and to evaluate the therapy-related costs. Patient recruitment was successfully performed at eight investigational sites. Patient enrollment was completed in an 11-month period with 117 patients included. Patient follow-up is ongoing, with intermediate assessment at one year. The two-year follow-up results were presented at the AFU congress in November 2004. Follow-up with these patients will continue to evaluate the long-term efficacy of the treatment.

In March 2004, French authorities approved a new treatment protocol concerning the treatment of patients who failed radiotherapy. We obtained CE Marking, which currently allows us to market this new Ablatherm treatment option.

In February 2004, we entered into the Distribution Agreement with HealthTronics. The terms of the distribution agreement granted HealthTronics the right to pursue market approval from the FDA for the Ablatherm. Under the terms of the distribution agreement, HealthTronics would be granted exclusive distribution rights for the Ablatherm in the United States. In November 2006, HealthTronics informed us that they intended to discontinue Ablatherm FDA trials. On April 3, 2007, we executed an Agreement and Release whereby HealthTronics agreed to transfer the Ablatherm FDA study to us. See Item 4, “Information on the Company – History and Development of the Company.”

On June 29, 2007, the FDA officially approved the transfer of the study to EDAP Technomed Inc. and the trials resumed as per the approved protocol. As of December 31, 2008, a total of 25 universities and hospitals were participating in the trials and 54 patients have undergone HIFU under the clinical protocol. In October 2007, we completed a private placement raising net proceeds of \$17.4 million allowing us to finance and conduct the US trials for the expected period of time. See Item 5, “Operating and Financial Review and Prospects – Liquidity and Capital Resources.”

In 2005, a clinical trial was started in France to validate the efficacy and safety of Ablatherm as rescue treatment in patients after brachytherapy failure. Patients are still being enrolled.

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

In 2007, a new clinical trial using Ablatherm-HIFU and dedicated to the treatment of high risk patients was started in France. Patient enrolment is in progress.

The first clinical paper reporting long term results using Ablatherm HIFU was published in November 2007. The results of the study confirm the efficacy of HIFU in patients with localized prostate cancer.

We are currently setting up an extensive worldwide database called “@-registry.” This on-line database is designed to compile treatment information and follow-up data for patients who have undergone HIFU for prostate cancer. The goal of the @-Registry is to further demonstrate the safety, effectiveness and durability of Ablatherm HIFU. Information from the registry will be submitted to medical conferences for presentation and to peer-reviewed medical journals for publication. The first presentation of results will be based on abstracts that have been accepted for presentation at the 2009 Annual European Association of Urology Congress in March 2009 and the 2009 Annual American Urological Association Congress in April 2009.



### ***HIFU Division Market Potential***

Prostate cancer is currently the first or second most common form of cancer among men in many populations. In the United States, the American Cancer Society estimates the number of new prostate cancers diagnosed every year to be approximately 186,000, of which 70% are diagnosed with localized stage prostate cancer. Additionally, the HIFU division believes, based on figures provided by the World Health Organization, that the worldwide incidence of localized prostate cancer is approximately twice this US figure. A more effective diagnostic method for prostate cancer, the PSA test, has increased public awareness of the disease in developed countries since its introduction. The PSA test measures the blood level of a protein, the PSA, which is produced only by the prostate. PSA levels jump sharply when cancer is present. Prostate cancer is an age-related disease, and its incidence in developed countries is expected to increase as the population ages.

If the efficacy of HIFU therapy is established, the HIFU division believes that its application could be expanded to other medical conditions, such as certain localized thyroid, breast, gynecological, bladder, kidney, liver, brain, pancreatic and retroperitoneal tumors. However, the expansion of the use of HIFU to other areas of treatment will require a significant investment in research and development, an investment we will undertake gradually while focusing on the acceptance of HIFU as a treatment for localized prostate cancer.

### ***HIFU Competition***

The principal current therapies for prostate cancer carry side effects that can seriously affect a patient's quality of life. One of the current therapies is radical prostatectomy (surgery), which involves the ablation of the entire prostate gland. Radical prostatectomy requires several days of hospital stay and several weeks of recovery, usually with catheterization, and may result in partial and/or total urinary incontinence. In addition, it almost invariably renders patients impotent. A new surgical technique, nerve-sparing prostatectomy, has been developed to address that problem. However, the procedure can only be applied when the tumor is not located close to the surface of the prostate and requires a very skilled surgeon. Other therapies for localized prostate cancer include brachytherapy, a therapy that involves the implantation of radioisotopes into the prostate gland, external beam radiotherapy and cryotherapy.

Our Ablatherm-HIFU device competes with all current treatments for localized tumors, which include surgery, brachytherapy, radiotherapy, cryotherapy and hormonotherapy. We believe that HIFU competes against those treatments on the basis of efficacy, limited side effects and cost-effectiveness.

Other companies are working with HIFU for the minimally invasive treatment of tumors, including Focus Surgery, which has developed a device called the Sonablate SB500 for the treatment of localized prostate cancer. Misonix, USHIFU and UKHIFU are also involved in the manufacturing, marketing and distribution of the Sonablate. Insightec, an Israeli company majority owned by General Electric and Elbit Medical Imaging, has developed a device using HIFU technology to treat uterine fibroids. St. Jude Medical has developed a device using HIFU to treat atrial fibrillation. Haifu, a Chinese company developing HIFU products addressing various cancers, signed a development partnership agreement with Siemens Medical Solutions to offer a HIFU device coupled with IRM imaging system.

We have also entered into cooperative arrangements with other companies. On April 25, 2007, we signed an exclusive distribution agreement with Chinamed to distribute their HIFU devices in the European Union and Russia once their devices are approved for use in those jurisdictions. Prior to this agreement, Chinamed had been developing HIFU products for various types of cancer tumors, but only marketing its HIFU products in China. 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, 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."

Certain existing and potential competitors of our HIFU division may have substantially greater financial, research and development, sales and marketing and personnel resources than us and may have more experience in

developing, manufacturing, marketing and supporting new products. We believe that an important factor in the potential future market for HIFU treatments will be the ability to make the substantial investments in research and development in advancing the technology beyond the treatment of prostate cancer. This future investment is wholly dependent on the successful acceptance of the device for the treatment of prostate cancer.

#### ***HIFU Division Sales and Distribution of Products***

The HIFU division markets and sells its products through our own direct marketing and sales organization as well as through selected third-party distributors and agents in several countries. Using our direct subsidiaries or representative offices network, the HIFU division maintains direct marketing and sales forces in France, Germany, Russia and Italy, which currently represent its largest HIFU markets. Additionally, the HIFU division markets and sells its products through our distribution platform in South Korea and South East Asia.

The HIFU division's customers are located worldwide and have historically been principally public and private hospitals and urology clinics. The HIFU division believes that as it increases its customer base it will gain further access to the urological community, which will enable it to monitor the urological market, introduce new products and conduct trials under satisfactory conditions. No single customer of the HIFU division represents a significant portion of the division's installed base.

The HIFU division's marketing efforts include the organization of informative and training programs for urologists, mainly in key European countries where HIFU awareness is growing, comprehensive media and web programs to educate patients on the availability of HIFU technology to treat localized prostate cancer and strong participation in focused dedicated urological events. Our dedicated web site [www.hifu-planet.com](http://www.hifu-planet.com) for patients and physicians is regularly visited.

#### **Urology Devices and Services (“UDS”) Division**

The UDS division is engaged in the development, marketing, manufacturing and servicing of medical devices for the minimally invasive diagnosis or treatment of urological disorders, mainly urinary stones, and other clinical indications. The UDS division contributed €13.8 million to consolidated net sales during the fiscal year ended December 31, 2008.

#### ***UDS Division Business Overview***

The UDS division's primary business is producing and marketing devices, known as lithotripters, for the treatment of urinary tract stones by means of ESWL technology. ESWL uses extracorporeal shockwaves, which can be focused at urinary stones within the human body to fragment the stones, thereby permitting their natural elimination and preventing the need for incisions, transfusions, general anaesthesia, and the resulting complications. The UDS division currently manufactures three models of lithotripters: the Sonolith Praktis, which is available for commercial distribution in the European Union, Japan, Canada and the United States, the Sonolith Vision, which is available for commercial distribution in the European Union, Japan and Canada and the Sonolith I-Sys, which is available in the European Union, Korea, Canada and Australia. The newly designed fully integrated ESWL device: the Sonolith I-Sys is to gradually replace the Sonolith Vision when the Sonolith I-Sys is approved in the United States and Japan. The UDS division has sold 517 ESWL lithotripters worldwide to this date and actively maintained or otherwise served 374 installed lithotripters as of December 31, 2008.

In addition to its manufacturing and selling of lithotripters, the UDS division also generates revenues from the leasing of lithotripters, as well as from the sale of disposables, spare parts and maintenance services. Up to December 31, 2007, the UDS division, as an additional part of its contract manufacturing business, manufactured HIFU related devices and accessories, including disposables, on behalf of the HIFU division. As from January 1, 2008, the HIFU division integrated its own manufacturing as part of EDAP TMS France. The UDS division through our Japanese and Italian subsidiaries also derives marginal revenues from the distribution of Prostatron parts and related services under the distribution agreement entered into with Urologix in October 2000.



### ***UDS Division Business Strategy***

The UDS division’s business strategy is to capitalize on its expertise in ESWL and its position in urology to achieve long-term growth as a leader in the development, production, marketing and distribution of minimally invasive medical devices for urological and other clinical indications. To achieve this strategic goal, the UDS division intends to capitalize and expand on its expertise as the manufacturer of minimally invasive devices such as its ESWL lithotripters. Until December 31, 2007, the UDS division manufactured the Ablatherm and the disposable Ablapack on behalf of the HIFU division. All the costs related to the manufacturing of these machines were supported by the UDS division, which invoiced the HIFU division at cost plus a margin and records the sales of the devices as revenues. As from January 1, 2008, all manufacturing costs are born by EDAP TMS France. The key elements of the UDS division’s strategy are:

- *Capitalize on the Current ESWL Installed Base.* The UDS division’s long-term growth strategy relies on its ability to capitalize on its extensive installed base of ESWL lithotripters to recognize ongoing revenue from sales of disposables, accessories, services and replacement machines. We believe that a combination of continued investment in lowering end-user costs and offering units that are easily adaptable to various treatment environments, as well as a commitment to quality and service will allow the UDS division to achieve this goal. See “—UDS Division Products”.
- *Capitalize on an Established Distribution Platform in Urology by Expanding Distribution Possibilities.* We believe that we can achieve additional long-term growth by offering our established distribution platform in urology to other developers of medical technologies and acting as a distributor for their devices. Our distribution platform in urology consists of a series of well-established subsidiaries in Europe and Asia as well as a network of third-party distributors worldwide.
- *Provide Manufacturing Solutions to Other Developers of Medical Technologies.* Building upon its established position in the high-tech medical devices market, we believe that the UDS division can become a provider of manufacturing alternatives to other developers of medical technologies that do not have or do not wish to invest in their own manufacturing facilities. We believe that our FDA-inspected and ISO 9001 (V:2000) and ISO 13485 (V:2003) certified facilities allow to offer manufacturing services to a wide range of potential medical equipment developers.

### ***UDS Division Products***

The UDS division offers the Sonolith Praktis to small and mid-size hospitals, while the Sonolith I-Sys and the Sonolith Vision are offered to large hospitals that can afford a fully dedicated and integrated lithotripter. The UDS division also sells disposable parts for lithotripters, including the piezo-electric elements of the LT02 (although the manufacturing of new machines was discontinued in 2002) and the electrodes of the Sonolith line, which need to be replaced approximately every year and approximately every ten treatments, respectively. These parts incorporate key proprietary technologies, and the UDS division has retained sole marketing rights for these parts.

<b>Product</b>	<b>Procedure</b>	<b>Development Stage</b>	<b>Clinical and Regulatory Status</b>
Sonolith Praktis compact lithotripter	Electroconductive treatment of urinary stones	Commercial Production	Approved for distribution: European Union Japan United States Canada Russia South Korea Australia New Zealand
Sonolith Vision	Electroconductive treatment of urinary stones	Commercial Production	Approved for distribution: European Union Japan Canada South Korea Australia New Zealand

Sonolith I-Sys	Electroconductive treatment of urinary stones	Commercial Production	Approved for distribution: European Union Korea Canada Australia
----------------	---	-----------------------	--

The Sonolith Praktis, the Sonolith Vision and the Sonolith I-Sys rely on an electroconductive technology for shockwave generation. The electroconductive technology, which is derived from the electrohydraulic technology on which the first ESWL lithotripters were based, permits improved focusing of the shockwave, reduces the variability in the shockwave pressure and allows a better transfer of energy to the calculus. These features result in a faster, more effective treatment as compared to electrohydraulic lithotripters.

The UDS division’s ESWL customers are located worldwide and have historically been principally large hospitals, urology clinics and research institutions. To increase its penetration of the market segment of smaller hospitals and outpatient clinics, the UDS division developed the Sonolith Praktis, an electroconductive lithotripter designed for smaller clinics which is more compact than the Sonolith Vision or I-Sys, which are more fully dedicated and integrated electroconductive lithotripters for larger hospitals.

***UDS Division Patents and Intellectual Property***

As of December 31, 2008, the UDS division’s patent portfolio contained 15 patents consisting of 4 in the United States, 7 in the European Union and Japan and 4 in Israel and the rest of the world. They belong to 6 groups of patents covering key technologies relating to ESWL systems and associated software capabilities.

During 2008, one additional patent covering a new shock wave generation technology was granted last year in the United States, China and Israel. Two additional patents, 1 in the European Union and 1 in Japan, are also in the examination process. One patent is dedicated to the I-Sys lithotripter technology.

The UDS division’s patents cover both piezoelectricity and electroconductivity technologies associated to ESWL treatment head, electrodes and localization systems. The UDS division’s ongoing research and development objectives in ESWL are to further increase the clinical efficacy, the cost-effectiveness and the ease of use of its products to make them accessible to wider patient and user populations.

As with the development of our HIFU technology, we cooperate with INSERM to develop our ESWL technology. This cooperation gave rise to co-owned patents in some cases. We have entered into various license agreements with INSERM whereby we commit to pay a fixed amount of royalties to INSERM based on the net revenues generated from the sales of ESWL devices using co-owned patents. Under these agreements, which last for the life of each co-owned patents we have the exclusive right to the commercial use of the co-owned patents, including the right to out-license such commercial rights.

***UDS Division Regulatory Status***

The Sonolith Praktis is available for commercial distribution in the United States, Canada, the European Union, South Korea, Australia, New Zealand and Japan. The Sonolith Vision is available for commercial distribution in the European Union, Canada, South Korea, Australia, New Zealand and Japan. The Sonolith I-Sys is available in the European Union, Korea, Canada and Australia. The UDS division continues to provide disposables, replacement parts and services for the current installed base of LT02 machines, even though we discontinued the manufacture of these machines.

***UDS Division Market Potential***

We estimate that roughly 2% to 3% of the world population suffers from kidney or urethral stones during their lifetime. Urinary calculi are responsible for 10% of urological hospital admissions worldwide. Although urinary calculi may be eliminated naturally by the body, natural elimination is frequently accompanied by considerable pain and very often by serious complications, such as obstruction and infection of the urinary tract.

Since its introduction in clinical practice nearly 20 years ago, ESWL has become the standard treatment for urinary calculi. ESWL consists of fragmenting calculi within the body using extracorporeal shockwaves without

any surgery. We believe that the market for lithotripters includes both buyers looking for a sophisticated, higher-priced machine (generally hospitals and larger urology clinics) and buyers looking for simpler and less expensive machines (typically smaller clinics). We also believe that after a period of fast growth in the mid-1980s and early 1990s, the market for lithotripters is now mature and has become primarily a replacement and service and maintenance market.

We believe that companies with a large installed base of ESWL lithotripters will be most successful in the replacement market. Consequently, we intend to capitalize on our share of the installed base of ESWL lithotripters to gain a significant position in the replacement market for those machines. We expect the ESWL business to continue to contribute, at historically consistent levels, to the UDS division's financial results despite the mature nature of the market, due to revenues from maintenance contracts and demand for replacement machines. See Item 5, "Operating and Financial Review and Prospects".

#### ***UDS Division Competition***

The ESWL market is characterized by severe price competition among manufacturers, with the result that, in recent years, the average unit price of ESWL lithotripters has declined. The UDS division expects this trend to continue. See Item 5, "Operating and Financial Review and Prospects." The UDS division's major competitors in developed countries are Siemens, Storz and Dornier.

#### ***UDS Division Sales and Distribution of Products***

The UDS division markets, sells and services its products through our direct sales and service platform in France, Italy, Japan, South Korea and Malaysia and markets its products through agents and third-party distributors in several other countries. See Item 4, "Information on the Company—History and Development of the Company."

The UDS division's customers are located worldwide and have historically been mainly public and private hospitals and urology clinics. We believe that the division's customer base provides it with excellent access to the urological community and enables it to monitor the urological market, introduce new products and conduct trials under satisfactory conditions. No single customer of the UDS division represents a significant portion of the division's installed base. The UDS division's marketing efforts include the organization of training programs for urologists worldwide.

#### ***UDS Division Services and Distribution***

The UDS division is also pursuing various distribution options that use its strong network of worldwide subsidiaries and agents. Currently, the UDS division distributes products on behalf of Urologix in Italy and Japan on behalf of Andromeda in Japan. We believe that the UDS division can successfully market its worldwide distribution platform to a wide range of medical equipment development companies, thus allowing for quick, easy and economically sound entry for these companies into markets covering most of the world.

#### **Manufacturing**

Our current operations consist of manufacturing medical products in our facility that is FDA-approved and certified under international standards ISO 9001 and ISO 13485. We believe that this facility can extend its outsourced services to provide device and disposable development and manufacturing services to a wide range of medical equipment development companies. Up until December 31, 2007, the HIFU division subcontracted the manufacturing of its HIFU devices and accessories, including disposables. From January 1, 2008, each division is manufacturing its own products through EDAP TMS France.

Our manufacturing policy is to manufacture the critical components for our devices and accessories (unless a subcontractor can manufacture the component more cost-effectively), perform final assembly and quality control processes and maintain our own set of production standards. We purchase the majority of the raw materials used in our products from a number of suppliers, but for several components of our products, rely on a single source. Our policy is to conduct regular quality audits of suppliers' manufacturing facilities. Our principal suppliers are located in France, Germany, Denmark, Korea and the United States. Management believes that the relationships with our suppliers are good.

## **Quality and Design Control**

The manufacturing operations of EDAP TMS France must comply with the GMP regulations enacted by the FDA, which establish requirements for assuring quality by controlling components, processes and document traceability and retention, among other things. EDAP TMS France's facilities are also subject to scheduled inspections by the FDA. TMS has obtained the ISO 9001 (V:2000) and ISO 13485 (V:2003) certifications, which indicate compliance by EDAP TMS France's manufacturing facilities with international standards for quality assurance, design and manufacturing process control. EDAP TMS France also complies with the applicable requirements that will allow it to affix the CE Marking to certain of its products. Our manufacturing site also complies with Japanese and Canadian regulations, as well as with the US Quality System Regulation. See “—Government Regulation—Healthcare Regulation in the United States” and “—Government Regulation—Healthcare Regulation in the European Union.”

## **Property and Equipment**

We have one principal facility, which is located in Vaulx-en-Velin, on the outskirts of Lyon, France. The premises comprise 3,740 square meters and are rented under a renewable nine-year commercial lease agreement. We believe the terms of the lease reflect commercial practice and market rates. The manufacturing facility, and principal offices, which we utilize to manufacture and/or assemble all of our products, has ISO 9001 and ISO 13485 certifications. We are not aware of any environmental issues that could affect utilization of the facility.

In addition, we rent office and/or warehouse facilities in Kuala Lumpur (Malaysia), Rome (Italy), Flensburg (Germany), Moscow (Russia), Seoul (South Korea), Fukuoka, Osaka, Sapporo and Tokyo (Japan).

## **Government Regulation**

Government regulation in our major markets, in particular the United States, the European Union and Japan, is a significant factor in the development and marketing of our products and in our ongoing research and development activities. We are principally subject to regulation of our medical devices and of the healthcare systems in these jurisdictions generally.

### ***Healthcare Regulation in the United States***

We and our products are regulated in the United States by the FDA under a number of statutes including the Federal Food, Drug and Cosmetic Act (“FDC Act”). Pursuant to the FDC Act, the FDA regulates the preclinical and clinical testing, manufacturing, labeling, distribution, sale, marketing, advertising and promotion of medical devices in the United States. Medical devices are classified in the United States into one of three classes - Class I, II or III - on the basis of the controls reasonably necessary to ensure their safety and effectiveness. Class I devices are those whose safety and effectiveness can be ensured through general controls, such as establishment and registration, medical device listing, FDA-mandated good manufacturing practices (GMP), labeling, and pre-market notification (known as “510(k)”). Most Class I devices are exempt from premarket notification and/or GMP regulations. Class II devices are those whose safety and effectiveness can reasonably be ensured through the use of general controls and “special controls,” such as special labeling requirements, mandatory performance standards, and post-market surveillance. FDA may require the submission of clinical data as part of pre-market notifications for Class II devices. Class III devices are those that must receive pre-market approval (“PMA”) by the FDA to ensure their safety and effectiveness. Before a new Class III device may be introduced on the market, the manufacturer generally must obtain FDA approval of a PMA. The PMA process is expensive and often lengthy, typically requiring several years, and may never result in approval. The manufacturer or the distributor of the device must obtain an Investigational Device Exemption (“IDE”) from the FDA before commencing human clinical trials in the United States in support of the PMA. The lithotripsy range of products has been reclassified by the FDA as a Class II device. However, the Ablatherm device, a Class III device, has not yet been approved by FDA; it is currently under IDE Study G050103. The regulatory pathway for placement in the US market may include the pre-market notification or PMA routes. Regardless of the regulatory route to market, FDA has mandated the submission of clinical evidence of safety and effectiveness.

Advertising and promotional activities in the United States are subject to regulation by the FDA and, in certain instances, by the US Federal Trade Commission. The FDC Act also regulates our quality control and

manufacturing procedures by requiring us to demonstrate and maintain compliance with current GMP regulations. Our manufacturing facilities are in compliance with GMP regulations. No major deficiencies have been observed during inspections carried out by FDA auditors in the past few years.

#### ***Healthcare Regulation in the European Union***

In the European Union, we have received the ISO 9001 (V:2000) and ISO 13485 (V:2003) certifications, showing that we comply with standards for quality assurance and manufacturing and design process control. In the European Union, our products are also subject to legislation implementing the European Union Council Directive concerning medical devices (the “Medical Device Directive”). The Medical Device Directive provides that medical devices that meet certain safety standards must bear a certification of conformity, the European Community approval “CE Marking.” Except in limited circumstances, member states of the European Union may not prohibit or restrict the sale, free movement or use for its intended purpose of a medical device bearing the CE Marking. Medical devices marketed throughout the European Union must comply with the requirement of the Medical Device Directive to bear a CE Marking (subject to certain exceptions). All of our products bear the CE Marking.

Pursuant to the Medical Device Directive, medical devices are classified into four classes, Class I, Class IIa, Class IIb and Class III, on the basis of their invasiveness and the duration of their use. The classification serves as a basis for determining the conformity assessment procedures that apply to medical devices to be eligible to receive a CE Marking. The conformity assessment procedures for Class I devices can be carried out, as a general rule, under the sole responsibility of the manufacturer, while for devices of other classes, the involvement of an authorized supervisory body is required. The extent of the involvement of such body in the development and manufacturing of a device varies according to the class under which it falls, with Class III devices being subject to the greatest degree of supervision. All of the devices currently marketed by us are Class IIb devices.

#### ***Healthcare Regulation in Japan***

The import and sales of medical devices in Japan is regulated by the Ministry of Health, Labour and Welfare (the “MHLW”) under the license “Marketing Authorization Holder”. Our Japanese subsidiary has obtained a general license as well as specific approvals to import our products that have been approved in Japan. The MHLW also administers various national health insurance programs to which each Japanese citizen is required to subscribe. These programs cover, among other things, the cost of medical devices used in operations. The MHLW establishes a price list of reimbursable prices applicable to certain medical devices under the national health insurance programs and until a new device is included in this list its costs are not covered by the programs. The LT02, the SONOLITH Praktis, the SONOLITH Vision and the Prostatron are all included on the MHLW’s list for reimbursement.

#### **Item 4A. Unresolved Staff Comments**

Not applicable.

#### **Item 5. Operating and Financial Review and Prospects**

The following discussion of our results of operations and liquidity and capital resources for the fiscal years ended December 31, 2008, 2007 and 2006 is based on, and should be read in conjunction with, the Consolidated Financial Statements included elsewhere in this annual report. The Consolidated Financial Statements have been prepared in accordance with U.S. GAAP.

The following discussion contains certain forward-looking statements that involve risks and uncertainties. See “Forward-Looking Information” elsewhere in this Annual Report.

#### **Critical Accounting Policies**

The discussion and analysis of our financial condition and results of operations are based upon the Consolidated Financial Statements, which have been prepared in accordance with accounting principles generally



accepted in the United States. The preparation of these financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, revenues and expenses, and related disclosure of contingent assets and liabilities. On an on-going basis, we evaluate our estimates, including those related to revenue recognition, accounts receivable, bad debts, inventories, warranty obligations, litigation and deferred tax assets. We base our estimates on historical experience and on various other assumptions that are believed to be reasonable under the circumstances. These estimates and assumptions form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

We believe our more significant judgments and estimates used in the preparation of its Consolidated Financial Statements are made in connection with the following critical accounting policies.

### ***Revenue Recognition***

Sales of goods:

For medical device sales with no significant remaining vendor obligation, payments contingent upon customer financing, acceptance criteria that can be subjectively interpreted by the customer, or tied to the use of the device, revenue is recognized when evidence of an arrangement exists, title to the device passes (depending on terms, either upon shipment or delivery), and the customer has the intent and ability to pay in accordance with contract payment terms that are fixed or determinable. For sales in which payment is contingent upon customer financing, acceptance criteria can be subjectively interpreted by the customer, or payment depends on use of the device, revenue is recognized when the contingency is resolved. We provide training and usually provide a one-year warranty upon installation. We accrue the estimated training and warranty costs at the time of sale. Revenues related to disposables are recognized when goods are delivered.

Sales of Revenue-Per-Procedure Treatments and leases:

Revenues related to the sale of Ablatherm treatments invoiced on a “Revenue-Per-Procedure” (“RPP”) basis are recognized when the treatment procedure has been completed. If a contract of RPP includes a minimum number of treatments, the revenue is recognized on a linear basis over the contract period. For treatments in excess of minimum levels, the revenue is recognized when the treatment procedure has been completed. Revenues from devices leased to customers under operating leases are recognized on a straight-line basis.

Sales of spare parts and services:

Revenues related to spare parts are recognized when goods are delivered. Maintenance contracts rarely exceed one year and are recognized on a linear basis. Billings or cash receipts in advance of services due under maintenance contracts are recorded as deferred revenue.

### ***Leases and Sales and leaseback transactions***

In accordance with SFAS 13, Accounting for Leases, we classify all leases at the inception date as either a capital lease or an operating lease. A lease is a capital lease if it meets any one of the following criteria; otherwise, it is an operating lease:

- Ownership is transferred to the lessee by the end of the lease term;
- The lease contains a bargain purchase option;
- The lease term is at least 75% of the property's estimated remaining economic life;
- The present value of the minimum lease payments at the beginning of the lease term is 90% or more of the fair value of the leased property to the lessor at the inception date.

We enter into sale and leaseback transactions from time to time. In accordance with SFAS 13 and EITF 93-8, any profit or loss on the sale is deferred and amortized prospectively over the term of the lease, in proportion to the leased asset if a capital lease, or in proportion to the related gross rental charged to expense over the lease term, if an operating lease.

### ***Warrants***

As part of the October 2007 \$20 million issuance of the convertible debentures, we issued warrants to both the investors in the convertible debentures and to the bank that assisted us as placement agent (the “Placement Agent”). In accordance with EITF 00-19, the warrants issued to the investors in the convertible debentures (the “Investor Warrants”) and the Placement Agent (the “Placement Agent Warrants”) are classified as a liability because the Company may be required to settle them on a net cash basis upon the occurrence of certain events outside the control of the Company. We accounted for the Investor Warrants based on their fair value at inception date, with subsequent changes in fair value recorded as financial earnings (or loss) at each balance sheet date. We use a binomial pricing model to determine the fair value of the Investor Warrants: the binomial model was developed to capture the specific nature of this instrument, and in particular the possibility that the holder may exercise the call option at any time from the inception date. The application of the model to the warrants requires the use of subjective assumptions, including historical share price volatility, the expected life of the warrants, our risk-free interest rate, and the liquidity discount factor. A change in one or more of these assumptions could result in a material change to the estimated fair value of the Investor Warrants and the Placement Agent Warrants. See Item 3, “Key Information – Risk Factors – Changes in the fair value of the debentures and warrants issued in the October 2007 private placement of each balance sheet date could have a significant impact on our financial condition and results of operations”, “– Convertible Debentures” below and Notes 14 and 20 to the Financial Statements.

### ***Convertible Debentures***

On October 29, 2007, the Company raised \$20 million in non-secured, convertible debentures with detachable warrants. At the inception date, the Company elected to measure the instrument and its embedded derivatives in their entirety at fair value, with changes in fair value reported in the income statement under financial income, pursuant to §16 of SFAS 133, as amended by SFAS 155. Thus, the convertible debentures together with their embedded derivatives are recorded as a liability, with subsequent changes in fair value recorded in financial income and expenses. The Company used a binomial valuation model to measure the fair value of the Investor Warrants and a binomial valuation model with a Company specific credit spread to measure the fair value of the convertible debentures. – See Item 3, “Key Information – Risk Factors – Changes in the fair value of the debentures and warrants issued in the October 2007 private placement of each balance sheet date could have a significant impact on our financial condition and results of operations” and Notes 14 and 20 to the Financial Statements for a detailed description of the fair value calculations.

