

EDAP TMS SA  
Form 20-F  
May 20, 2005  
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As filed with the Security and Exchange Commission on May 20, 2005

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**SECURITIES AND EXCHANGE COMMISSION**  
Washington, D.C. 20549  
**FORM 20-F**

REGISTRATION STATEMENT PURSUANT TO SECTION 12(b) OR (g) OF THE SECURITIES EXCHANGE ACT OF 1934

or

ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the Fiscal Year Ended December 31, 2004

or

TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

**0-29374**

(Commission file number)

**EDAP TMS S.A.**

(Exact name of registrant as specified in its charter)

**France**

(Jurisdiction of incorporation or organization)

**Parc d Activites la Poudrette-Lamartine**

**4/6, rue du Dauphine**

**69120 Vaulx-en-Velin, France**

(Address of principal executive offices)

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

Title of each class

None

Name of each exchange  
on which registered

None

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

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**American Depositary Shares, each  
representing one Ordinary Share  
Ordinary Shares, nominal value  
0.13 per share**

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, 2004:

**7,781,731 Ordinary Shares**

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  No

Indicate by check mark which financial statement item the registrant has elected to follow.

Item 17  Item 18

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## PRESENTATION OF FINANCIAL AND OTHER INFORMATION

Unless the context otherwise requires, references herein to the Company, the Group or EDAP TMS are to EDAP TMS S.A. and its consolidated subsidiaries and references herein to this Annual Report are to the Company's Annual Report on Form 20-F for the year ended December 31, 2004.

The Company prepares its 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 = 0.7387, 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, 2004. 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, Technomed, Ablatherm, Ablasonic, Ablapak and Praktis. This Annual Report also makes references to trade names and trademarks of companies other than the Company.

## FORWARD-LOOKING INFORMATION

This Annual Report includes certain forward-looking statements, usually containing words such as believe, plan, intend, estimate, expect and anticipate or similar expressions, which reflect the Company's 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 the Company's control. These factors include, without limitation: the effects on the Company of the intense competition existing in the markets in which it operates; the uncertainty of market acceptance for the Company's HIFU devices; the clinical status of the Company's HIFU devices; the impact on the Company of government regulation, particularly relating to public healthcare systems and the commercial distribution of medical devices; dependence on the Company's strategic partners; reliance on patents, licenses and key proprietary technologies; product liability risk; risk of exchange rate fluctuations, particularly between the euro and the U.S. dollar and between the euro and the Japanese yen; and potential fluctuations in results of operations due to the cyclical nature of demand for medical devices. Readers 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 the Company's periodic filings with the Securities and Exchange Commission (including the Company's 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 and is qualified by reference to, and should be read in conjunction with, the Consolidated Financial Statements and the Notes thereto appearing elsewhere in this Annual Report (the Consolidated Financial Statements ) and Item 5, Operating and Financial Review and Prospects. The balance sheet data as of December 31, 2002, 2003 and 2004 and the income statement data for the years ended December 31, 2002, 2003 and 2004 set forth below have been derived from the Consolidated Financial Statements. The balance sheet data as of December 31, 2000 and 2001 and the income statement data for the year ended December 31, 2000 and 2001 have been derived from the Company's audited consolidated financial statements. The Consolidated Financial Statements were prepared in accordance with U.S. GAAP. To date, the Company has not been required, and presently is not required under French law, to prepare consolidated financial statements under French GAAP, nor has it prepared any consolidated financial statements under French GAAP.

	Year Ended and at December 31,					
	(in thousands)					
	2000	2001	2002	2003	2004	2004 <sup>(1)</sup>
	\$					
<b>INCOME STATEMENT DATA</b>						
Total revenues	27,252	23,965	19,961	18,473	22,163	30,003
Net sales	24,809	23,804	19,725	18,030	21,955	29,721
Gross profit	13,060	7,979	8,458	5,379	8,487	11,489
Operating expenses	(16,795)	(13,093)	(13,234)	(13,500)	(9,317)	(12,613)
Income (loss) from operations	(3,735)	(5,114)	(4,776)	(8,121)	(830)	(1,124)
Income (loss) before income taxes	12,032	8,019	(3,873)	(9,090)	(871)	(1,179)
Income taxes	(323)	(882)	(167)	114	(278)	(376)
Net income (loss)	11,709	7,137	(4,040)	(8,976)	(1,149)	(1,555)
Net income (loss) per Share	1.5	0.92	(0.52)	(1.15)	(0.15)	(0.20)
Dividends per Share <sup>(2)</sup>						
Weighted average shares outstanding used in diluted calculation	8,266,361	7,941,869	7,833,514	7,817,303	8,074,210	8,074,210
Diluted earnings per Share	1.42	0.9	(0.52)	(1.15)	(0.15)	(0.20)
<b>BALANCE SHEET DATA</b>						
Total current assets	39,881	45,927	34,091	25,870	22,041	29,838
Property, plant and equipment, net	1,825	2,233	1,985	2,903	2,807	3,800
Total current liabilities <sup>(4)</sup>	10,185	11,916	9,880	11,076	8,272	11,198
Total assets	50,287	53,115	39,787	31,910	27,901	37,770
Long-term debt, less current portion <sup>(3)</sup>	3,478	304	95	7		
Total shareholders' equity	34,679	38,909	28,375	18,961	17,964	24,318





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- (1) Translated for the convenience of the reader at the Noon Buying Rate on December 31, 2004 of \$1 = 0.7387. See Presentation of Financial and Other Information elsewhere in this Annual Report.
- (2) No dividends were paid with respect to fiscal years 2000 through 2003 and subject to approval of the annual shareholders meeting to be held in June 2005, the Company does not anticipate paying any dividend with respect to fiscal year 2004. See Item 8, Financial Information Dividends and Dividend Policy.
- (3) Long-term debt includes the long-term portion of capital lease obligations.
- (4) Certain prior years amounts have been reclassified to conform the current years presentation.

### 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 Depository of dividends, if any, paid on the Shares in the form of ADSs. Moreover, such fluctuations may affect the dollar price of the ADSs on Nasdaq.

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

Year ended December 31,	High	Low	Average <sup>(1)</sup>	End of Year
2004	0.85	0.73	0.80	0.74
2003	1.12	0.79	0.88	0.79
2002	1.16	0.95	1.05	0.95
2001	1.19	1.05	1.12	1.12
2000	1.21	0.97	1.08	1.07

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

The following table sets forth, for each of the previous six months, the high and low Noon Buying Rates expressed in euro per \$1.00.

	High	Low
October	0.81	0.78
November	0.79	0.75
December	0.76	0.73
January	0.77	0.74
February	0.78	0.75
March	0.78	0.74

On May 12, 2005, the latest practicable date before the filing of this Annual Report with the U.S. Securities and Exchange Commission (the Commission ), the Noon Buying Rate was U.S.\$1.00 = 0.7870.

### Risk Factors

#### *Dependence on HIFU Technology*

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The Company is dependent on its High Intensity Focused Ultrasound ( HIFU ) technology for future growth in its revenues and net income. In October 2000, EDAP TMS sold its Prostatron business to Urologix, Inc. ( Urologix ). The Prostatron, a medical device using transurethral microwave thermotherapy ( TUMT ) for the minimally invasive treatment of Benign Prostatic Hyperplasia ( BPH ), a non-cancerous urological condition, was one of the Company s three principal lines of medical devices. Although the Company continued to manufacture the Prostatron on behalf of Urologix after the sale, it only derived approximately 1% of its total revenues for the year ended December 31, 2004 and 2% of total revenues for the year ended December 31, 2003 from these sales. The Company does not expect to generate any additional revenues from the supply of machines to Urologix for the year ended December 31, 2005 and beyond, as the agreements between the Company and Urologix to manufacture the devices have expired. In addition, the Company s 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. Consequently, the Company will be dependent on the successful development and commercialization of its other line of products, medical devices based on HIFU, particularly the Ablatherm, to generate significant additional revenues and achieve and sustain profitability in the future. The Ablatherm is in its commercialization phase in the European Union. The Ablatherm is not approved for commercial distribution in the United States and none of the Company's other HIFU products (excluding Ablatherm) has obtained approval for commercial distribution anywhere in the world. In December 2001, the Company's 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. In order to assist in the successful completion of clinical trials to obtain FDA approval, the Company has identified a U.S. partner to assist in the approval process for re-submission of an IDE to the FDA, with the execution of a Distribution Agreement with HealthTronics Surgical Services, Inc. ( HealthTronics ), in February 2004. The identification of HealthTronics as the Company's U.S. partner does not guarantee the successful completion of clinical trials nor does it guarantee that the FDA will grant approval to market a device if clinical trials are successfully completed. See *Uncertainty Relating to Clinical Trials; Clinical Status of Certain Products Using HIFU Technology* and Item 4, *Information on the Company High Intensity Focused Ultrasound Division HIFU Division Clinical and Regulatory Status*.

***Uncertainty Relating to Clinical Trials; Clinical Status of Certain Products Using HIFU Technology***

Before obtaining regulatory approvals for the commercial sale of any of its devices under development, the Company 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 the Company's clinical trials will demonstrate the safety and effectiveness of any products or will result in marketable products. A number of companies have suffered significant setbacks in advanced clinical trials, even after promising results in earlier trials. The Company, the FDA or other regulatory authorities may suspend or terminate clinical trials at any time and regulating agencies such as the FDA may even refuse to grant exemptions to conduct clinical trials, as occurred in the United States in connection with the Company's December 2001 request for an additional IDE enabling the Company to conduct clinical trials for the Ablatherm as a primary therapy. See Item 4, *Information on the Company High Intensity Focused Ultrasound Division HIFU Division Clinical and Regulatory Status*.

The Company relies on scientific, technical and clinical data supplied by its academic collaborators in the evaluation and development of its related devices. There can be no assurance that there are or will be no errors or omissions in such data that would materially adversely affect the development of such products.

The process of applying for regulatory approval is unpredictable, often lengthy and requires the expenditure of substantial resources. There can be no assurance that the Company's HIFU devices that have not received regulatory approval will prove to be effective or safe in clinical trials or will be approved by the appropriate regulatory authorities. If the Company's HIFU devices do not prove to be effective and safe in clinical trials to the satisfaction of the relevant regulatory authorities, the Company's business, financial condition and results of operations could be materially adversely affected. The Company, through its U.S. partner HealthTronics, does not anticipate receiving FDA approval for any HIFU device, including the Ablatherm, for several years, if at all.

***Uncertainty of Market Acceptance of Certain Products Using HIFU Technology***

The Company's HIFU devices represent new therapies for the conditions that they are designed to treat. Notwithstanding any positive clinical results that the Company's HIFU devices may have achieved or may achieve in the future in terms of safety and effectiveness, and any marketing approvals that the Company may have obtained or may obtain in the future with respect thereto, 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 the Company's HIFU products in any country, except Italy and Germany, and evidence of the cost-effectiveness of a therapy as compared to existing therapies. Patient acceptance 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.

***Uncertain and unpredictable liquidity and cash flow***

The Company's 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 2004, 2003 and 2002, moreover, the Company's cash flow was negative due to the cash requirements of operating activities, which the Company financed using cash and cash equivalents on hand. In addition, because the Company anticipates relying principally on cash flow from operating activities to meet its liquidity requirements, a decrease in the demand for the Company's products, or the inability of the Company's customers to meet their financial obligations to the Company, would reduce the availability of funds to the Company. The Company's future cash flow may also be affected to the extent the Company continues to expand the leasing of its products, or to expand its mobile activity (which is invoiced on a charge-per-procedure basis), since each of these activities generates smaller immediate revenues than device sales. In the future, the Company's liquidity may therefore be constrained and its cash flows may be uncertain, negative or significantly different from period to period. In 2003, the Company performed an extensive review of its business and adopted measures designed to address its cash flow problems in the near term. There is no assurance, however, that these problems will not recur in the medium to long term.

***History of Operating Losses; Uncertainty of Future Profitability***

The Company has incurred operating losses in each fiscal year since 1998 and may never achieve profitability. The Company expects that its marketing, selling and research and development expenses will increase as it attempts to develop and commercialize HIFU devices. The Company may not 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 2004, the Company registered an operating income in both divisions, reflecting its efforts in restructuring the Company and reducing expenses. There can be no assurance, however, that the Company will realize sufficient revenue to sustain or increase profitability in the future. See Item 5, Operating and Financial Review and Prospects.

***Competition and Technological Advances***

In each of its principal businesses, the Company faces competition both directly from other manufacturers of medical devices that apply the same technologies as the Company, as well as indirectly from existing or emerging alternative therapies for the treatment of urological disorders. Competition in the markets in which the Company operates is intense and is expected to increase in the future.

The Company believes 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 the Company targets for its HIFU products, competition comes from new market entrants and alternative therapies, as well as current manufacturers of medical devices. In HIFU, the Company's devices, in particular the Ablatherm, compete with all current treatments for localized tumors, which include 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. Finally, St. Jude Medical Inc. has developed a device using HIFU to treat atrial fibrillation. 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 the Company's competitors have significantly greater financial, technical, research, marketing, sales, distribution and other resources than the Company and may have more experience in developing, manufacturing, marketing and supporting new medical devices. In addition, the Company's future success will depend in large part on its ability to maintain a leading position in technological innovation, and there can be no assurance that the Company will be able to develop or enhance its products, or develop new products, to compete successfully with new or existing technologies. Rapid technological development by competitors may result in the Company's products becoming obsolete before the Company recovers a significant portion of the research, development and commercialization expenses incurred with respect to those products.

The Company also faces competition for its maintenance and service contracts. Larger hospitals often utilize their in-house maintenance departments in lieu of contracting with equipment manufacturers such as the Company. In addition, third-party medical equipment maintenance companies increasingly compete against equipment manufacturers by offering broad repair and maintenance service contracts to hospitals and clinics. Increased competition by the Company's current or future competitors for its medical devices or its maintenance and service contracts could have a material adverse effect on the Company's business, financial condition and results of operations. With respect to ESWL product, the Company is currently experiencing declining revenues in its maintenance and service contract business and may not be able to offset these decreases with increases in other businesses.

### ***Government Regulation***

Government regulation in countries in which the Company sells its products, particularly in the United States, is a significant factor in the development and marketing of the Company's products and in the Company's ongoing manufacturing and research and development activities. The Company is regulated in each of its major markets with respect to preclinical and clinical testing, manufacturing, labeling, distribution, sale, marketing, advertising and promotion of its products. In order to market and sell those of its products that are still in the clinical trial stage, the Company will be required to obtain marketing approval or clearance from the relevant regulatory agencies, including the FDA in the United States. Moreover, if regulatory approval to market a product is granted, such approval may entail limitations on the indicated uses for which it may be marketed. Failure to comply with applicable regulatory requirements can, among other things, 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 the Company's products. Delays in receipt of, or failure to receive, regulatory approvals, or the loss of previously received approvals, would have a material adverse effect on the Company's business, financial condition and results of operations. For more information on the regulation of the Company's business, see Item 4, Information on the Company Government Regulation.

There can be no assurance that additional statutes or regulations applicable to the Company's business will not be adopted, impose substantial additional costs or otherwise have a material adverse effect on the Company's business, financial condition and results of operations.

### ***Uncertainty Relating to Third-Party Reimbursement***

The Company's success is dependent upon, among other things, the extent to which satisfactory reimbursement for the procedures performed with its devices can be obtained from healthcare payers in the United States and elsewhere. In the United States, the Company is 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, and any such revision might affect reimbursement for the procedures performed using the Company's 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, relevant approvals have to be sought in each Member State. Failure to establish sufficient reimbursement from healthcare payers or adverse changes in governmental and private healthcare payers' policies could have a material adverse effect on the Company's business, financial condition and results of operations.

Lithotripsy procedures are reimbursed in the European Union, in Japan and in the United States. However, there can be no assurance that a decision to modify reimbursement will not affect the Company's business, financial conditions and results of operations. Procedures performed with the Company's Ablatherm device are not reimbursed in the United States or in any of the European Union countries with the exception of Italy and Germany, and there is no assurance that such reimbursement will be obtained.

### ***Manufacturing***

The Company's 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 the European Union standards for quality assurance and manufacturing process control. Any failure by the Company to comply with such regulations may have a material adverse effect on the Company's business, financial condition and results of operations.

Substantially all assembly of the Company's products currently takes place in a single facility located in Vaulx-en-Velin, on the outskirts of Lyon, France. A significant interruption for any reason, including but not limited to failure to obtain regulatory approval or in the operations of the Company's sole facility could have a material adverse effect on the Company's business, financial condition and results of operations.

### ***Dependence Upon Key Suppliers***

The Company purchases the majority of the components used in its products from a number of suppliers but for several components of its products, relies on a single source. In addition, the Company relies on single suppliers for certain services. If the supply of certain components or services were interrupted, the Company's manufacturing, marketing and selling of the relevant products would be delayed. These delays could be extensive in situations where a component substitution would require regulatory approval. The Company expects to be dependent upon its 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 the Company's business, financial condition and results of operations.