### ***Accounts Receivable***

We generate most of our revenues and corresponding accounts receivable from sales of medical equipment, spare parts, maintenance and service to public and private hospitals and physicians worldwide. We perform initial credit evaluations of our customers and adjust credit terms based upon customers’ creditworthiness as determined by such things as their payment history, credit ratings and our historical experiences.

### ***Allowance for Doubtful Accounts***

We evaluate the collectibility of our accounts receivable based on the individual circumstances of each customer on a quarterly basis. In circumstances where we are aware of a specific customer’s inability to meet its financial obligations to us (e.g., bankruptcy filings, substantial downgrading of credit scores), we record a specific reserve for bad debts against amounts due to reduce the net recognized receivable to the amount we reasonably believe we will collect. If circumstances change (i.e. higher than expected defaults or an unexpected material adverse change in a major customer’s ability to meet its financial obligations to us), our estimates of the recoverability of amounts due to us could be reduced by a material amount.



## Operating Results

### Overview

Total revenues include sales of our medical devices and sales of disposables ("sales of goods"), sales of RPPs and leases, and sales of spare parts and services, all net of commissions, as well as other revenues.

Net sales of goods have historically been comprised of net sales of medical devices (Prostatrons, ESWL lithotripters and Ablatherms) and net sales of disposables (mostly Ablapaks in the HIFU division and electrodes in the Lithotripsy division). The sale price of our medical devices is subject to variation based on a number of factors, including market competitive environment, warranties and payment terms. Consequently, a particular sale of a medical device may, depending on its terms, result in significant fluctuations in the average unit sale price of the product for a given period, which may not be indicative of a market trend.

Net sales of RPP (Revenue-Per-Procedure) and leases include the revenues from the sale of Ablatherm treatment procedures and from the leasing of Ablatherm machines. We provide Ablatherms to clinics and hospitals for free for a limited period, rather than selling the devices. These hospitals and clinics perform treatments using the devices and pay us on the basis of the number of individual treatments provided. With this business model, the hospital or clinic does not make an initial investment until the increase in patient demand justifies the purchase of an Ablatherm. As a consequence, we are able to make Ablatherm treatments available to a larger number of hospitals and clinics, which we believe should serve to create more long-term interest in the product. Compared to the sale of devices, this business model initially generates a smaller, but more predictable stream of revenue but, if successful, should lead to more purchases of Ablatherms in the long term. This activity has already increased significantly in the past years and now accounts for approximately half of the net sales of the HIFU division.

Net sales of spare parts and services include revenues arising from maintenance services furnished by us for the installed base of Prostatrons, ESWL lithotripters and Ablatherms.

We derive a significant portion of both net sales of medical devices and net sales of spare parts and services from our operations in Asia, through our wholly owned subsidiaries or representative offices in Japan (Edap Technomed Co. Ltd), Malaysia (Edap Technomed Sdh Bhd) and Korea (Edap Technomed Korea). Revenue derived from our operations in Asia represented approximately 25% of our total consolidated revenue in 2008. Net sales of medical devices in Asia represented approximately 23% of such sales in 2008 and consisted primarily of sales of ESWL lithotripters and consumables. Net sales of spare parts, supplies and services in Asia represented approximately 25% of such sales in 2008 and related primarily to ESWL lithotripters, reflecting the fact that approximately 58% of the installed base of our ESWL lithotripters that we actively maintain or otherwise serve are located in Asia.

We sell our products in many parts of the world and, as a result, our business is affected by fluctuations in currency exchange rates. We are exposed to foreign currency exchange rate risk because the mix of currencies in which our costs are denominated is different from the mix of currencies in which we earn revenues. In 2008, approximately 73% of our research and development, selling, marketing and general and administrative expenses were denominated in euro, while approximately 25% of our sales were denominated in currencies other than euro (primarily the US Dollar and Japanese yen). Our operating profitability could be materially affected by large fluctuations in the rate of exchange between the euro and such other currencies. To minimize our exposure to exchange rate risks, we sometimes use certain financial instruments for hedging purposes.

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

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

Consolidated research and development expenses, as described above, amounted to €4.3 million, €3.2 million and €2.4 million in 2008, 2007 and 2006, respectively, representing approximately 18.5%, 14% and 12% of total revenues in 2008, 2007 and 2006, respectively. The increase in research and development in 2008 compared to 2007 was primarily due to an increase in clinical expenses for the Phase II/III PMA trials in the United States to expand our leadership in HIFU for prostate cancer (the cost of which represented 9% of total revenues in 2008). Beginning in 2009, management expects the budget for research and development expenses in Europe (excluding the conduct of FDA clinical trials in the United States) to level off at approximately 12% of total revenues, which we expect will allow us to maintain our strategy to launch new clinical studies (thus strengthening our clinical credibility), to continue to focus our efforts on getting regulatory approvals and reimbursement in key countries, to continue to develop our HIFU and ESWL product range and to fund projects to expand the use of HIFU beyond the treatment of prostate cancer.

Selling and marketing expenses amounted to €5.7 million in 2008, €5.5 million in 2007 and, €4.6 million in 2006. The increase of 18.5% from 2006 to 2007 was primarily due to an increase in marketing expenses to increase awareness and educate patients and physicians on the availability of the Ablatherm-HIFU technology for treating localized prostate cancer. Management expects marketing and sales efforts to stay at significant levels in the future to consolidate the Ablatherm-HIFU technology's status as a standard of care for prostate cancer in Europe.

In 2008, we did not record any non-recurring operating expense. In 2007, we recorded €0.2 million of non-recurring operating expenses, net, including €0.5 million of employee termination expenses and a €0.3 million non-recurring profit with the return of the lithotripsy and HIFU devices from HealthTronics as part of the termination of the Distribution Agreement. In 2006, we recorded €0.3 million of non-recurring operating expenses, including €0.2 million of employee termination expenses and €0.1 million of capital increase expenses. See Note 18 of the Notes to the Consolidated Financial Statements.

In several past years, we experienced declining sale prices in the market for ESWL lithotripters. In 2008, however, our ESWL sales had a significant increase as a result of the success of our recently launched Sonolith Isys device, and a sustained commercial effort in both the European and Asian markets. We believe that the market for ESWL lithotripters is now mature and has become primarily a replacement and maintenance market, with high equipment penetration rates driving down demand and increasing price competition. As a result of these factors, we expect unit sale prices for ESWL lithotripters worldwide to continue to decline and total market volumes to remain stable at current levels in the foreseeable future.

We believe that our results of operations in the near future will be affected by our ability to control expenses in connection with the development, marketing and commercial launch of HIFU applications, including the Ablatherm, and the funding of Ablatherm trials in the United States in order to continue the FDA process. See “—Liquidity and Capital Resources.” Increases, if any, in expenses may only be offset partially in the near future by revenues arising from sale of HIFU devices and treatments.

See Item 3, “Key Information—Risk Factors—We sell our products in many parts of the world and, as a result, our business is affected by fluctuations in currency exchange rates” and Item 11, “Quantitative and Qualitative Disclosures About Market Risk” for a description of the impact of foreign currency fluctuations on our business and results of operations.

### **Fiscal Year Ended December 31, 2008 Compared to Fiscal Year Ended December 31, 2007**

We report our segment information on a “net contribution” basis, so that each segment's results comprise the elimination of our intra-group revenues and expenses and thus reflect the true contribution to consolidated results of the segment. See Note 28 to the Financial Statements.

Total revenues.

Our total revenues increased 3.3% from €22.3 million in 2007 to €23.1 million in 2008, principally due to sustained equipment and RPP sales in the HIFU division and the increase in Lithotripsy equipment sales.

*HIFU division.* The HIFU division's total net revenues remained stable at €9.2 million in 2008 as compared to €9.3 million in 2007. We experienced an unusually lower level of both equipment and RPP sales in the first two quarters of 2008, which we believe was due to the uncertainty in the economic and financial market

worldwide. However, we increased our marketing and promotional activities in the latter half of 2008, and we experienced a higher sales level in the last quarter, offsetting the slower sales activities in the first two quarters.

The HIFU division's net sales of medical devices remained stable at €2.7 million in 2008, with 7 Ablatherm units sold in 2008, as compared €2.7 million in 2007, with 6 units sold. The decrease in the average unit sales price from €444 thousand in 2007 to €384 thousand in 2008 was mostly due to the higher price level we achieved in 2007 for sales into Russia.

Net sales of treatments on a mobile and fixed RPP basis slightly decreased from €3.7 million in 2007 to €3.5 million in 2008.

Net sales of consumables decreased 17% from €1.2 million in 2007 to €1.0 million in 2008 as the equipment sales to Russian customers in 2007 accompanied orders for an usually higher amount of consumables, and net sales of HIFU-related spare parts, supplies, leasing and services increased 7.5% from €1.7 million in 2007 to €1.9 million in 2008.

Other HIFU-related revenue increased from €60 thousand in 2007 to €138 thousand in 2008, as a result of the increase in the HIFU related consulting services and government subsidies for HIFU research.

*UDS division.* The UDS division's net revenues increased 6.6% from €13.0 million in 2007 to €13.9 million in 2008.

The UDS division's net sales of medical devices increased 15.9% from €6.5 million in 2007 to €7.5 million in 2008 with 49 devices sold in 2008 compared to 38 units sold in 2007. The 10% decrease in the average sales price in 2008 was mostly due a higher number of lower-priced Sonolith Praktis units sold in 2008 with less optional equipment.

Net sales of UDS-related spare parts, supplies and services decreased 2.8% from €6.4 million in 2007 to €6.3 million in 2008, primarily related to the ongoing expiration of service contracts with the relatively higher price levels on older generation lithotripsy machines.

Other UDS-related revenue increased from €53 thousand in 2007 to €59 thousand in 2008.

#### Cost of sales.

Cost of sales increased 6.1% from €13.1 million in 2007 to €14.0 million in 2008, and represented 61.1% as a percentage of net sales in 2008, up from 59.2% as a percentage of net sales in 2007.

#### Operating expenses.

Operating expenses increased 4%, or €0.5 million, from €13.3 million in 2007 to €13.8 million in 2008. Without the effect of the FDA/PMA trials, operating expenses decreased 2.2%, largely due to the €0.5 million of non-recurring expenses in 2007.

The costs associated with the FDA/PMA trial accounted for €2.2 million in 2008 compared to €1.7 million in 2007, comprising mostly clinical and administrative expenses due to the ongoing PMA trials in the United States. These FDA/PMA trials also included in 2007 a one-time settlement that resulted in a €0.3 million gain recognized as part of the termination agreement negotiated with HealthTronics.

Excluding the FDA/PMA trials, marketing and sales expenses increased €0.3 million, or 5.4%, mostly due to the UDS division's activities to support the commercial introduction of the new Sonolith Isys lithotripsy device, while HIFU marketing and sales efforts remained stable in uncertain markets.

Excluding the FDA/PMA trials, research and development expenses remained stable at €2.2 million in 2008 and 2007.

Excluding the FDA/PMA trials, general and administrative expenses decreased 11.1% from €4.2 million in 2007 to €3.8 million in 2008, mostly due to the €0.5 million of non-recurring expenses in 2007 relating to the severance packages for certain senior executives.

Operating loss.

As a result of the factors discussed above, we recorded a consolidated operating loss of €4.7 million in 2008, as compared to a consolidated operating loss of €4.1 million in 2007.

Excluding the expenses of the FDA/PMA trials, the consolidated operating loss in 2008 was €2.5 million, an improvement of €0.2 million when compared to the previous year.

We realized an operating profit in the HIFU division of €0.5 million in 2008, compared to €0.2 million in 2007 and an operating loss in the UDS division of €1.0 million in 2008, as compared to operating loss of €0.6 million in 2007.

*Interest result, net.* Interest result, net was a gain of €5.2 million in 2008, including €6.7 million of debt fair value variation, compared with a loss of €1.2 million in 2007.

*Foreign currency exchange gains (loss), net.* In 2008, we recorded a net foreign currency exchange gain of €0.6 million, mainly due to favorable exchange rate variation of the US Dollar and the Japanese Yen against the euro, compared to a loss of €0.3 million in 2007 mainly due to the weakening of the Japanese yen against the euro.

*Other income (expense), net.* Other income (expense), net was a loss of €1 thousand in 2008, compared to a gain of €16 thousand in 2007.

*Income taxes.* We recorded a corporate income tax benefit of €492 thousand in 2008 compared to a benefit of €140 thousand in 2007. The increase was mainly due to exceptional research and development tax credits in 2008, resulting from the French government decision to increase R&D tax advantages, and from an exceptional acceleration in tax filings that allowed us to record in 2008 of both 2007 and 2008 R&D tax credits.

Net profit / loss.

We realized a consolidated net profit of €1.6 million in 2008 compared with consolidated net loss of €5.4 million in 2007, as a result of the factors mentioned above.

**Fiscal Year Ended December 31, 2007 Compared to Fiscal Year Ended December 31, 2006**

As from the first quarter of 2007, we elected to report our segment information on a “net contribution” basis, so that each segment’s results comprise the elimination of our intra-group revenues and expenses and thus reflect the true contribution to consolidated results of the segment. See Note 28 to the Financial Statements. We have reclassified our 2006 results using this method for comparative purposes.

Total revenues.

Our total revenues increased 10% from €20.3 million in 2006 to €22.3 million in 2007, principally due to the transition in the HIFU division to the new RPP model and the increase in the number of HIFU treatments.

*HIFU division.* The HIFU division’s total net sales increased 22% from €7.6 million in 2006 to €9.3 million in 2007, principally due to an increase in Ablatherm RPP and revenues related to disposables and service activity.

The HIFU division’s net sales of medical devices increased 2%, from €2.6 million in 2006 to €2.7 million in 2007, with six Ablatherm units sold in 2007 compared to eight units sold in 2006. The increase in the average unit sales price from €326 thousand in 2006 to €444 thousand in 2007 was due to the fact that three of the devices sold in 2006 were used machines and only new machines were sold in 2007.

Net sales of treatments on a mobile and fixed RPP basis increased 33%, from €2.8 million in 2006 to €3.7 million in 2007. This was a result of our efforts to increase patient and physician awareness about the availability of Ablatherm-HIFU treatment for localized prostate cancer, which has increased demand from hospitals and clinics, as well as from patients, for this HIFU treatment.

As a result of that increase in the number of total HIFU treatments, net sales of consumables increased 60% from €0.7 million in 2006 to €1.2 million in 2007, and net sales of HIFU-related spare parts, supplies, leasing and services increased 17% from €1.5 million in 2006 to €1.7 million in 2007.

Other HIFU-related revenue decreased from €66 thousand in 2006 to €60 thousand in 2007.

*UDS division.* The UDS division's net sales increased 3% from €12.6 million in 2006 to €12.9 million in 2007.

The UDS division's net sales of medical devices increased 8% from €6.0 million in 2006 to €6.5 million in 2007 with 38 devices sold in 2006 and 2007 and a better Average Sales Price in 2007 due to better sales in the higher price segment, mostly due to the launch of the new Sonolith I-sys and despite a negative Japanese yen/euro exchange rate.

Net sales of UDS-related spare parts, supplies and services decreased 2% from €6.6 million in 2006 to €6.4 million in 2007, primarily related to the expiration of more profitable service contracts on older generation lithotripsy machines that were not renewed.

Other UDS-related revenue increased from €26 thousand in 2006 to €53 thousand in 2007.

#### Cost of sales.

Cost of sales increased 10% from €11.9 million in 2006 to €13.1 million in 2007, stable at 59.2% as a percentage of net sales.

#### Operating expenses.

Operating expenses increased 16%, or €1.9 million, from €11.4 million in 2006 to €13.3 million in 2007. This increase in operating expenses resulted from costs associated with the resumption of the FDA clinical trials and sustained efforts in Europe to improve market education on HIFU and to enhance our Ablatherm-HIFU position.

The costs associated with the FDA/PMA trial accounted for €1.7 million of expenses, comprising mostly clinical and administrative expenses due to the takeover of the PMA trial sponsorship from HealthTronics and the resumption of the selection of clinical centers and patient enrollment. These FDA/PMA trials also included a one-time settlement that resulted in a €0.3 million gain recognized as part of the termination agreement negotiated with HealthTronics.

Excluding the FDA/PMA trials, marketing and sales expenses increased €0.8 million, or 17%, mostly in the HIFU division which accounted for €0.5 million of the increase, or 21%, as a result of the continuing efforts to increase market acceptance and penetration in Europe through the HIFU-RPP model, while expenses in the UDS division increased €0.3 million to prepare for the launch of the new Sonolith I-Sys lithotripsy device.

Excluding the FDA/PMA trials, research and development expenses decreased from €2.4 million in 2006 to €2.3 million in 2007, mostly due to the reallocation of research and development resources to support the FDA/PMA trials, while research and development expenses in the UDS division were stabilized after a more significant effort in the previous year to develop the new lithotripsy machine.

Excluding the FDA/PMA trials, general and administrative expenses decreased from €4.1 million in 2006 to €3.7 million in 2007, a decrease of 9%, while non-recurring expenses increased €0.3 million due to the impact of the severance packages of some senior executives.

#### Operating loss.

As a result of the factors discussed above, we recorded a consolidated operating loss of €4.1 million in 2007, which included expenses for general corporate purposes and the expenses incurred for the resumption of the FDA/PMA trials, as compared to a consolidated operating loss of €3.1 million in 2006.

Excluding the expenses of the FDA/PMA trials, the consolidated operating loss in 2007 was €2.7 million, an improvement of €0.4 million when compared to the previous year.



We realized an operating profit in the HIFU division of €0.2 million in 2007, compared to an operating loss of €0.1 million in 2006 and an operating loss in the UDS division of €0.6 million in 2007, as compared to operating loss of €1.1 million in 2006.

*Interest result, net.* Interest result, net was a loss of €1.2 million in 2007, including €1.1 million of debt fair value variation, compared with a profit of €0.2 million in 2006.

*Foreign currency exchange gains (loss), net.* In 2007, we recorded a net foreign currency exchange loss of €0.3 million, compared to a loss of €0.4 million in 2006, in each case mainly due to the continued weakening of the Japanese yen against the euro.

*Other income (expense), net.* Other income (expense), net was a gain of €16 thousand in 2007, compared to a loss of €5 thousand in 2006.

*Income taxes.* We recorded a corporate income tax profit of €140 thousand in 2007 compared to an expense of €56 thousand in 2006.

Net loss.

We realized a consolidated net loss of €5.4 million in 2007 compared with consolidated net loss of €3.4 million in 2006, as a result of the factors mentioned above.

### **Effect of Inflation**

Management believes that the impact of inflation was not material to our net sales or loss from operations in the three years ended December 31, 2008.

### **Liquidity and Capital Resources**

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. Cyclical demand has historically resulted in significant annual and quarterly fluctuations in trade and other receivables and inventories, and therefore led to significant variations in working capital requirements and operating cash flows that were not necessarily indicative of changes in our business. We believe our working capital is sufficient for our present working capital requirements although we have in the past experienced negative cash flows and associated risks to liquidity, and may in the future experience the same. Our negative cash flow situation is described in more detail below.

We anticipate that cash flow in future periods will be mainly derived from ongoing operations and any capital raising the Company would potentially undertake. We do not have any commercial commitments nor do we employ any off-balance sheet financing. Because we anticipate relying principally on cash and cash equivalent balances to meet our liquidity requirements, a decrease in the demand for our products, or the inability of our customers to meet their financial obligations to us due to operating difficulties or adverse market conditions, would reduce the availability of funds to us. Additionally, failure to meet our obligations arising out of the convertible debentures issued in the October 2007 private placement would cause us to incur substantial penalties in the form of liquidated damages and could, over the passage of time, lead to an event of default under the debentures. Payment of liquidated damages or mandatory default amount will have a material adverse effect on our financial condition and results of operation. See Item 3, “Key Information – Risk Factors – Risks Relating to the October 2007 Private Placement.”

Our cash position as of December 31, 2008, 2007 and 2006, was €15.0 million (including €1.1 million of short-term treasury investments), €18.6 million (including €1.1 million of short-term treasury investments) and €10.9 million (including €1.0 million of short-term treasury investments), respectively. We experienced negative cash flows of €3.6 million in 2008, and positive cash flows of €7.6 million in 2007 and €1.6 million in 2006. In 2008, our negative cash flow situation was primarily due to the lack of external financing similar to those raised in 2007 and 2006. In 2007, our positive cash flow situation was primarily due to raising approximately \$17.4 million (€11.9 million) in net proceeds by issuing \$20 million aggregate principal amount of our convertible debentures in a private placement to fund the FDA/PMA trial for the Ablatherm-HIFU device. Excluding the proceeds from the issuance of the convertible debentures, we experienced negative cash flows of €4.2 million in 2007. In 2006, our positive cash flow situation was primarily due to the net capital increase of €5.2 million realized during the summer



through a \$7.5 million private placement. Excluding the proceeds from this capital raise, we experienced negative cash flows of €3.7 million in 2006.

In 2008, net cash used in operating activities was €4.6 million compared with net cash used in operating activities of €2.7 million in 2007 and €1.9 million in 2006, respectively.

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

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

In 2007, net cash used in operating activities reflected principally:

- a net loss of €5.3 million;
- elimination of €3.1 million of net expenses without effects on cash, including €1.3 million of depreciation and amortization and €1.1 million due to changes in the fair value of financial debt and warrants;
- an increase in trade accounts receivable of €1.6 million;
- an increase in inventories of €0.8 million, mostly in anticipation of the launch of the new lithotripsy machine;
- an increase in payables of €1.0 million; and
- an increase in accrued expenses and other current liabilities of €0.7 million.

In 2006, net cash used in operating activities was €1.9 million compared with net cash used in operating activities of €0.3 million and €1.1 million in 2005 and 2004, respectively. In 2006, net cash used in operating activities reflected principally:

- a net loss of €3.4 million;
- elimination of €1.9 million of net expenses without effects on cash, including €1.3 million of depreciation and amortization;
- an increase in trade accounts receivable of €1.2 million;
- a decrease in inventories of €0.4 million, reflecting dedicated actions to reduce the level of both the inventory of finished goods and spare parts; and
- an increase in accrued expenses and other current liabilities of €0.3 million.

In 2008, net cash used in investing activities was €712 thousand compared with net cash used of €1.2 million in investing activities in 2007 and €1.6 million in 2006, reflecting investments of €0.7 million in capitalized assets produced by the Company (mainly Ablatherm devices as a support of the RPP business model in HIFU), an investment of €0.4 million in property and equipment, and net proceeds from sales of leased-back assets of €1.1 million.

In 2007, net cash used in investing activities was €1.2 million, reflecting principally an increased investment of €1.9 million in capitalized assets produced by the company (mainly Ablatherm devices as a support of the RPP business model in HIFU), an investment of €0.5 million in property and equipment, net proceeds from sales of leased-back assets of €1.2 million and net proceeds from sales of assets of €0.2 million.

In 2006, net cash used in investing activities reflected principally an increased investment of €1.3 million in capitalized assets produced by the Company (mainly Ablatherm devices as a support of the Revenue-Per-Procedure business model in HIFU), an investment of €0.2 million in property and equipment, net proceeds from sales of leased-back assets of €0.7 million and net proceeds from sales of assets of €0.2 million. Cash flows from investing activities also include short term treasury investments of €1.0 million, as part of the cash management investment support.

In 2008, net cash provided by financing activities was €0.3 million compared with net cash provided in financing activities of €11.8 million in 2007, and net cash used of €5.2 million in 2006, reflecting principally the increase in capital of €0.6 million linked with the issuance of new shares in payment of the interest coupons on the convertible debt, a long-term debt increase of €0.2 million through the Japanese subsidiary, repayment of long term borrowing for €0.1 million, repayment of capital lease obligations totaling €0.6 million, and an increase of €0.2 million in bank overdrafts.

In 2007, net cash provided by financing activities was €11.8 million, reflecting principally the raising of net proceeds of €11.9 million in convertible debt, €0.4 million of net proceeds of capital raising through the exercise of warrants and stock options, a short-term debt increase of €0.3 million, repayment of long term borrowing for €0.1 million and repayment of capital lease obligations totaling €0.6 million.

In 2006 net cash provided by financing activities reflected principally a share capital increase of €5.2 million, a short-term debt increase of €0.4 million, an increase in long term borrowing for €0.2 million reimbursed of €0.2 million and repayment of capital lease obligations totaling €0.5 million.

Our future cash flow may also be affected by the expansion of our mobile RPP business. In 1999, in an effort to increase the availability of our equipment, we implemented a new marketing strategy of leasing our medical devices on a monthly, quarterly or yearly basis, rather than selling them directly to end-users, and in 2002, we began to develop our mobile activity by making certain devices available to hospitals and clinics free of charge, charging instead on the basis of each procedure that was performed. Relative to the sale of devices, this business model initially generates smaller, but more predictable cash flows. The RPP model is now established in Europe as a growth and profitability model, and we will continue to expand this business model in the near future.

On October 31, 2007, we completed the private placement of \$20 million aggregate principal amount of our 9% Senior Convertible Debentures due 2012. In addition, the purchasers of the convertible debentures and our Placement Agent received warrants to purchase our ordinary shares, which expire in 2013. The October 2007 private placement resulted in net proceeds of approximately \$17.4 million. The terms of the convertible debentures allow us to use the proceeds of the private placement to finance costs associated with the regulatory approval for the commercialization of Ablatherm HIFU in the United States (including related clinical trials) and for general and administrative expenses. The warrants may be exercised for cash or, under certain circumstances, through a cashless exercise procedure. If all of the warrants issued under the October 2007 private placement are fully exercised for cash, including the warrants issued to the 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. For further description on the terms of the convertible debentures and the use of proceeds relating to the issuance of the convertible debentures, see the Form of Securities Purchase Agreement dated as of October 29, 2007, included as Exhibit 4.5 to this annual report.

Our policy is that the treasury function should maintain liquidity with the use of short-term borrowings and the minimal use of long-term borrowings. The treasury function currently adheres to this objective with the use of fixed-rate debt, which normally consists of long-term borrowing from a Japanese bank and with certain long-term borrowings consisting of sale and leaseback equipment financing. Currently the majority of our short-term debt is based on an annual variable rate: Euribor+0.5 and Eonia+0.5. We maintain bank accounts for each of our subsidiaries in the local currencies of each subsidiary. The primary currencies in which we maintain balances are the euro, the U.S. dollar and the Japanese yen. To minimize our exposure to exchange rate risks, we may use certain financial instruments for hedging purposes from time to time. As of December 31, 2008, there were no outstanding hedging instruments.

**Contractual Obligations and Commercial Commitments as of December 31, 2008 (in thousands of euro, excluding interest expenses)**

	<b>Payments Due by Period</b>				
	<b>Total</b>	<b>Less than 1 year</b>	<b>1-3 years</b>	<b>4-5 years</b>	<b>More than 5 years</b>
Short-Term Debt.....	1,753	1,753	—	—	—
Long-Term Debt.....	9,579	79	—	9,500	—
Capital Lease Obligations.....	2,019	708	1,271	40	—
Operating Leases .....	1,275	532	743	—	—

**New Accounting Pronouncements**

In February, 2008, the FASB issued FASB Staff Position (“FSP”) FASB 157-2, “Effective Date of FASB Statement No. 157.” This FSP delays the effective date of SFAS No. 157 for all nonfinancial assets and nonfinancial liabilities, except those that are recognized or disclosed at fair value in the financial statements on a recurring basis (at least annually). The effective date for nonfinancial assets and nonfinancial liabilities has been delayed by one year to fiscal years beginning after November 15, 2008 and interim periods within those fiscal years. The Company has not completed its analysis of the potential impact of the adoption of SFAS No. 157 for nonfinancial assets and nonfinancial liabilities (effective January 1, 2009) on the Company’s financial position and results of operations.

In March 2008, the FASB issued SFAS No. 161 (SFAS 161), “Disclosures about Derivative Instruments and Hedging Activities.” SFAS 161 amends and expands the disclosure requirements of SFAS No. 133, “Accounting for Derivative Instruments and Hedging Activities”, and is effective for fiscal years beginning after November 15, 2008. The Company has not determined yet the effect on consolidated financial statements, if any, upon adoption of SFAS 161.

In April 2008, the FASB issued FASB Staff Position (“FSP”) SFAS No. 142-3, “*Determination of the Useful Life of Intangible Assets*”. This FSP amends the factors that should be considered in developing renewal or extension assumptions used to determine the useful life of a recognized intangible asset under FASB Statement No. 142, “*Goodwill and Other Intangible Assets*” (“SFAS 142”). The intent of this FSP is to improve the consistency between the useful life of a recognized intangible asset under SFAS 142 and the period of expected cash flows used to measure the fair value of the asset under SFAS 141R, and other GAAP. This FSP is effective for financial statements issued for fiscal years beginning after December 15, 2008, and interim periods within those fiscal years. Early adoption is prohibited. The Company has not determined yet the effect on consolidated financial statements, if any, upon adoption of SFAS 142-3.

In May 2008, the FASB issued Staff Position FSP APB 14-1 (FSP APB 14-1), “Accounting for Convertible Debt Instruments That May Be Settled in Cash upon Conversion (Including Partial Cash Settlement).” FSP APB 14-1 requires companies that have issued convertible debt that may be settled wholly or partly in cash when converted, to account for the debt and equity components separately. The value assigned to the bond liability is the estimated value of a similar bond without the conversion feature as of the issuance date. The difference between the proceeds for the convertible debt and the amount reflected as a bond liability is recorded as additional paid-in-capital. Interest expense is recorded using the issuer’s comparable debt rate. FSP APB 14-1 is effective for fiscal years beginning after December 15, 2008 and interim periods within those fiscal years and will require retrospective application. The Company does not expect that this will have a significant impact on its consolidated financial statements.