### ***Patents, Licenses and Proprietary Technologies***

The Company's success depends in large part on its 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. The Company's products, including its 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 the Company's technical and management personnel. An adverse determination in any such litigation or proceeding to which the Company may become a party could subject the Company to significant liability to third parties, require the Company to seek licenses from third parties and to pay ongoing royalties, require the Company to redesign certain products or subject the Company to injunctions preventing the manufacture, use or sale of such products. In addition to being costly, protracted litigation to defend or prosecute intellectual property rights could result in the Company's customers or potential customers deferring or limiting their purchase or use of the Company's products until resolution of such litigation. 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.

The Company owns patents covering several of its technologies and has 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 the Company's patent applications will result in patents being issued, or that the Company's issued patents, or any patents which may be issued as a result of existing or future applications, will be sufficient to provide meaningful protection or commercial advantage to the Company. There can be no assurance that any of the Company's patents or patent applications will not 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 adversely affect the Company's business, financial condition or results of operations. Litigation may be necessary to enforce patents issued to the Company or to determine the enforceability, scope and validity of the proprietary rights of others. There can be no assurance that competitors, many of which have substantial resources and have made substantial investments in competing technologies, will not apply for or obtain patents that will prevent, limit or interfere with the Company's ability to make, use or sell its products either in the United States or in foreign markets, including its HIFU devices.

The Company also relies on trade secrets and proprietary know-how, which it seeks to protect through non-disclosure agreements with employees, consultants and other parties. There can be no assurance that those non-disclosure agreements will not be breached, that the Company will have adequate remedies for any breach, or that the Company's trade secrets will not otherwise become known to, or independently developed by, competitors. Litigation may be necessary to protect trade secrets or know-how owned by the Company. 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 the Company's business, financial condition and result of operations.

### ***Product Liability Risk***

The Company faces a significant risk of exposure to product liability claims in the event that the use of its products results in personal injury or death, and there can be no assurance that material product liability claims will not be assessed against the Company in the future. To date, the Company is a party to two product liability actions in the United States by patients claiming to have been injured in the course of a Prostatron procedure, for which it has agreed to retain liability following the sale of the Prostatron business in October 2000. See Item 5,

Operating and Financial Review and Prospects Critical Accounting Policies Litigation and Item 8, Financial Information Legal Proceedings for more information about these actions. These product liability claims, if successful, could have a material adverse impact on the Company.

The Company maintains separate product liability insurance policies for the United States and the other markets in which it sells its 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, there can be no assurance that product liability claims will be covered by such insurance or will not exceed such insurance coverage limits. Also, in the event that any of the Company's products proves to be defective, the Company may be required to recall or redesign such product. A product liability claim or series of claims brought against the Company with respect to uninsured liabilities or in excess of the Company's insurance coverage, or any claim or product recall that results in significant cost to or adverse publicity against the Company, could have a material adverse effect on the Company's business, financial condition and results of operations.

### ***Risk of Exchange Rate Fluctuations***

The Company sells its products in many parts of the world and, as a result, the Company's business is affected by fluctuations in currency exchange rates. The Company is exposed to foreign currency exchange rate risk because the mix of currencies in which its costs are denominated is different from the mix of currencies in which it earns revenues. In 2004, approximately 70% of the Company's selling and general and administrative expenses and approximately 94% of the Company's research and development expenses were denominated in euro, while approximately 51% of the Company's sales were denominated in currencies other than euro (primarily the U.S. dollar and the Japanese yen). 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. 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 the Company's revenues which may not be offset by an equal reduction in operating expenses and would therefore negatively impact operating profitability. The Company from time to time enters into foreign exchange forward sale contracts to hedge against fluctuations in the exchange rates of the principal foreign currencies in which its 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 the Company's results of operations. As of December 31, 2004, the Company had two foreign exchange sale contracts, one for Japanese yen which expires on December 28, 2005 and one for U.S. dollars which expires on May 27, 2005. As of March 31, 2005, the Company had five new foreign exchange sale contracts, three for the Japanese yen and two for U.S. dollars. In addition, since any dividends that may be declared by the Company will be denominated in euro, exchange rate fluctuations will affect the U.S. dollar equivalent of any dividends received by holders of ADSs.

#### ***Potential Fluctuations in Results of Operations***

The Company's 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, cyclicalities of demand for the Company's products, changes in pricing policies by the Company or its competitors, new product announcements by the Company or its competitors, customer order deferrals in anticipation of new or enhanced products offered by the Company or its competitors, product quality problems and exchange rate fluctuations. Furthermore, because the Company's main products have relatively high unit prices, the amount and timing of individual orders can have a substantial effect on the Company's results of operations in any given quarter.

#### ***Passive Foreign Investment Company Status***

Unfavorable U.S. tax rules apply to a U.S. holder of shares in a company that is considered a passive foreign investment company ( PFIC ) for any taxable year during any part of which the U.S. holder owns such shares. The unfavorable consequences of the rules can be alleviated by making the mark-to-market election described in Item 10, Additional Information Taxation of U.S. Investors Passive Foreign Investment Company Rules. Although the Company believes that it was not a PFIC in 2004 and does not anticipate being a PFIC in 2005, the Company believes that it was a PFIC in prior years. If a U.S. holder held Shares or ADSs during any year in which the Company was a PFIC, such U.S. holder generally would be subject to unfavorable U.S. tax rules applicable to PFICs. Such U.S. holders, therefore, should consider making a mark-to-market election. U.S. holders should consult their own tax advisors regarding the potential applicability and consequences of PFIC treatment to them and the implications of the mark-to-market election.

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

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

Founded in 1979, the Company originally specialized in the manufacturing and distribution of lithotripters and produced the first piezo-electric lithotripter in 1985. In 1994, the Company purchased most of the assets of Technomed International S.A. ( Technomed ) out of liquidation. Technomed was established in 1985 and launched an electrohydraulic lithotripter in 1986 and the Prostatron, a medical device using TUMT for the minimally invasive treatment of BPH in the European Union in 1990. The assets acquired by the Company in Technomed's liquidation included the ownership of, and full distribution rights to, the Prostatron, the Sonolith series of lithotripters and the Ablatherm HIFU device.

In October 2000, the Company sold its 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. As a result of the transaction, the Company held securities that represented approximately 12.7% of Urologix's total share capital (assuming the Company's warrants had been exercised) on the date of the closing of the transaction. On December 31, 2003 the Company sold all of its shares in Urologix, and it no longer holds any Urologix shares. Additionally, the Company and Urologix entered into a supply agreement, which expired October 1, 2003, for certain components of the Prostatron unit (the Supply Agreement ), as well as a distribution agreement for the Prostatron in Japan and Italy (the Distribution Agreement ).



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In July 2002, the shareholders of the Company approved the reorganization of the Company's management structure and the creation of two separate operating divisions. The implementation of the new corporate structure consolidated the management structure of the Company 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. Additionally, two separate, fully consolidated operating divisions were created: the HIFU division and the UDS division.

In December 2003, in consideration of the economic situation prevailing at the time and in order to maintain competitiveness, the Company had to restructure its organization and implemented a headcount reduction in its two French operational divisions.

In December 2003, the Company also entered into a letter of intent with a subsidiary of HealthTronics Inc. ( HealthTronics ) granting it the right to begin clinical trials with the Ablatherm, which utilizes HIFU to provide minimally invasive treatment of prostate cancer, to obtain Pre-Market Approval ( PMA ) from the FDA, and granting HealthTronics exclusive distribution rights in the United States for the Ablatherm, when and if a PMA is granted. Certain aspects of the letter of intent required the approval of the shareholders of the Company, which approval was obtained at an extraordinary shareholder meeting held on January 29, 2004.

On February 25, 2004, the Company and HealthTronics finalized a distribution agreement based on the terms outlined in the letter of intent. On January 28, 2005, as per the approval of the January 29, 2004 extraordinary shareholders' meeting, 1,000,000 warrants were allocated to HealthTronics. These warrants can be exercised upon the completion of certain milestones linked to the grant of the Ablatherm (PMA) and certain minimum sales of lithotripters in the US.

The Company's legal name is EDAP TMS S.A. 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. The Company's principal executive offices are located at Parc d' Activités la Poudrette-Lamartine, 4/6, rue du Dauphiné, 69120 Vaulx-en-Velin, France and its telephone number is +33 (0) 4 72 15 31 50. On July 1, 2004, the Company closed its U.S. offices, but retained EDAP Technomed Inc as a Delaware registered company.

### ***Business Overview & Strategy***

The Company is engaged, through its HIFU and UDS divisions, in the development, production and marketing of minimally invasive medical devices, mainly for urological diseases. The Company believes that the creation of these two operating divisions has allowed it to expand its market share by optimizing worldwide distribution capabilities, all of which is coordinated through the Company's subsidiaries. It also allows for cost synergies, mainly in manufacturing and administrative expenses.

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

See Note 26 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>
Technomed Medical Systems S.A	France	100%
EDAP S.A	France	100%
EDAP Technomed Inc. <sup>(2)</sup>	United States	100%
EDAP Technomed Co. Ltd	Japan	100%
EDAP Technomed Sdn Bhd	Malaysia	100%
EDAP Technomed Srl	Italy	100%

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

<sup>(2)</sup> EDAP Technomed Inc is still registered in the Delaware and maintained as a dormant company.



## **High Intensity Focused Ultrasound ( HIFU ) Division**

The Company's HIFU division consists of two wholly owned and fully consolidated subsidiaries: EDAP S.A. ( EDAP ), a French Corporation, and EDAP Technomed Srl, an Italian Corporation. The HIFU division also has branch offices in Germany and Russia. The HIFU division is engaged in the development 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 6.9 million during the fiscal year ended December 31, 2004

### ***HIFU Division Business Overview***

The HIFU division currently develops 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 anaesthesia and associated complications. The Ablatherm, 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 are to begin soon, with the assistance of the Company's U.S. partner, HealthTronics. The HIFU division had a fixed installed base of 27 Ablatherm machines worldwide and 67 clinical sites were using this technology as of March 31, 2005.

In addition to developing and marketing HIFU devices, the HIFU division also generates revenues from the leasing of this equipment, as well as from the sale of disposables, spare parts and maintenance services. The Company is developing a HIFU mobile treatment activity which enables to provide access to the HIFU technology without an initial investment. Hospitals and clinics perform treatments using the devices and remunerate the Company on a charge-per-procedure ( CPP ) 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 will become more attractive, leading to the sale of the device in many of the large locations.

### ***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, marketing and distribution of minimally invasive medical devices for urological and other indications, using HIFU technology. 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 Prostate Cancer using HIFU.* Building upon the Company's established position in the ESWL market of the UDS division, the HIFU division is striving to become the leading provider of this minimally invasive treatment option for prostate cancer. It believes 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. The HIFU division believes 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 achieves this through a direct sales network in Europe, through the distribution platform of the UDS division in Asia and selected distributors in key countries, and in partnership with HealthTronics in the United States. The HIFU division has built a strong clinical credibility based on clinical articles published in peer reviewed journals. The Company ensures effective patient and physician education through a focused communication program.

*Achieve Long-Term Growth by Expanding HIFU Applications Beyond Prostate Cancer.* The HIFU division's long-term growth strategy is to apply its HIFU technology toward the minimally invasive treatment of indications beyond prostate cancer. The HIFU division believes 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. However, the HIFU division lowered spending on research and development ( R&D ) projects in 2004 so that it could utilize those resources in expanding the acceptance of HIFU for the treatment of localized prostate cancer. The division is considering increasing R&D spending in 2005 and onwards to develop HIFU applications beyond urology in order to strengthen its technological leadership in HIFU and expand it beyond prostate cancer.

### ***HIFU Products***

Currently, the only commercial product produced by the HIFU division utilizing HIFU technology is the Ablatherm. The Ablatherm treats organ-confined prostate cancer and is cleared for distribution in the European Union, South Korea, Canada and Russia. Clinical trials will soon be underway in the United States, in partnership with HealthTronics. The Company has developed the Ablatherm, an ultrasound-guided HIFU device for the treatment of organ-confined prostate cancer. 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 volume has been treated. 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 anaesthesia.

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

As of March 31, 2005, the HIFU division's patent portfolio contained 53 patents (consisting of 27 in the United States, 20 in the European Union and Japan and 6 in Israel) covering key technologies relating to HIFU systems and associated software. Additional patents covering certain other aspects of the Company's HIFU technology in the European Union, the United States and Japan are still in the examination process. During 2004, two patents (one covering obsolete technology and one continuation in part ) were abandoned in the United States. An additional patent covering HIFU transducer design was obtained in Israel. In Europe one patent covering the disposable Ablapack has been obtained and one patent covering obsolete technology was abandoned.

Although the HIFU division believes that its HIFU patents are valid and should be enforceable against third parties and that its 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. The HIFU division's 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 the HIFU division's ability to market HIFU systems.

As part of the reorganization of the Company into two separate operating units, the Company transferred the assets and related intellectual property of the HIFU research program to the HIFU division.

In August 2004, the Company licensed its HIFU technology for the specific treatment of the cervico-facial lesions, including the thyroid, to Theraclion, a French company created by the former R&D Director of the Company. This license agreement allows for the payment of certain royalties calculated on the basis of Theraclion's future sales of devices. The Company determined that it could not invest in these specific applications for the time being, and this license agreement therefore allows Theraclion to pursue the development of HIFU for this application. The Company owns no interest in Theraclion.

### ***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.

There are primarily two methods to evaluate the presence of cancerous tissue in the prostate. The first method is based on biopsies. A sextant biopsy is performed inside the prostate to reveal the presence of a tumor. The second method is based on a blood test for the Prostate Specific Antigen ( PSA ), which, although not specific to cancer tumors, measures the proliferation of cells inside the prostate.

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 as 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, the Company obtained, in May 1999, a CE Marking which allows the Company 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. The application is still under review. The process of requesting approval to market the Ablatherm in Japan has been ongoing for a significant period of time, and may never result in the approval to market the Ablatherm in Japan. See Item 3, Key Information Risk Factors Dependence on HIFU Technology.

In 2001, the French Urology Association ( AFU ) conducted an independent clinical trial in order 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 enrolment 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 for the next two years to evaluate the long-term efficacy of the treatment.

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

In February 2004, the Company entered into a distribution agreement with a subsidiary of HealthTronics Surgical Services, Inc. ( HealthTronics ). The terms of the distribution agreement grant HealthTronics the right to pursue market approval from the FDA for the Ablatherm. When and if HealthTronics receives market approval from the FDA, HealthTronics will be granted exclusive distribution rights for the Ablatherm in the United States. The company continues to work with its U.S. partner, HealthTronics, in pursuit of clinical trials for the Ablatherm device. Site selection is underway and patient enrollment is expected to begin in late third quarter.

### ***HIFU Division Manufacturing***

The HIFU division's policy is to subcontract the manufacture for its devices and accessories, including disposables. The HIFU division purchases all of the devices and accessories, including disposables used in its marketing and sales functions, from a single supplier, Technomed, part of the UDS division of the Company. It is the HIFU division's belief that, since its only supplier is also a subsidiary of the same parent, there is no significant risk associated with the use of a single supplier.

### ***HIFU Division Quality and Design Control***

The HIFU division has obtained the ISO 9001 (V2000) and ISO 13485 (V1996) certifications which indicate compliance with international standards for quality and design control.



### ***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 that approximately 230,110 new cases of prostate cancer were diagnosed in 2004 and that there will be approximately 232,090 new cases of prostate cancer diagnosed in 2005. 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 U.S. 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 indications, such as certain localized thyroid, breast, gynaecological, bladder, kidney, liver, brain, pancreatic and retroperitoneal tumors. However, the expansion of HIFU to other indications will require a significant investment in R&D by the Company, an investment which the Company will be undertaking 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 very seriously affect a patient's quality of life. One of the current therapies is radical prostatectomy, 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.

The HIFU division's devices compete with all current treatments for localized tumors, which include surgery, brachytherapy, radiotherapy, cryotherapy and hormone therapy. The HIFU division believes 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 held mainly by General Electric and Elbit Medical Imaging, has developed a device using HIFU technology to treat uterine fibroids. Finally, St. Jude Medical has developed a device using HIFU to treat atrial fibrillation. Certain existing and potential competitors of the HIFU division may have substantially greater financial, R&D, sales and marketing and personnel resources than the HIFU division or its parent and may have more experience in developing, manufacturing, marketing and supporting new products. The HIFU division believes that an important factor in the potential future market for HIFU treatments will be the ability to make the substantial investments in R&D 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 its own direct marketing and sales organization as well as through third-party distributors and agents. The HIFU division established direct marketing and sales forces in France, Germany, Russia and Italy, which currently represent EDAP's largest markets. The Company opened a direct representative office in Moscow to increase its penetration of this large, key market. Additionally, the HIFU division markets and sells its products through the Company's UDS division's distribution platform in South Korea and South East Asia and further markets its products through selected agents and third-party distributors in several countries. The Company finalized its partnership in the United States with HealthTronics in February 2004. HealthTronics is now responsible for U.S. clinical trials, and it has exclusive distribution rights in the United States for the Ablatherm, when and if it receives FDA approval.

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; however, if the partnership with HealthTronics is successful, HealthTronics could become a significant customer of the HIFU division in the future.

The HIFU division's marketing efforts include the organization of training programs for urologists worldwide and education of patients on the availability of HIFU technology to treat localized prostate cancer.

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

The UDS division consists of four wholly owned and fully consolidated subsidiaries of the Company: Technomed Medical Systems S.A. ( TMS ), a French corporation, EDAP Technomed Co. Ltd, a Japanese corporation, EDAP Technomed Sdn Bhd, a Malaysian corporation and EDAP Technomed Inc., a U.S. corporation. The UDS division also includes a South Korean branch office, Technomed Korea. The UDS division is engaged in the development, marketing, manufacturing and servicing of medical devices for the minimally invasive diagnosis or treatment of urological and other clinical indications. The UDS division had total revenues of 17.4 million during the fiscal year ended December 31, 2004.

#### ***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 urinary stones, thereby permitting their natural elimination and preventing the need for incisions, transfusions, general anaesthesia, and the resulting complications. The UDS division currently manufactures two models of lithotripters: the Sonolith Praktis, which is available for commercial distribution in the European Union, Japan, Canada and the United States, and the Sonolith Vision, which is available for commercial distribution in the European Union, Japan and Canada only. During 2002, the UDS division discontinued its production of the LT02 line of lithotripters. The UDS division had an installed base of 423 ESWL lithotripters worldwide as of March 31, 2005.

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, including the maintenance and services business of HIFU-related devices and accessories on behalf of the HIFU division. It also derives revenues from the distribution of Prostatron parts and related services, in Japan and Italy under the Distribution Agreement entered into with Urologix in October 2000.

Under the Supply Agreement entered into with Urologix in connection with the sale of the Company's Prostatron business in October 2000, the UDS division previously manufactured certain components of the Prostatron. Although the Supply Agreement expired in October 2003, the UDS division continued to manufacture machines on behalf of Urologix to produce the machines that had been ordered prior to the expiration of the Agreement. Once the final machines have been manufactured, the UDS division does not expect to generate any additional revenues from the supply of machines to Urologix. The UDS division expects to derive only a small amount of revenues related to the sales of Prostatron parts. The UDS division, as an additional part of its contract manufacturing business, manufactures HIFU-related devices and accessories, including disposables, on behalf of the HIFU division.



**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 and HIFU devices. The UDS division manufactures the Ablatherm and the disposable Ablapack on behalf of the HIFU division. All the costs related to the manufacturing of these machines are supported by the UDS division, which invoices the HIFU division at cost plus a margin and records the sales of the devices as revenues.

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. The UDS division believes that a combination of continued investment in lowering end-user costs and offering units that are easily adaptable to various treatment environments, and 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.* The UDS division believes that it can achieve additional long-term growth by offering its established distribution platform in urology to other developers of medical technologies and acting as a distributor for their devices. The UDS division's 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, the UDS division believes that it 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. The UDS division believes that its FDA-inspected and ISO 9001 (V2000) and ISO 13485 (V1996) certified facilities allow it 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 Vision is offered to large hospitals which 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><u>Product</u></b>	<b><u>Procedure</u></b>	<b><u>Development Stage</u></b>	<b><u>Clinical and Regulatory Status</u></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
Sonolith Vision	Electroconductive treatment of urinary stones	Commercial Production	Approved for distribution: European Union Japan Canada South Korea



The Sonolith Praktis and the Sonolith Vision 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, resulting in 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. In order 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, a fully dedicated and integrated electroconductive lithotripter for larger hospitals.

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

As of March 31, 2005, the UDS division's patent portfolio contained 17 patents (consisting of 7 in the United States, 8 in the European Union and Japan and 2 in Israel) covering key technologies relating to ESWL systems and associated software capabilities. During 2004, one patent older than 20 years expired in the United States, the European Union and Japan. This patent covered in-line imaging for lithotripsy. Four other patents covering obsolete technologies were abandoned in Europe and Japan. One patent covering a new technology for shockwave generation, which was previously obtained in France, has been also obtained in Europe.

The UDS division's patents in ESWL cover certain technologies relating to the association of a piezo-electric treatment head with an ultrasound imaging probe, as well as the electrodes for the Sonolith line. Following the settlement in 1989 of patent infringement actions against Richard Wolf GmbH and Disonics Inc., TMS granted both companies a non-exclusive license to use its patented technology. The related patent expired in 2004, and thus the corresponding license is no longer valid. The UDS division's ongoing research and development objectives in ESWL are to further increase the cost-effectiveness and clinical efficacy of its products.

#### ***UDS Division Regulatory Status***

The Sonolith Praktis is available for commercial distribution in the United States, Canada, the European Union and Japan. The Sonolith Vision is available for commercial distribution in the European Union, Canada and Japan. The UDS division continues to provide disposables, replacement parts and services for the current installed base of LT02 machines, even though the Company has discontinued the manufacture of these machines.

#### ***UDS Division Market Potential***

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. The UDS division believes 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. The UDS division believes 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.

The UDS division believes that companies with a large installed base of ESWL lithotripters will be most successful in the replacement market. Consequently, the Company intends to capitalize on its share of the installed base of ESWL lithotripters to gain a significant position in the replacement market for those machines. The Company expects 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 its own direct sales and service organization as well as through third-party distributors and agents. The UDS division has an established 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 countries. In December 2002, the UDS division closed its direct sales and service office in the United States. As of February 2004, HealthTronics has been appointed distributor in the United States for the Company's Sonolith Praktis lithotripters. As part of the Company's Agreement with HealthTronics related to their responsibility in obtaining the FDA approval for the Ablatherm device, HealthTronics is entitled to exercise part the warrants granted to them if they purchase a certain number of lithotripters per year.

The UDS division's customers are located worldwide and have historically been principally public and private hospitals and urology clinics. It believes that its 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 Manufacturing Services and Distribution***

The UDS division manufactures the Ablatherm on behalf of the HIFU division and Prostatron spare parts for Urologix. It believes that it can extend its outsourced services to provide device, disposable and software development and manufacturing services to a wide range of medical equipment development companies. The UDS division's current operations consist of custom design, development and manufacture of medical products and software development, in its manufacturing facility that is FDA-approved and certified under international standards ISO 9001 and ISO 13485.

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, and on behalf of the HIFU division in Malaysia and South Korea. The UDS division believes that it 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.

### ***UDS Division Manufacturing***

The UDS division's policy is to manufacture the critical components for its devices and accessories (unless a subcontractor can manufacture the component more cost-effectively) perform final assembly and quality control processes and maintain its own set of production standards. The UDS division purchases the majority of the raw materials used in its products from a number of suppliers, but for several components of its products, relies on a single source. The UDS division's policy is to conduct frequent quality audits of suppliers' manufacturing facilities. The UDS division's principal suppliers are located in France, Switzerland, Austria, the United Kingdom and the United States. Management believes that the relationships between the UDS division and its suppliers are good.

In addition, the manufacturing operations of TMS (a French corporation that is the primary manufacturing organization of the UDS division) must comply with the GMP regulations enacted by the FDA, which establish requirements for assuring quality by controlling components, processes and document tractability and retention, among other things. TMS's facilities are also subject to scheduled inspections by the FDA. TMS has obtained the ISO 9001 and ISO 13485 certifications, which indicate compliance by TMS's manufacturing facilities with international standards for quality assurance, design and manufacturing process control. TMS also complies with the applicable requirements that will allow it to affix the CE Marking to certain of its products. See Government Regulation Healthcare Regulation in the United States and Government Regulation Healthcare Regulation in the European Union.



## **Property, Plants and Equipment**

The Company has 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. The Company believes that the terms of the lease reflect commercial practice and market rates. The manufacturing facility, which the Company utilizes to manufacture and/or assemble all of its products, has ISO 9001 and ISO 13485 certifications. The Company is not aware of any environmental issues that could effect utilization of the facility.

In addition, the Company rents office and/or warehouse facilities in Kuala Lumpur (Malaysia), Rome (Italy), Moscow (Russia), Seoul (South Korea), Fukuoka, Osaka and Tokyo (Japan).

## **Government Regulation**

Government regulation in the Company's major markets, in particular the United States, the European Union and Japan, is a significant factor in the development and marketing of the Company's products and in the Company's ongoing research and development activities. The Company is principally subject to regulation of medical devices and of the healthcare system.

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

The Company and its 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 labeling, premarket notification (known as 510(k) ) and adherence to FDA-mandated GMP. Class II devices are those whose safety and effectiveness can reasonably be ensured through the use of special controls, such as performance standards, post-market surveillance, patient registries and FDA guidelines. Class III devices are those that must receive premarket approval ( PMA ) by the FDA to ensure their safety and effectiveness. Except for the lithotripsy range of products, which has been recently reclassified by the FDA as a Class II device, all of the Company's products are classified as Class III products. 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 IDE from the FDA prior to commencing human clinical trials in the United States in support of the PMA.

Advertising and promotional activities in the United States are subject to regulation by the FDA and, in certain instances, by the Federal Trade Commission. The FDC Act also regulates the Company's quality control and manufacturing procedures by requiring the Company to demonstrate and maintain compliance with current GMP regulations. The Company's 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, the Company has received the ISO 9001 (V2000) and ISO 13485 (V1996) certifications, showing that the Company complies with standards for quality assurance and manufacturing and design process control. In the European Union, the Company's 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 CE Marking. Except in limited circumstances, Member States 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 the Company's 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 which apply to medical devices in order 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 the Company 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 Japanese Pharmaceutical Affairs Law, two types of licenses are required for the import and sale of medical devices, a general license to engage in the import and sale of such devices by the importer and specific approvals for each device. The Company 's Japanese subsidiary has obtained a general license and has also obtained a specific approvals to import those of the Company 's products that are approved in Japan. The MHLW also administers various national health insurance programs to which each Japanese citizen is required to subscribe. These programs cover, inter alia, 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 5. Operating and Financial Review and Prospects**

The following discussion of the results of operations and liquidity and capital resources of the Company with respect to the fiscal years ended December 31, 2004, 2003 and 2002 is based on the Consolidated Financial Statements included elsewhere in this Annual Report and should be read in conjunction with the Consolidated Financial Statements. 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 Company 's discussion and analysis of its 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 the Company 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, the Company evaluates its estimates, including those related to revenue recognition, accounts receivable, bad debts, inventories, warranty obligations, litigation and deferred tax assets. The Company bases its estimates on historical experience and on various other assumptions that are believed to be reasonable under the circumstances, the results of which 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.

The Company believes its 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***

The Company recognizes revenues from the sale of equipment at the point where no significant vendor obligation, payment contingent upon customer financing or acceptance criteria that can be subjectively interpreted or tied to the use of the equipment exist, and when title to the machine passes (depending on the terms of the contract, either upon shipment or delivery) to the customer who has the intent and ability to pay in accordance within the fixed and determinable contract terms. For sales that do not immediately meet all of the criteria for recognition at the time of shipment or delivery (as the contract terms dictate) revenue is recognized when the contingency is resolved.

Revenues related to service and maintenance contracts are recognized when services are rendered. Billings or cash receipts in advance of service due under maintenance contracts are recorded as deferred revenue and are recognized in equal monthly installments over the course of the contract.

Revenues related to the leasing of devices are recognized on a linear basis. Revenues related to the sale of Ablatherm treatments invoiced on a charge-per-procedure ( CPP ) basis are recognized once the treatment has been completed.

### ***Warrants***

In accordance with EITF 96-18, the Company accounts for the warrants issued to HealthTronics under the distribution agreement based on their fair value measured at the date of milestone achievement. The related amount, which is a non-cash charge, is then recorded either as an operating expense (specifically, a clinical trial expense) for warrants that vest when HealthTronics achieves a milestone in the FDA approval process for the Ablatherm, or as a reduction of revenue if the warrants vest as a result of HealthTronics' s purchase of a specified number of lithotripters.

The Company uses the Black-Scholes options pricing model to determine the fair value of the warrants that vest pursuant to the distribution agreement. The model was developed to estimate the fair value of traded options that have no vesting restrictions and are fully transferable. 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 option and the risk-free interest rate of the warrants. A change in one or more of these assumptions could result in a material change to the fair value of the vested warrants.

### ***Warranty***

The Company provides for the estimated cost of equipment warranties, which are generally for a period of one year, in full at the time revenue from the equipment sale is recognized. While the Company engages in product quality programs and processes, its warranty obligation is affected by product failure rates, material usage and service delivery costs incurred in correcting a product failure. Should actual product failure rates, material usage or service delivery costs differ from the Company' s estimates, revisions to the provision for estimated warranty liability would be required.

### ***Accounts Receivable***

The Company generates a majority of its revenues and corresponding accounts receivable from sales of medical equipment, spare parts, maintenance and service to public and private hospitals and physicians worldwide. The Company performs initial credit evaluations of its customers and adjusts credit terms based upon customers' creditworthiness as determined by such things as their payment history, credit ratings and the Company' s historical experiences.

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

The Company evaluates the collectibility of its accounts receivable based on the individual circumstances of each customer on a quarterly basis. In circumstances where the Company is aware of a specific customer' s inability to meet its financial obligations to the Company (e.g., bankruptcy filings, substantial downgrading of credit scores), the Company records a specific reserve for bad debts against amounts due to reduce the net recognized receivable to the amount the Company reasonably believes it 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 the Company), the Company' s estimates of the recoverability of amounts due to it could be reduced by a material amount.



### ***Inventories***

On an annual basis, the Company analyses its inventories for obsolescence and upon identification of obsolete stock the Company records a full valuation reserve. Inventories are stated at the lower of costs, determined by the first-in, first-out ( FIFO ), or market. The Company's inventory valuation policy is based on a review of forecasted demand compared with existing inventory levels. At December 31, 2002, the Company determined that it had certain inventories that were in excess of its current requirements based on forecasted demand for these inventories. As a result, the Company recorded a reserve for inventory obsolescence of these inventories at December 31, 2002 with a charge of 0.6 million. At December 31, 2003, the Company determined that it had certain inventories that were not appropriately valued and therefore reserved 0.6 million against these inventories. At December 31, 2004, the Company determined that it had certain inventories that were not appropriately valued and therefore reserved 0.3 million against these inventories.

### ***Litigation***

The Company is currently a defendant in two legal proceedings, both of which are associated with product liability matters. During 2004, the Company settled a claim alleging a patient was injured during a Prostatron treatment procedure. The cost for settling this claim, \$0.5 million, was covered by the Company's product liability insurance. Additionally, in 2003, the Company settled one claim (at a cost that was not material to it) and was found not guilty on another claim alleging fraud related to the sale of medical equipment brought, separately, against two of its subsidiaries. The Company believes that the patients' claims in the product liability matters against the Company are without merit. In addition, if the claims against the Company are successful, the Company believes any potential damages assessed against it would be covered by insurance and/or by a contribution obligation of the physicians and/or the organization which provided services with the product. However, these product liability claims could have a material adverse impact on the Company. It is possible, moreover, that future results of operations for any particular quarterly or annual period could be materially affected by changes in its assumptions related to these proceedings. It is the policy of the Company, in the case of product liability litigation, to recognize the full amount of the self-insurance portion of the Company's product liability insurance, unless a separate indemnification is being sought.

### ***Deferred Tax Assets***

As of December 31, 2004, the Company had approximately 0.1 million of deferred tax assets principally related to 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 Company also has a history of operating loss carryforwards with various future expirations. However, it is the Company's policy to recognize a full valuation reserve against these deferred tax assets because the Company cannot be assured of future operating profits sufficient to utilize these assets before their expiration.

## **Operating Results**

### ***Overview***

Total revenues includes sales of the Company's medical devices and sales of disposables, spare parts, supplies and services, both net of commissions, as well as other revenues.

Net sales of medical devices has historically been comprised of net sales of Prostatrons, ESWL lithotripters and Ablatherms. With respect to lithotripter revenues, the Company books a non-cash charge as a reduction in revenue if the warrants it has granted to HealthTronics under the distribution agreement vest as a result of HealthTronics' purchase of a certain number of lithotripters. Net sales of lithotripters may therefore be reduced in the future by the vesting of warrants to HealthTronics upon the purchase of a specified number of lithotripters.

The sale price of the Company's 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.



The Company is developing its HIFU mobile treatment activity which enables it to provide access to the HIFU technology without an initial investment. Hospitals and clinics perform treatments using the devices and remunerate the Company on a charge-per-procedure ( CPP ) basis (i.e., on the basis of the number of individual treatments provided). Net sales of treatments from this mobile activity include only the revenues arising from the sale of Ablatherm treatments themselves. The treatment is invoiced and paid only when it is performed. With this business model, the hospital or clinic makes no initial investment until the increase in patient demand justifies the purchase of an Ablatherm. As a consequence, the Company is able to make Ablatherm treatments available to a larger number of hospitals and clinics, which 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 and, if successful, should lead to more purchases of Ablatherms in the long term.

Net sales of spare parts, supplies and services include revenues arising from maintenance services furnished by the Company for the installed base of Prostatrons, ESWL lithotripters and Ablatherms, and from sales of disposable parts for Prostatrons, ESWL lithotripters and Ablatherms, net of commissions, as well as from operating leases of the Company's medical devices and CPP revenue related to the HIFU mobile treatment activity.

The Company derives a significant portion of both net sales of medical devices and net sales of spare parts, supplies and services from its operations in Japan. Net sales of medical devices in Japan represented approximately 31.9% of such sales in 2004 and consisted primarily of sales of ESWL lithotripters. Net sales of spare parts, supplies and services in Japan represented approximately 25.8% of such sales in 2004 and related primarily to ESWL lithotripters, reflecting the fact that approximately 24.8% of the installed base of the Company's ESWL lithotripters is located in Japan. Sales in Japan are effected through EDAP Technomed Co. Ltd., the Company's wholly owned Japanese subsidiary.