In June 2008, the FASB issued Financial Accounting Standards Board Staff Position EITF 03-6-1, *Determining Whether Instruments Granted in Share-Based Payment Transactions Are Participating Securities* (“FSP EITF 03-6-1”). The FSP provides that unvested share-based payment awards that contain nonforfeitable rights to dividends or dividend equivalents (whether paid or unpaid) are participating securities and shall be included in the computation of earnings per share pursuant to the two-class method in accordance with SFAS 128, Earnings per Share. The FSP is effective for financial statements issued for fiscal years beginning after December 15, 2008, and interim periods within those years. Upon adoption, the Company is required to retrospectively adjust its earnings per share data to conform with the provisions in this FSP. Early application of this FSP is prohibited. The Company has not determined yet the effect on consolidated financial statements, if any, upon adoption of FSP EITF 03-6-1.

### **Research and Development, Patents and Licenses**

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

### **Off-Balance Sheet Arrangements**

We have no off-balance sheet arrangements.

## Item 6. Directors, Senior Management and Employees

### Senior Executive Officers

The following table sets forth the name, age and position of each of our Senior Executive Officers as of March 16 2009. The Chief Executive Officer and the Chief Financial Officer listed below have entered into employment contracts with us or our subsidiaries (which permit the employee to resign subject to varying notice periods). In addition, in case of a change of control of the Company, or of a termination of their employment contract by the Company without cause, the Senior Executive Officers are entitled to receive severance packages totaling approximately € 0.4 million.

Name	Age	Position
Philippe Chauveau	73	Chairman of the Board of Directors
		In 1997, Philippe Chauveau was named chairman of EDAP TMS S.A.'s Supervisory Board, involving a two-tier board structure overseeing a Management Board. In 2002, both these boards were replaced by a single Board of Directors, which Philippe Chauveau headed as Chairman and CEO. While remaining Chairman of the Board, he was succeeded by Hugues de Bantel as CEO in 2004, and by Marc Oczachowski in 2007. Since 2000, and up to 2007, Philippe Chauveau also served as founding Chairman of the Board of Scynexis Inc., funded by private equity, which is an innovative drug discovery company based in the United States, partnering with major pharmaceutical companies worldwide. He is also personal executive coach to senior research leaders at Hoffmann LaRoche. Additionally, he is involved in management development programs at Solvay Business School in Brussels, Belgium. He was Vice-President of research and development at AT&T Bell Labs and has also served as Chairman of Apple Computer Europe, preceded by increasing marketing roles in ITT and in Procter & Gamble. He has an Honours Degree from Trinity College Dublin with a B.A. and a Bsc.
Marc Oczachowski	38	Chief Executive Officer of EDAP TMS S.A. and President of the HIFU Division and the UDS Division
		Marc Oczachowski joined the Company in May 1997 as Area Sales Manager, based in Lyon, France. From March 2001 to January 2004, he held management positions as General Manager of EDAP Technomed Malaysia. He was appointed Chief Operating Officer of EDAP TMS in November 2004 and became Chief Executive Officer of the Company on March 31, 2007. Previously he worked for Sodem Systems, which manufactures orthopaedic power tools, as Area Sales Manager. He is a graduate of Institut Commercial de Lyon, France.
Eric Soyer	42	Chief Financial Officer of EDAP TMS S.A.
		Eric Soyer joined the Company in December 2006. He was previously CFO of Medica, a €270 million French company operating 108 nursing home and post-care clinics throughout France and Italy. Previously he was CFO and a Managing Director of April Group, an insurance services company listed on the Paris stock exchange, with 22 subsidiaries in France, the UK, Spain, Germany and Italy. He has international experience as a controller and cost accountant for Michelin Group in France, the United States and Africa. Eric Soyer has a BA degree from Clermont Graduate School of Management, an MBA degree from the University of Kansas and an Executive MBA degree from the HEC Paris School of Management.

## Board of Directors

The following table sets forth the names and backgrounds of the members of the Board of Directors. The mandate for each member of the Board of Directors expires on the date of the annual meeting of shareholders approving the financial results for fiscal year 2013, in June 2014. There is no contract providing for benefits upon termination of the directors' mandates.

Philippe Chauveau See biography under “—Senior Executive Officers.”

Pierre Beysson  
Age: 67

Pierre Beysson was appointed as a member of the Board of Directors in September 2002. Pierre Beysson was then the Chief Financial Officer of Compagnie des Wagons-Lits ("CWL"), the on-board train service division of Accor, a French multinational Hotel and Business Services Group. In this capacity, he sat on a number of boards of companies related to the Accor Group. He is now a mergers and acquisitions consultant. Before his assignment at CWL, Pierre Beysson held a number of senior financial positions with Nixdorf Computers, Trane (Air Conditioning), AM International (Office Equipment) and FMC (Petroleum Equipment). Pierre Beysson was trained as a CPA, has auditing experience and has an MBA from Harvard Business School.

Karim Fizazi  
Age: 43

Dr. Karim Fizazi was appointed as a member of the Company's Board of Directors in November 2002. He is currently Chairman of the Genito-Urinary Oncology group at Institut Gustave Roussy in Villejuif, France, which is the biggest cancer center in Europe. He was appointed Head of Department of Medicine of Institut Gustave Roussy in 2005. He was visiting Assistant Professor, Genitourinary Medical Oncology Department, MD Anderson Cancer Center in Houston, Texas for 18 months. His residency included a position at the Institut Curie in Paris.

Jean-Philippe Deschamps  
Age: 67

Pr. Jean-Philippe Deschamps was appointed as a member of the Company's Board of Directors in March 2007. He is Emeritus Professor of Technology and Innovation Management at IMD, in Lausanne, Switzerland. Prior to joining IMD in November 1996, he was based in Brussels as a corporate Vice-President with Arthur D. Little and Chairman of the firm's technology and innovation management practice, which he created in 1981. Before that, he was Arthur D. Little's first European practice leader for strategy and organization. He has thirty years of international management consulting experience throughout Europe, North America, Asia and the Middle East. He graduated from Ecole des Hautes Etudes Commerciales in Paris and received his MBA from INSEAD and from the Harvard Business School.

## Compensation and Options

The entire Board of Directors acts as a “Compensation Committee” to review the compensation of our Senior Executive Officers, as per the approved charter of the “Compensation Committee”, and to propose any changes to compensation paid to the Board of Directors, provided that the majority of independent members participate in the votes for Management compensations. Aggregate compensation paid or accrued for services in all capacities by the Company and its subsidiaries to Senior Executive Officers and to the Board of Directors as a group for the fiscal year 2008 was approximately €0.77 million. No amount was set aside or accrued by us to provide pension, retirement or similar benefits for Senior Executive Officers and to the Board of Directors as a group in respect of the year 2008.

As of December 31, 2008, Senior Executive Officers held an aggregate of 191,763 options to purchase or to subscribe to shares of our common stock, with a weighted average exercise price of €3.71 per shares. Of these options, 6,425 expire on June 18, 2012, 30,000 expire on February 24, 2014 and 155,338 expire on October 29, 2017.



## Audit Committee

The Board of Directors' Audit Committee comprises four fully independent members: Mr. Pierre Beysson, acting as Head of the Audit Committee, Mr. Philippe Chauveau, Dr. Karim Fizazi and Pr. Jean-Philippe Deschamps. The purpose of the Committee, conforming to its annually approved charter, is to:

- Provide assistance to the Board of Directors in fulfilling their oversight responsibility to the shareholders, potential shareholders, the investment community and others relating to: the integrity of our financial statements, our compliance with legal and regulatory requirements, our accounting practices and financial reporting processes, the effectiveness of our disclosure controls and procedures and internal control over financial reporting, the independent auditor's qualifications and independence, and the performance of our internal audit function and independent auditors.
- Prepare the Audit Committee report that SEC proxy rules require to be included in our annual proxy statement. The Audit Committee may request any officer or employee of the Company or our outside counsel or independent auditor to attend a meeting of the Committee or to meet with any members of, or consultants to, the Committee.

## Employees

As of December 31, 2006, we employed 142 individuals on a full-time basis, employed as follows:

	Sales & Marketing	Manufac-turing	Service	Research & Dvpt	Regula-tory	Clinical Affairs	Adminis-trative	Total
France .....	15	22	24	9	3	3	17	93
Italy.....	3	0	0	0	0	0	2	5
Germany .....	2	0	2	0	0	0	2	6
Japan.....	9	0	14	0	2	0	4	29
Malaysia .....	2	0	3	0	0	0	2	7
South Korea.....	1	0	0	0	0	0	1	2
Total = .....	32	22	43	9	5	3	28	142

As of December 31, 2007, we employed 148 individuals on a full-time basis, employed as follows:

	Sales & Marketing	Manufac-turing	Service	Research & Dvpt	Regula-tory	Clinical Affairs	Adminis-trative	Total
France .....	14	29	20	10	4	2	16	95
Italy.....	3	0	0	0	0	0	2	5
Germany .....	3	0	2	0	0	0	3	8
Japan.....	8	0	15	0	2	0	4	29
Malaysia .....	2	0	3	0	0	0	2	7
South Korea.....	1	0	0	0	0	0	1	2
Russia .....	1	0	0	0	0	0	0	1
USA.....	0	0	0	0	0	1	0	1
Total = .....	32	29	40	10	6	3	28	148

As of December 31, 2008, we employed 149 individuals on a full-time basis, employed as follows:

	Sales & Marketing	Manufacturing	Service	Research & Dvpt	Regulatory	Clinical Affairs	Administrative	Total
France .....	16	31	19	11	4	2	13	96
Italy.....	3	0	0	0	0	0	2	5
Germany .....	4	0	2	0	0	0	2	8
Japan .....	9	0	15	0	2	0	3	29
Malaysia .....	2	0	3	0	0	0	2	7
South Korea.....	1	0	0	0	0	0	1	2
Russia .....	1	0	0	0	0	0	0	1
USA .....	0	0	0	0	0	1	0	1
Total = .....	36	31	39	11	6	3	23	149

Management considers labor relations to be good. Employee benefits are in line with those specified by applicable government regulations.

### Share Ownership

As of March 20, 2009, the total number of shares issued was 10,006,333, with 423,740 shares held as Treasury Stocks, thus bringing the total number of shares outstanding to 9,582,593.

As of March 20, 2009, the Board of Directors and the Senior Executive Officers of the Company held a total of 224 Shares.

### Options to Purchase or Subscribe for Securities

As of March 16 2009, we had sponsored five stock purchase and subscription option plans.

On May 14, 1998, the shareholders of EDAP TMS S.A. authorized the Board of Directors to grant up to 713,425 options to purchase pre-existing Shares at a fixed exercise price to be set by the Board of Directors. The shareholders also authorized the Board of Directors to cause EDAP TMS S.A. to repurchase up to 535,675 of its own Shares (treasury stock) to cover the options granted under the new plan. Up to 279,000 of the 713,425 options were reserved for modification of the terms of pre-existing options.

On June 12, 2001, the shareholders of EDAP TMS S.A. authorized the Board of Directors to grant up to 300,000 options to purchase pre-existing Shares and 80,000 options to subscribe to new Shares, at a fixed exercise price to be set by the Supervisory Board.

On January 29, 2004, the shareholders of EDAP TMS S.A. authorized the Board of Directors to grant up to 240,000 options to purchase pre-existing Shares and 100,000 options to subscribe to new Shares, at a fixed price to be set by the Board of Directors. All of the Shares that may be purchased through the exercise of stock options are currently held as treasury stock.

On February 17, 2005, the shareholders of EDAP TMS S.A. authorized the Board of Directors to grant up to 625,000 free shares to be issued to certain employees of the Company, subject to compliance with the conditions and performance criteria fixed by the Board of Directors. On March 30, 2005, 500,900 rights to subscribe for free shares were granted by the Board of Directors, based on certain performance criteria to be met for years 2005 and 2006. However, given the dramatic shift of business model during 2005 from the sales of Ablatherm equipment towards the sales of treatment procedures (RPPs), on January 6, 2006, the Board of Directors decided to cancel the 2005 allocation plan and to set up a new one reflecting the new business model for years 2006 and 2007. On January 6, 2006, in accordance with the Performance Stock Plan authorized by the shareholders, 564,100 rights to subscribe to new shares were distributed, including new entrants. On July 3, 2006, an additional 13,800 rights to

subscribe to new shares were distributed to new entrants. On March 8, 2007, 47,100 rights to subscribe to new shares were granted to new entrants by the Board of Directors, based on certain performance criteria to be met for years 2007 and 2008. On that same date, upon reviewing and approving the consolidated 2006 results, the Board confirmed that 2006 performance criteria fixed by the Board on January 6, 2006 were not met. 313,680 rights to subscribe to new shares, based on these fixed performance criteria were then cancelled and these shares will then never be subscribed and issued. On March 8, 2007, a revised business model was approved by the Board of Directors for years 2007 and 2008. On that date, 47,100 rights to subscribe to new shares were granted to new entrants, subject to the achievement of certain milestones based on the revised 2007-2008 business model. As of December 31, 2007 none of the milestones for the year 2007, fixed by the January 6, 2006 Board of Directors, have been reached, and only one milestone fixed by the March 8, 2007 Board of Directors has been reached, thus triggering the allocation of 7,065 new shares to some employees. As per the Performance Stock Plan approved on March 8, 2007, these shares will only be issued on July 2009. As of December 31, 2007, 211,435 rights to subscribe to new shares, based on these fixed performance criteria for the year 2007 were then cancelled and these shares will then never be subscribed and issued. As of December 31, 2007, only 18,840 rights out of the 625,000 initially granted were still in force, based on 2008 milestones. As of December 31, 2008, only one milestone, out of four milestones fixed by the Board of Directors on March 8, 2007, was reached on 2008 performance goals, thus triggering the allocation of 4,710 new shares to some employees. A total of 11,775 new shares will then be issued in July 2009 conforming the March 8, 2007 plan. As of December 31, 2008, no right under the February 2005 authorization remained in force.

On May 22, 2007, the shareholders of EDAP TMS S.A. authorized the Board of Directors to grant up to 600,000 options to subscribe to 600,000 new Shares and up to 105,328 options to purchase pre-existing Shares at a fixed price to be set by the Board of Directors. All of the Shares that may be purchased through the exercise of stock options are currently held as treasury stock.

On December 31, 2008, the duration of our stock option contracts was as follows:

<b>Months until expiration</b>	<b>Number of Shares</b>
12 .....	1,212
33 .....	52,000
42 .....	6,425
62 .....	162,000
106 .....	485,088

As of December 31, 2008, a summary of stock option activity to purchase or to subscribe to Shares under these plans is as follows:

	<b>2008</b>		<b>2007</b>		<b>2006</b>	
	Options	Weighted average exercise price (€)	Options	Weighted average exercise price (€)	Options	Weighted average exercise price (€)
Outstanding on January 1, .....	781,625	3.51	502,162	2.49	593,262	2.58
Granted .....			504,088	3,99		
Exercised .....			(183,750)	2.03	(72,600)	3,20
Forfeited .....	(34,000)	3.59	(7,250)	2,60	(18,500)	2,60
Expired .....	(40,900)	3.37	(33,625)	3.81	-	-
Outstanding on December 31, .....	706,725	3.51	781,625	3.51	502,162	2.49
Exercisable on December 31, .....	342,929	3.00	234,787	2,63	405,162	2,73
Shares purchase options available for grant on December 31 .....	105,328		105,328	-	0	-

The following table summarizes information about options to purchase Shares already held by the Company as treasury Shares, or to subscribe to new Shares, at December 31, 2008:

Exercise price (€)	Outstanding options			Exercisable options	
	Options	Weighted average contractual life	Weighted average exercise price (€)	Options	Weighted average exercise price (€)
3.99	485,088	8.8	3.99	121,292	3.99
2.60	162,000	5.2	2.60	162,000	2.60
2.08 <sup>(1)</sup>	52,000	2.8	2.08	52,000	2.08
2.02 <sup>(2)</sup>	6,425	3.5	2.02	6,425	2.02
1.83	1,212	1.0	1.83	1,212	1.83
1.83 to 3.99	706,725	4.2	3.51	342,929	3.00

- (1) All the 52,000 options were granted on September 25, 2001 with an exercise price expressed in U.S. dollars (\$1.92) and converted here to euros based on the noon buying rate on September 25, 2001 (\$1 = €1.085).
- (2) All the 6,425 options were granted on June 18, 2002 with an exercise price expressed in U.S. dollars (\$1.92) and converted here to euros based on the noon buying rate on June 18, 2002 (\$1 = €1.0545).

## Item 7. Major Shareholders and Related Party Transactions

### Major Shareholders

To our knowledge, we are not directly or indirectly owned or controlled by another corporation, by any foreign government, or by any other natural or legal person or persons acting severally or jointly. At March 16, 2009, to our knowledge, the following persons had beneficial ownership of more than 5% of the Shares: Siemens France Holding owned 1,003,250 Shares representing 10.03% of the total share capital of the Company and (after subtracting treasury stock, which under French law carries no voting rights) 10.47% of voting rights, Bruce & Co., Inc, owned 742,044 shares representing 7.42% of the total share capital of the Company and (after subtracting treasury stock, which under French law carries no voting rights) 7.74% of voting rights, and Wells Capital Management, Inc. and Wells Fargo, together owned 667,234 Shares representing 6.67% of the total share capital of the Company and (after subtracting treasury stock, which under French law carries no voting rights) 6.96% of voting rights. The Shares owned by these persons do not carry special voting rights.

To our knowledge, there have been no significant changes in the percentage of ownership of our Shares over the past three years.

There are no arrangements known to us, the operation of which may at a later date result in a change of control of the Company.

As of March 13 2009, 10,006,333 Shares were issued, including 9,582,593 outstanding and 423,740 treasury Shares. At the same date, there were 9,843,850 ADSs, each representing one Share, all of which were held of record by 15 registered holders in the United States (including The Depository Trust Company).

### Related Party Transactions

The General Manager of the Company's Korean branch "EDAP-TMS Korea" is also Chairman of a Korean company named Dae You. EDAP-TMS Korea subcontracts to Dae You the service contract maintenance of our medical devices installed in Korea. The amounts payable under this contract were €61 thousand, €71 thousand and €61 thousand, for 2008, 2007 and 2006 respectively. Dae You also acts as an agent to promote our medical devices in South Korea, and receives commissions on sales. Dae You has purchased medical devices from us, which it operates in partnership with hospitals or clinics. These purchases amounted to €539 thousand, €558 thousand and

€588 thousand in 2008, 2007 and 2006 respectively. As of December 31, 2008, receivables from Dae You amounted to €384 thousand and our payables to them amounted to €31 thousand. As of December 31, 2007, receivables amounted to €52 thousand and payables to €28 thousand.

We purchase certain technological elements from Siemens AG, an affiliate of our shareholder Siemens France Holding. Total purchases amounted to €212 thousand, €183 thousand in 2007 and €444 thousand in 2006. As of December 31, 2008, payables due to Siemens AG amounted to €10 thousand and as of December 31, 2007, payables amounted to €1 thousand.

## **Item 8. Financial Information**

### **Consolidated Financial Statements**

See Item 18, “Financial Statements.”

### **Export Sales**

As of December 31, 2008, total consolidated export net sales, which we define as sales made outside of France, were €17.9 million, which represented 78% of total net sales.

### **Legal Proceedings**

As of the date of this annual report, the Company is not involved in any material legal proceedings.

In 2000, a patient made a product liability claim against the Company in the United States, alleging that he was injured in the course of a Prostatron procedure. In connection with the sale of the Prostatron business in October 2000, the Company agreed to retain liability for this claim. In February 2008, we reached a settlement for this claim with the cost of \$15,000 which was fully covered by our Product Liability Insurance.

### **Dividends and Dividend Policy**

The payment and amount of dividends depend on our earnings and financial condition and such other factors that our Board of Directors deems relevant. Dividends are subject to recommendation by the Board of Directors and a vote by the shareholders at the shareholders’ ordinary general meeting. Dividends, if any, would be paid in euro and, with respect to ADSs, would be converted at the then-prevailing exchange rate into U.S. dollars. Holders of ADSs will be entitled to receive payments in respect of dividends on the underlying Shares in accordance with the Deposit Agreement.

In France, dividends are paid out of after-tax income. Dividends paid to holders of Shares who are not residents of France generally will be subject to French withholding tax at a rate of 25%. Holders who qualify for benefits under an applicable tax treaty and who comply with the procedures for claiming treaty benefits may be entitled to a reduced rate of withholding tax and, in certain circumstances, certain other benefits, under conditions provided for in the relevant treaty under French law. See Item 10, “Additional Information—French Taxation—Taxation of Dividends on Shares or ADSs—Withholding Tax.”

No dividends were paid with respect to fiscal years 2004 through 2008, and we 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.

### **Significant Changes**

Except as otherwise disclosed in this Annual Report, there has been no material change in the financial position of EDAP TMS S.A. and its consolidated subsidiaries since December 31, 2008.

## Item 9. The Offer and Listing

### Description of Securities

The Shares are traded solely in the form of ADSs, each ADS representing one Share. Each ADS may be evidenced by an American Depositary Receipt issued by The Bank of New York, our Depositary. The principal United States trading market for the ADSs, which is also the principal trading market for the ADSs overall, is the NASDAQ Global Market of the NASDAQ Stock Market, Inc. (“NASDAQ”), on which the ADSs are quoted under the symbol “EDAP.” The principal non-U.S. trading market for the ADSs was NASDAQ Europe, formerly known as the European Association of Securities Dealers Automated Quotation System (“EASDAQ”), on which the ADSs were quoted under the symbol “EDAP”. We requested and received a conditional approval from NASDAQ Europe for the delisting of our ADSs effective on April 25, 2002.

### Trading Markets

The following tables set forth, for the years 2004 through 2008, the reported high and low sales prices of the ADSs on NASDAQ.

	NASDAQ	
	High	Low
	\$	
2008 .....	5.12	1.05
2007 .....	9.40	4.25
2006 .....	21.64	5.12
2005 .....	5.68	3.10
2004 .....	3.92	1.55

The following tables set forth, for the years 2007 and 2008, the reported high and low sales prices of the ADSs on NASDAQ for each full financial quarter:

	NASDAQ	
	High	Low
	\$	
<b><u>2007:</u></b>		
First Quarter.....	9.40	5.62
Second Quarter .....	8.85	5.67
Third Quarter .....	8.00	4.60
Fourth Quarter .....	6.62	4.25
<b><u>2008:</u></b>		
First Quarter.....	5.12	3.31
Second Quarter .....	4.00	2.74
Third Quarter .....	3.46	1.56
Fourth Quarter .....	2.24	1.05



The following table sets forth, for the most recent six months (from October 2008 through March 20, 2009), the reported high and low sale prices of the ADSs on NASDAQ for each month:

	<b>NASDAQ</b>	
	<b>High</b>	<b>Low</b>
	<b>\$</b>	
<b><u>2008:</u></b>		
October .....	2.24	1.05
November .....	2.19	1.22
December.....	1.57	1.10
<b><u>2009:</u></b>		
January.....	1.95	1.37
February.....	2.06	1.40
March (through March 20, 2009) .....	1.20	1.11

## **Item 10. Additional Information**

### **Memorandum and Articles of Association**

Set forth below is a brief summary of significant provisions of our articles of association (*statuts*) and applicable French laws. This is not a complete description and is qualified in its entirety by reference to our *statuts*. Each time they are modified, we file copies of our articles of association with, and such articles of association are publicly available from, the Registry of Commerce and Companies in Lyon, France, under number 316488204 RCS-LYON.

Our corporate affairs are governed by its articles of association and by Book II of the French Commercial Code, as amended.

Our articles of association were last updated in January 2009 to act the recent increase in share capital related to the issuance of additional shares in 2008.

### **Corporate Purposes**

Pursuant to Article 2 of the articles of association, the purposes of the Company are:

- the taking of financial interests, under whatever form, in all French or foreign groups, companies or businesses which currently exist or which may be created in the future, mainly through contribution, subscription or purchasing of stocks or shares, obligations or other securities, mergers, holding companies, groups, alliances or partnerships;
- the management of such financial interests;
- the direction, management, control and coordination of its subsidiaries and interests;
- the provision of all administrative, financial, technical or other services; and
- generally, all operations of whatever nature, financial, commercial, industrial, civil, relating to property and real estate which may be connected directly or indirectly, in whole or in part, to the Company's purposes or to any other similar or related purposes which may favor the extension or development of said purposes.

### **Board of Directors**

The Board of Directors is currently composed of four members who were appointed by the shareholders for a period of six years expiring upon the date of the annual general shareholders' meeting approving the financial results for fiscal year 2013 See Item 6, "Directors, Senior Management and Employees". The tenure of a director terminates at the end of the ordinary general shareholders' meeting convened to vote upon the accounts of the then-preceding fiscal year and is held in the year during which the term of such Director comes to an end. Directors may always be re-elected; a director may also be dismissed at any time at the shareholders' meeting.

The mandate for each member of the current Board of Directors expires on the date of the ordinary general shareholders' meeting approving the financial results for the 2013 fiscal year.

Each Director must own at least one share during his/her term of office. If, at the time of his/her appointment, a director does not own the required number of shares or if during his/her term, he/she no longer owns the required number of shares, he/she is considered to have automatically resigned if he/she fails to comply with the shareholding requirement within three months.

An individual person cannot be on more than five Boards of Directors or Supervisory Boards in companies registered in France; directorships in controlled companies (as defined by Section L.233-16 of the French Commercial Code) by the Company are not taken into account.

In case of the death or resignation of one or more director, the Board of Directors may make provisional appointments to fill vacancies before the next general shareholders meetings. These provisional appointments must be ratified by the next following ordinary shareholders meeting. Even if a provisional appointment is not ratified, resolutions and acts previously approved by the Board of Directors nonetheless remain valid.

When the number of directors falls below the compulsory legal minimum, the remaining directors must convene an ordinary general shareholders' meeting to reach the full complement of the Board of Directors.

Any director appointed in replacement of another director whose tenure has not expired remains in office only for the remaining duration of the tenure of his predecessor.

One of our employees may be appointed to serve as a director. His/her contract of employment must however entail actual work obligations. In this case, he/she does not lose the benefit of his/her employment contract.

The number of directors who are also linked to the Company by an employment contract cannot exceed one third of the directors then in office and in any case five members.

Directors cannot be more than seventy-five years old. If one of the directors reaches this limit during his/her tenure, such director is automatically considered to have resigned at the next general shareholders meeting.

The Board of Directors determines the direction of our business and supervises our operations. Within the limits set out by the corporate purposes and the powers expressly granted by law to the general shareholders' meeting, the Board of Directors may deliberate upon our operations and make any decisions in accordance with our business. However, a director must abstain from voting on matters in which the director has an interest. The resolutions passed in a meeting of the Board of Directors are valid only if a quorum of half of the directors is reached. A Director cannot borrow money from the Company.

### **The Chairman of the Board**

The Board of Directors must elect one of its members as Chairman of the Board of Directors, who must be an individual person. The Board of Directors determines the duration of the tenure of the Chairman, which cannot exceed that of his/her tenure as a director. The Board of Directors may dismiss the Chairman at any time. The remuneration of the Chairman is decided by the Board of Directors, upon recommendation of the Compensation Committee.

The Chairman represents the Board of Directors and organizes its work. The general shareholders' meeting must be informed of this work by the Chairman. The Chairman is responsible for the good functioning of our organization and for supervising the ability of the Board members to perform their mission.

Pursuant to Section 706-43 of the French Criminal Proceedings Code, the Chairman may validly delegate to any person he/she chooses the power to represent us in any criminal proceedings that we may face.

As with any other director, the Chairman cannot be over seventy-five years old. In case the Chairman reaches this limit during his/her tenure, he/she will automatically be considered to have resigned. However, his/her tenure is extended until the next Board of Directors meeting, during which his/her successor will be appointed. Subject to the age limit provision, the Chairman of the Board may also be re-elected.

### **The Chief Executive Officer**

We are managed by the Chairman of the Board of Directors or an individual elected by the Board of Directors bearing the title of Chief Executive Officer. The choice between these two methods of management belongs to the Board of Directors and must be made as provided for by our articles of association. On March 31, 2008, the Board of Directors appointed Mr. Marc Oczachowski as Chief Executive Officer.

The Chief Executive Officer is vested with the powers to act under all circumstances on behalf of the Company, within the limits set out by the Company's corporate purposes, and subject to the powers expressly granted by law to the Board of Directors and the general shareholders' meeting.

The Chief Executive Officer represents us with respect to third parties. We are bound by any acts of the Chief Executive Officer even if they are contrary to corporate purposes, unless it is proven that the third party knew such act exceeded the Company's corporate purposes or could not ignore it in light of the circumstances. Publication of the articles of association alone is not sufficient evidence of such knowledge.

The remuneration of the Chief Executive Officer is set by the Board of Directors, upon recommendation of the Compensation Committee. The Chief Executive Officer can be terminated at any time by the Board of Directors. If such termination is found to be unjustified, damages may be allocated to the Chief Executive Officer, except when the Chief Executive Officer is also the Chairman of the Board.

The Chief Executive Officer may not hold another position as Chief Executive Officer or member of a Management Board in a company registered in France except when (a) such company is controlled (as referred to in Section L.233-16 of the French Commercial Code) by the Company and (b) when this controlled company's shares are not quoted on a regulated market.

The Chief Executive Officer cannot be over seventy years old. In case the Chief Executive Officer reaches this limit during his/her office, he/she is automatically considered to have resigned. However, his/her tenure is extended until the next Board of Directors meeting, during which his/her successor must be appointed.

### ***Dividend and Liquidation Rights (French Law)***

Net income in each fiscal year, as increased or reduced, as the case may be, by any profit or loss of the Company carried forward from prior years, less any contributions to legal reserves, is available for distribution to our shareholders as dividends, subject to the requirements of French law and our articles of association.