The Company sells its products in many parts of the world and, as a result, the Company's business is affected by fluctuations in currency exchange rates. The Company is exposed to foreign currency exchange rate risk because the mix of currencies in which its costs are denominated is different from the mix of currencies in which it earns revenues. In 2004, approximately 70% of the Company's selling and general and administrative expenses and approximately 94% of the Company's research and development expenses were denominated in euro, while approximately 51% of the Company's sales were denominated in currencies other than euro (primarily the U.S. dollar and the Japanese yen). The Company's operating profitability could be materially affected by large fluctuations in the rate of exchange between the euro and such other currencies.

Other revenues consists principally of license fee and royalty payments from third parties with respect to the Company's intellectual property and operating subsidies from French governmental agencies. See Note 17 of the Notes to the Consolidated Financial Statements.

The principal elements of cost of sales have historically been salaries and wages, component and equipment costs and subcontracting costs. Also included in cost of sales are royalties paid to third parties on product sales.

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.

Operating expenses include research and development expenses, marketing, selling expenses, general and administrative expenses, depreciation and amortization and non-cash charges for impairment of long-lived assets.

In December 2003, the Company decided to restructure its organization and implemented a headcount reduction in 2004 in its two French operational divisions. This reorganization mainly entailed a reduction of operating expenses in R&D, marketing and manufacturing.

R&D 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. The Company does not capitalize any of its 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. These machines are amortized over a five-year period equivalent to the clinical trial period.

R&D expenses amounted to 1.5 million, 3.1 million and 3.2 million in 2004, 2003 and 2002, respectively, representing approximately 7%, 17% and 16% of total revenues in 2004, 2003 and 2002, respectively. The decrease in R&D in 2004 was primarily due to the suspension of funding on projects to expand the use of HIFU beyond the treatment of prostate cancer. Beginning 2005, management expects the budget for R&D expenses to increase to approximately 10% of total revenues, with the start of clinical trials in the U.S., in line with its strategy to launch new clinical studies, thus strengthening its clinical credibility, to focus its efforts on getting regulatory approvals and reimbursement in key countries and to fund projects to expand the use of HIFU beyond the treatment of prostate cancer. Because the Company books a non-cash charge as an operating expense (specifically, an R&D clinical trial expense) for warrants that vest when HealthTronics achieves a milestone in the FDA approval process for the Ablatherm, R&D expenses could be affected in the future by the vesting of the HealthTronics warrants.

Marketing expenses amounted to 0.7 million in 2004, 1.3 million in 2003 and 1.4 million in 2002. The decline of 42% from 2003 to 2004 was primarily due to the restructuring undertaken in December 2003. Management expects marketing expenses to grow in line with its efforts to increase awareness and educate patients and physicians on the availability of the Ablatherm-HIFU technology for treating localized prostate cancer.

In 2004, the Company recorded a non-recurring operating expense of 0.3 million reflecting mainly the costs associated with the reduction of headcount initiated in 2003. In 2003, the Company recorded a non-recurring operating expense of 2.1 million reflecting mainly the costs associated with the reduction of headcount at the Company's two French operating divisions. In 2002, the Company recorded a non-recurring operating expense of 1.2 million reflecting mainly the costs associated with restructuring the Company into two separate operating units. See Note 18 of the Notes to the Consolidated Financial Statements.

In accordance with Statement of Financial Accounting Standards No. 142 (SFAS No. 142), *Goodwill and Other Intangible Assets*, the Company no longer amortizes its goodwill on a straight line basis over its estimated useful life but, instead, tests it for impairment on an annual basis and/or whenever indicators of impairment arise. The Company did not record any charge in 2002, 2003 or 2004 for the impairment of goodwill. See Note 7 of the Notes to the Consolidated Financial Statements.

On February 25, 2004, the Company entered into a distribution agreement with HealthTronics granting it, among other things, (i) the right to begin clinical trials in the U.S. with the Ablatherm, (ii) the right to seek PMA for the Ablatherm from the FDA and (iii) exclusive Ablatherm distribution rights in the United States, when and if a PMA is granted. Under the terms of the distribution agreement, the Company also granted HealthTronics 1 million warrants on January 28, 2005, each which will entitle HealthTronics to purchase a share of the Company at a price of U.S.\$1.50 upon their vesting. The distribution agreement allows HealthTronics to exercise specified numbers of warrants as it meets various specified milestones set out in the distribution agreement, some of which relate to HealthTronics's commitment to purchase a specified number of lithotripter units and others which relate to the completion of various stages of the clinical trials and the regulatory process leading to the PMA for the Ablatherm. In accordance with EITF 96-18, the Company accounts for the warrants issued to HealthTronics under the distribution agreement based on their fair value, measured at the date that the warrants vest (which corresponds to the date that a milestone in the distribution agreement is achieved). The related amount, which is a non-cash charge, is then recorded either as an operating expense for warrants that vest when HealthTronics achieves a milestone in the FDA approval process for the Ablatherm, or as a reduction of revenue if the warrants vest as a result of HealthTronics's purchase of a specified number of lithotripters. The non-cash charge recorded for 2004 as a reduction of revenue related to a series of warrants linked to HealthTronics's purchase of four lithotripters in 2004, in accordance with the terms of the agreement.

The Company has no control over the pace at which HealthTronics may achieve the milestones set forth in the distribution agreement and, consequently, the dates on which the warrants may vest. Because the fair valuation of the warrants is based in part on the price of the Company's Shares on a given vesting date, and further because the number of warrants issued to HealthTronics represents a significant portion of the Company's share capital, the amount of the non-cash charges that may be recorded when series of warrants vest could be large and subject to significant variation from period to period. Accounting for the cost of vested warrants may therefore significantly affect the Company's reported income statements.

For the last several years, the Company experienced declining sale prices in the market for ESWL lithotripters. The Company believes 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. In addition, the trend toward more compact devices with lower unit sale prices is driving down unit sale prices worldwide. As a result of these factors, the Company expects 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.

The Company believes that its results of operations in the near future will be affected by the Company's ability to control expenses in connection with the development, marketing and commercial launch of HIFU applications, including the Ablatherm. See Liquidity and Capital Resources. Increases, if any, in expenses may only be offset partially in the near future by revenues arising from sales of HIFU devices.

The Company believes that its partnership with HealthTronics will facilitate the penetration of the U.S. lithotripsy market and will help in further expanding its market share in placing Ablatherm devices in the U.S., when and if the PMA is granted.

See Item 3, Key Information Risk Factors Risk of Exchange Rate Fluctuations and Item 11, Quantitative and Qualitative Disclosures About Market Risk for a description of the impact of foreign currency fluctuations on the Company.

In October 2000, the Company sold its Prostatron business to Urologix. See Item 4, Information on the Company. Historically the Company has derived a significant proportion of net sales of medical devices and net sales of spare parts, supplies and services from its Prostatron business. Following the sale of the Prostatron business, the Company continued to generate revenues from the manufacturing and distribution of Prostatron units and disposable parts on behalf of Urologix under the Supply Agreement and the Distribution Agreement, although significantly less than before the sale. Revenues from sales under the Supply Agreement and the Distribution Agreement represented 2.1 million, or approximately 10% of total revenues, in 2002, further decreasing in 2003 to 0.4 million or approximately 2% of total revenues and in 2004, to 0.2 million or approximately 1% of total revenues. The Supply Agreement terminated in 2003.

#### **Fiscal Year Ended December 31, 2004 Compared to Fiscal Year Ended December 31, 2003**

*Total revenues.* The Company's total revenues increased 20.0% from 18.5 million in 2003 to 22.2 million in 2004, principally due to a 2.5 times revenue increase in the HIFU division, despite the strength of the euro during the year, which reduced the value of sales denominated in other currencies, mainly the Japanese yen and the U.S. dollar, once converted into euro.

*HIFU division.* The HIFU division's total revenues increased 136% from 3.0 million in 2003 to 7.0 million in 2004 (including 0.3 million and 0.1 million of internal segment revenues in 2003 and 2004, respectively), principally due to an increase in the number of Ablatherm units sold and a progression in its Ablatherm mobile activity.

The HIFU division's net sales of medical devices increased approximately 3.5 times, from 1.1 million in 2003 to 4.0 million in 2004, with 9 Ablatherm units sold in 2004 versus 3 in 2003.

Net sales of CPPs directly related to the Company's HIFU mobile activity increased 153%, from 0.6 million in 2003 to 1.4 million in 2004. This is primarily due to the Company's 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. Net sales of HIFU-related spare parts, supplies, leasing and services increased 31% from 1.2 million in 2003 to 1.5 million in 2004.

Other HIFU-related revenue decreased 66% from 99 thousand in 2003 to 34 thousand in 2004, primarily related to an decrease in subsidies received.

*UDS division.* The UDS division's total revenues were stable at 17.5 million in 2003 compared to 17.4 million in 2004 (including 0.2 million related to the recognition of the expenses associated with the warrants issued to HealthTronics and 2.0 million and 1.9 million of internal segment revenues in 2003 and 2004, respectively).

The UDS division's net sales of medical devices increased 8% from 7.4 million in 2003 to 8.0 million in 2004 (which more than offset a 174,000 reduction in revenue reflecting the impact of the warrants), primarily due to an increase in the number of units sold in 2004 compared to 2003. The increase in the number of units sold in 2004 resulted principally from the Company's aggressive marketing strategy to take market share in Asia and Europe and its increased penetration of the U.S. market via its partner HealthTronics.





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Net sales of UDS-related spare parts, supplies and services decreased 6% from 7.8 million in 2003 to 7.3 million in 2004, primarily related to a decrease in annual service contract revenue, as most units in the installed base were still under warranty after the replacement of older machines with new machines. The decrease was also due to the replacement of high cost service contracts for LT02 lithotriptors, which yielded higher revenues, by lower cost, lower revenue, service contracts for the new Sonolith device line. See Operating Results Overview.

Other UDS-related revenue decreased 49% from 342 thousand in 2003 to 174 thousand in 2004, primarily related to an accounting of an insurance reimbursement in 2003.

*Cost of sales.* Cost of sales, increased 4.4% from 13.1 million in 2003 to 13.7 million in 2004, but as a percentage of net sales decreased from 73% in 2003 to 62% in 2004, primarily due to the cost reduction program initiated in 2003 and the increase in net sales in 2004 compared with 2003

*Operating expenses.* Operating expenses decreased 31% from 13.5 million in 2003 (including a 2.1 million one-time charge related to the restructuring) to 9.3 million in 2004. This decrease in operating expenses was mainly due to the restructuring of the Company's two operating divisions initiated at the end of 2003. See Note 18 of the Notes to the Consolidated Financial Statements.

HIFU division R&D expenses decreased 68% from 1.5 million in 2003 to 0.5 million in 2004, as a result of the restructuring of the HIFU division initiated at the end of 2003. R&D spending is primarily related to ongoing research into HIFU technologies. The Company anticipates these expenses will increase in the future to fund projects to expand the use of HIFU beyond the treatment of prostate cancer. See Operating Results Overview.

UDS division R&D expenses remained stable at 0.3 million in 2003 and 2004 See Operating Results Overview.

HIFU division clinical trial expenses decreased 50% from 0.7 million in 2003 to 0.3 in 2004, as a result of the restructuring of the HIFU division initiated at the end of 2003. The Company anticipates these expenses will increase in the future, in line with its strategy to launch new clinical studies, thus strengthening its clinical credibility and focusing its efforts on getting regulatory approvals and reimbursement in key countries.

HIFU division marketing expenses decreased 70% from 0.9 million in 2003 to 0.3 million in 2004, as a result of the restructuring of the HIFU division initiated at the end of 2003. The Company anticipates these expenses will increase in the future as part of its effort to increase awareness and educate patients and physicians on the availability of the Ablatherm-HIFU technology for treating localized prostate cancer. See Operating Results Overview.

HIFU division selling expenses decreased 8% from 1.1 million in 2003 to 1.0 million in 2004, as a result of the restructuring of the HIFU division initiated at the end of 2003. As a percentage of net sales, HIFU division related selling expenses decreased from 38% in 2003 to 14% in 2004.

UDS division selling expenses decreased 11% from 1.9 million in 2003 to 1.7 million in 2004., primarily due to continued control of expenses. The Company anticipates that these expenses will remain stable in the future. As a percentage of net sales, selling expenses decreased from 12% in 2003 to 10% in 2004.

General and administrative expenses, at the consolidated level, decreased 4% from 4.1 million in 2003 to 4.0 million in 2004. As a percentage of net sales, general and administrative expenses decreased from 23% in 2003 to 18% in 2004. The holding company continues to manage these expenses so that the expenses at each of the divisions remain consistent with the business and revenue levels of each segment.

*Operating loss.* As a result of the factors discussed above, the Company realized an operating loss of 0.8 million in 2004, as compared to an operating loss of 8.1 million in 2003.

The Company realized an operating profit in its HIFU division of 0.4 million in 2004, as compared to an operating loss of 5.8 million in 2003 and an operating profit in its UDS division of 0.2 million, as compared to operating loss of 0.7 million in 2003.

*Interest income (expense), net.* Interest income (expense), net decreased to income of 0.1 million in 2004 compared to an income of 0.2 million in 2003, reflecting lower interest income received by the Company on its short-term cash investment due to lower cash balances and lower interest rates during the year.



*Currency exchange gains, net.* Net currency exchange gains increased from a loss of 0.9 million in 2003 to a loss of 38,000 in 2004.

*Other income, net.* Other income, net decreased to a loss of 0.1 million in 2004 compared to 0.2 million in 2003.

*Income taxes.* The Company recorded a corporate income tax benefit of 0.3 million in 2004, principally reflecting income tax with respect to the results of various subsidiaries and an exceptional exit tax in France of 2.5% (which was enacted in compensation for the mandatory reclassification as equity of the capital gains tax on participation). The Company has booked a deferred tax liability amounting 161,000 related to this exit tax, which will be paid in two equal installments in 2006 and 2007, pursuant to the Amended Finance Law of 2004, dated December 30, 2004.

*Net income.* The Company realized consolidated net loss of 1.2 million in 2004 compared with consolidated net loss of 9.0 million in 2003, as a result of the factors mentioned above.

### **Fiscal Year Ended December 31, 2003 Compared to Fiscal Year Ended December 31, 2002**

*Total revenues.* The Company's total revenues decreased 7.5% from 20.0 million in 2002 to 18.5 million in 2003, principally due to a decrease in the average selling price of those Ablatherm units sold, a decrease in the average selling price of those lithotripsy units sold, and the strength of the euro during the year, which reduced the value of sales denominated in other currencies once converted into euro.

*HIFU division.* The HIFU division's total revenues decreased 11.8% from 3.4 million in 2002 to 3.0 million in 2003 (including 0.3 million and 0.1 million of internal segment revenues in 2002 and 2003, respectively), principally due to a decrease in the number of Ablatherm units sold.

The HIFU division's net sales of medical devices decreased 42.1% from 1.9 million in 2002 to 1.1 million in 2003, primarily due to the fact that the HIFU division was unable to sell any Ablatherm units in the second half of 2003.

Net sales of HIFU-related spare parts, supplies and services increased 41.7% from 1.2 million in 2002 to 1.7 million in 2003, primarily due to a 34% increase in the number of patients treated and an increase in services provided on the division's increased installed base.

Other HIFU-related revenue increased 182.9% from 35 thousand in 2002 to 99 thousand in 2003, primarily related to an increase in subsidies received.

*UDS division.* The UDS division's total revenues decreased 5.1% from 18.4 million in 2002 to 17.5 (including 1.6 million and 2.0 million of internal segment revenues in 2002 and 2003, respectively), principally due to the decrease in the average sales price of lithotripsy units in 2003 compared to 2002, partially offset by an increase in the number of units sold. Decreases in revenues were also related to the strength of the euro during 2003, which reduced the value of sales denominated in other currencies once converted into euro.

The UDS division's net sales of medical devices decreased 13.2% from 8.5 million in 2002 to 7.4 million in 2003, primarily due to a decrease in the average sales price of lithotripsy units in 2003 compared to 2002, partially offset by an increase in the number of units sold, and a decrease of 77% in the number of Prostatron units sold to Urologix in 2003 compared to 2002. Decreases in revenues were also related to the strength of the euro during 2003, which reduced the value of sales denominated in other currencies once converted into euro. The increase in the number of lithotripters sold in 2003 resulted principally from the continued successful penetration of the Japanese market with the Company's Sonolith Praktis, a compact lithotripter launched in the European Union in October 1998. The decrease in the number of units sold to Urologix during 2003 under the Supply Agreement was a result of a lower total number of orders from Urologix during the year and the expiration of the Supply Agreement during the year.

Net sales of UDS-related spare parts, supplies and services decreased 4.3% from 8.2 million in 2002 to 7.8 million in 2003, primarily related to a decrease in annual service contract revenue, as most units in the installed base were still under warranty after the replacement of older machines with new machines, and due to the strength of the euro during 2003, which reduced the value of sales denominated in other currencies once converted into euro. A substantial portion of the UDS division's maintenance services are derived from its Japanese operations. See Operating Results Overview.

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Other UDS-related revenue increased 70.1% from 201 thousand in 2002 to 342 thousand in 2003, primarily related to an increase in royalties received. See Note 1-4 of the Notes to the Consolidated Financial Statements.

*Cost of sales.* Cost of sales increased 13.8% from 11.5 million in 2002 to 13.1 million in 2003, and as a percentage of net sales increased from 58.3% in 2002 to 72.6% in 2003, due to a decrease in gross margin on sales of ESWL lithotripters, as the Company needed to sell more units at the lower average sales prices to keep revenues stable, fewer sales of higher-margin Ablatherms and, a charge against inventory valuation in the fourth quarter of 2003, due to a revaluation of work-in-progress inventories into finished goods inventories and cost of sales.

*Operating expenses.* Operating expenses increased 2.0% from 13.2 million in 2002 to 13.5 million in 2003, mainly due to 2.1 million in one-time charges related to the restructuring of the Company's two operating divisions at the end of 2003 and as further described, by division, below. See Note 18 of the Notes to the Consolidated Financial Statements.

HIFU division R&D expenses remained at 1.5 million in 2002 and 2003. R&D spending is primarily related to ongoing research into HIFU technologies. The Company anticipates these expenses will decrease in the future as a result of the restructuring of the HIFU division at the end of 2003. See Operating Results Overview.

UDS division R&D expenses decreased 17.4% from 0.4 million in 2002 to 0.3 million in 2003. This decrease is primarily due to the termination of research and development projects related to TUMT. The remaining expenses were related to the continued research and development of ESWL technologies. The Company anticipates these expenses will remain consistent in the future. See Operating Results Overview.

HIFU division selling expenses increased 44.4% from 0.7 million in 2002 to 1.1 million in 2003, primarily due to the increase in sales activities after the commercialization of the division's primary product, the Ablatherm, in the European Union. The Company anticipates that these expenses will decrease in the future as a result of the restructuring of the HIFU division at the end of 2003 and the mandate to focus on current markets. As a percentage of net sales, HIFU division related selling expenses increased from 24.3% in 2002 to 37.8% in 2003.

UDS division selling expenses decreased 5.7% from 2.0 million in 2002 to 1.9 million in 2003, primarily due to continued control of expenses. The Company anticipates that these expenses will remain consistent in the future. As a percentage of net sales, selling expenses decreased from 13.4% in 2002 to 12.4% in 2003.

General and administrative expenses, at the consolidated level, decreased 11.1% from 4.6 million in 2002 to 4.1 million in 2003, mainly as a result of continued cost cutting measures. As a percentage of net sales, general and administrative expenses decreased from 23.6% in 2002 to 22.9% in 2003. The holding company continues to manage these expenses so that the expenses at each of the divisions remain consistent with the business and revenue levels of each segment.

*Operating loss.* As a result of the factors discussed above, the Company realized an operating loss of 8.1 million in 2003, as compared to an operating loss of 4.8 million in 2002.

As a result of the factors discussed above, the Company realized an operating loss in its HIFU division of 5.8 million in 2003, as compared to an operating loss of 3.4 million in 2002 and realized an operating loss in its UDS division of 0.7 million in 2003, as compared to operating income of 0.6 million in 2002.

*Interest income (expense), net.* Interest income (expense), net decreased to income of 0.2 million in 2003 compared to an income of 0.5 million in 2002, reflecting lower interest income received by the Company on its short-term cash investment due to lower cash balances and lower interest rates during the year.

*Currency exchange gains, net.* Net currency exchange gains increased from a loss of 1.0 million in 2002 to a loss of 0.9 million in 2003, reflecting the continued weakness of the U.S. dollar and the Japanese yen against the euro in 2003.

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*Other income, net.* Other income, net decreased to a loss of 0.2 million in 2003 compared to 1.5 million in 2002. The loss in 2003 was attributable to net losses incurred on the sale of Urologix common stock received as part of the sale of the Prostatron business in 2000. The decrease between 2002 and 2003 was primarily due to a decrease in value of the common shares of Urologix, Inc. on the open market.

*Income taxes.* The Company recorded a corporate income tax benefit of 0.1 million in 2003, principally reflecting the variation in the deferred tax assets between December 31, 2002 and December 31, 2003.

*Net income.* The Company realized consolidated net loss of 9.0 million in 2003 compared with consolidated net loss of 4.0 million in 2002, as a result of the factors mentioned above.

### **Effect of Inflation**

Management believes that the impact of inflation was not material to the Company's net sales or income from operations in the three years ended December 31, 2004.

### **Liquidity and Capital Resources**

The Company's 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 which were not necessarily indicative of changes in the Company's business. The Company believes its working capital is sufficient for its present working capital requirements, although it has in the past experienced, and may in the future experience, negative cash flows and associated risks to liquidity. The Company's negative cash flow situation, and management's plans to address it, are described in more detail below.

The Company anticipates that cash flow in future periods will be mainly derived from ongoing operations and the collection of current receivables. The Company does not have any commercial commitments nor does it employ any off-balance sheet financing. Because the Company anticipates relying principally on cash flow from operating activities and cash and cash flow equivalent balances to meet its liquidity requirements, a decrease in the demand for the Company's products, or the inability of the Company's customers to meet their financial obligations to the Company due to operating difficulties or adverse market conditions, would reduce the availability of funds to the Company.

Cash position as of December 31, 2004, 2003 and 2002, was 9.4 million, 10.4 million and 15.7 million respectively. In 2004, 2003 and 2002, the Company's cash flow was negative due to the cash requirements of operating activities, which the Company financed using cash and cash equivalents on hand. As a result of two consecutive years of significant negative cash flow ( 5.3 million in 2003 and 3.6 million in 2002) and the associated risks to liquidity, the Company performed an extensive review of its businesses in 2003, in the face of the prevailing economic situation and with the goal of maintaining the competitiveness of the Company. The Company believes that it has sufficiently reduced the risk of future illiquidity in the near term and continues to monitor its liquidity in order to determine what future risks may occur.

In 2004, net cash used in operating activities was 1.1 million, compared with net cash used in operating activities of 3.6 million and 8.0 million in 2003 and 2002, respectively. In 2004, net cash used in operating activities reflected principally:

- a net loss of 1.2 million;

- a decrease in inventories of 2.3 million related to both a reduction of the inventory of finished goods and work-in-progress and the retirement of previously depreciated spare parts assets;

- a decrease in trade accounts payable of 0.4 million and;

- a decrease in accrued expenses and other current liabilities of 1.9 million, primarily related to severance packages linked to the restructuring that took place at the end of 2003.

In 2003, net cash used in operating activities reflected principally a net loss of 9.0 million, elimination of 0.8 million of expenses and benefits without effects on cash, a decrease in trade accounts receivable of 3.1 million, a decrease in inventories of 1.1 million, a decrease in trade accounts payable of 1.0 million and an increase in accrued expenses and other current liabilities of 1.4 million. In 2002, net cash used in operating activities reflected principally a net loss of 4.0 million, the elimination of 0.6 million of expenses and benefits without effects on cash, an increase in trade accounts receivable of 0.3 million, a decrease in inventories of 0.4 million, a decrease in trade accounts payable of 1.4

million and a decrease in accrued expenses and other current liabilities of 1.2 million.

In 2004, there was no net cash used in investing activities, compared with 0.5 million in 2003 and net cash provided by investing activities of 5.1 million in 2002. During 2004, net cash flow used in investing activities reflected principally an increased investment of 0.8 million in capitalized assets produced by the Company, net proceeds from sales of capitalized assets produced by the Company for 0.7 million, an investment of 0.2 million in property, plant and equipment, net proceeds from sales of lease-back assets for 0.3 million and a decrease in financial assets for 0.1 million. In 2003, net cash used in investing activities reflected principally an increased investment of 0.8 million in capitalized assets produced by the Company, an investment of 0.4 million in property, plant, equipment, net proceeds from sales of lease-back assets for 0.3 million and a decrease in financial assets for 0.4 million. In 2002, net cash provided by investing activities reflected principally net proceeds from the sale of Urologix common stock of 5.5 million, a decrease of 0.9 million in restricted cash equivalents and an investment of 1.5 million in property, plant, equipment, the acquisition of intangible assets and capitalized assets produced by the Company.

In 2004, net cash used in financing activities was 0.1 million, reflecting mainly repayment of capital lease obligations totaling 0.3 million, an increase in short term borrowing of 0.3 million, and long-term debt repayment for 0.1 million. In 2003, net cash used in financing activities was 0.7 million, reflecting mainly scheduled long term debt repayment totaling 0.4 million, a decrease in short-term borrowings of 0.2 million and repayments of obligations under a capital lease totaling 0.1 million. In 2002, net cash used in financing activities was 0.3 million, reflecting mainly scheduled long-term debt repayment totaling 0.6 million, scheduled payments made under capital leases totaling 0.3 million and offset by an increase in short-term borrowings totaling 0.7 million.

The Company anticipates that cash flows from operations, together with its current cash balances, will provide it with sufficient resources to meet its expenditure requirements for approximately three years. The Company's expectation that cash flows from operations, together with its current cash and cash equivalent balances, will sustain the Company into the future and that significant negative cash flow will not continue are based on the extensive review of the businesses conducted by the Company at the end of 2003. The Company continues to review its business to ensure that it will continue to have enough liquidity to meet its goals, but to the extent that the Company is unsuccessful, if any opportunities for the sale of non-strategic assets become available, the Company may seek to exploit those opportunities in order to obtain liquidity.

The Company's future cash flow may also be affected to the extent the Company decides to continue to expand the leasing of its products and to grow its mobile CPP business. In 1999, in an effort to increase the availability of its equipment, the Company implemented a new marketing strategy of leasing its medical devices on a monthly, quarterly or yearly basis, rather than selling them directly to end-users, and in 2002, the Company began to develop its mobile activity by making certain devices available to hospitals and clinics, charging them on the basis of each procedure that was performed. Relative to the sale of devices, these business models initially generate smaller, but more predictable cash flows. The Company anticipates continuing to make these options available.

It is the policy of the Company that its treasury function should maintain the liquidity of the Company without the expectation of future outside funding, except for the use of short-term borrowing options and the minimal use of long-term borrowing options. The treasury function currently adheres to this objective with the use of fixed-rate debt, which normally consists of short-term borrowing from a Japanese bank and with certain long-term options primarily consisting of promissory notes and sale-leaseback equipment financing. Currently the majority of the Company's short-term and long-term debt is at fixed interest rates. The Company maintains bank accounts, at each of its subsidiaries, in the local currencies of each subsidiary. The primary currencies in which the Company maintains balances are the euro, the U.S. dollar and the Japanese yen. In order to minimize the Company's exposure to exchange rate risks, the Company uses certain financial instruments for hedging purposes. As of March 31, 2005, the Company had seven foreign exchange sale contracts, four for the Japanese yen and three for the U.S. dollar.

	Payments Due by Period				After 5 years
	Total	Less than 1 year	1-3 years	4-5 years	
Short-Term Debt	525	525			
Long-Term Debt	6	6			
Capital Lease Obligations	998	334	552	111	
Operating Leases	1,050	350	700		

## New Accounting Pronouncements

On December 16, 2004, the Financial Accounting Standards Board (FASB) issued FASB Statement No. 123 (revised 2004), *Share-Based Payment*, which is a revision of FASB Statement No. 123, *Accounting for Stock-Based Compensation*. Statement 123(R) supersedes APB Opinion No. 25, *Accounting for Stock Issued to Employees*, and amends FASB Statement No. 95, *Statement of Cash Flows*. Generally, the approach in Statement 123(R) is similar to the approach described in Statement 123. However, Statement 123(R) *requires* all share-based payments to employees of the Company, including grants of employee stock options, to be recognized in the income statement based on their fair values. Pro forma disclosure is no longer an alternative.

Statement 123(R) must be adopted no later than the first fiscal year beginning after June 15, 2005. Early adoption will be permitted in periods in which financial statements have not yet been issued. The Company expects to adopt Statement 123(R) as of January 1, 2005, and the performance stock plan approved by the shareholders in February 2005 will be booked in accordance with the dispositions of FASB 123(R).

Statement 123(R) permits public companies to adopt its requirements using one of two methods:

1. A modified prospective method, in which compensation cost is recognized beginning with the effective date (a) based on the requirements of Statement 123(R) for all share-based payments granted after the effective date and (b) based on the requirements of Statement 123 for all awards granted to employees prior to the effective date of Statement 123(R) that remain unvested on the effective date.
2. A modified retrospective method, which includes the requirements of the modified prospective method described above, but also permits entities to restate based on the amounts previously recognized under Statement 123 for purposes of pro forma disclosures either (a) all prior periods presented or (b) prior interim periods of the year of adoption.

The Company plans to adopt Statement 123 using the modified prospective method.

As permitted by Statement 123, the Company currently accounts for share-based payments to employees using Opinion 25's intrinsic value method and, as such, generally recognizes no compensation cost for employee stock options. Accordingly, the adoption of Statement 123(R)'s fair value method will have a significant impact on the Company's result of operations, although it will have no impact on the Company's overall financial position. The impact of the adoption of Statement 123(R) cannot be predicted at this time because it will depend on levels of share-based payments granted in the future. However, had the Company adopted Statement 123(R) in prior periods, the impact of that standard would have approximated the impact of the application of the principles in Statement 123.

## Research and Development, Patents and Licenses

See 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**

The Company has 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 Senior Executive Officer of the Company. Each of the persons listed below has entered into an employment contract with the Company or its subsidiaries (which permits 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.

<u>Name</u>	<u>Age</u>	<u>Position</u>
Philippe Chauveau	69	Chairman of the Board of Directors
Hugues de Bantel	35	Chief Executive Officer of EDAP TMS S.A. and President of the HIFU Division and the UDS Division
Thierry Turbant	44	Chief Financial Officer
Philippe Chauveau		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. Since 2002, Philippe Chauveau has also served as 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 in Switzerland. He was R&D Vice-President 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 BA. and a Bsc.
Hugues de Bantel		Hugues de Bantel joined the Company in 1996, and since then has served as Asia Pacific Area Manager and Manager of EDAP Technomed Malaysia from its founding in 1997 and, since April 2000 as President of EDAP Technomed Japan. He was appointed President of TMS S.A. on November 6, 2002, and President of EDAP S.A. on November 13, 2003. Prior to joining EDAP Technomed, Mr. de Bantel was Sales Manager for Europe and Asia at AFE's Lifts Division. He previously worked at Procter & Gamble as Area Sales Manager. Mr. de Bantel graduated from Ecole Superieure de Commerce, Rouen (France).
Thierry Turbant		Thierry Turbant was appointed Chief Financial Officer of the Company on July 1, 2004. He joined the Company in 1997, and since then has served as Group Financial Controller. Prior to joining the Company, Mr. Turbant was Accounting Manager and Controller at Gatefosse, specialized in Pharmaceutical and Cosmetic Products. He previously worked at EGL and at Clemessy (Civil Engineering) as a Controller. Mr. Turbant graduated from the Business and Management Institute (IAE) at Lyon University (France).

## Board of Directors

The following table sets forth the names of the members of the Board of Directors and the background of the members of the Board of Directors who are individuals. The mandate for each member of the Board of Directors expires on the date of the assembly meeting of shareholders approving the financial results for fiscal year 2007.

<p>Pierre Beysson Age: 63</p>	<p>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 in a number of boards of companies related to the Accor Group. He is now an M&amp;A consultant. Prior to 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). His background also includes Industrial Project &amp; Distribution Network Management with Computervision (Computer Aided Design) and Customer Service &amp; Distribution Network Management with Siemens-Nixdorf International. Pierre Beysson was trained as a CPA, has auditing experience and holds an MBA from Harvard Business School.</p>
<p>Karim Fizazi Age: 39</p>	<p>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 (IGR) in Villejuif, France, which is the biggest cancer center in Europe. He is also Assistant Professor in Medical Oncology at IGR. 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.</p>
<p>Olivier Missoffe Age: 48</p>	<p>Olivier Missoffe was appointed as a member of the Company's Board of Directors in November 2002. He is Chairman and CEO of Société Services de Santé (SSS), a services and support provider to hospitals and clinics. He is an advisor to the Management Board of the French healthcare group Générale de Santé. He was Chief Executive Officer of the Company until 1998.</p>
<p>Siemens France S.A., represented by Holger Schmidt Age: 39</p>	<p>Siemens France S.A. was appointed as a member of the Company's Supervisory Board in January 1997 and became a member of the Company's Board of Directors in July 2002.</p>
<p>Guy Vallancien Age: 58</p>	<p>Dr. Guy Vallancien was appointed as a member of the Company's Board of Directors in November 2002. He is Professor of Urology and Chief of the Urology Department at the Institut Mutualiste Montsouris (Paris, France). He is a member of the Executive Committee of the French Urological Association (AFU) and a member of the European and International Urological Association.</p>

## Compensation and Options

On December 17, 2002, the Board of Directors decided that the whole Board of Directors will act as a Compensation Committee to review the compensation of the Company's Senior Executive Officers and to propose any changes to compensation to the Board of Directors, which under French law is the competent body to approve any such change. On March 30, 2005, the Board of Directors decided to review the composition of the Compensation Committee and nominated three members out of the six Directors Mr. Olivier Missoffe, Mr. Pierre Beysson and Mr. Philippe Chauveau, to act as the Compensation Committee. Mr. Philippe Chauveau was elected Chairman of the Compensation Committee. During that meeting, the Board of Directors approved an updated version of the charter of the Compensation Committee. 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 2004 was approximately 0.4 million. No amount was set aside or accrued by the Company 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 2004.