Under French law and our articles of association, we are required to allocate 5% of our net profits in each fiscal year to a legal reserve fund until the amount in such reserve fund is equal to 10% of the nominal amount of the registered capital. The legal reserve is distributable only upon the liquidation of the Company.

Our shareholders may, upon recommendation of the Board of Directors, decide to allocate all or a part of distributable profits, if any, among special or general reserves, to carry them forward to the next fiscal year as retained earnings, or to allocate them to the shareholders as dividends.

Our articles of association provide that, if so agreed by the shareholders, reserves that are available for distribution under French law and our articles of association may be distributed as dividends, subject to certain limitations.

If we have made distributable profits since the end of the preceding fiscal year (as shown on an interim income statement certified by our statutory auditors), the Board of Directors has the authority under French law, without the approval of shareholders, to distribute interim dividends to the extent of such distributable profits. We have never paid interim dividends.

Under French law, dividends are distributed to shareholders pro rata according to their respective shareholdings. Dividends are payable to holders of shares outstanding on the date of the annual shareholders' meeting deciding the distribution of dividends, or in the case of interim dividends, on the date of the Board of Directors meeting approving the distribution of interim dividends. However, holders of newly issued shares may have their rights to dividends limited with respect to certain fiscal years. The actual dividend payment date is decided by the shareholders in an ordinary general meeting or by the Board of Directors in the absence of such a decision by the shareholders. The payment of the dividends must occur within nine months from the end of our

fiscal year. Under French law, dividends not claimed within five years of the date of payment revert to the French State.

If the Company is liquidated, our assets remaining after payment of our debts, liquidation expenses and all of our remaining obligations will be distributed first to repay in full the nominal value of the shares, then the surplus, if any, will be distributed pro rata among the shareholders based on the nominal value of their shareholdings and subject to any special rights granted to holders of priority shares, if any.

#### ***Changes in Share Capital (French Law)***

Our share capital may be increased only with the approval of the shareholders entitled to vote at an extraordinary general meeting, following a recommendation of the Board of Directors. Increases in the share capital may be effected either by the issuance of additional shares (including the creation of a new class of shares) or by an increase in the nominal value of existing shares. Additional Shares may be issued for cash or for assets contributed in kind, upon the conversion of debt securities previously issued by the Company, by capitalization of reserves, or, subject to certain conditions, in satisfaction of indebtedness incurred by the Company. Dividends paid in the form of Shares may be distributed in lieu of payment of cash dividends, as described above under “—Dividend and Liquidation Rights (French law).” French law permits different classes of shares to have liquidation, voting and dividend rights different from those of the outstanding ordinary shares.

Our share capital may be decreased only with the approval of the shareholders entitled to vote at an extraordinary general meeting. The share capital may be reduced either by decreasing the nominal value of the shares or by reducing the number of outstanding shares. The conditions under which the registered capital may be reduced will vary depending upon whether or not the reduction is attributable to losses incurred by the Company. The number of outstanding shares may be reduced either by an exchange of shares or by the repurchase and cancellation by us of our shares. Under French law, all the shareholders in each class of shares must be treated equally unless the inequality in treatment is accepted by the affected shareholder. If the reduction is not attributable to losses incurred by us, each shareholder will be offered an opportunity to participate in such capital reduction and may decide whether or not to participate therein.

#### ***Repurchase of Shares (French Law)***

Pursuant to French law, the Company may not acquire its own shares except (a) to reduce its share capital under certain circumstances with the approval of the shareholders at an extraordinary general meeting, (b) to provide shares for distribution to employees under a profit sharing or stock option plan and (c) after obtaining approval from the shareholders at an ordinary general meeting, to make purchases for stabilization of quotations on a regulated stock exchange. In either case, the amounts to be repurchased under (b) and (c) may not result in the Company holding more than 10% of its shares then-issued. A subsidiary of the Company is prohibited by French law from holding shares of the Company and, in the event it becomes a shareholder of the Company, such shareholder must transfer all the shares of the Company that it holds.

#### ***Attendance and Voting at Shareholders’ Meetings (French Law)***

In accordance with French law, there are two types of general shareholders’ meetings, ordinary and extraordinary. Ordinary general meetings are required for matters such as the election of directors, the appointment of statutory auditors, the approval of the report prepared by the Board of Directors and the annual accounts, the declaration of dividends and the issuance of (non-convertible) bonds.

Extraordinary general meetings are required for approval of matters such as amendments to the Company’s articles of association, modification of shareholders’ rights, approval of mergers, increases or decreases in share capital (including a waiver of preferential subscription rights), the creation of a new class of shares, the authorization of the issuance of investment certificates or securities convertible or exchangeable into shares and for the sale or transfer of substantially all of the Company’s assets.

The Board of Directors is required to convene an annual ordinary general shareholders meeting, which must be held within six months of the end of our fiscal year, for approval of the annual accounts. Other ordinary or extraordinary meetings may be convened at any time during the year. Shareholders meetings may be convened by

the Board of Directors or, if the Board of Directors fails to call such a meeting, by our statutory auditors or by a court-appointed agent. The court may be requested to appoint an agent either by one or more shareholders holding at least 5% of the our registered capital or by an interested party under certain circumstances, or, in case of an urgent matter, by the Work Council (*Comité d'entreprise*) representing the employees. The notice calling a meeting must state the agenda for such meeting.

French law provides that, at least 15 days before the date set for any general meeting on first notice, and at least six days before the date set for any general meeting on second notice, notice of the meeting must be sent by mail to all holders of properly registered shares who have held such shares for more than one month before the date of the notice. A preliminary written notice (*avis de réunion*) must be sent to each shareholder who has requested to be notified in writing. Under French law, one or several shareholders together holding a specified percentage of shares may propose resolutions to be submitted for approval by the shareholders at the meeting. Upon our request, the Bank of New York will send to holders of ADSs notices of shareholders' meetings and other reports and communications that are made generally available to shareholders. The Work Council may also require the registration of resolution proposals on the agenda.

Attendance and exercise of voting rights at ordinary and extraordinary general meetings are subject to certain conditions. Shareholders deciding to exercise their voting rights must have their shares registered in their names in the shareholder registry maintained by or on behalf of the Company before the meeting. An ADS holder must timely and properly return its voting instruction card to the Depositary to exercise the voting rights relating to the shares represented by its ADSs. The Depositary will use its reasonable efforts to vote the underlying shares in the manner indicated by the ADS holder. In addition, if an ADS holder does not timely return a voting instruction card or the voting instruction card received is improperly completed or blank, that holder will be deemed to have given the Depositary a proxy to vote, and the Depositary will vote in favor of all proposals recommended by the Board of Directors and against all proposals that are not recommended by the Board of Directors.

All shareholders who have properly registered their shares have the right to participate in general meetings, either in person, by proxy, or by mail, and to vote according to the number of shares they hold. Each share confers on the shareholder the right to one vote. Under French law, an entity we control directly or indirectly is prohibited from holding shares in the Company and, in the event it becomes a shareholder, such entity would not be entitled to any voting rights. A proxy may be granted by a shareholder whose name is registered on our share registry to his or her spouse, to another shareholder or to a legal representative, in the case of a legal entity, or by sending a proxy in blank to the Company without nominating any representatives. In the latter case, the Chairman of the shareholders' meeting will vote such blank proxy in favor of all resolutions proposed by the Board of Directors and against all others.

The presence in person or by proxy of shareholders having not less than 20% (in the case of an ordinary general meeting or an extraordinary general meeting deciding upon any capital increase by capitalization of reserves) or 25% (in the case of an extraordinary general meeting) of the Shares entitled to vote is necessary to reach a quorum. If a quorum is not reached at any meeting, the meeting is adjourned. Upon recommencement of an adjourned meeting, there is no quorum requirement in the case of an ordinary general meeting or an extraordinary general meeting deciding upon any capital increase by capitalization of reserves. The presence in person or by proxy of shareholders having not less than 20% of the Shares is necessary to reach a quorum in the case of any other type of extraordinary general meeting.

At an ordinary general meeting or an extraordinary general meeting deciding upon any capital increase by capitalization of reserves, a simple majority of the votes of the shareholders present or represented by proxy is required to approve a resolution. At any other extraordinary general meeting, a two-thirds majority of the votes cast is required. However, a unanimous vote is required to increase liabilities of shareholders. Abstention from voting by those present or represented by proxy is viewed as a vote against the resolution submitted to a vote.

In addition to his/her rights to certain information regarding the Company, any shareholder may, during the two-week period preceding a shareholders' meeting, submit to the Board of Directors written questions relating to the agenda for the meeting. The Board of Directors is required to respond to such questions during the meeting.

Under French law, shareholders can nominate individuals for election to the Board of Directors at a shareholders' meeting. When the nomination is part of the agenda of the shareholders' meeting, the nomination



must contain the name, age, professional references and professional activity of the nominee for the past five years, as well as the number of shares owned by such candidate, if any. In addition, if the agenda for the shareholders' meeting includes the election of members of the Board of Directors, any shareholder may require, during the meeting, the nomination of a candidate for election at the Board of Directors at the shareholders' meeting, even if such shareholder has not followed the nomination procedures. Under French law, shareholders cannot elect a new member of the Board of Directors at a general shareholders meeting if the agenda for the meeting does not include the election of a member of the Board of Directors, unless such nomination is necessary to fill a vacancy due to the previous resignation of a member.

As set forth in our articles of association, shareholders' meetings are held at our registered office of the Company or at any other locations specified in the written notice. We do not have staggered or cumulative voting arrangements for the election of Directors.

#### ***Preferential Subscription Rights (French Law)***

Shareholders have preferential rights to subscribe for additional shares issued by the Company for cash on a pro rata basis (or any equity securities of the Company or other securities giving a right, directly or indirectly, to equity securities issued by the Company). Shareholders may waive their preferential rights, either individually or at an extraordinary general meeting under certain circumstances. Preferential subscription rights, if not previously waived, are transferable during the subscription period relating to a particular offering of shares. U.S. holders of ADSs may not be able to exercise preferential rights for Shares underlying their ADSs unless a registration statement under the Securities Act is effective with respect to such rights or an exemption from the registration requirement thereunder is available.

#### ***Form and Holding of Shares (French Law)***

##### *Form of Shares*

Our articles of association provide that shares can only be held in registered form.

##### *Holding of Shares*

The shares are registered in the name of the respective owners thereof in the registry maintained by or on behalf of the Company.

Stock certificates evidencing shares, in a manner comparable to that in the United States, are not issued by French companies, but we may issue or cause to be issued confirmations of shareholdings registered in such registry to the persons in whose names the shares are registered. Such confirmations do not constitute documents of title and are not negotiable instruments.

#### ***Ownership of ADSs or Shares by Non-French Residents (French Law)***

Under French law, there is no limitation on the right of non-French residents or non-French security holders to own, or where applicable, vote securities of a French company. A non-resident of France must file a *déclaration administrative*, or administrative notice, with French authorities in connection with the acquisition of a controlling interest in any French company. Under existing administrative rulings, ownership, by a non-resident of France or a French corporation which is itself controlled by a foreign national, of 33.33% or more of a company's share capital or voting rights is regarded as a controlling interest, but a lower percentage may be held to be a controlling interest in certain circumstances (depending upon such factors as the acquiring party's intentions, its ability to elect directors or financial reliance by the French company on the acquiring party).

#### ***Certain Exemptions (French Law)***

Under the U.S. securities laws, as a foreign private issuer, we are exempt from certain rules that apply to domestic U.S. issuers with equity securities registered under the U.S. Securities Exchange Act of 1934, including the proxy solicitation rules and the rules requiring disclosure of share ownership by directors, officers and certain shareholders. We are also exempt from certain of the current NASDAQ corporate governance requirements. For more information on these exemptions, see Item 16 G – “Corporate Governance —Exemptions from Certain NASDAQ Corporate Governance Rules.”



### ***Enforceability of Civil Liabilities (French Law)***

We are a *société anonyme*, or limited liability corporation, organized under the laws of the Republic of France. The majority of our directors and executive officers reside in the Republic of France. All or a substantial portion of our assets and the assets of such persons are located outside the United States. As a result, it may not be possible for investors to effect service of process within the United States upon such persons or to enforce, either inside or outside the United States, judgments against such persons obtained in U.S. courts or to enforce in U.S. court judgments obtained against such persons in courts in jurisdictions outside the United States, in each case, in any action predicated upon the civil liability provisions of the federal securities laws of the United States. In an original action brought in France predicated solely upon the U.S. federal securities laws, French courts may not have the requisite jurisdiction to grant the remedies sought, and actions for enforcement in France of judgments of U.S. courts rendered against French persons referred to in the second sentence of this paragraph would require such French persons to waive their right under Article 15 of the French Civil Code to be sued in France only. We believe that no such French persons have waived such right with respect to actions predicated solely upon U.S. federal securities laws. In addition, actions in the United States under the U.S. federal securities laws could be affected under certain circumstances by the French law of July 16, 1980, which may preclude or restrict obtaining evidence in France or from French persons in connection with such actions.

### **Material Contracts**

On August 3, 2006, we closed a private placement of 961,676 ordinary shares in the form of ADSs, resulting in net proceeds of approximately \$7.5 million. The Securities Purchase Agreement among EDAP TMS S.A. and each purchaser set forth the purchase price for the ordinary shares. The terms for registering the ADSs with the SEC are covered by the Registration Rights Agreement.

On October 31, 2007, we completed the private placement of \$20 million principal amount of 9% Senior Convertible Debentures due 2012. In addition, the purchasers of the convertible debentures and the 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. The Securities Purchase Agreement, dated as of October 29, 2007, among EDAP TMS S.A. and each purchaser was furnished to the SEC on Form 6-K dated October 31, 2007, and incorporated by reference in our Form F-3 registration statement filed with the SEC on November 30, 2007. The terms for registering the underlying ADSs with the SEC are included in the Registration Rights Agreement, dated as of October 29, 2007, among EDAP TMS S.A. and the investors signatory thereto, which was furnished to the SEC on Form 6-K dated October 31, 2007 and incorporated by reference in our Form F-3 filed with the SEC on November 30, 2007.

### **Exchange Controls**

Under current French foreign exchange control regulations, there are no limitations on the amount of cash payments that we may remit to residents of foreign countries. Laws and regulations concerning foreign exchange controls do require, however, that all payments or transfers of funds made by a French resident to a non-resident be handled by an accredited intermediary. All registered banks and credit institutions in France are accredited intermediaries.

Under French law, there is no limitation on the right of non-French residents or non-French security holders to own, or where applicable, vote securities of a French company. A non-resident of France must file a *déclaration administrative*, or administrative notice, with French authorities in connection with the acquisition of a controlling interest in any French company. Under existing administrative rulings, ownership by a non-resident of France or a French corporation which is itself controlled by a foreign national, of 20% or more of a listed company's share capital or voting rights is regarded as a controlling interest, but a lower percentage may be held to be a controlling interest in certain circumstances (depending upon such factors as the acquiring party's intentions, its ability to elect directors or financial reliance by the French company on the acquiring party).

## **French Taxation**

The following generally summarizes the material French tax consequences of purchasing, owning and disposing of Shares or ADSs. The statements relating to French tax laws set forth below are based on the laws in force as of the date hereof, and are subject to any future changes in applicable laws and tax treaties.

This discussion is intended only as a descriptive summary and does not purport to be a complete analysis or listing of all potential tax effects of the purchase, ownership or disposition of Shares or ADSs. It does not constitute legal or tax advice. The following summary does not address the treatment of Shares or ADSs that are held by a resident of France (except for purposes of describing related tax consequences for other holders) or in connection with a permanent establishment or fixed base through which a holder carries on business or performs personal services in France, or by a person that owns, directly or indirectly, 5% or more of the stock of the Company. Moreover, the following discussion of the tax treatment of dividends only deals with distributions made on or after January 1, 2006.

There are currently no procedures available for holders that are not U.S. residents to claim tax treaty benefits in respect of dividends received on ADSs or Shares registered in the name of a nominee. Such holders should consult their own tax advisor about the consequences of owning and disposing of ADSs or Shares.

Investors should consult their own tax advisors regarding the tax consequences of the purchase, ownership and disposition of shares in light of their particular circumstances.

### ***Taxation of Dividends on Shares or ADSs - Withholding Tax***

In France, dividends are paid out of after-tax income. Dividends paid by a French corporation, such as EDAP, to non-residents normally are subject to a 25% French withholding tax (reduced to 18% since January 1, 2008 when non-residents are individuals resident from one of the countries of the European Economic Area, except Liechtenstein. However, non-resident holders that are entitled to and comply with the procedures for claiming benefits under an applicable tax treaty may be subject to a reduced rate (generally 15%) of French withholding tax. If a non-resident holder establishes its entitlement to treaty benefits prior to the payment of a dividend, then French tax generally will be withheld at the reduced rate provided under the treaty.

### ***Taxation of dividends***

Dividends received by French resident individuals are either included in their total income and subject to the progressive income tax, or they can alternatively be subject to an 18% levy source at the option of the beneficiary.

When no option is exercised by the French resident individuals, they are only taxed on 60% of the dividends they receive and, in addition to a second fixed annual allowance of €3,050 for couples subject to joint taxation and €1,525 for single persons, widows or divorced persons, are entitled to a tax credit equal to 50% of all dividends received within one year (the "Tax Credit"). The Tax Credit is capped for all dividends received within one year at €230 for married couples and members of a civil union agreement subject to joint taxation and €115 for single persons, widows or widowers, divorcees or married persons subject to separate taxation.

As a result of the French Finance Act for 2008, French resident individuals can elect to have all or part of the dividends received subject to an 18% levy at source at the irrevocable option of the shareholder exercised no later than at the time of the payment if it occurs in France. If the option is exercised only for a portion of the dividends received during the year (whether they are distributed by EDAP or any other company), the remaining dividends subject to the progressive income tax lose the benefit of the aforementioned allowances and the Tax Credit. Holders of Shares are invited to contact their financial or tax advisor to be informed of the consequences of such option on their tax situation and the terms and conditions of exercising the option and the payment of the levy at source as well as the reporting obligations related to such option when the paying agent is not located in France.

Dividends paid to non-residents are not normally eligible for the Tax Credit described above. However, qualifying non-resident individuals who were previously entitled to a refund of the *avoir fiscal* may benefit, under the same conditions as for the *avoir fiscal*, from a refund of the Tax Credit (net of applicable withholding tax) under

certain conditions, subject to compliance with the procedures for claiming benefits under the applicable treaty. The French tax authorities have not yet issued any guidance with regard to the procedures for claiming the refund of the Tax Credit to non-resident individuals.

Individual investors are urged to consult their own tax advisors in this respect.

#### ***Taxation on Sale or Disposition of Shares or ADSs***

Subject to the more favorable provisions of a relevant tax treaty, holders that are not residents of France for tax purposes, do not hold Shares or ADSs in connection with the conduct of a business or profession in France, and have not held more than 25% of dividend rights (*droits aux bénéfices sociaux*) of the Company, directly or indirectly, alone or together with their spouse, ascendants or descendants, at any time during the preceding five years, are not subject to French income tax or capital gains tax on the sale or disposition of Shares or ADSs.

A 3% *ad valorem* registration duty (subject to a maximum of €5,000 per transfer) applies to certain transfers of shares in French companies. This duty does not apply to transfers of shares in listed companies that are not evidenced by a written agreement, or if any such agreement is executed outside France.

#### ***Estate and Gift Tax***

France imposes estate and gift tax on shares or ADSs of a French corporation that are acquired by inheritance or gift. The tax applies without regard to the tax residence of the transferor. However, France has entered into estate and gift tax treaties with a number of countries pursuant to which, assuming certain conditions are met, residents of the treaty country may be exempted from such tax or obtain a tax credit.

#### ***Wealth Tax***

Individuals who are not residents of France for purposes of French taxation are not subject to a wealth tax (*Impôt de Solidarité sur la Fortune*) in France as a result of owning an interest in the share capital of a French corporation, provided that such ownership interest is, directly or indirectly, less than 10% of the corporation's share capital and does not enable the shareholder to exercise influence over the corporation. Double taxation treaties may provide for a more favorable tax treatment.

#### **Taxation of U.S. Investors**

The following is a summary of the material French and U.S. federal income tax consequences of the purchase, ownership and disposition of Shares or ADSs by a holder that is a resident of the United States for purposes of the Convention Between the Government of the United States of America and the Government of the French Republic for the Avoidance of Double Taxation and the Prevention of Fiscal Evasion with Respect to Taxes on Income and Capital of August 31, 1994 (the "Treaty"), which entered into force on December 30, 1995 (as amended by any subsequent protocols), and the tax regulations issued by the French tax authorities, and are fully eligible for benefits under the Treaty (a "U.S. holder").

In particular, the United States and France signed a protocol on January 13, 2009, that, upon ratification, will make several significant changes to the Treaty, including changes to the "Limitation of Benefits" provision. The provisions of the protocol will be effective as soon as the ratification occurs in both jurisdictions and with respect to withholding taxes will be effective for amounts paid or accrued on or after the first day of the year in which the protocol enters into force. US holders are advised to consult their own tax advisors regarding the effect the protocol may have on their eligibility for Treaty benefits in light of their own particular circumstances.

A holder generally will be entitled to Treaty benefits in respect of Shares or ADSs if he is concurrently:

- the beneficial owner of the shares or ADSs (and the dividends paid with respect thereto);
- an individual resident of the United States, a U.S. corporation, or a partnership, estate or trust to the extent its income is subject to taxation in the United States in its hands or in the hands of its partners or beneficiaries;
- not also a resident of France for French tax purposes; and

- not subject to an anti-treaty shopping article that applies in limited circumstances.

Special rules apply to pension funds and certain other tax-exempt investors.

If a partnership holds Shares of ADSs, the tax treatment of a partner generally will depend on the status of the partner and the activities of the partnership. If a US Holder is a partner in a partnership that holds Shares or ADSs, the holder is urged to consult its own tax advisor regarding the specific tax consequences of owning and disposing of its Shares and ADSs.

For U.S. federal income tax purposes, a U.S. holder's ownership of the Company's ADSs will be treated as ownership of the Company's underlying shares.

This summary does not purport to be a comprehensive description of all of the tax considerations that may be relevant to any particular investor, and does not discuss tax considerations that arise from rules of general application or that are generally assumed to be known by investors. In particular, the summary does not deal with Shares or ADSs that are not held as capital assets, and does not address the tax treatment of holders that are subject to special rules, such as banks, insurance companies, dealers in securities or currencies, regulated investment companies, persons that elect mark-to-market treatment, persons holding Shares or ADSs as a position in a synthetic security, straddle or conversion transaction, persons that own, directly or indirectly, 5% or more of the Company's voting stock or 10% or more of the Company's outstanding capital and persons whose functional currency is not the U.S. dollar.

This summary does not discuss the treatment of shares or ADSs that are held in connection with a permanent establishment or fixed base through which a holder carries on business or performs personal services in France. Moreover, the following discussion of the tax treatment of dividends only deals with distributions made on or after January 1, 2006.

The summary is based on laws, treaties, regulatory interpretations and judicial decisions in effect on the date hereof, all of which are subject to change. Such changes could apply retroactively and could affect the consequences described below.

Holders should consult their own tax advisors regarding the tax consequences of the purchase, ownership and disposition of Shares or ADSs in the light of their particular circumstances, including the effect of any state, local, or other national laws.

### ***Dividends***

Generally, dividend distributions to non-residents of France are subject to French withholding tax at a 25% rate. However, under the Treaty, the rate of French withholding tax on dividends paid to a U.S. holder is reduced to 15% and a US holder may claim a refund from the French tax authorities of the amount withheld in excess of the Treaty rate of 15%, if any. For U.S. holders that are not individuals, the requirements for eligibility for Treaty benefits, including the reduced 15% withholding tax rate, contained in the "Limitation on Benefits" provision of the Treaty are complicated, and there are certain technical changes being made to these requirements by the new protocol. U.S. holders are advised to consult their own tax advisors regarding their eligibility for Treaty benefits, and whether the new protocol to the Treaty may affect their eligibility, in light of their own particular circumstances.

French withholding tax will be withheld at the 15% Treaty rate if a U.S. holder has established before the date of payment that the holder is a resident of the United States under the Treaty by following the simplified procedure described below.

In addition, individual U.S. holders may be entitled to a refund of the Tax Credit, less a 15% withholding, provided that (i) they are subject to U.S. federal income tax on the Tax Credit and the dividend to which it relates, and (ii) they are the effective beneficiaries of such dividend. The French tax authorities have not yet issued guidance with respect to the procedures for claiming the refund of the Tax Credit to non-resident individuals. However, it should be noted that when the new protocol to the Treaty enters into force, the Treaty will no longer specifically provide for any entitlement to a refund of the Tax Credit, and individual U.S. holders should not continue to benefit from such a refund.

The gross amount of dividends and Tax Credit that a U.S. holder receives (before the deduction of French withholding tax) generally will be subject to U.S. federal income taxation as ordinary dividend income to the extent paid or deemed paid out of the current or accumulated earnings and profits of the Company (as determined under U.S. federal income tax principles). Such dividends will not be eligible for the dividends received deduction generally allowed to U.S. corporations. To the extent that an amount received by a U.S. holder exceeds the allocable share of current and accumulated earnings and profits of the Company, such excess will be applied first to reduce such U.S. holder's tax basis in its Shares or ADSs and then, to the extent it exceeds the U.S. holder's tax basis, it will constitute capital gain from a deemed sale or exchange of such Shares or ADSs. As the Company does not maintain "earnings and profits" computations, holders should assume that all distributions constitute dividends.

Subject to certain exceptions for short-term and hedged positions, the U.S. dollar amount of dividends received by an individual before January 1, 2011 with respect to the Shares or ADSs will be subject to taxation at a maximum rate of 15% if the dividends are "qualified dividends." Dividends paid on the Shares or ADSs will be treated as qualified dividends if (i) the issuer is eligible for the benefits of a comprehensive income tax treaty with the United States that the IRS has approved for the purposes of the qualified dividend rules and (ii) the Company was not, in the year prior to the year in which the dividend was paid, and is not, in the year in which the dividend is paid, a passive foreign investment company ("PFIC"). The Treaty has been approved for the purposes of the qualified dividend rules. Based on the Company's audited financial statements and relevant market and shareholder data, we believe that the Company was not treated as a PFIC for U.S. federal income tax purposes with respect to its 2008 taxable year. In addition, based on the Company's audited financial statements and our current expectations regarding the value and nature of its assets, the sources and nature of its income, and relevant market and shareholder data, we do not anticipate it becoming a PFIC for the 2009 taxable year. Accordingly, dividends paid by us in 2009 to a U.S. holder should constitute "qualified dividends" unless such holder acquired its Shares or ADSs during a year in which the Company was a PFIC and such holder did not make a mark-to-market election (as described under "—Passive Foreign Investment Company Rules" below).

Holders of ADSs and Shares should consult their own tax advisers regarding the availability of the reduced dividend tax rate in light of their own particular circumstances.

Dividends distributed with respect to the Shares or ADSs generally will be treated as dividend income from sources outside of the United States, and generally will be treated as "passive category" (or, in the case of certain U.S. holders, "general category") income for U.S. foreign tax credit purposes. Subject to certain limitations, French income tax withheld in connection with any distribution with respect to the Shares or ADSs may be claimed as a credit against the U.S. federal income tax liability of a U.S. holder if such U.S. holder elects for that year to credit all foreign income taxes. Alternatively, such French withholding tax may be taken as a deduction against taxable income. Foreign tax credits will not be allowed for withholding taxes imposed in respect of certain short-term or hedged positions in securities and may not be allowed in respect of certain arrangements in which a U.S. holder's expected economic profit is insubstantial. U.S. holders should consult their own tax advisors concerning the implications of these rules in light of their particular circumstances.

Dividends paid in euro will be included in the income of a U.S. holder in a U.S. dollar amount calculated by reference to the exchange rate in effect on the date of receipt by the holder (or, in the case of the ADSs, by the Depositary), regardless of whether the payment is in fact converted into U.S. dollars. If such a dividend is converted into U.S. dollars on the date of receipt, a U.S. holder generally should not be required to recognize foreign currency gain or loss in respect of the dividend income.

#### ***Procedures for Claiming Treaty Benefits***

The French tax authorities issued guidelines in Instruction n° 4-J-1-05, dated February 25, 2005 that significantly changed the formalities to be complied with by non-resident shareholders, including U.S. holders, in order to obtain the reduced withholding tax rate on distributions made on or after January 1, 2005.

Pursuant to these guidelines, U.S. holders can either claim Treaty benefits under a simplified procedure or under the normal procedure. The procedure to be followed depends on whether the application for Treaty benefits is filed before or after the dividend payment.



Under the simplified procedure, in order to benefit from the lower rate of withholding tax applicable under the Treaty before the payment of the dividend, a U.S. holder must complete and deliver to the paying agent (through its account holder) a treaty form (Form 5000), to certify in particular that:

- the U.S. holder is beneficially entitled to the dividend;
- the U.S. holder is a U.S. resident within the meaning of the Treaty;
- the dividend is not derived from a permanent establishment or a fixed base that the U.S. holder has in France; and
- the dividend received is or will be reported to the tax authorities in the United States.

For partnerships or trusts, claims for Treaty benefits and related attestations are made by the partners, beneficiaries or grantors who also have to supply certain additional documentation.

In order to be eligible for Treaty benefits, pension funds and certain other tax-exempt U.S. holders must comply with the simplified procedure described above, though they may be required to supply additional documentation evidencing their entitlement to those benefits.

If Form 5000 is not filed prior to the dividend payment, a withholding tax will be levied at the 25% rate, and a holder would have to claim a refund for the excess under the normal procedure by filing both Form 5000 and Form 5001 no later than December 31 of the second calendar year following the year in which the dividend is paid.

Pension funds and certain other tax-exempt entities are subject to the same general filing requirements as other U.S. holders except that they may have to supply additional documentation evidencing their entitlement to these benefits.

Copies of Form 5000 and Form 5001 may be downloaded from the French tax authorities' website ([www.impots.gouv.fr](http://www.impots.gouv.fr)) and are also available from the U.S. Internal Revenue Service and from the *Centre des Impôts des Non-Résidents* in France (10 rue du Centre 93160, Noisy-le-Grand).

Finally, as mentioned above, the French tax authorities have not yet issued any guidance with respect to the procedures for claiming the refund of the Tax Credit to non-resident individuals. However, it should be noted that when the new protocol to the Treaty enters into force, the Treaty will no longer specifically provide for any entitlement to a refund of the Tax Credit, and individual U.S. holders should not continue to benefit from such a refund.

### ***Capital Gains***

Under the Treaty, a U.S. holder will not be subject to French tax on any gain derived from the sale or exchange of Shares or ADSs, unless the gain is effectively connected with a permanent establishment or fixed base maintained by the holder in France.

For U.S. federal income tax purposes, gain or loss realized by a U.S. holder on the sale or other disposition of Shares or ADSs will be capital gain or loss, and will be long-term capital gain or loss if the Shares or ADSs were held for more than one year. The net amount of long-term capital gain recognized by an individual U.S. holder before January 1, 2011 generally is subject to taxation at a maximum rate of 15%. U.S. holders' ability to offset capital losses against ordinary income is limited.

### ***Passive Foreign Investment Company Rules***

Unfavorable U.S. tax rules (the "PFIC rules") apply to companies that are considered passive foreign investment companies ("PFICs"). The Company will be classified as a PFIC in a particular taxable year if either (a) 75% or more of its gross income is treated as passive income for purposes of the PFIC rules; or (b) the average percentage of the value of its assets that produce or are held for the production of passive income is at least 50%.

As explained above, the Company believes that it was not a PFIC for U.S. tax purposes with respect to the year 2008, and also does not anticipate becoming a PFIC with respect to the year 2009. However, as discussed in Forms 20-f filed by the Company with respect to certain prior years the Company believes that it was a PFIC in the past.



U.S. holders that held Shares or ADSs at any time during the years when the Company was a PFIC and did not make certain U.S. tax elections (a "mark-to-market election" or a "QEF election") will be subject to adverse tax treatment. For instance, such holders will be subject to a special tax at ordinary income tax rates on certain dividends that the Company pays and on gains realized on the sale of Shares or ADSs ('excess distributions') in all subsequent years, even though the Company ceased to qualify as a PFIC. The amount of this tax will be increased by an interest charge to compensate for tax deferral, calculated as if the excess distributions had been earned ratably over the period the U.S. holder held its Shares or ADSs. It may be possible, in certain circumstances, for a holder to avoid the application of the PFIC rules by making a "deemed sale" election for its taxable year that includes the last day of the Company's last taxable year during which it qualified as a PFIC. The PFIC rules are extremely complex, and holders should consult their own tax advisers regarding the possible application of the PFIC rules to their Shares or ADSs and the desirability and availability of a "deemed sale election".

#### ***French Estate and Gift Tax***

Under the estate and gift tax convention between the United States and France, a transfer of Shares or ADSs by gift or by reason of the death of a U.S. holder entitled to benefits under that convention will not be subject to French gift or inheritance tax, so long as the donor or decedent was not domiciled in France at the time of the transfer, and Shares or ADSs were not used or held for use in the conduct of a business or profession through a permanent establishment or fixed base in France.

#### ***French Wealth Tax***

The French wealth tax does not generally apply to Shares or ADSs of a U.S. holder if the holder is a resident of the United States for purposes of the Treaty.

#### **U.S. Information Reporting and Backup Withholding Rules**

Payments of dividends and sales proceeds that are made within the United States or through certain U.S.-related financial intermediaries are subject to information reporting and may be subject to backup withholding unless the holder (i) is a corporation or other exempt recipient or (ii) provides a taxpayer identification number and certifies that no loss of exemption from backup withholding has occurred. Holders that are not U.S. persons generally are not subject to information reporting or backup withholding. However, such a holder may be required to provide a certification of its non- U.S. status in connection with payments received within the United States or through a U.S.-related financial intermediary.

#### **Documents on Display**

We are subject to the informational requirements of the Securities Exchange Act of 1934, as amended. In accordance with these requirements, we file reports and other information with the Securities and Exchange Commission ("SEC"). These materials, including this annual report and the exhibits hereto, may be inspected and copied at the SEC's public reference room at 100F Street, N.E., Washington, D.C. 20549 and at the SEC's regional offices at 500 West Madison Street, Suite 1400, Chicago, Illinois 60661, and 233 Broadway, New York, New York 10279. Copies of the materials may be obtained from the public reference room of the Commission at 450 Fifth Street, N.W., Washington, D.C. 20549 at prescribed rates. 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.

## **Item 11. Quantitative and Qualitative Disclosures about Market Risk**

We are exposed to market risk from changes in both foreign currency exchange rates and interest rates. We do not hold or issue derivative or other financial instruments for trading purposes. As of December 31, 2008, we had no outstanding foreign exchange sale contracts.

### **Exchange Rate Risk**

#### *Revenues and Expenses in Foreign Currencies*

We are exposed to foreign currency exchange rate risk because a significant portion of our costs are denominated in currencies other than those in which we earn revenues. In 2008, approximately 66% of our total operating expenses were denominated in euro. During the same period, approximately 75% of our sales were denominated in euro, the rest being denominated primarily in U.S. dollars and Japanese yen.

A uniform 10% strengthening in the value of the euro as of December 31, 2008 relative to the U.S. dollar and the Japanese yen would have resulted in an increase in income before taxes and minority interests of approximately €384,000 for the year ended December 31, 2008, compared to a increase of approximately €118,000 for the year ended December 31, 2007. This calculation assumes that the U.S. dollar and Japanese yen exchange rates would have changed in the same direction relative to the euro. In addition to the direct effect of changes in exchange rates quantified above, changes in exchange rates also affect the volume of sales.

We regularly assess the exposure of our receivables to fluctuations in the exchange rates of the principal foreign currencies in which our sales are denominated (in particular, the U.S. dollar and the Japanese yen) and, from time to time, hedge such exposure by entering into forward sale contracts for the amounts denominated in such currencies that we expect to receive from our local subsidiaries. As of December 31, 2008 we had no outstanding hedging instruments.

#### *Financial Instruments and Indebtedness*

Over the past three years, we also had exchange rate exposures with respect to indebtedness and assets denominated in Japanese yen and U.S. dollars. Approximately €0.231 million and €0.05 million of our outstanding indebtedness at December 31, 2008 and 2006, respectively, were denominated in Japanese yen. At December 31, 2007, we had no outstanding indebtedness denominated in Japanese yen. Approximately €9.3 million and €15.3 million of our outstanding indebtedness at December 31, 2008 and 2007, respectively, were denominated in U.S. dollars. None of our outstanding indebtedness was denominated in U.S. dollars at December 31, 2006.

In addition, we had approximately €9.6 million, €11.4 million and €0.4 million of cash denominated in U.S. dollars at December 31, 2008, 2007 and 2006, respectively, and €0.5 million, €1.0 million and €1.2 million of cash denominated in Japanese yen at December 31, 2008, 2007 and 2006, respectively.

## **Item 12. Description of Securities Other than Equity Securities**

Not applicable.

## PART II

### **Item 13. Defaults, Dividend Arrearages and Delinquencies**

Not applicable.

### **Item 14. Material Modifications to the Rights of Security Holders and Use of Proceeds**

Not applicable.

### **Item 15. Controls and Procedures**

#### ***Disclosure Controls and Procedures***

Under the supervision and with the participation of the Company's management, including the Chief Executive Officer and Chief Financial Officer, the Company conducted an evaluation of the effectiveness of its disclosure controls and procedures (as such term is defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended (the "Exchange Act")), as of December 31, 2008. Based on this evaluation, the Company's Chief Executive Officer and Chief Financial Officer concluded that the Company's disclosure controls and procedures were effective as of such date. The Company's disclosure controls and procedures are designed to ensure that information required to be disclosed by us in the reports we file under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms and that such information is accumulated and communicated to management, including the Chief Executive Officer and Chief Financial Officer, to allow timely discussions regarding required disclosure.

#### ***Management's Report on Internal Control Over Financial Reporting***

Management is responsible for establishing and maintaining adequate internal control over financial reporting. Internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles.

The Company's internal controls over financial reporting include those policies and procedures that:

- Pertain to the maintenance of records that in reasonable detail accurately and fairly reflect the transactions and dispositions of the assets of the Company;
- Provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the Company are being made only in accordance with authorizations of the Company's management and directors; and
- Provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of the Company's assets that could have a material effect on the financial statements.

Because of inherent limitations, internal controls over financial reporting may not prevent or detect misstatements. Projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

Management assessed the effectiveness of internal control over financial reporting as of December 31, 2008 based upon the framework as set forth by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) in Internal Control-Integrated Framework. Based on the Management's assessment, management concluded that the Company's internal control over financial reporting was effective as of December 31, 2008.

This annual report does not include the attestation report of the Company’s registered public accounting firm regarding internal control over financial reporting. Management’s report was not subject to attestation by the Company’s registered public accounting firm pursuant to temporary rules of the Securities and Exchange Commission that permit the Company to provide only management’s report in this annual report.

***Change in Internal Control over Financial Reporting***

No change in the Company’s internal control over financial reporting occurred as of the end of the period covered by this report that has materially affected, or is reasonably likely to materially affect the Company’s internal control over financial reporting.

**Item 16A. Audit Committee Financial Expert**

Our Board of Directors has determined that the chair of the Board’s audit committee, Mr. Pierre Beysson, an independent Director, qualifies as an audit committee financial expert.

**Item 16B. Code of Ethics**

We have adopted a code of ethics applicable to our Chief Executive Officer, Chief Financial Officer, principal accounting officers and to any persons performing similar functions. The code of ethics is reviewed every year by the Board of Directors. In 2008, there were no waivers of its applicability. Our code of ethics has previously been filed with the SEC and we have made it available on our website at [www.edap-tms.com](http://www.edap-tms.com).

**Item 16C. Principal Accountant Fees and Services**

The “Audit and Non-Audit Services Pre-Approval Policy” was approved by our Audit Committee on December 22, 2003 (the “2003 Rules”) and reviewed on July 22, 2005. This requires all services which are to be performed by our external auditors to be pre-approved. This may be in the form of a general pre-approval or as pre-approval on a case-by-case basis. All services to be performed by the external auditors were subjected to the above policy and approved in advance. The Audit Committee has been regularly informed of the services and the fees to be paid. No services which are classified as prohibited services by the U.S. Securities and Exchange Commission under the 2003 Rules were commissioned after May 6, 2003. Our external auditors Ernst & Young Audit (“E&Y”) billed the following services related to our 2008 financial year:

<b>Nature of the Fees</b>	<b>2006 (in €)</b>	<b>2007 (in €)</b>	<b>2008 (in €)</b>
Audit fees .....	175,780	162,394	213,380
Audit-related fees .....	96,850	53,040	1,360
Tax fees .....	-	-	-
All other fees .....	-	-	-
<b>Total .....</b>	<b>272,630</b>	<b>215,434</b>	<b>214,740</b>

***Audit Fees***

The following services were billed under the category “audit services”: audit of financial statements and services performed in relation to legal obligations, including the formulation of audit opinions and reports, domestic and international legal audits and support in the preparation and auditing of the documents to be filed. Audit services also included the auditing of information systems and processes and tests, which serve to promote understanding and reliability of the systems and internal corporate controls, as well as advice on issues of billing, accounting and reporting.

### ***Audit-Related Fees***

Audit-related services mainly consisted of services that are normally performed by the external auditor in connection with the auditing of the annual financial statements. Audit-related services also included advice on issues of accounting and reporting which were not classified as audit services, support with the interpretation and implementation of new accounting and reporting standards, auditing of employee benefit plans and support with the implementation of corporate control requirements for reporting.

### ***Tax Fees***

Tax services consisted of services relating to issues of domestic and international taxation (adherence to tax law, tax planning and tax consulting). Furthermore, services were commissioned for the review of tax returns, assistance with tax audits, as well as assistance relating to tax law. No tax services were rendered during the 2008 fiscal year.

### ***All Other Fees***

Other services mainly consisted of routine and administrative follow-up of patents and brand names. All these services were unrelated to the audits of our financial statements.

### **Item 16D. Exemptions from the Listing Standards for Audit Committees**

Not applicable.

### **Item 16E. Purchases of Equity Securities by the Issuer and Affiliated Purchasers**

In 2008, neither the Company nor affiliated purchasers made purchases of equity securities of the Company registered pursuant to Section 12 of the Exchange Act.

### **Item 16F. Change in Registrant's Certifying Accountant**

Not applicable.

### **Item 16G. Corporate Governance**

#### **Exemptions from Certain NASDAQ Corporate Governance Rules**

NASDAQ rules provide for exemptions from the NASDAQ corporate governance standards to a foreign issuer when those standards are contrary to a law, rule or regulation of any public authority exercising jurisdiction over such issuer or contrary to generally accepted business practices in the issuer's country of domicile. We received from NASDAQ an exemption from compliance with one certain corporate governance standard that is contrary to the law, rules, regulations or generally accepted business practices of France. The exemption, and the practices followed by the Company, are described below.

We are exempt from NASDAQ's quorum requirements applicable to meetings of shareholders. In keeping with French law and generally accepted business practices in France, the presence in person or by proxy of shareholders having not less than 20% (in the case of an ordinary general meeting or an extraordinary general meeting deciding upon any capital increase by capitalization of reserves) or 25% (in the case of an extraordinary general meeting) of the shares is necessary for a quorum. If a quorum is not present at any meeting, the meeting is adjourned. Upon recommencement of an adjourned meeting, there is no quorum requirement in the case of an ordinary general meeting or an extraordinary general meeting deciding upon any capital increase by capitalization of reserves. The presence in person or by proxy of shareholders having not less than 20% of the Shares is necessary for a quorum in the case of any other type of extraordinary general meeting. We petitioned for this exemption because there are doubts as to whether it would be legally permissible for a French company to adopt in its articles of association quorum requirements that would be more stringent than those prescribed by French law, and this would in any event be contrary to generally accepted business practice in France.

**PART III**

**Item 17. Financial Statements.**

See Item 18, "Financial Statements."

**Item 18. Financial Statements**

The financial statements listed in the Index to Financial Statements are filed as a part of this Annual Report.

**Item 19. Exhibits**

The exhibits listed in the Index to Exhibits are filed or incorporated by reference as a part of this Annual Report.



## INDEX TO EXHIBITS

Pursuant to the rules and regulations of the Securities and Exchange Commission, the Company has filed certain agreements as exhibits to this annual report on Form 20-F. These agreements may contain representations and warranties by the parties. These representations and warranties have been made solely for the benefit of the other party or parties to such agreements and (i) may be intended not as statements of fact, but rather as a way of allocating the risk to one of the parties to such agreements if those statements turn out to be inaccurate; (ii) may have been qualified by disclosures that were made to such other party or parties and that either have been reflected in the Company's filings or are not required to be disclosed in those filings; (iii) may apply materiality standards different from what may be viewed as material to investors; and (iv) were made only as of the date of such agreements or such other date(s) as may be specified in such agreements and are subject to more recent developments. Accordingly, these representations and warranties may not describe the Company's actual state of affairs at the date hereof.

### Exhibit Description

#### Number:

- 1.1 By-laws (*statuts*) of EDAP TMS S.A. as amended as of January 8, 2009.
- 4.1 (a) Commercial Leases dated October 1, 2002 and Amendment No. 1 dated October 15, 2002, between Maison Antoine Baud and EDAP TMS S.A., EDAP S.A. and Technomed Medical Systems S.A. (together with an English translation thereof) (incorporated herein by reference to Exhibit 4.4 to the Annual Report on Form 20-F filed on May 8, 2003 (File No. 000-29374)).<sup>(1)</sup>  
(b) Amendment No. 2 to commercial leases between TMS S.A. and Maison Antoine Baud, signed on June 28, 2004 (incorporated herein by reference to Exhibit 4.2(b) to the Annual Report on Form 20-F filed on May 20, 2005 (File No. 000-29374)).<sup>(1)</sup>
- 4.2 Form of Registration Rights Agreement dated as of July 27, 2006, among EDAP TMS S.A. and the investors signatory thereto (incorporated herein by reference to Exhibit 2 to the Report of Foreign Private Issuer on Form 6-K/A furnished on August 18, 2006 (File No. 000-29374)).<sup>(1)</sup>
- 4.3 Form of Securities Purchase Agreement dated as of October 29, 2007 among EDAP TMS S.A. and each purchaser identified on the signature pages thereto (incorporated herein by reference to Exhibit 1 to the Report of Foreign Private Issuer on Form 6-K furnished on October 31, 2007 (File No. 000-29374)).<sup>(1)</sup>
- 4.4 Form of Registration Rights Agreement dated as of October 29, 2007, among EDAP TMS S.A. and the investors signatory thereto (incorporated herein by reference to Exhibit 2 to the Report of Foreign Private Issuer on Form 6-K furnished on October 31, 2007 (File No. 000-29374)).<sup>(1)</sup>
- 4.5 Amended and Restated Depositary Agreement with Bank of New York), filed with the SEC on March 27, 2008 as Post-Effective Amendment No.1 to Form F-6 (File No. 333-07314).<sup>(1)</sup>
- 8.1 List of subsidiaries of EDAP TMS S.A. as of March 31, 2009.
- 11.1 Code of Ethics of the Company, approved by the Board of Directors on July 22, 2005.<sup>(1)</sup>
- 12.1 Certification of Chief Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
- 12.2 Certification of Chief Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
- 13.1 Certification of Chief Executive Officer and Chief Financial Officer pursuant to Section 906 of the Sarbanes Oxley Act of 2002.
- 15.1 Consent of Ernst & Young.

(1) Previously filed.

**SIGNATURES**

The registrant hereby certifies that it meets all of the requirements for filing on Form 20-F and that it has duly caused and authorized the undersigned to sign this annual report on its behalf.

EDAP TMS S.A.



Dated: March 31, 2009

---

*Marc Oczachowski*  
*Chief Executive Officer*



Dated: March 31, 2009

---

*Eric Soyer*  
*Chief Financial Officer*

## INDEX TO FINANCIAL STATEMENTS

### **Audited Consolidated Financial Statements for EDAP TMS S.A. and Subsidiaries for the Years Ended December 31, 2008, 2007 and 2006**

Report of Independent Auditors .....	F-2
Consolidated Balance Sheets as of December 31, 2008 and 2007 .....	F-3
Consolidated Statements of Income for the years ended December 31, 2008, 2007 and 2006 .....	F-4
Consolidated Statements of Comprehensive Income for the years ended December 31, 2008, 2007 and 2006 .....	F-5
Consolidated Statements of Shareholders' Equity for the years ended December 31, 2008, 2007 and 2006 .....	F-6
Consolidated Statements of Cash Flows for the years ended December 31, 2008, 2007 and 2006.....	F-7
Notes to Consolidated Financial Statements .....	F-8

## Report of Independent Registered Public Accounting Firm

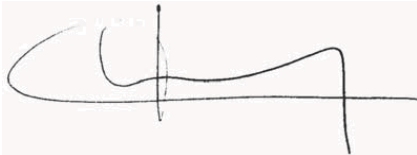
Board of Directors and Shareholders of EDAP TMS S.A.

We have audited the accompanying consolidated balance sheets of EDAP TMS S.A. and subsidiaries as of December 31, 2007 and 2008, and the related consolidated statements of income, comprehensive income, changes in shareholders' equity and cash flows for the three years ended December 31, 2008. These consolidated financial statements are the responsibility of EDAP TMS's management. Our responsibility is to express an opinion on these consolidated financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. We were not engaged to perform an audit of the Company's internal control over financial reporting. Our audits included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion. An audit also includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, and evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of EDAP TMS S.A. and subsidiaries at December 31, 2007 and 2008, and the consolidated results of its operations and its cash flows for the three years ended December 31, 2008, in conformity with U.S. generally accepted accounting principles.

ERNST & YOUNG Audit

A handwritten signature in black ink, appearing to read 'L. Chapoulaud', is written over a horizontal line. The signature is stylized and cursive.

Represented by  
Laurent Chapoulaud

March 31, 2009  
Lyon, France

**EDAP TMS S.A. AND SUBSIDIARIES**  
**CONSOLIDATED BALANCE SHEETS**  
As of December 31, 2008 and 2007  
(in thousands of euros unless otherwise noted)

<b>ASSETS</b>	<b>Notes</b>	<b>2008</b>	<b>2007</b>
<b>Current assets</b>			
Cash and cash equivalents .....	2	13,827	17,523
Net Trade accounts and notes receivable .....	3	14,611	10,876
Other receivables .....	4	951	1,149
Inventories .....	5	4,023	4,306
Deferred tax assets .....	22-3	322	245
Other assets, current portion .....	6	909	935
Short-term investment.....	2	1,143	1,089
Total current assets .....		35,786	36,124
Other assets, non-current .....	6	1,330	1,800
Property and equipment, net .....	7	3,763	4,179
Intangible assets, net .....	8	102	79
Goodwill .....	8	2,412	2,412
Deposits and other non-current assets.....		471	410
Total assets .....		43,863	45,003
<b>LIABILITIES AND SHAREHOLDERS' EQUITY</b>			
<b>Current liabilities</b>			
Trade accounts and notes payable .....	9	6,046	5,661
Deferred revenues, current portion .....	10	704	452
Social security and other payroll withholdings taxes.....		770	813
Employee absences compensation .....		450	443
Income taxes payable .....		38	49
Other accrued liabilities .....	11	3,908	3,293
Short-term borrowings.....	13	1,753	1,593
Current portion of capital lease obligations .....	12	708	521
Current portion of long-term debt .....	14	79	58
Total current liabilities .....		14,457	12,884
Deferred revenues, non current.....	10	582	708
Capital lease obligations, non current.....	12	1,311	1,035
Convertible debentures carried at fair value .....	14	8,901	11,691
Financial instruments carried at fair value.....	14	447	3,484
Long-term debt, non current .....	14	152	-
Other long-term liabilities .....	15	822	703
Total liabilities .....		26,672	30,504
<b>Shareholders' equity</b>			
Common stock, €0.13 par value; 10,006,333 shares issued and 9,582,593 shares outstanding; 9,624,497 shares issued and 9,200,757 shares outstanding; at December 31, 2008 and 2007, respectively .....		1,301	1,251
Additional paid-in capital .....		27,145	25,896
Retained earnings .....		(6,668)	(8,265)
Cumulative other comprehensive loss .....		(3,285)	(3,082)
Treasury stock, at cost; 423,740 at December 31, 2008 and 2007, respectively		(1,301)	(1,301)
Total shareholders' equity .....	16	17,191	14,499
Total liabilities and shareholders' equity .....		43,863	45,003

**EDAP TMS S.A. AND SUBSIDIARIES**

**CONSOLIDATED STATEMENTS OF INCOME**  
**For the years ended December 31, 2008, 2007 and 2006**  
**(in thousands of euros unless otherwise noted)**

	<b>Notes</b>	<b>2008</b>	<b>2007</b>	<b>2006</b>
Sales of goods .....		12,547	11,752	10,849
Sales of RPPs & leases .....		4,664	4,814	3,805
Sales of spare parts and services .....		5,645	5,647	5,520
Total sales .....		<u>22,856</u>	<u>22,213</u>	20,174
Total net sales .....	17	<u>22,856</u>	<u>22,213</u>	20,174
Other revenues .....	18	197	113	91
Total revenues.....		<u>23,053</u>	<u>22,327</u>	20,265
Cost of goods .....		(8,395)	(7,130)	(5,582)
Cost of RPPs & leases .....		(2,546)	(2,169)	(1,576)
Cost of spare parts and services .....		(3,014)	(3,849)	(4,789)
Total cost of sales .....		<u>(13,955)</u>	<u>(13,148)</u>	(11,946)
Gross profit .....		9,099	9,179	8,319
Research and development expenses .....		(4,255)	(3,194)	(2,442)
Selling and marketing expenses .....		(5,684)	(5,476)	(4,621)
General and administrative expenses .....		(3,862)	(4,374)	(4,082)
Non-recurring operating expenses .....	19		(224)	(267)
Loss from operations .....		(4,703)	(4,089)	(3,094)
Financial (expense) income, net .....	20	5,232	(1,243)	153
Foreign currency exchange gain (loss), net .....		577	(254)	(430)
Other income (expense), net .....	21	(1)	16	(5)
Income (loss) before taxes .....		1,105	(5,571)	(3,375)
Income tax (expense) benefit .....	22	492	140	(56)
Net income (loss) .....		<u>1,597</u>	<u>(5,430)</u>	(3,431)
Basic income (loss) per share .....	23	0.17	(0.59)	(0.39)
Diluted income (loss) per share <sup>(1)</sup> .....	23	0.17	(0.59)	(0.39)
Basic Weighted average shares outstanding .....	23	9,582,593	9,200,757	8,817,007
Diluted Weighted average shares outstanding .....	23	9,658,295	9,200,757	8,817,007

<sup>(1)</sup> Due to the net losses in 2006 and 2007, the assumed net exercise of stock options/warrants and stock relating to the convertible bonds in those years was excluded, as the effect would have been anti-dilutive.

The accompanying notes are an integral part of the consolidated financial statements.



**EDAP TMS S.A. AND SUBSIDIARIES**

**CONSOLIDATED STATEMENTS OF COMPREHENSIVE INCOME**  
**For the years ended December 31, 2008, 2007 and 2006**  
**(in thousands of euros unless otherwise noted)**

	<u>2008</u>	<u>2007</u>	<u>2006</u>
Net income(loss).....	1,597	(5,430)	(3,431)
Other comprehensive loss:			
Foreign currency translation adjustments .....	(168)	(71)	(55)
Provision for retirement indemnities .....	(34)	5	(84)
Comprehensive income (loss), net of tax.....	<u>1,395</u>	<u>(5,496)</u>	<u>(3,570)</u>

The accompanying notes are an integral part of the consolidated financial statements.

**EDAP TMS S.A. AND SUBSIDIARIES**

**CONSOLIDATED STATEMENTS OF SHAREHOLDERS' EQUITY**  
**For the years ended December 31, 2008, 2007 and 2006**  
**(in thousands of euros unless otherwise noted)**

	<b>Number of Shares</b>	<b>Common Stock</b>	<b>Additional paid-in Capital</b>	<b>Retained Earnings</b>	<b>Cumulative Other Compre- hensive Income (loss)</b>	<b>Treasury Stock</b>	<b>Total</b>
Balance as of January 1, 2006	7,782,731	1,087	20,359	597	(2,877)	(1,794)	17,372
Net loss .....				(3,431)			(3,431)
Translation adjustment.....					(55)		(55)
Warrants and stock options granted .....	72,600		4			256	260
Capital increase.....	961,676	125	5,114				5,239
Provision for retirement indemnities.....					(84)		(84)
Balance as of December 31, 2006	8,817,007	1,212	25,476	(2,835)	(3,016)	(1,538)	19,300
Net loss .....				(5,430)			(5,430)
Translation adjustment.....					(71)		(71)
Warrants and stock options granted .....	383,750	39	420			237	695
Capital increase.....							
Provision for retirement indemnities.....					5		5
Balance as of December 31, 2007	9,200,757	1,251	25,896	(8,265)	(3,082)	(1,301)	14,499
Net income .....				1,597			1,597
Translation adjustment.....					(168)		(168)
Warrants and stock options granted .....			699				699
Capital increase.....	381,836	50	550				599
Provision for retirement indemnities.....					(34)		(34)
Balance as of December 31, 2008	9,582,593	1,301	27,145	(6,668)	(3,285)	(1,301)	17,191

The accompanying notes are an integral part of the consolidated financial statements.

**EDAP TMS S.A. AND SUBSIDIARIES**  
**CONSOLIDATED STATEMENTS OF CASH FLOWS**  
**For the years ended December 31, 2008, 2007 and 2006**  
**(in thousands of euros unless otherwise noted).**

	<b>2008</b>	<b>2007</b>	<b>2006</b>
<b>Cash flows from operating activities</b>			
Net income (loss) .....	1,597	(5,430)	(3,431)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization .....	1,785	1,296	1,257
Change in fair value on Convertible Debentures .....	(3,465)	747	—
Change in fair value on Investors Warrants and Placement Agent Warrants .....	(3,238)	371	—
Other Non-cash compensation.....	684	72	32
Change in allowances for doubtful accounts & slow-moving inventories .....	394	412	273
Change in long-term provisions .....	325	(18)	229
Net capital loss on disposals of assets.....	255	407	245
Deferred tax expense/(benefit) .....	(77)	(161)	(91)
Net loss (gain) on sale of assets .....	—	—	—
Operating cash flow .....	(1,740)	(2,304)	(1,486)
Increase/Decrease in operating assets and liabilities:			
Decrease/(Increase) in trade accounts and notes and other receivables .....	(3,467)	(1,599)	(1,201)
Decrease/(Increase) in inventories .....	(126)	(820)	429
Decrease/(Increase) in other assets .....	26	278	(353)
(Decrease)/Increase in trade accounts and notes payable .....	561	1,009	395
(Decrease)/Increase in accrued expenses, other current liabilities .....	152	707	315
Net increase/decrease in operating assets and liabilities.....	(2,854)	(426)	(415)
<b>Net cash used in operating activities .....</b>	<b>(4,593)</b>	<b>(2,729)</b>	<b>(1,901)</b>
<b>Cash flows from investing activities</b>			
Additions to capitalized assets produced by the Company .....	(687)	(1,947)	(1,287)
Net proceeds from sale of leased back assets .....	1,108	1,192	737
Acquisitions of property and equipment .....	(373)	(513)	(208)
Acquisitions of intangible assets .....	(57)	(46)	(43)
Acquisitions of short term investments .....	(691)	(58)	(1,031)
Net proceeds from sale of assets.....		168	221
Increase in deposits and guarantees .....	(11)	(34)	(18)
Reimbursement of deposits and guarantees .....	—	—	—
<b>Net cash used in investing activities .....</b>	<b>(712)</b>	<b>(1,238)</b>	<b>(1,629)</b>
<b>Cash flow from financing activities</b>			
Proceeds from capital increase (2007: exercise of warrants and stock options) .....	600	352	5,239
Proceeds from long term borrowings, net of financing costs .....	238	11,876	150
Repayment of long term borrowings .....	(65)	(121)	(148)
Repayment of obligations under capital leases .....	(636)	(569)	(464)
Increase/(decrease) in bank overdrafts and short-term borrowings .....	159	285	409
<b>Net cash used in financing activities.....</b>	<b>296</b>	<b>11,824</b>	<b>5,186</b>
Net effect of exchange rate changes on cash and cash equivalents .....	1,313	(227)	(80)
<b>Net increase/(decrease) in cash and cash equivalents .....</b>	<b>(3,696)</b>	<b>7,629</b>	<b>1,575</b>
Cash and cash equivalents at beginning of year .....	17,523	9,894	8,317
<b>Cash and cash equivalents at end of year .....</b>	<b>13,827</b>	<b>17,523</b>	<b>9,894</b>

The accompanying notes are an integral part of the consolidated financial statements.