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 options 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 options is equivalent to the higher of either (a) the share value of the capital of each company or (b) the net account 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 options allow today's President of both 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 subscription options granted, if exercised, would represent 3.5% and 2.5% of the respective share capital of TMS S.A. and EDAP S.A. after subscription. These options begin vesting three years after their date of grant, but can be exercised earlier in the event of a change in control of the relevant company. These options to subscribe to shares expire on the earlier of December 18, 2007 or when employment with the Company ceases.

As of December 31, 2004, Senior Executive Officers held an aggregate of 146,000 options to purchase or to subscribe to shares of the Company's common stock, with a weighted average exercise price of 1.69. Of these options, 9,000 expire on December 31, 2008, 24,000 expire on September 25, 2011 and 113,000 expire on February 24, 2014.

#### **Audit Committee**

On December 17, 2002, the Board of Directors decided that the whole Board of Directors will act as an Audit Committee headed by Mr. Pierre Beysson to, among other things, review the Company's annual and interim reports and accounts and monitor the Company's auditors involvement in that process. The ultimate responsibility for reviewing the Company's annual and interim accounts lies with the Board of Directors. On March 30, 2005, the Board of Directors approved an updated version of the Audit Committee Charter.

#### **Employees**

As of December 31, 2002, the Company employed 150 individuals on a full-time basis, of whom 30 were employed in sales and marketing, 26 in manufacturing, 37 in service, 16 in R&D, 9 in regulatory, 4 in clinical affairs and 28 in administration. Of the Company's employees, 104 were located in France, 30 in Japan, 1 in the United States, 7 in Malaysia, 6 in Italy and 2 in South Korea.

As of December 31, 2003, the Company employed 148 individuals on a full-time basis, of whom 31 were employed in sales and marketing, 26 in manufacturing, 41 in service, 14 in R&D, 6 in regulatory, 4 in clinical affairs and 26 in administration. Of the Company's employees, 102 were located in France, 30 in Japan, 1 in the United States, 7 in Malaysia, 6 in Italy and 2 in South Korea. The restructuring of the French operating divisions was approved as of December 31, 2003 and was implemented in 2004.

As of December 31, 2004, the Company employed 122 individuals on a full-time basis, of whom 26 were employed in sales and marketing, 21 in manufacturing, 38 in service, 8 in R&D, 5 in regulatory, 1 in clinical affairs and 23 in administration. Of the Company's employees, 80 were located in France, 28 in Japan, 7 in Malaysia, 5 in Italy and 2 in South Korea.

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

#### **Share Ownership**

As of March 31, 2005, Siemens France S.A. owned 1,003,250 Shares representing 12.0% of the total share capital and (after subtracting treasury stock which under French law carries no voting rights) 12.9% of the voting rights of the Company. No other member of the Board of Directors or Senior Executive Officers is the beneficial owner of securities representing or giving the right to subscribe for or purchase more than 1% of the Shares.

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As of March 31, 2005, the Board of Directors and the Senior Executive Officers of the Company hold a total of 1,236,400 Shares representing 14.8% of the total share capital and (after subtracting treasury stock which under French law carries no voting rights) 15.9% of the voting rights of the Company.

### Options to Purchase or Subscribe for Securities

As of March 31, 2005, the Company had sponsored eight 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 to newly issued Shares at a fixed exercise price of 6.97 per Share.

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 24, 1999, the shareholders of EDAP TMS S.A. authorized the Board of Directors to grant up to 68,540 options to purchase pre-existing Shares and 86,885 options to subscribe to new Shares, at a fixed exercise price to be set by the Supervisory Board.

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 January 29, 2004, the shareholders also authorized the Board of Directors to grant up to 1,000,000 warrants to H.T. Prostate LLC, a fully owned subsidiary of HealthTronics Surgical Services Inc, at a fixed price of U.S.\$1.50. These warrants were granted by the Board of Directors on January 28, 2005.

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. 501,600 rights to subscribe to free shares were granted by the Board of Directors on March 30, 2005; this plan will be accounted for in compliance with FASB 123(R). See Item 5, Operating and Financial Review and Prospects New Accounting Pronouncements.

On December 31, 2004, the duration of stock option contracts was as follows:

<b>Years until expiration</b>	<b>Number of Shares</b>
0-3	0
3	33,625
4	93,000
5	1,212
7	113,000
7.5	14,425
9.2	325,000

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A summary of stock option activity to purchase or to subscribe to Shares under these plans is as follows:

	2004		2003		2002	
	Options	Weighted average exercise price ( )	Options	Weighted average exercise price ( )	Options	Weighted average exercise price ( )
Outstanding on January 1,	391,262	2.68	654,341	2.58	721,550	2.53
Granted	325,000	2.19	0	-	26,425	2.02
Exercised	0	-	0	-	(47,421)	1.76
Forfeited	(136,000)	2.34	(263,079)	2.43	(46,213)	2.37
Expired	-	-	-	-	-	-
Outstanding on December 31,	580,262	2.49	391,262	2.68	654,341	2.58
Exercisable on December 31,	219,547	2.99	272,442	2.94	353,324	3.00
Share purchase options available for grant on December 31	15,000	-	0	-	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, 2004:

Exercise price ( )	Outstanding options			Exercisable options		
	Options	Weighted average remaining contractual life	Weighted average exercise price ( )	Options	Weighted average exercise price ( )	
3.81	117,625	3.5	3.81	117,625	3.81	
2.60	225,000	9.2	2.60	0	0	
2.08 <sup>(1)</sup>	113,000	7.0	2.08	84,500	2.08	
2.02 <sup>(2)</sup>	14,425	7.5	2.02	7,210	2.02	
1.83	10,212	4.5	1.83	10,212	1.83	
1.28	100,000	9.2	1.28	0	0	
1.28 to 3.81	580,262	5.3	2.49	219,547	2.99	

<sup>(1)</sup> All the 113,000 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).

<sup>(2)</sup> All the 14,425 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).

### Exemptions from Certain Nasdaq Corporate Governance Rules

Nasdaq rules permit Nasdaq to provide 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

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accepted business practices in the issuer's country of domicile. The Company has 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, is described below:

The Company is 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 25% (in the case of an ordinary general meeting or an extraordinary general meeting deciding upon any capital increase by capitalization of reserves) or 33 1/3% (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 25% of the Shares is necessary for a quorum in the case of any other type of extraordinary general meeting. The Company has 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.

## **Item 7. Major Shareholders and Related Party Transactions**

### **Major Shareholders**

To the Company's knowledge, it is 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 31, 2005, to the Company's knowledge, the following persons had beneficial ownership of more than 5% of the Shares: Siemens France S.A. owned 1,003,250 Shares representing 12.0% of the total share capital of the Company and (after subtracting treasury stock, which under French law carries no voting rights) 12.9% of voting rights and Wells Capital Management, Inc., formerly Benson Associates LLC, owned 1,667,975 Shares representing 19.9% of the total share capital of the Company and (after subtracting treasury stock, which under French law carries no voting rights) 21.4% of voting rights. The Shares owned by these persons do not carry special voting rights.

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

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

As of March 31, 2005, 8,362,821 Shares were issued, including 7,781,731 outstanding and 581,090 treasury Shares. At the same date, there were 7,353,863 ADSs, each representing one Share, all of which were held of record by 9 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 the Chairman of Dae You, a company incorporated in Korea and unrelated to EDAP TMS. Dae You acts as an agent for the promotion of the Company's medical devices in Korea, and EDAP TMS Korea also subcontracts the maintenance of its medical devices installed in Korea to Dae You. Dae You also purchases medical devices from the Company and operates them in partnership with hospitals and clinics in Korea.

In 2004, EDAP TMS Korea paid Dae You 63,000 for its services under service maintenance contracts, and Dae You purchased 401,000 of medical devices from the Company.

## **Item 8. Financial Information**

### **Consolidated Financial Statements**

See Item 18, Financial Statements.

### **Export Sales**

As of December 31, 2004, total export sales, which the Company defines as sales made outside of France, amounted to 17 million, which represented 76% of total sales.





## Legal Proceedings

To date, the Company is a party to two product liability actions in the United States by patients claiming to have been injured in the course of a Prostatron procedure. The Company has agreed to retain liability for these two cases following the sale of the Prostatron business in October 2000. However, in one of the two cases, the Company believes that it may be able to claim indemnification from Urologix. The Company believes that the patients' claims against the Company are without merit. In addition, if the claims against the Company are successful, the Company believes any potential damages assessed against it would be covered by insurance and/or by a contribution obligation of the physicians and/or the organization which provided services with the product. However, these product liability claims could have a material adverse impact on the Company.

## Dividends and Dividend Policy

The payment and amount of dividends depend on the earnings and financial condition of the Company and such other factors that the Company's 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.

No dividends were paid with respect to fiscal years 2000 through 2003. Subject to the approval of the shareholders' meeting to be held on or before June 30, 2005, the Company does not anticipate paying any dividends with respect to fiscal year 2004.

## Significant Changes

Except as otherwise disclosed in this Annual Report, there has been no material change in the financial position of EDAP TMS and its consolidated subsidiaries since December 31, 2004. As from January 2005, EDAP Technomed Inc is still registered in the Delaware, but it has no business activity in the United States, it will not be consolidated.

## 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 is evidenced by an American Depositary Receipt issued by The Bank of New York acting as Depositary in respect thereof. The principal United States trading market for the ADSs, which is also the principal trading market for the ADSs overall, is the Nasdaq National 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. The Company requested and received a conditional approval from Nasdaq Europe for the delisting of its ADSs effective on April 25, 2002.

### Trading Markets

The following tables set forth, for the years 1999 through 2004, the reported high and low sales prices of the ADSs on Nasdaq and Nasdaq Europe (through to April 25, 2002 for Nasdaq Europe).

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	Nasdaq	
	High	Low
	<hr/> \$ <hr/>	
2000	3.13	0.5
2001	3.43	0.59
2002	2.49	1.15
2003	1.99	1
2004	3.92	1.55
2005 (through March 31)	5.50	3.41

The following tables set forth, for the years 2003 and 2004 and the first quarter of 2005, the reported high and low sales prices of the ADSs on Nasdaq for each full financial quarter and on Nasdaq Europe for 2003 and 2004:

	Nasdaq	
	High	Low
	<hr/> \$ <hr/>	
2003		
First Quarter	2.49	1.62
Second Quarter	1.92	1.47
Third Quarter	1.88	1.00
Fourth Quarter	1.82	1.35
2004		
First Quarter	2.12	1.55
Second Quarter	3.61	1.95
Third Quarter	2.51	1.64
Fourth Quarter	3.92	1.96
2005		
First Quarter	5.50	3.41

	Nasdaq Europe	
	High	Low
	<hr/> \$ <hr/>	
2003 <sup>(1)</sup>	Not traded	Not traded
2004	Not traded	Not traded

<sup>(1)</sup> The Company voluntarily delisted from Nasdaq Europe effective April, 25, 2002.

The following table sets forth, for the most recent six months (from October 2004 through March 2005), the reported high and low sale prices of the ADSs on Nasdaq for each month:

	Nasdaq	
	High	Low

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\$

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2004		
October	2.89	1.96
November	2.91	2.14
December	3.92	2.67
2005		
January	5.50	3.41
February	5.24	4.01
March	4.95	3.44

## **Item 10. Additional Information**

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

Set forth below is a brief summary of significant provisions of the Company's articles of association (*statuts*) and applicable French laws. This description does not purport to be complete and is qualified in its entirety by reference to the Company's *statuts*. Each time they are modified, the Company files copies of its 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.

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

The Company's articles of association were last updated in July 2002 in order formally to comply with French Rules on Economic Regulation (the NRE law) and to reflect the new management structure.

### ***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***

On July 30, 2002, the shareholders approved a new management structure for EDAP TMS. The shareholders opted for management by a Board of Directors instead of a Management Board controlled by a Supervisory Board.

The Board of Directors is currently composed of six members who were appointed by the shareholders on July 30, 2002 and November 26, 2002, for a period of three years. (See Item 6, "Directors, Senior Management and Employees"). However, as the Company's articles of association set the duration of the Directors' mandate at six years (one year being calculated as the period in between two consecutive annual ordinary general shareholder's meetings), the next annual general shareholders' meeting will acknowledge the Directors' mandate as six years, expiring upon the date of the general shareholders' meeting approving the financial results for fiscal year 2007. 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 office of such Director comes to an end. Directors may always be re-elected; the Director may also be dismissed at any time at the shareholders' meeting.

The mandate for each member of the Board of Directors expires on the date of the ordinary general shareholders' meeting approving the financial results for fiscal year 2007.

Each Director must own at least one share during his/her term of office. If, at the time of his/her appointment, the 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 has failed 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.

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In case of the death or resignation of one or more Director, the Board of Directors may make provisional appointments to fill vacancies between two general shareholders meetings. Any such 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, in order 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.

An employee of the Company may be appointed 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 years old. In case one of the Directors reaches this limit during his/her tenure, the said Director is automatically considered to have resigned at the next general shareholders meeting.

The Board of Directors determines the direction of the Company's business and supervises its 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 the operations of the Company and make any decisions in accordance with the Company's business. However, a Director must abstain from voting on matters in which he 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 the Company's 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 the Company with regard to criminal proceedings which might be taken against the Company.

As with any other Director, the Chairman cannot be over seventy 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***

The Company is managed by the Chairman of the Board of Directors or an individual elected by the Board 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 the articles of association. On July 1, 2004, the Board of Directors appointed Mr. Hugues de Bantel 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 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 the Company with respect to third parties. The Company is bound by any acts of the Chief Executive Officer even if they are contrary to the corporate purposes, unless it is proven that the third party knew such act exceeded the corporate purposes or could not ignore so 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 the shareholders of the Company as dividends, subject to the requirements of French law and the Company's articles of association.

Under French law and the Company's articles of association, the Company is required to allocate 5% of its 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.

The shareholders of the Company 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.

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

If the Company has made distributable profits since the end of the preceding fiscal year (as shown on an interim income statement certified by the Company's 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. The Company has never paid interim dividends in the past.

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

In the event that the Company is liquidated, the Company's assets remaining after payment of its debts, liquidation expenses and all of its 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)***

The share capital of the Company 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.

The share capital of the Company 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 the Company of its 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 the Company, 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 the Company's 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 the Company's 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 Company's 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 prior to 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. Holders of ADSs will receive notices of shareholders meetings and other reports and communications that are made generally available to shareholders from the Bank of New York, the Depository for the ADSs. 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 prior to the meeting. Certain procedures to effect such requirements will be required of a holder of ADSs to exercise the voting rights relating to the shares represented by such ADSs.

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 controlled directly or indirectly by the Company 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 the Company's 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 25% (in the case of an ordinary general meeting or an extraordinary general meeting deciding upon any capital increase by capitalization of reserves) or 33 1/3% (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 25% 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 the Company's articles of association, shareholders' meetings are held at the registered office of the Company or at any other locations specified in the written notice. The Company has no 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*

The Company's 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 the Company 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 1/3% 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, EDAP TMS is 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. EDAP TMS is also exempt from certain of the current corporate governance requirements of the Nasdaq Stock Market. For more information on these exemptions, see Item 6, Directors, Senior Management and Employees Exemptions from Certain Nasdaq Corporate Governance Rules.

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

EDAP TMS is a *société anonyme*, or limited liability corporation, organized under the laws of the Republic of France. The majority of the directors and executive officers of EDAP TMS reside in the Republic of France. All or a substantial portion of the assets of such persons and of the Company 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. The Company believes 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 the obtaining of evidence in France or from French persons in connection with such actions.

## Material Contracts

The Company is a party to a commercial lease agreement for its corporate headquarters and R&D and manufacturing facilities are located in Vaulx-en-Velin, on the outskirts of Lyon. The premises comprise 3,740 square meters. The lease has a term of nine years and is renewable at the lessee's option. The Company believes that the terms of the lease reflect commercial practice and market rates.

On February 25, 2004, the Company entered into a distribution agreement with a subsidiary of HealthTronics granting HealthTronics, among other things, (i) the right to begin clinical trials with the Ablatherm (which utilizes HIFU to provide minimally invasive treatment of prostate cancer), (ii) the right to seek Pre-Market Approval ( PMA ) from the FDA and (iii) exclusive distribution rights in the United States, when and if a PMA is granted. Under the terms of the distribution agreement, the Company also agreed to grant HealthTronics 1 million warrants (*bons de souscription d'actions*) on January 28, 2005, each which will entitle HealthTronics to purchase a Share of the Company at a price of U.S.\$1.50. The warrants are subject to the terms and conditions of an accompanying escrow agreement, which, among other things, include restraints on subsequent resale of the warrant Shares. The distribution agreement allows HealthTronics to exercise specified numbers of warrants as it meets various specified distribution milestones. Under a December 2004 amendment to the distribution agreement, HealthTronics's exclusive use of the Ablatherm trade names was waived until such time as it obtained the PMA from the FDA.

## Exchange Controls

Under current French foreign exchange control regulations, there are no limitations on the amount of cash payments that may be remitted by the Company 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 changes in applicable laws and tax treaties after such date.

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. 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, 2005.

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.

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

***Elimination of the *avoir fiscal* mechanism***

The French Finance Law of 2004 implemented a new tax treatment of dividends. Prior to enactment of this law, certain qualifying French resident shareholders were entitled to a tax credit, known as the *avoir fiscal*, on dividends received from French companies. The French Finance Law of 2004 eliminated the *avoir fiscal* mechanism with respect to distributions made on or after January 1, 2005.

Dividends paid to non-residents were not normally eligible for the *avoir fiscal*. However, France has entered into tax treaties with certain countries under which qualifying residents of those countries that complied with the procedures for claiming benefits under an applicable tax treaty were entitled, in addition to a reduced rate of withholding tax, to a refund of the *avoir fiscal*, net of applicable withholding tax. As a result of the French Finance Law of 2004, qualifying non-resident individuals will no longer be entitled to *avoir fiscal* refunds with respect to distributions made on or after January 1, 2005 and qualifying non-resident shareholders other than individuals are no longer entitled to *avoir fiscal* refunds with respect to distributions made from 2004.

***New Tax Credit***

Beginning January 1, 2005, French resident individuals will only be taxed on half of the dividends they receive and, in addition to the annual allowance that is already applicable, will be entitled to a tax credit equal to 50% of the dividend (the Tax Credit). The Tax Credit will have a cap of 230 for married couples and members of a union agreement subject to joint taxation and 115 for single persons, widows or widowers, divorcees or married persons subject to separate taxation. French resident individuals will not be entitled to the *avoir fiscal* with respect to distributions made on or after January 1, 2005.

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* (net of applicable withholding tax) under a tax treaty entered into between France and their country of residence, may benefit from a refund of the Tax Credit (net of applicable withholding tax) under the same conditions as for the *avoir fiscal*, 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 refund of the Tax Credit to non-resident individuals. If it is possible to claim this refund, the claims process may entail compliance with cumbersome formalities.

***Elimination of the *précompte* 25% equalization tax***

Until December 31, 2004, dividends paid out of profits that had not been taxed at the ordinary corporate tax rates or were earned and taxed more than five years before the distribution, were subject to an equalization tax called the *précompte*. Non-resident shareholders entitled to the benefits of the tax treaty but not to a refund of the *avoir fiscal* were generally able to obtain a refund of the *précompte* (net of applicable withholding tax). As a result of the reform of the tax treatment of dividends, distributions made on or after January 1, 2005 will no longer give rise to any *précompte*.

A temporary equalization tax will apply to distributions made in 2005 out of profits that have not been taxed at the ordinary corporate tax rate, or which were earned and taxed more than five years before the distribution. This equalization tax will be equal to 25% of the amount of the dividends paid to the shareholder. This equalization tax will not be refundable to non-resident shareholders, as it will be refunded to the distributing corporation in three installments of one third each with respect to the three fiscal years closed after the distribution, either as a credit against its corporate tax liability or in cash, if the corporate tax liability is insufficient to offset the entire tax credit.

Distributions made on or after January 1, 2006 will not give rise to any equalization tax liability.



### ***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, 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 1% *ad valorem* registration duty (subject to a maximum of 3,049 per transfer) applies to certain transfers of shares or ADSs in French companies. As from January 1, 2006, the rate of this registration duty will increase to 1.10% (subject to a maximum of 4,000 per transfer). This duty does not apply to transfers of shares or ADSs 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 company 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 company, provided that such ownership interest is less than 10% of the company's share capital and does not enable the shareholder to exercise influence over the company. 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 income tax convention between the United States and France (the Treaty) and is fully eligible for benefits under the Treaty (a U.S. holder). A holder generally will be entitled to Treaty benefits in respect of Shares or ADSs if he is:

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.

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. 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.

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, 2005.

Holders should consult their own tax advisers 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 laws.

### *Dividends*

As discussed in more detail above, the French Finance Law of 2004 implemented a reform of the French tax treatment of distributions and dividends paid by French companies. Generally, dividend distributions to non-residents of France are subject to French withholding tax at a 25% rate and are not eligible for the benefit of the Tax Credit available to French resident individuals, as described above. However, under the Treaty, holders can claim the benefit of a reduced dividend withholding tax rate of 15%.

In addition, individual U.S. holders, subject to the discussion of the Tax Credit above, may be entitled to a refund of the Tax Credit, less a 15% withholding tax, provided that they are subject to U.S. federal income tax on the Tax Credit and the dividend to which it relates. The French tax authorities have not yet issued guidance with respect to the refund of the Tax Credit to non-resident individuals. If it is possible to claim this refund, the claims process may entail compliance with cumbersome formalities.

U.S. holders that are legal entities, pension funds or other tax-exempt holders are no longer entitled to tax credit payments from the French Treasury.

French withholding tax will be withheld at the 15% Treaty rate for holders that have established before the date of payment that they are residents of the United States under the Treaty by following the simplified procedure described below.

The gross amount of dividend and Tax Credit that a U.S. holder receives (prior to 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.

Subject to certain exceptions for short-term and hedged positions, the U.S. dollar amount of dividends received by an individual prior to January 1, 2009 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) a passive foreign investment company ( PFIC ) or (b) for dividends paid prior to the 2005 tax year, a foreign personal holding company ( FPHC ) or foreign investment company ( FIC ). 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, the Company believes that it was not treated as a PFIC, FPHC or FIC for U.S. federal income tax purposes with respect to its 2004 taxable year. In addition, based on the Company's audited financial statements and its current expectations regarding the value and nature of its assets, the sources and nature of its income, and relevant market and shareholder data, the Company does not anticipate becoming a PFIC for its 2005 taxable year. Accordingly, dividends paid by the Company in 2005 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).

The U.S. Treasury has announced its intention to promulgate rules pursuant to which holders of ADSs or common stock and intermediaries through whom such securities are held will be permitted to rely on certifications from issuers to establish that dividends are treated as qualified dividends. Because such procedures have not yet been issued, it is not clear whether the Company will be able to comply with them.

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

Distributions out of earnings and profits 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 separately along with other items of passive (or, in the case of certain U.S. holders, financial services ) income for purposes of determining the credit for foreign income taxes allowed under the Code. 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.

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.

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 new guidelines in February 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 the new 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.

In order to benefit from the lower rate of withholding tax applicable under the Treaty before the payment of the dividend, you must use the simplified procedure and are no longer allowed to file a Form RF 1 A EU-No. 5052 or a Form RF 1 B EU-No. 5053.

The simplified procedure entails completing and delivering to the French tax authorities a certificate stating that:

- you are a U.S. resident within the meaning of the Treaty;
- the dividend is not derived from a permanent establishment or a fixed base that you own in France;
- the dividend received is subject to tax in the United States.

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 the certificate 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 an application for refund no later than December 31 of the second year following the year in which the dividend is paid.

The applicable forms to claim a refund under the normal procedure are currently Form RF 1 A EU-No. 5052 or Form RF 1 B EU-No. 5053. These forms will likely be replaced by new forms in the near future.

Copies of the simplified certificate and of the forms to be used in the normal procedure are available from the U.S. Internal Revenue Service and from the *Centre des Impôts des Non-Résidents* (9 rue d Uzès, 75094 Paris Cedex 2).

Finally, as mentioned above, the French tax authorities have not yet issued any guidance with respect to the refund of the Tax Credit to non-resident individuals.

### ***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 generally is subject to taxation at a maximum rate of 20%; however, net long-term capital gain recognized by an individual U.S. holder after May 5, 2003 and before January 1, 2009 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***

The Company will be classified as a PFIC in a particular taxable year if either:

75% or more of the Company's gross income is treated as passive income for purposes of the PFIC rules; or

the average percentage of the value of the Company's assets that produce or are held for the production of passive income is at least 50%.

As discussed above (see Dividends) the Company believes that it was not a PFIC in 2004 and does not anticipate being a PFIC in 2005. However, as discussed in Forms 20-F filed by the Company with respect to prior years, the Company believes that it was a PFIC during certain periods.

If a U.S. holder held Shares or ADSs during a year in which the Company was a PFIC and does not make the mark-to-market election, described in the next paragraph, such holder will be subject to a special additional tax, determined as described below, on certain dividends received and gains realized (excess distributions) in subsequent years, without regard to whether the Company was a PFIC in the year the excess distribution was received. The amount of this tax is equal to the sum of (i) tax at ordinary rates on the amount of the excess distribution, plus (ii) an interest charge to compensate for tax deferral, calculated as if the excess distribution had been earned ratably over the period the U.S. holder held its Shares or ADSs. Classification as a PFIC may also have other adverse tax consequences, including the denial of a step-up in the basis of Shares and ADSs at death.

U.S. holders can avoid the unfavorable treatment described above by electing to mark their Shares or ADSs to market. For any year in which the Company is a PFIC, a U.S. holder who makes a mark-to-market election would include as ordinary income the excess of the fair market value of the Shares or ADSs at year-end over the holder's basis in those Shares or ADSs. In addition, any gain recognized upon a sale of Shares or ADSs in such year would be taxed as ordinary income.

The Company does not intend to furnish holders with the information necessary to make a qualified electing fund (QEF) 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**

The Company is subject to the informational requirements of the Securities Exchange Act of 1934, as amended. In accordance with these requirements, the Company files reports and other information with the Securities and Exchange Commission. These materials, including this Annual Report and the exhibits hereto, may be inspected and copied at the Commission's Public Reference Room at 450 Fifth Street, N.W., Washington, D.C. 20549 and at the Commission'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 prescribe rates. The public may obtain information on the operation of the Commission's Public Reference Room by calling the Commission in the United States at +1 800 SEC 0330.

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

The Company is exposed to market risk from changes in both foreign currency exchange rates and interest rates. The Company does not hold or issue derivative or other financial instruments for trading purposes. As of December 31, 2004, the Company had two foreign exchange sale contracts, one for the Japanese yen which expires on December 28, 2005 and one for U.S. dollar which expires on May 27, 2005. As of March 31, 2005, the Company had five new foreign exchange sale contracts, three for the Japanese yen and two for U.S. dollars.

**Exchange Rate Risk**

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

The Company is exposed to foreign currency exchange rate risk because a significant portion of its costs are denominated in currencies other than those in which it earns revenues. In 2004, approximately 70% of the Company's selling and general and administrative expenses and approximately 94% of the Company's R&D expenses were denominated in euro. During the same period, only 49% of the Company's sales were denominated in euro, the remainder being denominated primarily in U.S. dollars and Japanese yen.

A uniform 10% strengthening in the value of the euro as of December 31, 2004 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 43,000 for the year ended December 31, 2004, compared to an increase of approximately 38,000 for the year ended December 31, 2003. 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 effects of changes in exchange rates quantified above, changes in exchange rates also affect the volume of sales. The foreign exchange sale contracts in place as of December 31, 2004 will be effective as from January 2005. The Company regularly assesses the exposure of its receivables to fluctuations in the exchange rates of the principal foreign currencies in which its sales are denominated (in particular, the U.S. dollar and the Japanese yen) and, from time to time, hedges such exposure by entering into forward sale contracts for the amounts denominated in such currencies that it expects to receive from its local subsidiaries. As of March 31, 2005, the Company had five new foreign exchange sale contracts, three for the Japanese yen and two for U.S. dollars.

#### ***Financial Instruments and Indebtedness***

Over the past three years, the Company also has had exchange rate exposures with respect to indebtedness and assets denominated in U.S. dollars and Japanese yen. Approximately 0.5 million, 0.3 million and 0.9 million of the outstanding indebtedness of the Company at December 31, 2004, 2003 and 2002, respectively, was denominated in Japanese yen. None of the Company's outstanding indebtedness over the past three years was denominated in U.S. dollars. In addition, the Company had approximately 1.2 million, 0.4 million and 0.7 million of financial assets denominated in U.S. dollars at December 31, 2004, 2003 and 2002, respectively, and 1.3 million, 0.7 million and 1.4 million of financial assets denominated in Japanese yen at December 31, 2004, 2003 and 2002, respectively. These assets principally represented investments available for sale and the cash balances of its U.S. and Japanese subsidiaries at such dates.

#### **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**

Within the 90 days prior to date of this Annual Report, the Company carried out an evaluation under supervision and with the participation of the Company's management, including the Chief Executive Officer and Chief Financial Officer, of the effectiveness of the design and operation of the Company's disclosure controls and procedures. There are inherent limitations to the effectiveness of any system of disclosure controls and procedures, including the possibility of human error and the circumvention or overriding of the controls and procedures. Accordingly, even effective disclosure controls and procedures can only provide reasonable assurance of achieving their control objectives. Based upon and as of the date of the Company's evaluation, the Chief Executive Officer and Chief Financial Officer concluded that the disclosure controls and procedures are effective in all material respects to ensure that information required to be disclosed in the reports the Company files and submits under the Exchange Act is recorded, processed, summarized and reported as and when required.

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There has been no change in the Company's internal control over financial reporting during the Company's 2004 fiscal year 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**

The board of directors of the Company 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**

The Company has adopted a code of ethics applicable to its 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 2004, there were no waivers of its applicability. The Company has attached its code of ethics as an exhibit to this report and has made it available on the Company's 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 the Audit Committee of EDAP TMS SA Board of Directors on December 22, 2003 and reviewed on December 21, 2004. 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 2004 financial year:

Nature of the Fees	2003 (in \$)	2004 (in \$)
Audit fees	121,865	143,265
Audit-related fees	9,000	8,010
Tax fees	23,348	0
All other fees	31,689	
Total	185,902	151,275

***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, which 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***

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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 over 2004 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 2004, neither the Company nor affiliated purchasers made purchases of equity securities of the Company registered pursuant to Section 12 of the Exchange Act.

**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 July 30, 2002 (together with an English translation thereof).<sup>(1)</sup>
- 4.1 (a) Distribution Agreement, dated as of February 25, 2004, among the Company, HT Prostate Therapy Management Company, LLC, EDAP S.A. and Technomed Medical Systems, S.A.<sup>(2)</sup>
- (b) Amendment No. 1 to the Distribution Agreement dated December 23, 2004.
- 4.2 (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).<sup>(1)</sup>
- (b) Appendix No. 2 to commercial leases between TMS S.A. and Maison Antoine Baud, signed on June 28, 2004.
- 8.1 List of subsidiaries of EDAP TMS S.A. as of March 31, 2005.
- 11.1 Code of Ethics of the Company, approved by the Board of Directors on March 30, 2005
- 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.

<sup>(1)</sup> *Previously filed.*

<sup>(2)</sup> *Previously filed with certain confidential portions omitted under Rule 24b-2 under the Securities Exchange Act of 1934.*

**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: May 20, 2005

*Hugues de Bantel*  
*Chief Executive Officer*

Dated: May 20, 2005

*Thierry Turbant*  
*Chief Financial Officer*

**INDEX TO FINANCIAL STATEMENTS**

**Audited Consolidated Financial Statements for EDAP TMS S.A. and Subsidiaries for the Years Ended December 31, 2004, 2003 and 2002**

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**Report of Independent Auditors**

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

We have audited the accompanying consolidated balance sheets of EDAP TMS S.A. (the Company) and its subsidiaries as of December 31, 2004 and 2003, and the related consolidated statements of income, comprehensive income, shareholders' equity and cash flows for each of the three years in the period ended December 31, 2004. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these 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. An audit includes 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, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the consolidated financial position of EDAP TMS S.A. and its subsidiaries at December 31, 2004 and 2003, and the consolidated results of their operations and their cash flows for each of the three years in the period ended December 31, 2004 in conformity with U.S. generally accepted accounting principles.