## EDAP TMS S.A. AND SUBSIDIARIES

### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (in thousands of euros unless otherwise noted, except per share data)

#### 1—SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

##### *1-1 Nature of operations*

EDAP TMS S.A. and its subsidiaries (“the Company”) are engaged in the development, production, marketing, distribution and maintenance of a portfolio of minimally-invasive medical devices for the treatment of urological diseases. The Company currently produces devices for treating stones of the urinary tract, benign prostatic hyperplasia and localized prostate cancer. Net sales consist primarily of direct sales to hospitals and clinics in France and Europe, export sales to third-party distributors and agents, and export sales through subsidiaries based in Italy and Asia.

The Company purchases the majority of the components used in its products from a number of suppliers but for some components, relies on a single source. Delay would be caused if the supply of these components or other components was interrupted and these delays could be extended in certain situations where a component substitution may require regulatory approval. Failure to obtain adequate supplies of these components in a timely manner could have a material adverse effect on the Company’s business, financial position and results of operation.

##### *1-2 Management estimates*

The preparation of financial statements in conformity with U.S. generally accepted accounting principles (“US GAAP”) requires management to make estimates and assumptions, such as business plans, that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. Actual results could differ from those estimates.

##### *1-3 Consolidation*

The accompanying consolidated financial statements include the accounts of EDAP TMS S.A. and all its domestic and foreign owned subsidiaries, which include EDAP TMS France SAS (formerly "Technomed Medical Systems S.A."), EDAP Technomed Inc., Edap Technomed Sdn Bhd, Edap Technomed Italia S.R.L, EDAP Technomed Co. Ltd. (formerly Nippon Euro Edap Technomed KK) and EDAP TMS GmbH (formerly EDAP GmbH). Edap Technomed Sdn Bhd was incorporated in early 1997. Edap Technomed Co. Ltd. was created in late 1996. EDAP TMS GmbH was created in July 2006. EDAP SA, a subsidiary incorporating HIFU activities merged all of its activity into EDAP TMS France SAS in 2008. All intercompany transactions and balances are eliminated in consolidation

##### *1-4 Revenue recognition*

Sales of goods:

For medical device sales with no significant remaining vendor obligation, payments contingent upon customer financing, acceptance criteria that can be subjectively interpreted by the customer, or tied to the use of the device, revenue is recognized when evidence of an arrangement exists, title to the device passes (depending on terms, either upon shipment or delivery), and the customer has the intent and ability to pay in accordance with contract payment terms that are fixed or determinable. For sales in which payment is contingent upon customer financing, acceptance criteria can be subjectively interpreted by the customer, or payment depends on use of the device, revenue is recognized when the contingency is resolved. The Company provides training and provides a minimum of one-year warranty upon installation. The Company accrues for the estimated training and warranty costs at the time of sale. Revenues related to disposables are recognized when goods are delivered.

Sales of RPPs and leases:

Revenues related to the sale of Ablatherm treatments invoiced on a “Revenue-Per-Procedure” (“RPP”) basis are recognized when the treatment procedure has been completed. Revenues from devices leased to customers under operating leases are recognized on a straight-line basis.

## EDAP TMS S.A. AND SUBSIDIARIES

### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (in thousands of euros unless otherwise noted, except per share data)

Sales of spare parts and services:

Revenues related to spare parts are recognized when goods are delivered. Maintenance contracts rarely exceed one year and are recognized on a linear basis. Billings or cash receipts in advance of services due under maintenance contracts are recorded as deferred revenue.

#### ***1-5 Shipping and handling costs***

The Company recognizes revenue from the shipping and handling of its products as a component of revenue. Shipping and handling costs are recorded as a component of cost of sales.

#### ***1-6 Cash equivalents and short term investments***

Cash equivalents are cash investments which are highly liquid and have initial maturities of 90 days or less.

Cash investments with a maturity higher than 90 days are considered as short-term investments.

#### ***1-7 Accounts Receivables***

Accounts receivables are stated at cost net of allowances for doubtful accounts. The Company makes judgments as to its ability to collect outstanding receivables and provides allowances for the portion of receivables when collection becomes doubtful. Provision is made based upon a specific review of all significant outstanding invoices. These estimates are based on our bad debt write-off experience, analysis of credit information, specific identification of probable bad debt based on our collection efforts, aging of accounts receivables and other known factors.

#### ***1-8 Inventories***

Inventories are valued at the lower of manufacturing cost, which is principally comprised of components and labor costs, or market (net realizable value). Cost is determined on a first-in, first-out basis for components and spare parts and by specific identification for finished goods (medical devices). The Company establishes reserves for inventory estimated to be obsolete, unmarketable or slow moving, first based on a detailed comparison between quantity in inventory and historical consumption and then based on case-by-case analysis of the difference between the cost of inventory and the related estimated market value.

#### ***1-9 Property and equipment***

Property and equipment is stated at historical cost. Depreciation and amortization of property and equipment are calculated using the straight-line method over the estimated useful life of the related assets, as follows:

Leasehold improvements.....	10 years or lease term if shorter
Equipment .....	3-10 years
Furniture, fixtures, fittings and other .....	2-10 years

Equipment includes industrial equipment and research equipment that has alternative future uses. Equipment also includes devices that are manufactured by the Company and leased to customers through operating leases related to Revenue-Per-Procedure transactions and devices subject to sale and leaseback transactions. This equipment is depreciated over a period of seven years.

## EDAP TMS S.A. AND SUBSIDIARIES

### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (in thousands of euros unless otherwise noted, except per share data)

#### *1-10 Long-lived assets*

The Company reviews the carrying value of its long-lived assets, including fixed assets and intangible assets, for impairment whenever events or changes in circumstances indicate that the carrying amount of such assets may not be fully recoverable. Recoverability of long-lived assets is assessed by a comparison of the carrying amount of the assets (or the Group of assets, including the asset in question, that represents the lowest level of separately-identifiable cash flows) to the total estimated undiscounted cash flows expected to be generated by the asset or group of assets. If the future net undiscounted cash flows is less than the carrying amount of the asset or group of assets, the asset or group of assets is considered impaired and an expense is recognized equal to the amount required to reduce the carrying amount of the asset or group of assets to its then fair value. Fair value is determined by discounting the cash flows expected to be generated by the assets, when the quoted market prices are not available for the long-lived assets. Estimated future cash flows are based on assumptions and are subject to risk and uncertainty.

#### *1-11 Goodwill and intangible assets*

Goodwill represents the excess of purchase price over the fair value of identifiable net assets of businesses acquired. Goodwill is not amortized but instead tested annually for impairment or more frequently when events or change in circumstances indicate that the assets might be impaired by comparing the carrying value to the fair value of the reporting units to which it is assigned. Under Statement of Financial Accounting Standards 142, "Goodwill and other intangible assets", the impairment test is performed in two steps. The first step compares the fair value of the reporting unit with its carrying amount, including goodwill. If the fair value of the reporting unit is less than its carrying amount, a second step is performed to measure the amount of impairment loss. The second step allocates the fair value of the reporting unit to the Company's tangible and intangible assets and liabilities. This derives an implied fair value for the reporting unit's goodwill. If the carrying amount of the reporting units goodwill exceeds the implied fair value of that goodwill, an impairment loss is recognized equal to that excess. For the purpose of any impairment test, the Company relies upon projections of future undiscounted cash flows and takes into account assumptions regarding the evolution of the market and its ability to successfully develop and commercialize its products.

Changes in market conditions could have a major impact on the valuation of these assets and could result in additional impairment losses.

Intangible assets consist primarily of purchased patents relating to lithotripters, purchased licenses, a purchased trade name and a purchased trademark. The basis for valuation of these assets is their historical acquisition cost. Amortization of intangible assets is calculated by the straight-line method over the shorter of the contractual or estimated useful life of the assets, as follows:

Patents .....	5 years
Licenses.....	5 years
Trade name and trademark .....	7 years

#### *1-12 Treasury Stocks*

Treasury stock purchases are accounted for at cost. The sale of treasury stocks is accounted for using the first in first out method. Gains on the sale or retirement of treasury stocks are accounted for as additional paid-in capital whereas losses on the sale or retirement of treasury stock are recorded as additional paid-in capital to the extent that previous net gains from sale or retirement of treasury stocks are included therein; otherwise the losses shall be recorded to accumulated benefit (deficit) account. Gains or losses from the sale or retirement of treasury stock do not affect reported results of operations.



## EDAP TMS S.A. AND SUBSIDIARIES

### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (in thousands of euros unless otherwise noted, except per share data)

#### *1-13 Warranty expenses*

The Company generally provides customers with a warranty for each product sold and accrues warranty expense at time of sale based upon historical claims experience. Actual warranty costs incurred are charged against the accrual when paid and are classified in cost of sales in the statement of income. Warranty expense amounted to €768 thousand, €645 thousand and €483 thousand for the years ended December 31 2008, 2007 and 2006 respectively.

#### *1-14 Income taxes*

The Company accounts for income taxes in accordance with SFAS No. 109, "Accounting for Income Taxes". Under SFAS No. 109, deferred tax assets and liabilities are determined based on differences between the financial reporting and tax basis of assets and liabilities and are measured by applying enacted tax rates and laws to taxable years in which such differences are expected to reverse. A valuation allowance is established if, based on the weight of available evidence, it is more likely than not that some portion, or all of the deferred tax assets, will not be realized. In accordance with SFAS No. 109, no provision has been made for income or withholding taxes on undistributed earnings of foreign subsidiaries, such undistributed earnings being permanently reinvested.

As of January 1, 2007, the Company adopted FIN48 "Accounting for uncertainty in income tax". Under FIN48, the measurement of a tax position that meets the more-likely-than-not recognition threshold must take into consideration the amounts and probabilities of the outcomes that could be realized upon ultimate settlement using the facts, circumstances and information available at the reporting date.

#### *1-15 Research and development costs*

Research and development costs are recorded as an expense in the period in which they are incurred.

The French government provides tax credits to companies for annual increased spending for innovative research and development. Income tax benefits correspond to these French research tax credits, which are credited against income taxes payable in each of the four years after being incurred or, if not utilized, are recoverable in cash. As of December 31, 2008, EDAP TMS had total research tax credits receivable of €701 thousand.

#### *1-16 Advertising costs*

Advertising costs are recorded as an expense in the period in which they are incurred. Advertising costs amounted to €1,408 thousand, €831 thousand and €584 thousand for the years ended December 31 2008, 2007 and 2006 respectively.

#### *1-17 Foreign currency translation and transactions*

##### *Translation of the financial statements of consolidated companies*

The reporting currency of EDAP TMS S.A. for all years presented, is the euro (€). The functional currency of each subsidiary is its local currency. In accordance with Statement of Financial Accounting Standards No. 52, all accounts in the financial statements are translated into euro from the functional currency at exchange rate as follows:

- assets and liabilities are translated at year-end exchange rates;
- shareholders' equity is translated at historical exchange rates (as of the date of contribution);
- statement of income items are translated at average exchange rates for the year; and
- translation gains and losses are recorded in a separate component of shareholders' equity.

## EDAP TMS S.A. AND SUBSIDIARIES

### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (in thousands of euros unless otherwise noted, except per share data)

#### *Foreign currencies transactions*

Transactions involving foreign currencies are translated into the functional currency using the exchange rate prevailing at the time of the transactions. Receivables and payables denominated in foreign currencies are translated at year-end exchange rates. The resulting unrealized exchange gains and losses are carried to the statement of income.

#### *1-18 Earnings per share*

Basic earnings per share is computed by dividing income available to common shareholders by the weighted average number of shares of common stock outstanding for the period. Diluted earnings per share reflects potential dilution that could occur if securities or other contracts to issue common stock were exercised or converted into common stock or resulted in the issuance of common stock that then shared in the earnings of the Company. The dilutive effects of the Company's common stock options and warrants is determined using the treasury stock method to measure the number of shares that are assumed to have been repurchased using the average market price during the period, which is converted from U.S. dollars at the average exchange rate for the period.

#### *1-19 Derivative instruments*

Financial Accounting Standards Board Statement No. 133 "Accounting for Derivative Instruments and Hedging Activities" ("SFAS 133") requires the Company to recognize all of its derivative instruments as either assets or liabilities in the statement of financial position at fair value. The accounting for changes in the fair value (i.e., gains or losses) of a derivative instrument depends on whether it has been designated and qualifies as part of a hedging relationship and further, on the type of hedging relationship. For those derivative instruments that are designated and qualify as hedging instruments, the Company must classify the hedging instrument, based upon the exposure being hedged, as fair value hedge, cash flow hedge or a hedge of a net investment in a foreign operation.

Gains and losses from derivative instruments are recorded in the income statement.

#### *1-20 Employee stock option plans*

At December 31, 2008, the Company had five stock-based employee compensation plans. The Company adopted SFAS 123R, "Share-Based Payment", effective January 1, 2006. SFAS 123R requires the recognition of fair value of stock compensation as an expense in the calculation of net income (loss).

The fair value of each stock option granted during the year is estimated on the date of grant using the Black-Scholes option pricing model with the following assumptions:

	<b>Year Ended December 31,</b>		
	<b>2008<sup>(1)</sup></b>	<b>2007</b>	<b>2006<sup>(1)</sup></b>
Weighted-average expected life (years) .....	—	10	—
Expected volatility rates.....	—	75%	—
Expected dividend yield .....	—	—	—
Risk-free interest rate .....	—	4.4%	—
Weighted-average exercise price (€).....	—	3.99	—
Weighted-average fair value of options granted during the year (€) .....	—	3.43	—

(1) The Company did not make any grants during the years ended December 31, 2006 and 2008.

## EDAP TMS S.A. AND SUBSIDIARIES

### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (in thousands of euros unless otherwise noted, except per share data)

#### *1-21 Convertible debentures and detachable warrants*

##### Convertible Debentures

On October 29, 2007, the Company issued \$20 million in aggregate principal amount of non-secured, convertible debentures with detachable warrants. See Note 14 for further discussion. At the inception date, the Company elected to measure the instrument and the embedded derivatives in their entirety at fair value, with changes in fair value reported in the income statement under financial income, pursuant to §16 of SFAS 133, as amended by SFAS 155. Thus, the convertible debentures together with their embedded derivatives are recorded as a liability, with subsequent changes in fair value recorded in financial income and expenses. The Company used a binomial valuation model to measure the fair value of the Investor Warrants and a binomial valuation model with a Company specific credit spread to measure the fair value of the convertible debentures.

##### Warrants:

As part of the October 2007 \$20 million issuance of the 9% Senior Convertible Debentures, we issued warrants to both the investors in the convertible debentures and to the bank that assisted us as the Placement Agent. See Note 14 for further discussion.

In accordance with EITF 00-19, the warrants issued to the investors in the convertible debentures (“Investor Warrants”) and the Placement Agent (“Placement Agent Warrants”) are classified as a liability because the Company may be required to net-cash and settle them upon the occurrence of certain events outside the control of the Company. We accounted for the Investor Warrants based on their fair value at inception date, with subsequent changes in fair value recorded as financial earnings (or loss) as each balance sheet date. We used a binomial pricing model to determine the fair value of the Investor Warrants: the binomial model was developed to capture the specific nature of this instrument, and in particular the possibility the holder may exercise the call option at any time from the inception date. The application of the model to the warrants therefore requires the use of subjective assumptions, including historical share price volatility, the expected life of the warrants and our risk-free interest rate, and the liquidity discount factor. A change in one or more of these assumptions could result in a material change to the estimated fair value of the vested warrants.

The warrants issued to the Placement Agent as partial consideration for placing the convertible debentures recorded as a liability, with changes in fair value at each balance sheet date reflected in financial income. We used the Black-Scholes option-pricing model to determine the fair value of the Placement Agent Warrants. The application of the model to the warrants at inception date therefore required the use of subjective assumptions, including historical share price volatility, the expected life of the warrants and our risk-free interest rate.

#### *1-22 Leases and Sales and leaseback transactions*

In accordance with SFAS 13, Accounting for Leases, we classify all leases at the inception date as either a capital lease or an operating lease. A lease is a capital lease if it meets any one of the following criteria; otherwise, it is an operating lease:

- Ownership is transferred to the lessee by the end of the lease term;
- The lease contains a bargain purchase option;
- The lease term is at least 75% of the property's estimated remaining economic life;
- The present value of the minimum lease payments at the beginning of the lease term is 90% or more of the fair value of the leased property to the lessor at the inception date.

We enter into sale and leaseback transactions from time to time. In accordance with SFAS 13 and EITF 93-8, any profit or loss on the sale is deferred and amortized prospectively over the term of the lease, in proportion to the leased asset if a capital lease, or in proportion to the related gross rental charged to expense over the lease term, if an operating lease.

## EDAP TMS S.A. AND SUBSIDIARIES

### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (in thousands of euros unless otherwise noted, except per share data)

#### *1-23 New accounting pronouncements*

In February, 2008, the FASB issued FASB Staff Position (“FSP”) FASB 157-2, “Effective Date of FASB Statement No. 157.” This FSP delays the effective date of SFAS No. 157 for all nonfinancial assets and nonfinancial liabilities, except those that are recognized or disclosed at fair value in the financial statements on a recurring basis (at least annually). The effective date for nonfinancial assets and nonfinancial liabilities has been delayed by one year to fiscal years beginning after November 15, 2008 and interim periods within those fiscal years.

The Company has not completed its analysis of the potential impact of the adoption of SFAS No. 157 for nonfinancial assets and nonfinancial liabilities (effective January 1, 2009) on the Company’s financial position and results of operations.

In March 2008, the FASB issued SFAS No. 161 (SFAS 161), “Disclosures about Derivative Instruments and Hedging Activities.” SFAS 161 amends and expands the disclosure requirements of SFAS No. 133, “Accounting for Derivative Instruments and Hedging Activities”, and is effective for fiscal years beginning after November 15, 2008. The Company has not determined yet the effect on consolidated financial statements, if any, upon adoption of SFAS 161.

In April 2008, the FASB issued FASB Staff Position (“FSP”) SFAS No. 142-3, “*Determination of the Useful Life of Intangible Assets*”. This FSP amends the factors that should be considered in developing renewal or extension assumptions used to determine the useful life of a recognized intangible asset under FASB Statement No. 142, “*Goodwill and Other Intangible Assets*” (“SFAS 142”). The intent of this FSP is to improve the consistency between the useful life of a recognized intangible asset under SFAS 142 and the period of expected cash flows used to measure the fair value of the asset under SFAS 141R, and other GAAP. This FSP is effective for financial statements issued for fiscal years beginning after December 15, 2008, and interim periods within those fiscal years. Early adoption is prohibited. The Company has not determined yet the effect on consolidated financial statements, if any, upon adoption of SFAS 142-3.

In May 2008, the FASB issued Staff Position FSP APB 14-1 (FSP APB 14-1), “Accounting for Convertible Debt Instruments That May Be Settled in Cash upon Conversion (Including Partial Cash Settlement).” FSP APB 14-1 requires companies that have issued convertible debt that may be settled wholly or partly in cash when converted, to account for the debt and equity components separately. The value assigned to the bond liability is the estimated value of a similar bond without the conversion feature as of the issuance date. The difference between the proceeds for the convertible debt and the amount reflected as a bond liability is recorded as additional paid-in-capital. Interest expense is recorded using the issuer’s comparable debt rate. FSP APB 14-1 is effective for fiscal years beginning after December 15, 2008 and interim periods within those fiscal years and will require retrospective application. The Company does not expect that this will have a significant impact on its consolidated financial statements.

In June 2008, the FASB issued Financial Accounting Standards Board Staff Position EITF 03-6-1, *Determining Whether Instruments Granted in Share-Based Payment Transactions Are Participating Securities* (“FSP EITF 03-6-1”). The FSP provides that unvested share-based payment awards that contain nonforfeitable rights to dividends or dividend equivalents (whether paid or unpaid) are participating securities and shall be included in the computation of earnings per share pursuant to the two-class method in accordance with SFAS 128, Earnings per Share. The FSP is effective for financial statements issued for fiscal years beginning after December 15, 2008, and interim periods within those years. Upon adoption, the Company is required to retrospectively adjust its earnings per share data to conform with the provisions in this FSP. Early application of this FSP is prohibited. The Company has not determined yet the effect on consolidated financial statements, if any, upon adoption of FSP EITF 03-6-1.

**EDAP TMS S.A. AND SUBSIDIARIES**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS  
(in thousands of euros unless otherwise noted, except per share data)**

**2—CASH EQUIVALENTS AND SHORT TERM INVESTMENTS**

Cash and cash equivalents are comprised of the following:

	<b>December 31,</b>	
	<b>2008</b>	<b>2007</b>
Total cash and cash equivalents .....	13,827	17,523
Short term investments .....	1,143	1,089
Total cash and cash equivalents, and short term investments .....	<u>14,970</u>	<u>18,611</u>

**3—TRADE ACCOUNTS AND NOTES RECEIVABLE, NET**

Trade accounts and notes receivable consist of the following:

	<b>December 31,</b>	
	<b>2008</b>	<b>2007</b>
Trade accounts receivable.....	15,214	11,370
Notes receivable.....	189	242
Less: allowance for doubtful accounts .....	(792)	(735)
Total .....	<u>14,611</u>	<u>10,877</u>

Notes receivable usually represent commercial bills of exchange (drafts) with initial maturities of 90 days or less.

Bad debt expenses amount to €149 thousand, €131 thousand and €86 thousand, for the years ended December 31, 2008, 2007, and 2006.

**4—OTHER RECEIVABLES**

Other receivables consist of the following:

	<b>December 31,</b>	
	<b>2008</b>	<b>2007</b>
Value-added taxes receivable .....	226	420
Research and development tax credit receivable from the French State .....	701	222
Personnel advances .....	41	353
Other receivables from the French State .....	6	100
Others .....	(23)	54
Total .....	<u>951</u>	<u>1,149</u>

At the end of 2007, Personnel advances included €300 thousand related to the severance package of a former senior executive.

## EDAP TMS S.A. AND SUBSIDIARIES

### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (in thousands of euros unless otherwise noted, except per share data)

#### 5—INVENTORIES

Inventories consist of the following:

	December 31,	
	2008	2007
Components, spare parts .....	4,541	3,751
Work-in-progress .....	592	688
Finished goods .....	302	888
Total gross inventories.....	5,435	5,327
Less: provision for slow-moving inventory .....	(1,412)	(1,021)
Total .....	4,023	4,306

The provision for slow moving inventory relates to components and spare parts. The allowance for slow moving inventory, the changes in which are classified within cost of sales, amounted to €390 thousand, €288 thousand and €388 thousand for the years ended December 31, 2008, 2007 and 2006, respectively.

#### 6—OTHER ASSETS

Other assets consist of the following:

	December 31,	
	2008	2007
Deferred financing costs , current portion .....	470	470
Other prepaid expenses, current portion .....	439	465
Total.....	909	935

	December 31,	
	2008	2007
Deferred financing costs , non-current.....	1,330	1,800

Deferred financing costs related to the debentures issued in the October 2007 private placement are being amortized over five years, the duration of the debt. The amortization of deferred financing costs, which is classified as financial expense, net, amounted to €470 thousand and €78 thousand, for the years ended December 31, 2008 and 2007, respectively.

#### 7—PROPERTY AND EQUIPMENT, NET

Property and equipment consist of the following:

	December 31,	
	2008	2007
Equipment.....	8,839	8,222
Furniture, fixture, and fittings and other .....	1,884	2,541
Total gross value .....	10,723	10,763
Less: accumulated depreciation and amortization .....	(6, 960)	(6,583)
Total .....	3,763	4,180

Depreciation and amortization expense related to property and equipment amounted to €1,273 thousand, to €1,180 thousand and €1,200 thousand for the years ended December 31, 2008, 2007 and 2006, respectively.



## EDAP TMS S.A. AND SUBSIDIARIES

### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (in thousands of euros unless otherwise noted, except per share data)

Capitalized costs on equipment held under capital leases of €2,945 thousand and €2,517 thousand and are included in property and equipment at December 31, 2008 and 2007, respectively. Accumulated amortization of these assets leased to third parties was €1,531 thousand and €1,159 thousand, at December 31, 2008 and 2007, respectively. Amortization expense on assets held under capital leases is included in total amortization expense and amounted to €372 thousand, €374 thousand and €277 thousand for the years ended December 31, 2008, 2007 and 2006, respectively.

#### 8—GOODWILL AND INTANGIBLE ASSETS

As discussed in Note 1-11, the Company adopted SFAS 142, “Goodwill and Other Intangible Assets”, on January 1, 2002. SFAS 142 requires that goodwill and other intangible assets that have indefinite lives not be amortized but instead be tested at least annually for impairment, or more frequently when events or change in circumstances indicate that the asset might be impaired, by comparing the carrying value to the fair value of the reporting unit to which they are assigned. The Company considers its SFAS 131 operating segment — High Intensity Focused Ultrasound (HIFU) and Urology Devices and Services (UDS) — to be its reporting units for purposes of testing for impairment, as the components within each operating segment have similar economic characteristics and thus do not represent separate reporting units. Goodwill amounts to €1,767 thousand for the UDS division and to €645 thousand for the HIFU division, at December 31, 2008.

The Company completed the required annual impairment test in the fourth quarter of 2008. To determine the fair value of the Company’s reporting units, the Company used the discounted cash flow approach for each of the two reportable units. The main assumptions used are the following: (i) a five-year business plan approved by management in late 2008 and revised in early 2009, (ii) a discount rate of 14% for HIFU, 12.5% for UDS, (iii) a residual value specific to each segment. In both cases, the fair value of the reporting unit was in excess of the reporting unit’s book value, which resulted in no goodwill impairment.

A one percentage point increase in the HIFU discount rate assumed in the impairment testing would not lead the company to record an impairment charge. Similarly, a one percentage point increase in the UDS discount rate assumed in the impairment testing would not lead the company to record an impairment charge.

Intangible assets consist of the following:

	<b>December 31,</b>	
	<b>2008</b>	<b>2007</b>
Licenses .....	356	532
Trade name and trademark .....	531	539
Patents .....	412	412
Organization costs .....	363	363
Total gross value .....	1,662	1,846
Less: accumulated amortization .....	(1,560)	(1,767)
Total .....	102	79

Amortization expenses related to intangible assets amounted to €37 thousand, €37 thousand and €57 thousand, for the years ended December 31, 2008, 2007 and 2006, respectively.

For the two coming years, the annual estimated amortization expense for intangible assets will be approximately €60 thousand.

## EDAP TMS S.A. AND SUBSIDIARIES

### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (in thousands of euros unless otherwise noted, except per share data)

#### 9—TRADE ACCOUNTS AND NOTES PAYABLE

Trade accounts and notes payable consist of the following:

	<b>December 31,</b>	
	<b>2008</b>	<b>2007</b>
Trade accounts payable.....	5,065	5,066
Notes payable.....	981	595
Total.....	6,046	5,661

Trade accounts payable usually represent invoices with a due date of 90 days or less.

Notes payable represent commercial bills of exchange (drafts) with initial maturities of 90 days or less.

#### 10—DEFERRED REVENUES

Deferred revenues consist of the following:

	<b>December 31,</b>	
	<b>2008</b>	<b>2007</b>
Deferred revenues on maintenance contracts .....	384	217
Deferred revenue on RPP .....	40	11
Deferred revenue on sale of devices .....	616	618
Deferral of the gain on sale-lease-back transactions.....	247	314
Total.....	1,286	1,160
Less long term portion .....	582	708
Current portion.....	704	452

#### 11—OTHER ACCRUED LIABILITIES

Other accrued liabilities consist of the following:

	<b>December 31,</b>	
	<b>2008</b>	<b>2007</b>
Provision for warranty costs .....	1,114	874
Value added tax payable .....	567	467
Accruals for social expenses.....	430	864
Conditional government subsidies.....	954	788
Advance from debtors.....	252	77
Retirement indemnities .....	24	17
Accrued interests .....	323	-
Others .....	243	206
Total.....	3,908	3,293

At the end of 2007, accruals for social expenses include €422 thousand related to the severance package of a former senior executive

**EDAP TMS S.A. AND SUBSIDIARIES**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS  
(in thousands of euros unless otherwise noted, except per share data)**

Changes in the provision for warranty costs are as follows:

	<b>December 31,</b>	
	<b>2008</b>	<b>2007</b>
Beginning of year .....	874	700
Amount used during the year (payments) .....	(527)	(471)
New warranty expenses .....	768	645
End of year .....	1,114	874

**12—LEASE OBLIGATIONS**

*12-1 Capital leases*

The Company leases certain of its equipment under capital leases. At December 31, 2008, this equipment consists of medical devices for an amount of €1,939 thousand and vehicles for an amount of €80 thousand. Future minimum lease payments under capital leases for the years ending December 31, 2008 are as follows:

	<b>December 31,</b>	
	<b>2008</b>	
2009 .....	817	
2010 .....	703	
2011 .....	457	
2012 .....	220	
Thereafter.....	40	
Total minimum lease payments .....	2,237	
Less: amount representing interest .....	(218)	
Present value of minimum lease payments .....	2,019	
Less: current portion .....	708	
Long-term portion.....	1,311	

Interest paid under capital lease obligations was €110 thousand, €64 thousand, and €48 thousand for the years ended December 31, 2008, 2007, and 2006, respectively.

*12-2 Operating leases*

As of December 31, 2008, operating leases having initial or remaining non-cancelable lease terms greater than one year consist of one lease for the facilities of TMS S.A. in Vaulx-en-Velin, France and several leases for facilities in Japan. The French lease contract has a lease term of nine years expiring at the option of the lessee at the end of a first four-year period, then a two-year and finally a three-year period, through 2011 (i.e., in 2006, 2008 or 2011).

Future minimum lease payments for these operating leases consist of the following amounts, unless leases are otherwise cancelled by the lessees:

	<b>France</b>	<b>Japan</b>
2009 .....	292	240
2010 .....	292	159
2011 .....	292	-
Total .....	876	399

## EDAP TMS S.A. AND SUBSIDIARIES

### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (in thousands of euros unless otherwise noted, except per share data)

Total rent expense under operating leases amounted to €753 thousand, €688 thousand and €689 thousand for the years ended December 31, 2008, 2007 and 2006, respectively. These total rent expenses include the above-mentioned operating leases, but also lease expenses related to subsidiaries office rentals, office equipment and car rentals.

#### 13—SHORT-TERM BORROWINGS

As of December 31, 2008, short-term borrowings consist of €753 thousand of account receivables factored and for which the Company is supporting the risk of uncollectibility and a loan in euro amounting to €1,000 thousand with the following conditions:

	Amount	Maturation	Interest rate
EDAP TMS France SAS.....	1,000	December 22, 2009	Euribor + 0,5%

As of December 31, 2007, short-term borrowings consist of €593 thousand of account receivables factored and for which the Company is supporting the collection risk and loans in euros amounting to €1,000 thousand with the following conditions:

	Amount	Maturation	Interest rate
TMS SA .....	225	December 22, 2008	Euribor + 0,5%
EDAP SA.....	258	December 22, 2008	Euribor + 0,5%
EDAP SA.....	207	December 22, 2008	Euribor + 0,5%
EDAP SA.....	310	December 22, 2008	Euribor + 0,5%
Total.....	<u>1,000</u>		

#### 14—LONG-TERM DEBT

Long-term debt consists of the following:

	December 31,	
	2008	2007
Japanese yen term loan .....	231	-
Convertible debentures carried at fair value .....	8,901	11,691
Investor Warrants.....	392	3,141
Placement Agent Warrants .....	55	343
Financial instruments carried at fair value .....	447	3,484
Italy.....	-	58
Total.....	9,579	15,232
Less current portion .....	(79)	(58)
Total long-term portion.....	<u>9,500</u>	<u>15,174</u>

## EDAP TMS S.A. AND SUBSIDIARIES

### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (in thousands of euros unless otherwise noted, except per share data)

Long-term debt at December 31, 2008 matures as follows:

2009 .....	79
2010 .....	79
2011 .....	73
2012 .....	8,956
2013 .....	392
Total .....	9,579

As of December 31, 2008, long-term debt in Japan consists of a loan in Yen amounting to Yen30 million with a fixed interest rate at 2.87% due to mature on November 17, 2011.

As of December 31, 2007, long-term debt in Italy consists of a loan in euro amounting to €150 thousand with a quarterly variable interest rate based on Euribor + 1.375%, due to mature on September 18, 2008.

As of December 31, 2007 and 2008, long-term in USD consists of a \$20 million convertible debt with warrants, raised on October 29, 2007 through a Private Investment in Public Equity deal with selected investors – see Note 1-21 on the accounting treatment of the convertible debentures and the detachable warrants.

At inception date, the fair value of the convertible debentures and detachable warrants was \$20 million. The Company has allocated the proceeds to the fair value of the debt host and the warrants.

The \$20 million convertible debt is in the form of 20,000 debentures with a face value of \$1,000 and each bond is convertible into 152 shares of common stock at any time at the election of the holder, using a conversion price of \$6.57, subject to standard anti-dilution adjustments.

The debentures mature in five years (October 28, 2012) and bear an annual interest rate of 9% payable on a quarterly basis in cash or in common stock, at the option of the company (decision made every quarter) with a 10% discount price over the average market price of common stock.

Investors in the convertible debentures also received an aggregate number of 1,680,000 detachable warrants to purchase one share of common stock for each warrant. The warrants have a six-year term and an exercise price of \$6.87, subject to standard anti-dilutive adjustments.

The company also granted to the bank acting as placement agent in the transaction warrants to purchase 188,965 shares of common stock, with a five-year term and the following exercise prices: 121,765 shares at \$6.57 and 67,200 shares at \$6.87.

Observable and unobservable inputs for fair value measurements:

Given the classification established by FAS157, the following table indicates each input or assumption and the level it belongs to:

<u>Input</u>	<u>FAS157 level</u>	<u>Comment</u>
Share price	Level 1	Quoted price directly linked to the instrument
Risk free rate	Level 2	Observable input
Volatility	Level 3	Unobservable input
Credit Spread	Level 3	Unobservable input
Liquidity discount	Level 3	Unobservable input

## EDAP TMS S.A. AND SUBSIDIARIES

### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (in thousands of euros unless otherwise noted, except per share data)

#### Fair Value of Investor Warrants:

The valuation model of Investor Warrants uses a binomial valuation model to capture the complexity of the instruments, and notably the possibility to exercise the call option at any time from the inception date.

As of October 29, 2007, the binomial model uses the following main assumptions and parameters:

- Share price at inception date: \$5.95
- Strike price of warrants: \$6.87
- Risk free interest rate at 6 years: 4.11%
- Share price volatility: 45%
- Liquidity discount factor: 26.91%

As of December 31, 2007, the binomial model uses the following main assumptions and parameters:

- Share price at closing date: \$4.80
- Strike price of warrants: \$6.87
- Risk free interest rate at 6 years: 3,55%
- Share price volatility: 75%
- Liquidity discount factor: 26.91%

As of December 31, 2008, the binomial model uses the following main assumptions and parameters:

- Share price at closing date: \$1.44
- Strike price of warrants: \$6.87
- Risk free interest rate at 6 years: 1,71%
- Share price volatility: 84%
- Liquidity discount factor: 37.59%

At inception and as of December 31, 2007, the company used a 30-day volatility to fit the monthly arbitration step of its binomial valuation model. At December 31, 2008, given the peculiar market conditions and the erratic changes in stock volatility, the company, in agreement with third-party experts, determined that a share price volatility based on the residual lifetime of the convertible instruments would be more relevant and should then be used for assessing the fair value of the instruments. Share price volatility was determined using the historical volatility methodology. Had this method been used in 2007, the stock volatility would have been 76%.

On that basis, the unit fair value of Investor Warrants was \$2.32 per warrant at inception date, \$2.75 per warrant as of December 31, 2007, and \$0.32 per warrant as of December 31, 2008. The total fair value for the 1,680,000 issued warrants was \$3.890 million at inception date, \$4.624 million at December 31, 2007, and \$0.545 million at December 31, 2008.



## EDAP TMS S.A. AND SUBSIDIARIES

### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (in thousands of euros unless otherwise noted, except per share data)

#### Fair Value of the Convertible Debt:

The total fair value of the convertible debt is the aggregate of the fair value of the underlying debt host instrument and the fair value of the embedded derivative (conversion option).

The estimate of the fair value of the underlying debt component is obtained by using the actual interest spread the Company would have had to pay if a straight, unsecured, debt had been raised, with no additional remuneration to lenders in the form of conversion options or warrants. Before and at inception date, the Company conducted an analysis of the terms on a non-convertible, unsecured, conventional debt. Based on this analysis, a rate of 30% has been used to assess the fair value of the debt host, which represents an interest spread of 26% over the risk-free interest rate at inception date. The present value of the debt host using an effective interest rate of 30% was \$10.330 million.

At December 31, 2007 the fair value has been measured again considering any changes required in underlying assumptions, and mostly the risk free interest rate and the credit spread. The spread, which depends on market conditions and the Company's specific risk profile, was unchanged at December 31, 2007 as no significant change occurred in the two months following inception. The present value of the debt host at December 31, 2007 was \$10.533 million.

At December 31, 2008 the fair value has been measured considering any changes required in underlying assumptions, and mostly the risk free interest rate and the credit spread. With the support of third-party experts, the Company determined that the spread to be used over the risk-free rate was 30.16%, in line with the increase in risk-aversion on financial markets. The present value of the debt host at December 31, 2008 was \$11.083 million.

The valuation model of the conversion option uses a binomial valuation model to capture the complexity of the instrument, and notably the continuous possibility of an arbitrage between holding common shares versus interest bearing bonds.

As of October 29, 2007, the binomial model uses the following main assumptions and parameters:

- Share price at inception date: \$5.95
- Strike price of convertible debentures: \$6.87
- Risk free interest rate at 5 years: 4.04%
- Share price volatility: 45%
- Liquidity discount factor: 26.91%

As of December 31, 2007, the Binomial model uses the following main assumptions and parameters:

- Share price at closing date: \$4.80
- Strike price of warrants: \$6.57
- Risk free interest rate at 5 years: 3.43%
- Share price volatility: 75%
- Liquidity discount factor: 26.91%

As of December 31, 2008, the Binomial model uses the following main assumptions and parameters:

- Share price at closing date: \$1.44
- Strike price of warrants: \$6.57
- Risk free interest rate at 5 years: 1.55%
- Share price volatility: 84%
- Liquidity discount factor: 37.59%

## EDAP TMS S.A. AND SUBSIDIARIES

### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (in thousands of euros unless otherwise noted, except per share data)

At inception and as of December 31, 2007, the company used a 30-day volatility to fit the monthly arbitration step of its binomial valuation model. At December 31, 2008, given the peculiar market conditions and the erratic changes in stock volatility, the company, in agreement with third-party experts, determined that a share price volatility based on the residual lifetime of the convertible instruments would be more relevant and should then be used for assessing the fair value of the instruments. Share price volatility was determined using the historical volatility methodology. Had this method been used in 2007, the stock volatility would have been 76%.

On that basis, the fair value of the conversion option was \$5.780 million (\$7.909 million before liquidity discount) at inception date, \$6.677 million (\$9.135 million before liquidity discount) as of December 31, 2007, and \$1,305 million (\$2.091 million before liquidity discount) as of December 31, 2008.

#### Placement Agent Warrants:

As part of the transaction costs, the Company granted to the bank acting as placement agent in the transaction warrants to purchase 188,965 shares of common stock, with a five year term and the following exercise prices: 121,765 shares at \$6.57 per share and 67,200 shares at \$6.87 per share. The fair value of the Placement Agent Warrants has been valued using the Black-Scholes option valuation method, using a 4.04% risk free interest rate and a 75% volatility at inception date, a 3.43% risk free interest rate and a 75% stock volatility at December 31, 2007 and a 1.55% risk free interest rate and a 84% stock volatility at December 31, 2008.

The following table summarizes the fair value of the entire indebtedness related to the convertible debentures, Investor Warrants and Placement Agent Warrants:

	<u>In '000 US Dollars</u>			
	<b>Total Fair Value At inception date</b>	<b>Total Fair Value At December 31, 2007</b>	<b>Total Fair Value At December 31, 2008</b>	<b>Change in Fair Value in USD 2008 vs 2007</b>
Convertible debt.....	16,110	17,210	12,388	(4,822)
Investor Warrants.....	3,890	4,624	545	(4,079)
Total.....	20,000	21,834	12,933	(8,901)
Placement Agent Warrants at \$6.57.....	448	327	50	(277)
Placement Agent Warrants at \$6.87.....	244	177	27	(150)
Total.....	20,692	22,338	13,010	(9,328)

The following table reflects the impact after translation in euros:

	<u>In '000 US Dollars</u>				
	<b>Total Fair Value At inception date</b>	<b>Total Fair Value At December 31, 2007</b>	<b>Total Fair Value At December 31, 2008</b>	<b>Change in Fair Value in EUR (reflected in Financial income – See Note 20)</b>	<b>Exchange Rate Impact</b>
Exchange Rate (USD/EUR) .....	1.4548	1.4721	1.3917	1.3917	-
Convertible debt.....	11,074	11,691	8,901	(3,465)	675
Investor Warrants.....	2,674	3,141	392	(2,931)	182
Total.....	13,748	14,832	9,293	(6,395)	857
Placement Agent Warrants .....	476	343	55	(307)	19
Total.....	14,224	15,174	9,348	(6,703)	877

**EDAP TMS S.A. AND SUBSIDIARIES**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS  
(in thousands of euros unless otherwise noted, except per share data)**

**15—OTHER LONG-TERM LIABILITIES**

Other long-term liabilities consist of the following:

	<b>December 31,</b>	
	<b>2008</b>	<b>2007</b>
Provision for retirement indemnities .....	771	652
Other .....	51	51
<b>Total .....</b>	<b>822</b>	<b>703</b>

Pension, post-retirement, and post-employment benefits for most of the Company's employees are sponsored by European governments. The Company's liability with respect to these plans is mostly limited to specific payroll deductions.

In addition to government-sponsored plans, certain subsidiaries in Japan and France have defined benefit retirement indemnity plans in place. The provision for retirement indemnities at December 31, 2008 represents an accrual for lump-sum retirement indemnity payments to be paid at the time an employee retires. The largest part of this liability relates to employees in France. This provision has been calculated taking into account the estimated payment at retirement (discounted to the current date), turnover and salary increases. Calculations have been performed by an actuary consultant.

A labor regulation evolution in France may have an impact of €170 thousand on the accrual. At December 31, 2008, the Company does not consider this risk as probable.

The actuarial assumptions as of year-end are as follows:

	<b>Pension Benefits – France</b>		
	<b>2008</b>	<b>2007</b>	<b>2006</b>
Discount rate .....	5.50%	5.50%	4.50%
Salary increase .....	2.50%	2.50%	2.00%
Retirement age .....	65	65	65
Average retirement remaining service period .....	26	27	26

	<b>Pension Benefits – Japan</b>		
	<b>2008</b>	<b>2007</b>	<b>2006</b>
Discount rate .....	1.25%	1.50%	1.75%
Salary increase .....	1.80%	1.80%	1.80%

**EDAP TMS S.A. AND SUBSIDIARIES**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS  
(in thousands of euros unless otherwise noted, except per share data)**

The reconciliation between projected benefit obligations and the accumulated benefit obligations is as follows as of December 31, 2008 (in thousands of euros):

	<b>France</b>	<b>Japan</b>
Projected benefit obligation .....	256	392
Normal cost.....	22	47
Accumulated benefit obligation .....	173	342
Provision presentation according to FAS 158 in euro:		
	<b>France</b>	<b>Japan</b>
Non current liabilities .....	255,877	367,273
Current liabilities .....	-	24,028
Non current asset .....	-	-
Accumulated other comprehensive income .....	44,529	(157,862)
Total .....	300,406	233,439

Detailed reconciliation of pension cost components (in thousands of euros) during fiscal year ending December 31, 2008:

<b>FRANCE</b>	<b>2008</b>	<b>2007</b>	<b>2006</b>
<b>Change in benefit obligations</b>			
Benefit obligations at beginning of year .....	240	218	229
Service cost.....	23	22	23
Interest cost.....	13	10	9
Plan amendments .....	-	-	-
(gain) / loss .....	(20)	(7)	(44)
Benefits paid .....		(3)	-
<b>Benefit obligations at end of year .....</b>	<b>256</b>	<b>240</b>	<b>218</b>
<b>Change in plan assets</b>			
Fair value of plan assets at beginning of year .....	-	-	-
Employer contribution .....	-	3	-
Return on plan assets .....	-	-	-
Benefits paid .....	-	(3)	-
<b>Fair value of plan assets at end of year</b>			
Unrecognized actuarial (gain) loss.....	(45)	(24)	(17)
Unrecognized prior service cost.....	-	-	-
<b>Accrued pension cost .....</b>	<b>300</b>	<b>264</b>	<b>235</b>

**EDAP TMS S.A. AND SUBSIDIARIES**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS  
(in thousands of euros unless otherwise noted, except per share data)**

<b>JAPAN</b>	<b>2008</b>	<b>2007</b>	<b>2006</b>
<b>Change in benefit obligations</b>			
Benefit obligations at beginning of year .....	278	239	262
Service cost.....	44	31	32
Interest cost.....	5	4	3
Plan amendments .....	-	-	-
Termination benefits .....	-	-	-
(gain) / loss .....	35	(16)	(3)
Benefits paid .....	(57)		(25)
Exchange rate impact.....	87	20	(30)
<b>Benefit obligations at end of year .....</b>	<b>392</b>	<b>278</b>	<b>239</b>
<b>Change in plan assets</b>			
Fair value of plan assets at beginning of year .....	-	-	-
Employer contribution .....	-	-	-
Return on plan assets .....	-	-	-
Benefits paid .....	-	-	-
<b>Fair value of plan assets at end of year</b>	<b>-</b>	<b>-</b>	<b>-</b>
Unrecognized actuarial (gain) loss.....	158	104	101
Unrecognized prior service cost.....	-	-	-
<b>Accrued pension cost .....</b>	<b>233</b>	<b>174</b>	<b>138</b>

## EDAP TMS S.A. AND SUBSIDIARIES

### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (in thousands of euros unless otherwise noted, except per share data)

#### 16—SHAREHOLDERS' EQUITY

##### *16-1 Common stock*

As of December 31, 2008, EDAP TMS S.A.'s common stock consisted of 10,006,333 issued shares, fully paid, and with a par value of €0.13 each. 9,582,593 of the shares were outstanding.

##### *16-2 Pre-emptive subscription rights*

Shareholders have preemptive rights to subscribe on a *pro rata* basis for additional shares issued by the Company for cash. Shareholders may waive such preemptive subscription rights at an extraordinary general meeting of shareholders under certain circumstances. Preemptive subscription rights, if not previously waived, are transferable during the subscription period relating to a particular offer of shares.

##### *16-3 Dividend rights*

Dividends may be distributed from the statutory retained earnings, subject to the requirements of French law and the Company's by-laws. The Company has not distributed any dividends since its inception. Distributable statutory retained earnings amounted to €22,955 thousand and €25,396 thousand at December 31, 2008 and 2007, respectively. Dividend distributions, if any, will be made in euros. The Company has no plans to distribute dividends in the foreseeable future.

##### *16-4 Treasury stock*

As of December 31, 2008, the 423,740 shares of treasury stock consisted of (i) 21,400 shares acquired on December 2, 1996 for €85 thousand, (ii) 352,800 shares acquired between August and December 1998 for €1,016 thousand, and (iii) 49,540 shares acquired in June and July 2001 for €150 thousand. All 423,740 shares of treasury stock have been acquired to cover outstanding stock options (see Note 15-5).

##### *16-5 Stock-option plans*

As of December 31, 2008, EDAP TMS S.A. sponsored five stock purchase and subscription option plans:

On December 2, 1996, the shareholders of EDAP TMS S.A. authorized the Board of Directors to grant up to 177,750 options to purchase pre-existing Shares and 156,625 options to subscribe for newly issued Shares at a fixed exercise price of €6.97 per share. The authorization to grant the options expired at the end of the five-year period beginning December 2, 1996. On February 7 and March 3, 1997, the Board of Directors granted the 177,750 options to buy pre-existing Shares and 134,750 of the options to subscribe for newly issued Shares to 10 employees. 25% of the options were exercisable as of the date of grant and the right to exercise the remaining 75% of the options vested at the rate of 25% each January 1 following the date of grant. The options expired five years after the date of grant. On October 29, 1998, the Board of Directors amended the terms of 124,125 of the options to conform to the terms of the 1998 option plan discussed below. This stock purchase plan is no longer valid as the related stock options contracts have expired.



## EDAP TMS S.A. AND SUBSIDIARIES

### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (in thousands of euros unless otherwise noted, except per share data)

On May 14, 1998, the shareholders of EDAP TMS S.A. authorized the Board of Directors to grant up to 713,425 options to purchase pre-existing Shares at a fixed exercise price to be set by the Board of Directors at the time of grant provided that the exercise price may not be less than the average stock market price of the Shares over the 20 business days preceding the date of grant. The shareholders also authorized the Board of Directors to cause EDAP TMS S.A. to repurchase up to 535,675 of its own Shares (treasury stock) to cover the options granted under the new plan. The authorization to grant the options expired one year after the completion of the share repurchase program, which was completed in December 1998. Up to 279,000 of the 713,425 options were reserved for modifications to the terms of pre-existing options.

On October 29, 1998, the Board of Directors granted 327,000 options to French employees meeting certain tenure criteria. The exercise price was fixed at €3.81 per Share for 152,000 options and €1.83 per Share for 175,000 options; both exercise prices were not less than the average stock market price of the Shares over the 20 business days preceding the date of grant and also exceeded the market price of the Shares on the date of grant. The options were to begin vesting two years after the date of grant and were fully vested as of January 1, 2002 (i.e., four years and two months after the date of grant). Shares acquired pursuant to the options cannot be sold prior to five years from the date of grant. The options expired on December 31, 2008 (i.e., ten years and two months after the date of grant) or when employment with the Company ceases, whichever occurs earlier. As noted above, on October 29, 1998, the Board of Directors amended the terms of 124,125 of the options granted in 1997 to conform to the terms of the 1998 stock option plan.

Conforming to the 1998 stock option plan, on January 4, 1999, the Board of Directors granted 24,000 options to French employees meeting certain tenure criteria. The exercise price was fixed at €3.81 per Share for 11,000 options and €1.83 per Share for 13,000 options. The options were to begin vesting two years after the date of grant and were fully vested as of January 1, 2002 (i.e., three years after the date of grant). Shares acquired pursuant to the options cannot be sold prior to five years from the date of grant. The options expired on December 31, 2008 (i.e., ten years after the date of grant) or when employment with the Company ceases, whichever occurs earlier. On March 15, 1999, the Board of Directors granted 60,000 options to certain employees of the Company; 40,000 options were granted with an exercise price of €3.81 and 20,000 options at an exercise price of €2.74. Exercise prices corresponding to options granted on these two dates were not less than the average stock market price of the Shares over the 20 business days preceding the date of grant. Among these options granted on March 15, 1999: 50,000 were to begin vesting two years after the date of grant and were fully vested as of June 1, 2002 (i.e. three years and two and half months after the date of grant); Shares acquired pursuant to the options cannot be sold prior to five years from the date of grant; 40,000 options expire on March 31, 2009 (i.e. ten years after the date of grant) and 10,000 options expire on December 31, 2009 (i.e. ten years and nine months after the date of grant) or when employment with the Company ceases, whichever occurs earlier. For the remaining 10,000 options, granted on March 15, 1999, 50% of the options are exercisable as of the date of grant and the right to exercise the remaining 50% of the options vested at the rate of 25% each January 1 following the date of grant. The options expired on December 31, 2003 (i.e., four years and nine months after the date of grant).

On September 27, 1999, the Board of Directors decided to grant 2,425 options to certain employees of the Company at an exercise price of €1.83, which is not less than the average stock market price of the Shares over the 20 business days preceding the date of grant. The options were to begin vesting two years after the date of grant and were fully vested as of January 1, 2003 (i.e., three years and three months after the date of grant). Shares acquired pursuant to the options cannot be sold prior to five years from the date of grant. The options expire on December 31, 2009 (i.e., ten years and three months after the date of grant) or when employment with the Company ceases, whichever occurs earlier.

## EDAP TMS S.A. AND SUBSIDIARIES

### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (in thousands of euros unless otherwise noted, except per share data)

On June 12, 2001, the shareholders of EDAP TMS S.A. authorized the Board of Directors to grant up to 300,000 options to purchase pre-existing Shares and 80,000 options to subscribe to new Shares, at a fixed exercise price to be set by the Supervisory Board. Conforming this plan, on September 25, 2001, the Board of Directors granted 307,115 options to purchase Shares (among which 33,540 options were related to the plan authorized by the shareholders on June 24, 1999) and granted 80,000 options to subscribe to new Shares to employees of the Company meeting certain tenure criteria. The exercise price was fixed at U.S.\$1.92 (€2.08) per share. Options were to begin vesting one year after the date of grant and will be fully vested as of September 25, 2005. Shares acquired pursuant to the options cannot be sold prior to four years from the date of grant. The options expire on September 25, 2011 (i.e., ten years after the date of grant) or when employment with the Company ceases, whichever occurs earlier.

On March 21, 2002, a Member of the Management Board exercised his option to subscribe to 47,421 new Shares (out of the 86,885 options to subscribe to new Shares authorized on June 24, 1999) at an exercise price of U.S.\$1.561 (€1.76). The capital of the Company was thus increased from €1,081 thousand to €1,087 thousand and the number of Shares issued increased from 8,315,400 to 8,362,821.

On June 18, 2002, conforming the June 12, 2001 stock option plan, the Board of Directors granted the remaining 26,425 options to French employees meeting certain tenure criteria. The exercise price was fixed at U.S.\$1.92 (€2.02) per share. Options were to begin vesting one year after the date of grant and will be fully vested as of June 18, 2006 (i.e., four years after the date of grant). Shares acquired pursuant to the options cannot be sold prior to four years from the date of grant. The options expire on June 18, 2012 (i.e., ten years after the date of grant) or when employment with the Company ceases, whichever occurs earlier. All Shares that may be purchased through the exercise of stock options are currently held as treasury stock.

On January 29, 2004, the shareholders of EDAP TMS S.A. authorized the Board of Directors to grant up to 240,000 options to purchase pre-existing Shares and 100,000 options to subscribe to new Shares, to employees of the Company meeting certain tenure criteria, at a fixed exercise price to be set by the Board of Directors.

Conforming to this stock option plan, on February 24, 2004, the Board of Directors granted 225,000 options to purchase pre-existing Shares to certain employees of EDAP TMS. The exercise price was fixed at €2.60 per share. Options were to begin vesting one year after the date of grant and will be fully vested as of February 24, 2008 (i.e., four years after the date of grant). Shares acquired pursuant to the options cannot be sold prior to four years from the date of grant. The options expire on February 24, 2014 (i.e., ten years after the date of grant) or when employment with the Company ceases, whichever occurs earlier. All Shares that may be purchased through the exercise of stock options are currently held as treasury stock.

On February 24, 2004, the Board of Directors granted 100,000 options to subscribe to new Shares to the Chief Executive Officer of EDAP S.A. and TMS S.A. The exercise price was fixed at €1.28 per share. All options were to begin vesting one year after the date of grant. Shares acquired pursuant to the options cannot be sold prior to four years from the date of grant. The options expire on February 24, 2014 (i.e., ten years after the date of grant) or when employment with the Company ceases, whichever occurs earlier.

On January 28, 2005, the Board of Directors granted 15,000 options to purchase pre-existing Shares to certain employees of EDAP TMS. The exercise price was fixed at €2.78 per share. 3,750 options were to begin vesting on December 31, 2005 and 11,250 on December 31, 2006. The options expire on January 28, 2015 (i.e., ten years after the date of grant) or when employment with the Company ceases, whichever occurs earlier. All Shares that may be purchased through the exercise of stock options are currently held as treasury stock.

## EDAP TMS S.A. AND SUBSIDIARIES

### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (in thousands of euros unless otherwise noted, except per share data)

On February 17, 2005, the shareholders of EDAP TMS S.A. authorized the Board of Directors to grant up to 625,000 free shares to be issued to certain employees of the Company, subject to compliance with the conditions and performance criteria fixed by the Board of Directors. On March 30, 2005, 500,900 rights to subscribe to free shares were granted to by the Board of Directors, based on certain performances and criteria to be met for years 2005 and 2006. However, given the shift of business model, during 2005, from the sales of Ablatherm equipment towards the sales of treatment procedures (RPPs), the Board of Directors decided to modify the conditions and performance criteria to be met by employees, to reflect the new business model. Therefore, on January 6, 2006, the Board of Directors cancelled the Free Performance Share Plan approved on March 30, 2005 and set up a new Plan with performance criteria based on the new RPP business model for years 2006 and 2007, in accordance with the Performance Stock plan approved by the shareholders. On January 6, 2006, 564.100 rights to subscribe to new shares were distributed, including new entrants, subject to the achievement of certain milestones in the years 2006 and 2007. On July 3, 2006, 13,800 rights to subscribe to new shares were distributed to new entrants, subject to the achievement of certain milestones in the years 2006 and 2007. As of December 31, 2006, none of the milestones for the year 2006 have been reached. As of December 31, 2006, only 524,900 rights were still in force due to employees' departure. This plan is accounted for in compliance with FASB 123-(R). On March 8, 2007, a revised business model was approved by the Board of Directors for years 2007 and 2008. On that date, 47,100 rights to subscribe to new shares were granted to new entrants, subject to the achievement of certain milestones based on the revised 2007-2008 business model. As of December 31, 2007 none of the milestones for the year 2007, fixed by the January 6, 2006 Board of Directors, have been reached, and only one milestone fixed by the March 8, 2007 Board of Directors, has been reached, thus triggering allocation of 7,065 new shares to some employees. As per the Performance Stock Plan approved on March 8, 2007, these shares will only be issued on July 2009. As of December 31, 2007, 211,435 rights to subscribe to new shares, based on these fixed performance criteria for the year 2007 were then cancelled and these shares will then never be subscribed and issued. As of December 31, 2007, only 18,840 rights out of the 625,000 initially granted were still in force, based on 2008 milestones. As of December 31, 2008, only one milestone, out of four milestones fixed by the Board of Directors on March 8, 2007, was reached on 2008 performance goals, thus triggering the allocation of 4,710 new shares to some employees. A total of 11,775 new shares will then be issued in July 2009 conforming the March 8, 2007 plan. As of December 31, 2008, no more right to subscribe to new shares were valid.

On May 22, 2007, the shareholders of EDAP TMS S.A. authorized the Board of Directors to grant up to 600,000 options to subscribe to 600,000 new Shares and up to 105,328 options to purchase pre-existing Shares at a fixed price to be set by the Board of Directors. All of the 105,328 Shares that may be purchased through the exercise of stock options are currently held as treasury stock.

Conforming to this stock option plan, on October 29, 2007, the Board of Directors granted 504,088 options to subscribe to new Shares to certain employees of EDAP TMS. The exercise price was fixed at €3.99 per share. Options were to begin vesting one year after the date of grant and will be fully vested as of October 29, 2011 (i.e., four years after the date of grant). Shares acquired pursuant to the options cannot be sold prior to four years from the date of grant. The options expire on October 29, 2017 (i.e., ten years after the date of grant) or when employment with the Company ceases, whichever occurs earlier. At December 31, 2007 the total fair value of the options granted under this plan was €1,731 thousand. This non-cash financial charge will be recognized in the Company's operating expenses over a period of 48 months; the impact on 2007 Operating Income was €156 thousand. The impact on 2008 operating income, in accordance with FAS123(R) was €661 thousand.

**EDAP TMS S.A. AND SUBSIDIARIES**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS  
(in thousands of euros unless otherwise noted, except per share data)**

As of December 31, 2008, a summary of stock option activity to purchase or to subscribe to Shares under these plans is as follows:

	2008		2007		2006	
	Options	Weighted average exercise price (€)	Options	Weighted average exercise price (€)	Options	Weighted average exercise price (€)
Outstanding on January 1, .....	781,625	3.51	502,162	2.49	593,262	2.58
Granted .....			504,088	3.99		
Exercised .....			(183,750)	2.03	(72,600)	3.20
Forfeited.....	(34,000)	3.59	(7,250)	2.60	(18,500)	2.60
Expired.....	(40,900)	3.37	(33,625)	3.81	-	-
Outstanding on December 31, .....	706,725	3.51	781,625	3.51	502,162	2.49
Exercisable on December 31, .....	342,929	3.00	234,787	2.63	405,162	2.73
Shares purchase options available for grant on December 31 .....	105,328	-	105,328	-	0	-

The following table summarizes information about options to purchase Shares already held by the Company as treasury Shares, or to subscribe to new Shares, at December 31, 2008:

Exercise price (€)	Outstanding options			Exercisable options	
	Options	Weighted average remaining contractual life	Weighted average exercise price (€)	Options	Weighted average exercise price (€)
3.99 .....	485,088	8.8	3.99	121,292	3.99
2.60 .....	162,000	5.2	2.60	162,000	2.60
2.08 <sup>(1)</sup> .....	52,000	2.8	2.08	52,000	2.08
2.02 <sup>(2)</sup> .....	6,425	3.5	2.02	6,425	2.02
1.83 .....	1,212	1.0	1.83	1,212	1.83
1.83 to 3.99 .....	706,725	4.2	3.51	342,929	3.00

(1) All the 52,000 options were granted on September 25, 2001 with an exercise price expressed in U.S. dollars (\$1.92) and converted here to euros based on the noon buying rate on September 25, 2001 (\$1 = €1.085).

(2) All the 6,425 options were granted on June 18, 2002 with an exercise price expressed in U.S. dollars (\$1.92) and converted here to euros based on the noon buying rate on June 18, 2002 (\$1 = €1.0545).

## EDAP TMS S.A. AND SUBSIDIARIES

### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (in thousands of euros unless otherwise noted, except per share data)

A summary of the status of the non-vested shares as of December 31, 2008, and changes during the year ended December, 2008, is presented below:

	Options	Weighted average Grant-Date Fair Value (€)	Free shares	Weighted average Grant-Date Fair Value (€)
Non-vested at January 1, 2008.....	504,088	2.97	7,065	5.39
Granted .....	-	-	4,710	5.39
Vested .....	(121,272)	2.97	-	-
Forfeited.....	(19,000)	2.97	-	-
Non-vested at December 31, 2008.....	363,816	2.97	11,775	5.39

#### *16-6 Warrants granted to certain employees*

As of December 18, 2002, the shareholders of two of the Company's wholly owned and fully consolidated subsidiaries, TMS S.A. and EDAP S.A., authorized the respective Boards of Directors to grant certain Senior Executive Officers warrants to subscribe to an aggregate of 604,538 new shares of TMS S.A.'s and EDAP S.A.'s common stock. The average exercise price of such warrants is equivalent to the higher of either (a) the share value of the capital of each company or (b) the net book value, each such amount to be calculated on the date of exercise. Following the resignation of the President of EDAP S.A. in November 2003, outstanding warrants allow the current President of each divisions, to subscribe to an aggregate of 252,111 new shares of each of TMS S.A.'s and EDAP S.A.'s common stock. The total number of warrants granted, if exercised, would represent 3.6% and 2.6% of the respective share capital of TMS S.A. and EDAP S.A. after subscription. These warrants begin vesting three years after their date of grant, i.e. December 18, 2005. These warrants to subscribe to shares expire on the earlier of December 18, 2007 or when employment with the Company ceases. A compensation charge has been booked for an amount of €0 thousand as at December 31, 2006, €115 as at December 31, 2005 and €0 as at December 31, 2004. On June 22, 2007, the beneficiary of the remaining warrants officially renounced to his allocated warrants.

#### 17—NET SALES

Net sales consist of the following:

	2008	2007	2006
Sales of goods .....	12,547	11,752	10,849
Sales of RPPs & Leases .....	4,664	4,814	3,805
Sales of spare parts & services.....	5,645	5,647	5,520
Total net sales .....	22,856	22,213	20,174

## EDAP TMS S.A. AND SUBSIDIARIES

### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (in thousands of euros unless otherwise noted, except per share data)

#### 18—OTHER REVENUES

Other revenues consists of the following:

	2008	2007	2006
Royalties .....	-	-	-
Grants and others .....	197	113	91
Total .....	197	113	91

In 2008, EDAP TMS France invoiced €58 thousand to China Medical Technologies for consulting services and received grants of €59 thousand from ANVAR a French government agency

In 2007, EDAP SA invoiced €43 thousand to China Medical Technologies for consulting services.

In 2006, EDAP SA received grants of €45 thousand from ANVAR a French government agency.

#### 19—NON-RECURRING OPERATING EXPENSES

In 2008, there were no non-recurring expense.

In 2007, the Company recorded non-recurring expenses of €0.2 million including €0.5 million of employee termination expenses and €0.3 million of other income linked to the recovery of medical equipments from HealthTronics as part of the Termination Agreement.

In 2006, the Company recorded non-recurring expenses of €0.3 million including €0.2 million of employee termination expenses and €0.1 million of capital increase expenses.

#### 20—FINANCIAL INCOME, NET

Interest (expense) income, net consists of the following:

	2008	2007	2006
Interest income.....	412	331	224
Interest expense .....	(1,413)	(378)	(71)
Depreciation of prepaid expenses on debt grant .....	(469)	(78)	-
Changes in fair value of the Convertible Debentures .....	3,465	(747)	-
Changes in fair value of the Investor Warrants .....	2,931	(498)	-
Changes in fair value of the Placement Agent Warrants .....	307	127	-
Total .....	5,232	(1,243)	153

The interest expense related to the payment of the 9% interest coupon on the convertible debentures amounted to €1,223 thousand and €218 thousand for the years ended December 31, 2008 and 2007, respectively.

#### 21—OTHER INCOME (EXPENSE), NET

Other income (expense), consists of the following:

	2008	2007	2006
Other income (expense), net .....	(1)	16	(5)
Total .....	(1)	16	(5)



**EDAP TMS S.A. AND SUBSIDIARIES**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS  
(in thousands of euros unless otherwise noted, except per share data)**

**22—INCOME TAXES**

**22-1 Loss before income taxes**

Loss before income taxes is comprised of the following:	<b>2008</b>	<b>2007</b>	<b>2006</b>
France .....	3,183	(5,055)	(2,990)
EDAP Inc.....	(1,896)	(87)	
Other countries .....	(181)	(429)	(385)
Total .....	<u>1,105</u>	<u>(5,571)</u>	<u>(3,375)</u>

**22-2 Income tax (expense)/ benefit**

Income tax (expense)/benefit consists of the following:	<b>2008</b>	<b>2007</b>	<b>2006</b>
<i>Current income tax expense:</i>			
France .....	543	107	4
Other countries .....	(35)	(58)	(69)
Sub-total current income tax expense .....	<u>508</u>	<u>49</u>	<u>(65)</u>
<i>Deferred income tax (expense) benefit:</i>			
France .....	(81)	21	72
Other countries .....	65	70	(63)
Sub-total deferred income tax (expense) benefit .....	<u>(15)</u>	<u>91</u>	<u>9</u>
Total .....	<u>492</u>	<u>140</u>	<u>(56)</u>

**22-3 Deferred income taxes:**

Deferred income taxes reflect the impact of temporary differences between the amounts of assets and liabilities reported for financial reporting purposes and such amounts as measured in accordance with tax laws. The tax effects of temporary differences which give rise to significant deferred tax assets (liabilities) are as follows:

	<b>December 31,</b>	
	<b>2008</b>	<b>2007</b>
Elimination of intercompany profit in inventory .....	102	139
Elimination of intercompany profit in fixed assets.....	355	203
Other items .....	736	548
Net operating loss carryforwards .....	<u>9,310</u>	<u>7,799</u>
Total deferred tax assets .....	10,503	8,689
Capital leases treated as operating leases for tax .....	(11)	(35)
Other items.....	<u>(120)</u>	<u>(161)</u>
Total deferred tax liabilities .....	(130)	(196)
Net deferred tax assets .....	10,372	8,493
Valuation allowance for deferred tax assets .....	<u>(10,050)</u>	<u>(8,248)</u>
Deferred tax assets (liabilities), net of allowance .....	<u>322</u>	<u>245</u>

## EDAP TMS S.A. AND SUBSIDIARIES

### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (in thousands of euros unless otherwise noted, except per share data)

Net operating loss carryforwards of €3,818 thousand, €2,644 thousand, €1,071 thousand, €146 thousand, €51 thousand and €19,492 thousand as of December 31, 2008 are available at EDAP Technomed Inc., EDAP-TMS France S.A.S., Edap Technomed Co Ltd Japan, Edap Technomed Sdn Bhd Malaysia, EDAP TMS GmbH and EDAP TMS S.A., respectively. These net operating losses generate deferred tax assets of €9,310 thousand. Realization of these assets is contingent on future taxable earnings in the applicable tax jurisdictions. As of December 31, 2008, €8,873 thousand out of these €9,310 thousand net operating loss carry-forwards have no expiration date. The remaining tax loss carry-forwards expire in years 2011 through 2015. In accordance with SFAS No. 109, a valuation allowance is recorded as realization of those amounts are not considered probable.

Deferred taxes have not been provided on the undistributed earnings of domestic subsidiaries as these earnings, with the exception of the earnings of EDAP-TMS France SAS, which benefited from the tax exemption, can be distributed tax-free to EDAP TMS S.A. The tax-exempted earnings of EDAP-TMS France SAS would normally be taxable if distributed to EDAP TMS S.A. via dividends. However, no taxes will be due if the Company first incorporates these earnings into statutory capital and then makes a distribution via a statutory capital reduction (redemption). As the Company intends on implementing this tax planning opportunity in the event a distribution were to be made, no deferred taxes have been provided on these earnings.

#### *22-4 Effective tax rate*

A reconciliation of differences between the statutory French income tax rate and the Company's effective tax rate is as follows:

	2008	2007	2006
French statutory rate .....	33.8%	33.8%	33.8%
Research and development tax credit.....	(49.2%)	2.0%	1.4%
Income of foreign subsidiaries taxed at different tax rates .....	(3.9%)	0.5%	1.3%
Effect of net operating loss carryforwards and valuation allowances	123.8%	(19.1%)	(27.6%)
Non taxable debt fair value variation.....	(205.3%)	(6.8%)	
Non deductible entertainment expenses .....	3.1%	(0.9%)	(1.4%)
Other .....	53.1%	(7.0%)	(9.1%)
Effective tax rate.....	(44.6%)	2.5%	(1.6%)

#### *22-5 Uncertainty in Income Taxes*

Through the adoption of FIN No 48, the Company reviewed the tax positions of each subsidiary. On December 31, 2008 there is no uncertainty in the Company's tax positions. As a result, there is no effect on the retained earnings

	Unrecognized tax benefits
Balance as of January 1 <sup>st</sup> , 2008.....	-
Impact of tax positions taken during a prior period .....	-
Impact of tax positions taken during the current period.....	-
Impact of settlements with taxing authorities .....	-
Impact of a lapse of the applicable statute of limitations .....	-
Balance as of December 31 <sup>st</sup> , 2008.....	-

In 2008, the Company did not record any interest and penalties. In case of interest and penalties, they would be recognized as non-recurring operating expenses. The tax years that remain subject to examination by major tax jurisdictions are 2006, 2007 and 2008.

## EDAP TMS S.A. AND SUBSIDIARIES

### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (in thousands of euros unless otherwise noted, except per share data)

#### 23—EARNINGS (LOSS) PER SHARE

A reconciliation of the numerators and denominators of the basic and diluted EPS calculations for the years ended December 31, 2008, 2007 and 2006 is as follows:

	For the year ended Dec. 31, 2008			For the year ended Dec. 31, 2007			For the year ended Dec. 31, 2006		
	Income in euro (Numerator)	Shares (Denominator)	Per-Share Amount	Loss in euro (Numerator)	Shares (Denominator)	Per-Share Amount	Loss in euro (Numerator)	Shares (Denominator)	Per-Share Amount
<b>Basic EPS</b>									
Income (loss) available to common Shareholders	1,597,189	9,582,593	0.17	(5,430,460)	9,200,757	(0.59)	(3,430,985)	8,817,007	(0.39)
Effect of dilutive securities:									
Stock options only in the money .....		75,702			516,730			740,526	
<b>Diluted EPS</b>									
Income (Loss) available to common shareholders, including assumed conversions .....	1,597,189	9,658,295	0.17	(5,430,460)	9,717,487	(0.59)	(3,430,985)	9,557,533	(0.39)

#### 24—COMMITMENTS AND CONTINGENCIES

##### *24-1 Commitments*

The Company currently has commitments regarding its operating leases as described in Note 12-2.

The Company also has commitments regarding its convertible debentures and warrants. Under the terms of the registration rights agreement the Company entered into in connection with the October 2007 private placement, the Company 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, and the Company 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, with penalties, including payment of liquidated damages in case of a default of these commitments. Also, the Company committed to a certain number of covenants regarding its convertible debentures and warrants, and any event of default on these covenants 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.

##### *24-2 Litigation*

As of the date of these financial statements, the Company is not involved in any material legal proceedings.

In 2000, a patient made a product liability claim against the Company in the United States, alleging that he was injured in the course of a Prostatron procedure. In connection with the sale of the Prostatron business in October 2000, the Company agreed to retain liability for this claim. In February 2008, we reached a settlement for this claim with the cost of \$15,000 which was fully covered by our Product Liability Insurance.

## EDAP TMS S.A. AND SUBSIDIARIES

### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (in thousands of euros unless otherwise noted, except per share data)

#### 24-3 Contingencies

The Company currently has contingencies relating to warranties provided to customers for products as described in Note 1-13 and Note 11.

#### 25—FAIR VALUE OF FINANCIAL INSTRUMENTS

The following disclosure of the estimated fair value of financial instruments was made in accordance with the requirements of SFAS No. 107 “Disclosure about fair value of financial instruments.” The estimated fair value amounts have been determined by the Company using available market information and appropriate valuation methodologies. The estimates of fair values of the Company’s financial instruments are compared below to the recorded amounts at December 31, 2008 and 2007.

	December 31,		December 31,	
	2008 Recorded Value	2008 Estimated Fair Value	2007 Recorded Value	2007 Estimated Fair Value
Assets:				
Cash and cash equivalents .....	13,827	13,827	17,523	17,523
Trade accounts and notes receivable, net .....	14,611	14,611	10,877	10,877
Short term investment.....	1,143	1,143	1,089	1,089
Liabilities:				
Short-term borrowings.....	1,753	1,753	1,593	1,593
Trade accounts payable .....	5,065	5,065	5,067	5,067
Notes payable .....	981	981	595	595
Convertible Debentures and other				
Long Term Debt.....	9,053	9,053	11,691	11,691
Investor Warrants.....	392	392	3,141	3,141
Placement Agent Warrants .....	55	55	343	343

The recorded amount of cash and cash equivalents, restricted short term investment, investments available for sale, trade accounts and notes receivable (drafts), short-term borrowings, and trade accounts and notes payable (drafts) are a reasonable estimate of their fair value due to the short-term maturities of these instruments.

The long-term debt is recorded at fair value.

#### 26—CONCENTRATION OF CREDIT RISK

Financial instruments, which potentially subject the Company to concentrations of credit risk, consist principally of cash and cash equivalents and trade accounts and notes receivable from customers, primarily located in France, Japan and the United States. The Company maintains cash deposits with major banks. Management periodically assesses the financial condition of these institutions and believes that any possible credit risk is limited.

The Company has procedures in effect to monitor the creditworthiness of its customers. The Company obtains bank guarantees for first-time or infrequent customers, and in certain cases obtains insurance against the risk of a payment default by the customer. The Company reviewed individual customer balances considering current and historical loss experience and general economic conditions in determining the allowance for doubtful accounts receivable of €0.8 million and €0.7 million, for the years ended December 31, 2008, and 2007, respectively.

## EDAP TMS S.A. AND SUBSIDIARIES

### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (in thousands of euros unless otherwise noted, except per share data)

Ultimate losses may vary from the current estimates, and any adjustments are reported in earnings in the periods in which they become known.

In 2008 and 2007, the Company did not generate significant revenue with a single customer.

#### 27—FOREIGN CURRENCY TRANSACTIONS

The Company generates a significant percentage of its revenues, and of its operating expenses, in currencies other than euro. The Company's operating profitability could be materially adversely affected by large fluctuations in the rate of exchange between the euro and such other currencies. The Company engages in foreign exchange hedging activities when it deems necessary, but there can be no assurance that hedging activities will be offset by the impact of movements in exchange rates on the Company's results of operations. As of December 31, 2008, there were no outstanding hedging instruments.

#### 28—SEGMENT INFORMATION

In July 2002, the Company announced an organizational realignment that created two operating divisions within the Company. For reporting purposes, this organizational realignment created three reporting segments: the holding company, EDAP TMS S.A., the High Intensity Focused Ultrasound division and the Urological Devices and Services division. Then, in 2007, the Company created a new reporting segment dedicated to the FDA approval for Ablatherm-HIFU activity. The following tables set forth the key income statement figures, by segment for fiscal years 2008, 2007 and 2006 and the key balance sheet figures, by segment, for fiscal years 2008, 2007 and 2006.

As from the first quarter of 2007, the Company elected to report its segment information on a "net contribution" basis, so that each segment's results comprise the elimination of our intra-group revenues and expenses and thus reflect the true contribution to consolidated results of the segment. The Company has reclassified its 2006 results using this method for comparative purposes with its 2007 results.

The business in which the Company operates is the development and production of minimally invasive medical devices, primarily for the treatment of urological diseases. Substantially all revenues result from the sale of medical devices and their related license and royalty payments from third parties. The segments derive their revenues from this activity.

Segment operating profit or loss and segment assets are determined in accordance with the same policies as those described in the summary of significant accounting policies except that interest income and expense, current and deferred income taxes, and goodwill are not allocated to individual segments. A reconciliation of segment operating profit or loss to consolidated net loss is as follows:

	<b>2008</b>	<b>2007</b>	<b>2006</b>
Segment operating loss .....	(4,703)	(4,089)	(3,094)
Financial income, net .....	5,232	(1,243)	153
Foreign Currency exchange (losses) gains, net .....	577	(254)	(430)
Other income, net.....	(1)	16	(5)
Income tax (expense) credit .....	492	140	(56)
Consolidated net loss .....	<u>1,597</u>	<u>(5,430)</u>	<u>(3,431)</u>

**EDAP TMS S.A. AND SUBSIDIARIES**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS  
(in thousands of euros unless otherwise noted, except per share data)**

A summary of the Company's operations by business unit is presented below for years ending December 31, 2008, 2007 and 2006:

	<b>HIFU Division</b>	<b>UDS Division</b>	<b>EDAP TMS (Corporate)</b>	<b>FDA</b>	<b>Total consolidated</b>
<b>2008</b>					
External sales of medical devices .....	2,687	7,532	-	-	10,219
External sales of spares parts, Supplies & services.....	6,373	6,264	-	-	12,637
Total sales .....	9,060	13,796	-	-	22,856
Warrants granted.....					
Total net sales .....	9,060	13,796	-	-	22,856
External other revenues .....	138	59	-	-	197
Total revenues.....	9,198	13,855	-	-	23,053
Total COS .....	(3,794)	(10,161)	-	-	(13,955)
Gross margin.....	5,405	3,694	-	-	9,099
R&D.....	(1,082)	(1,115)	-	(2,058)	(4,255)
Selling expenses.....	(2,960)	(2,724)	-	-	(5,684)
G&A .....	(887)	(841)	(2,036)	(97)	(3,862)
Non recurring operating expenses .....	-	-	-	-	-
Total expenses .....	(4,930)	(4,680)	(2,036)	(2,156)	(13,802)
Operating income (loss) .....	475	(986)	(2,036)	(2,156)	(4,703)
Total Assets .....	10,690	20,000	1,746	11,429	43,863
Capital expenditures .....	673	327	128	-	1,128
Long-lived assets .....	3,048	3,371	171	157	6,747
Goodwill .....	645	1,767	-	-	2,412



**EDAP TMS S.A. AND SUBSIDIARIES**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS  
(in thousands of euros unless otherwise noted, except per share data)**

	<b>HIFU Division</b>	<b>UDS Division</b>	<b>EDAP TMS (Corporate)</b>	<b>FDA</b>	<b>Total consolidated</b>
<b>2007</b>					
External sales of medical devices .....	2,661	6,496	-	-	9,157
External sales of spares parts, Supplies & services.....	6,610	6,447	-	-	13,057
Total sales .....	9,271	12,943	-	-	22,213
Warrants granted.....					
Total net sales .....	9,271	12,943	-	-	22,213
External other revenues .....	60	53	-	-	113
Total revenues.....	9,331	12,996	-	-	22,327
Total COS.....	(3,940)	(9,208)	-	-	(13,148)
Gross margin.....	5,391	3,788	-	-	9,179
R&D.....	(1,216)	(1,060)	-	(918)	(3,194)
Selling expenses.....	(2,986)	(2,408)	-	(81)	(5,476)
G&A .....	(985)	(944)	(1,786)	(659)	(4,374)
Non recurring operating expenses ....	-	(7)	(512)	295	(224)
Total expenses .....	(5,187)	(4,419)	(2,298)	(1,363)	(13,267)
Operating income (loss) .....	204	(631)	(2,298)	(1,363)	(4,089)
Total Assets .....	9,876	18,578	3,696	12,851	45,003
Capital expenditures .....	1,109	1,354	44	-	2,507
Long-lived assets .....	3,029	4,059	82	217	7,387
Goodwill .....	645	1,767	-	-	2,412

**EDAP TMS S.A. AND SUBSIDIARIES**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**  
**(in thousands of euros unless otherwise noted, except per share data)**

	<b>HIFU Division</b>	<b>UDS Division</b>	<b>EDAP TMS (Corporate)</b>	<b>FDA</b>	<b>Total consolidated</b>
<b>2006</b>					
External sales of medical devices .....	2,611	5,998	-	-	8,608
External sales of spares parts, Supplies & services.....	4,989	6,576	-	-	11,566
Total sales .....	7,600	12,574	-	-	20,174
Warrants granted.....					
Total net sales .....	7,600	12,574	-	-	20,174
External other revenues .....	65	26	-	-	91
Total revenues.....	7,666	12,599	-	-	20,265
Total COS .....	(3,169)	(8,776)	-	-	(11,946)
Gross margin.....	4,497	3,822	-	-	8,319
R&D.....	(1,423)	(1,019)	-	-	(2,442)
Selling expenses.....	(2,475)	(2,146)	-	-	(4,621)
G&A .....	(696)	(1,748)	(1,638)		(4,083)
Non recurring operating expenses .....	-	-	(267)	-	(267)
Total expenses .....	(4,595)	(4,913)	(1,905)	-	(11,413)
Operating income (loss) .....	(98)	(1,091)	(1,905)		(3,094)
Total Assets .....	12,544	16,816	3,112	-	32,473
Capital expenditures .....	1,050	515	-	-	1,565
Long-lived assets .....	2,384	3,650	46	-	6,080
Goodwill .....	645	1,767	-	-	2,412

## EDAP TMS S.A. AND SUBSIDIARIES

### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (in thousands of euros unless otherwise noted, except per share data)

#### 29—VALUATION ACCOUNTS

	Allowance for doubtful accounts	Slow- moving inventory
Restated balance as of January 1, 2006 .....	663	874
Charges to costs and expenses .....	86	388
Deductions: write-off provided in prior periods .....	(68)	(334)
Restated balance as of December 31, 2006 .....	681	928
Charges to costs and expenses .....	131	288
Deductions: write-off provided in prior periods .....	(77)	(195)
Restated balance as of December 31, 2007 .....	735	1021
Charges to costs and expenses .....	72	391
Deductions: write-off provided in prior periods .....	(15)	-
Restated balance as of December 31, 2008 .....	792	1,412

#### 30—SUPPLEMENTAL DISCLOSURES OF CASH FLOW INFORMATION

Interest and income taxes paid are as follows:

	2008	2007	2006
Income taxes paid (refunds received) .....	74	142	204
Interest paid .....	382	291	22
Interest received .....	273	284	150
Non-cash transactions: .....	2008	2007	2006
Capital lease obligations incurred .....	2,019	1,557	1,132

#### 31—RELATED PARTY TRANSACTIONS

The General Manager of the Company's Korean branch "EDAP-TMS Korea" is also Chairman of a Korean company named Dae You. EDAP-TMS Korea subcontracts to Dae You the service contract maintenance of our medical devices installed in Korea. The amounts payable under this contract were €61 thousand, €71 thousand and €61 thousand for 2008, 2007 and 2006 respectively. Dae You also acts as an agent to promote our medical devices in South Korea, and receives commissions on sales. Dae You has purchased medical devices from us, which it operates in partnership with hospitals or clinics. These purchases amounted to €539 thousand, €558 thousand and €588 thousand in 2008, 2007 and 2006 respectively. As of December 31, 2008, receivables amounted to €384 thousand and payables to €31 thousand. As of December 31, 2007, receivables from Dae You amounted to €52 thousand and our payables to them amounted to €28 thousand.

The Company purchases certain technological elements from Siemens AG, an affiliate of its shareholder, Siemens France Holding. Total purchases amounted to €212 thousand in 2008, €183 thousand in 2007 and €444 thousand in 2006. As of December 31, 2008, payables due to Siemens AG amounted to €10 thousand and as of December 31, 2007, payables due to Siemens AG amounted to €1 thousand.

## **EDAP TMS SA**

*Senior Executive Officers*

### **Philippe Chauveau**

*Chairman of the Board of Directors,*

### **Marc Oczachowski**

*Chief Executive Officer*

### **Eric Soyer**

*Chief Financial Officer*

## **EDAP TMS SA**

*Board of Directors*

### **Philippe Chauveau**

*Chairman*

### **Pierre Beysson**

Paris, France

### **Karim Fizazi**

Institut Gustave Roussy  
Villejuif, France

### **Jean-Philippe Deschamps**

Lausanne, Switzerland

## **EDAP TMS SA**

*Corporate Headquarters*

Parc d'Activités  
La Poudrette Lamartine  
4, Rue du Dauphiné  
F 69120 Vaulx-en-Velin  
France  
Tel : +33 (0)4 72 15 31 50  
Fax : +33 (0)4 72 15 31 51  
[www.edap-tms.com](http://www.edap-tms.com)  
[www.hifu-planet.com](http://www.hifu-planet.com)

### **Blandine Confort**

*Investor Relations*

Tel: +33 (0)4 72 15 31 72  
[bconfort@edap-tms.com](mailto:bconfort@edap-tms.com)

## **EDAP TMS's subsidiaries**

*Officers*

### **Marc Oczachowski**

*President*

EDAP TMS France SAS  
EDAP Technomed Inc

### **Judith Johannsen**

*General Manager*

EDAP TMS GmbH  
Germany

### **Sergio Pontecorvi**

*General Manager*

EDAP Technomed S.r.l.  
Rome, Italy

### **Jean-François Bachelard**

*General Manager*

EDAP Technomed Co. Ltd  
Tokyo, Japan

### **Young Hwan Park**

*General Manager*

EDAP TMS Korea  
Seoul, Korea

### **Hervé de Soultrait**

*General Manager*

EDAP Technomed (M) Sdn, Bhd  
Kuala Lumpur, Malaysia

## **EDAP TMS's branches**

*Officers*

### **Jean-François Bachelard**

*General Manager*

EDAP  
Moscow, Russia



Bringing New Horizons to Therapy

**EDAP TMS** – 4, rue du Dauphiné – PA La Poudrette Lamartine – 69120 Vaulx-en-Velin – FRANCE  
Tél : +33 (0)4 72 15 31 50 – Fax : +33 (0)4 72 15 31 51 – [www.edap-tms.com](http://www.edap-tms.com) – [contact@edap-tms.com](mailto:contact@edap-tms.com)

ISO 900: 2000 • ISO 13485: 2003