ERNST & YOUNG Audit

Represented by  
*Jean-Luc Desplat*

April 27, 2005  
Lyon, France



## EDAP TMS S.A. AND SUBSIDIARIES

## CONSOLIDATED BALANCE SHEETS

As of December 31, 2004 and 2003

(in thousands of euro unless otherwise noted)

ASSETS	Notes	2004	2003
<b>Current assets</b>			
Cash and cash equivalents	2	9,398	10,429
Trade accounts and notes receivable, net of allowance of 705 in 2004 and 526 in 2003	3	7,722	8,000
Other receivables	4	473	1,419
Inventories	5	3,939	5,267
Deferred income taxes	21-3	77	332
Prepaid expenses		432	423
<b>Total current assets</b>		<b>22,041</b>	<b>25,870</b>
Property, plant and equipment, net	6	2,807	2,903
Intangible assets	7	119	176
Goodwill, net of accumulated amortization of 2,359 in 2004 and 2003	7	2,412	2,412
Deposits and other non-current assets		522	549
<b>Total assets</b>		<b>27,901</b>	<b>31,910</b>
<b>LIABILITIES AND SHAREHOLDERS EQUITY</b>			
<b>Current liabilities</b>			
Short-term borrowings	12	525	222
Trade accounts and notes payable	8	3,675	3,855
Deferred revenues, current portion	9	843	1,693
Social security and other payroll withholdings taxes		513	708
Employee absences compensation		424	541
Income taxes payable			51
Accruals for restructuring	18	136	1,986
Other accrued liabilities	10	1,816	1,727
Current portion of capital lease obligations	11	334	211
Current portion of long-term debt	13	6	80
<b>Total current liabilities</b>		<b>8,272</b>	<b>11,074</b>
Deferred revenues, long term portion	9	442	633
Capital lease obligations, less current portion	11	663	581
Long-term debt	13		7
Other long-term liabilities	14	560	654
<b>Total liabilities</b>		<b>9,937</b>	<b>12,949</b>
<b>Shareholders equity</b>			
Common stock, 0.13 par value, 9,318,875 shares authorized; 8,362,821 shares issued; 7,781,731 shares outstanding at December 31, 2004 and 2003		1,087	1,087
Additional paid-in capital		19,999	19,811
Retained earnings		1,662	2,811
Cumulative other comprehensive loss		(2,987)	(2,951)
Treasury stock, at cost; 581,090 shares at December 31, 2004 and 2003		(1,797)	(1,797)
<b>Total shareholders equity</b>	15	<b>17,964</b>	<b>18,961</b>
<b>Total liabilities and shareholders equity</b>		<b>27,901</b>	<b>31,910</b>

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

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## EDAP TMS S.A. AND SUBSIDIARIES

**CONSOLIDATED STATEMENTS OF INCOME**  
**For the years ended December 31, 2004, 2003 and 2002**  
(in thousands of euro unless otherwise noted)

	Notes	2004	2003	2002
Sales of medical devices		11,922	8,512	10,527
Sales of disposables, CPPs, leases, spare parts and services		10,207	9,518	9,198
Total sales	16	22,129	18,030	19,725
Warrants granted		(174)		
Total net sales	16	21,955	18,030	19,725
Other revenues	17	208	443	236
Total revenues		22,163	18,473	19,961
Cost of sales		(13,676)	(13,094)	(11,503)
Gross profit		8,487	5,379	8,458
Research and development expenses		(1,523)	(3,069)	(3,186)
Selling expenses		(3,402)	(4,228)	(4,023)
General and administrative expenses		(4,074)	(4,106)	(4,784)
Non recurring operating expenses	18	(318)	(2,097)	(1,241)
Operating loss		(830)	(8,121)	(4,776)
Interest income (expense), net	19	71	177	455
Currency exchange gains (loss), net		(38)	(928)	(1,027)
Other income (loss), net	20	(74)	(218)	1,475
Income (loss) before taxes		(871)	(9,090)	(3,873)
Income tax (expense) benefit	21	(278)	114	(167)
Net (loss) income		(1,149)	(8,976)	(4,040)
Basic earnings (loss) per share	1-18	(0.15)	(1.15)	(0.52)
Weighted average shares outstanding used in basic calculation	1-18	7,781,731	7,781,731	7,771,467
Diluted earnings (loss) per share	1-18	(0.15)	(1.15)	(0.52)
Weighted average shares outstanding used in diluted calculation	1-18	8,074,210	7,817,303	7,833,514

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, 2004, 2003 and 2002**

**(in thousands of euro unless otherwise noted)**

	<b>2004</b>	<b>2003</b>	<b>2002</b>
Net (loss) income	(1,149)	(8,976)	(4,040)
Other comprehensive income:			
Unrealized (loss) gain on investments			(109)
Foreign currency translation adjustments	(36)	(547)	(442)
Comprehensive (loss) income, net of tax	(1,185)	(9,523)	(4,591)

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, 2004, 2003 and 2002**  
(in thousands of euro unless otherwise noted)

	Number of Shares	Common Stock	Additional Paid-in Capital	Retained Earnings	Cumula- tive Other Compre- hensive Income (loss)	Treasury Stock	Total
Balance as of December 31, 2001	7,734,310	1,081	19,811	15,827	3,987	(1,797)	38,909
Net loss				(4,040)			(4,040)
Translation adjustment					(442)		(442)
Increase of shares/Capital increase	47,421	6					6
Change in unrealized gain/loss on investments available for sale					(6,058)		(6,058)
Balance as of December 31, 2002	7,781,731	1,087	19,811	11,787	(2,513)	(1,797)	28,375
Net loss				(8,976)			(8,976)
Translation adjustment					(547)		(547)
Change in unrealized gain/loss on investments available for sale					109		109
Balance as of December 31, 2003	7,781,731	1,087	19,811	2,811	(2,951)	(1,797)	18,961
Net loss				(1,149)			(1,149)
Translation adjustment					(36)		(36)
Warrants and stock options granted			188				188
Balance as of December 31, 2004	7,781,731	1,087	19,999	1,662	(2,987)	(1,797)	17,964

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, 2004, 2003 and 2002**  
**(in thousands of euro unless otherwise noted)**

	2004	2003	2002
<b>Cash flows from operating activities</b>			
Net (loss) income	(1,149)	(8,976)	(4,040)
Adjustments to reconcile net loss to net cash provided by (used in) operating activities:			
Depreciation and amortization	1,049	983	1,116
Change in allowances for doubtful accounts & slow-moving inventories	(834)	(147)	(595)
Change in long-term provisions	(94)	46	36
Deferred tax expense/(benefit)	255	(226)	6
Net loss (gain) on sale of assets	(389)	(9)	384
Net loss (gain) on sale of investments available for sale		123	(1,535)
	(13)	770	(588)
Increase/Decrease in operating assets and liabilities, net of effects from sale of business:			
Decrease/(Increase) in trade accounts and notes and other receivables	20	3,076	(306)
Decrease/(Increase) in inventories	2,341	1,110	(428)
Decrease/(Increase) in prepaid expenses	(9)	(36)	(50)
(Decrease)/Increase in trade accounts and notes payable	(439)	(1,025)	(1,382)
(Decrease)/Increase in accrued expenses, other current liabilities	(1,884)	1,432	(1,168)
	29	4,557	(3,334)
<b>Net cash (used in) provided by operating activities</b>	(1,133)	(3,649)	(7,962)
<b>Cash flows from investing activities:</b>			
Acquisitions of property, plant and equipment	(247)	(400)	(859)
Acquisitions of intangible assets	(18)	(27)	(210)
Capitalized assets produced by the Company	(750)	(780)	(377)
Net proceeds from sale of assets	722	10	15
Net proceeds from sale of leased back assets	342	250	
Proceeds from sale of investments available for sale		55	5,521
Change in restricted cash equivalents			890
Increase in deposits and guarantees	(108)		
Reimbursement of deposits and guarantees	75	350	105
<b>Net cash (used in) provided by investing activities</b>	16	(542)	5,086
<b>Cash flow from financing activities:</b>			
Repayment of long term borrowings	(77)	(370)	(624)
Repayment of obligations under capital leases	(316)	(77)	(331)
Increase/(decrease) in bank overdrafts and short-term borrowings	310	(222)	699
<b>Net cash (used in) provided by financing activities</b>	(83)	(669)	(256)
Net effect of exchange rate changes on cash and cash equivalents	169	(466)	(474)
<b>Net increase/(decrease) in cash and cash equivalents</b>	(1,031)	(5,326)	(3,606)
Cash and cash equivalents at beginning of year	10,429	15,755	19,361
<b>Cash and cash equivalents at end of year</b>	9,398	10,429	15,755

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

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

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**  
**(in thousands of euro 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 and distribution 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 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 majority-owned subsidiaries, which include Technomed Medical Systems S.A. ( EDAP TMS 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 S.A. Edap Technomed Sdn Bhd was incorporated in early 1997. Edap Technomed Co. Ltd. was created in late 1996. EDAP S.A. was incorporated in May 2000. All intercompany transactions and balances are eliminated in consolidation.

*1-4 Revenue recognition*

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 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 usually provides a one-year warranty upon installation. The Company accrues for the estimated training and warranty costs at the time of sale.

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

Revenues related to the sale of Ablatherm treatments invoiced on a Charge-Per-Procedure ( CPP ) basis are recognized when the treatment procedure has been completed.





**EDAP TMS S.A. AND SUBSIDIARIES****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**  
**(in thousands of euro unless otherwise noted, except per share data)**

The Company receives royalty revenues under a license agreement with a third party that sells products using the Company's patented technology. There are no future performance obligations on the part of the Company under this license agreement. The license agreement provides for the payment of royalties to the Company based on sales of the licensed product. The Company records these revenues based on actual sales that occurred during the relevant period.

***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***

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

***1-7 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 inventory first based on detailed comparison between quantity in inventory and historical consumption and an additional case-by-case analysis equal to the difference between the cost of inventory and estimated market value based upon assumptions about future demand, technology change and market conditions.

***1-8 Property, plant and equipment***

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

Buildings	20 years
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 machines that are leased to customers through operating leases related to charge- per-procedure transactions. This equipment is depreciated over a period of five years.

***1-9 Long-lived assets***

Property, plant and equipment and other long-lived assets are reviewed for impairment whenever events or circumstances indicate that the carrying amount may not be recoverable. If undiscounted expected future cash flows are less than the carrying value of the assets, an impairment loss is recognized based on the excess of the carrying amount over the fair value of the assets.

***1-10 Goodwill and other intangible assets***

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Goodwill represents the excess of purchase price over the fair value of identifiable net assets of businesses acquired. The Company adopted Statement of Financial Accounting Standards No. 142 (SFAS 142) *Goodwill and other intangible assets*, effective January 1, 2002. Under SFAS 142, goodwill is no longer amortized but is tested for impairment on an annual basis, or more frequently, as impairment indicators arise.

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**EDAP TMS S.A. AND SUBSIDIARIES****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**  
**(in thousands of euro unless otherwise noted, except per share data)**

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

Patents	5 years
Licenses	5 years
Tradename and trademark	7 years

***1-11 Warranty costs***

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 amounts to 592 thousand, 897 thousand and 714 thousand for the years ended December 31, 2004, 2003 and 2002, respectively.

***1-12 Deferred income taxes***

The Company accounts for deferred 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. 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.

***1-13 Research and development costs***

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

***1-14 Advertising costs***

Advertising costs are recorded as an expense in the period in which they are incurred. Advertising costs for the years ended December 31, 2004, 2003 and 2002 were not material to the consolidated financial statements.

***1-15 Translation of transactions denominated in foreign currencies******Translation of the financial statements of consolidated companies***

The translation rules applicable to the financial statements of foreign subsidiaries (EDAP Technomed Inc., Edap Technomed Sdn Bhd and Edap Technomed Co. Ltd.) are 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 euro unless otherwise noted, except per share data)**

*Translation of balance sheet items denominated in foreign currencies*

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.

**1-16 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.

A reconciliation of the numerators and denominators of the basic and diluted EPS calculations for the years ended December 31, 2004, 2003 and 2002 is as follows:

	For the year ended Dec. 31, 2004			For the year ended Dec. 31, 2003			For the year ended Dec. 31, 2002		
	Income in euro (Numerator)	Shares (Denominator)	Per-Share Amount	Income in euro (Numerator)	Shares (Denominator)	Per-Share Amount	Income in euro (Numerator)	Shares (Denominator)	Per-Share Amount
<b>Basic EPS</b>									
Income available to common Shareholders	(1,148,792)	7,781,731	(0.15)	(8,975,846)	7,781,731	(1.15)	(4,039,835)	7,771,467	(0.52)
Effect of dilutive securities:									
Stock options		292,479			35,572			62,047	
<b>Diluted EPS</b>									
Income available to common shareholders, Including assumed Conversions	(1,148,792)	8,074,210	(0.15)	(8,975,846)	7,817,303	(1.15)	(4,039,835)	7,833,514	(0.52)

**1-17 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 instruments 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.



## EDAP TMS S.A. AND SUBSIDIARIES

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

The Company adopted SFAS 133 on January 1, 2001. Given the Company's minimal use of derivative Instruments, this standard does not have any effect on the Company's financial position, results of operations or cash flows.

***1-18 Employee stock option plans***

At December 31, 2004, the Company has seven stock-based employee compensation plans. The Company accounts for those plans under the recognition and measurement principles of APB Opinion No. 25, *Accounting for Stock Issued to Employees* (APB 25), and related Interpretations. In accordance with APB 25, the Company recognizes stock-based employee compensation costs over the vesting period when the options granted under those plans have an exercise price lower than the market value of the underlying common stock on the date of grant. The following table illustrates the effect on net income and earnings per share if the Company had applied the fair value recognition provisions of FASB Statement No. 123, *Accounting for Stock-Based Compensation*, to stock-based employee compensation.

	<b>Year Ended December 31,</b>		
	<b>2004</b>	<b>2003</b>	<b>2002</b>
Net income (loss), as reported	(1,149)	(8,976)	(4,040)
Add: Stock-based employee compensation expense included in reported net income (loss), net of related tax effects	14		
Deduct: Total stock-based employee compensation expense Determined under fair value-based method for all awards, net of related tax effects	(44)	(56)	(129)
Pro forma net income (loss)	(1,179)	(9,032)	(4,169)
Earnings per share:			
Basic, as reported	(0.15)	(1.15)	(0.52)
Basic, pro forma	(0.15)	(1.16)	(0.54)
Diluted, as reported	(0.15)	(1.15)	(0.52)
Diluted, pro forma	(0.15)	(1.16)	(0.54)

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>2004</b>	<b>2003</b>	<b>2002</b>
Weighted-average expected life (years)	3.08		5
Expected volatility rates	85%		54.16%
Expected dividend yield			
Risk-free interest rate	3.3%		4.25%
Weighted-average exercise price (€)	2.19		2.02
Weighted-average fair value of options granted during the year (€)	0.51		0.90

225,000 share purchase options and 100,000 share subscription options were granted in 2004.





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

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

*1-19 New accounting pronouncements*

On December 16, 2004, the Financial Accounting Standards Board (FASB) issued FASB Statement No. 123 (revised 2004), *Share-Based Payment*, which is a revision of FASB Statement No. 123, *Accounting for Stock-Based Compensation*. Statement 123(R) supersedes APB Opinion No. 25, *Accounting for Stock Issued to Employees*, and amends FASB Statement No. 95, *Statement of Cash Flows*. Generally, the approach in Statement 123(R) is similar to the approach described in Statement 123. However, Statement 123(R) *requires* all share-based payments to employees of the Company, including grants of employee stock options, to be recognized in the income statement based on their fair values. Pro forma disclosure is no longer an alternative.

Statement 123(R) must be adopted no later than the first fiscal year beginning after June 15, 2005. Early adoption will be permitted in periods in which financial statements have not yet been issued. The Company expects to adopt Statement 123(R) as of January 1, 2005, and the performance stock plan approved by the shareholders in February 2005 will be booked in accordance with the dispositions of FASB 123(R).

Statement 123(R) permits public companies to adopt its requirements using one of two methods:

1. A modified prospective method, in which compensation cost is recognized beginning with the effective date (a) based on the requirements of Statement 123(R) for all share-based payments granted after the effective date and (b) based on the requirements of Statement 123 for all awards granted to employees prior to the effective date of Statement 123(R) that remain unvested on the effective date.
2. A modified retrospective method, which includes the requirements of the modified prospective method described above, but also permits entities to restate based on the amounts previously recognized under Statement 123 for purposes of pro forma disclosures either (a) all prior periods presented or (b) prior interim periods of the year of adoption.

The Company plans to adopt Statement 123 using the modified prospective method.

As permitted by Statement 123, the Company currently accounts for share-based payments to employees using Opinion 25's intrinsic value method and, as such, generally recognizes no compensation cost for employee stock options. Accordingly, the adoption of Statement 123(R)'s fair value method will have a significant impact on the Company's result of operations, although it will have no impact on its overall financial position. The impact of the adoption of Statement 123(R) cannot be predicted at this time because it will depend on levels of share-based payments granted in the future. However, had the Company adopted Statement 123(R) in prior periods, the impact of that standard would have approximated the impact of Statement 123.

## EDAP TMS S.A. AND SUBSIDIARIES

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

**2 CASH AND CASH EQUIVALENTS**

Cash and cash equivalents are comprised of the following:

	December 31,	
	2004	2003
Cash held at bank	5,659	5,710
Money market funds	3,739	4,719
<b>Total</b>	<b>9,398</b>	<b>10,429</b>

Gross realized gains on sales of these available-for-sale securities amounted to 117 thousand, 214 thousand and 405 thousand for the years ended December 31, 2004, 2003 and 2002, respectively.

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

Trade accounts and notes receivable, net, consist of the following:

	December 31,	
	2004	2003
Trade accounts	8,335	8,137
Notes receivable	92	389
Less: allowance for doubtful accounts	(705)	(526)
<b>Total</b>	<b>7,722</b>	<b>8,000</b>

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

## EDAP TMS S.A. AND SUBSIDIARIES

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

**4 OTHER RECEIVABLES**

Other receivables consist of the following:

	<b>December 31,</b>	
	<b>2004</b>	<b>2003</b>
Tax loss carryback receivable from the French State	109	109
Value-added taxes receivable from the French State	210	462
Research and development tax credit receivable from the French State	0	150
Other receivables from the French State	16	210
Others	138	488
<b>Total</b>	<b>473</b>	<b>1,419</b>

The receivable for tax losses carried back to prior years, which was recorded in 1998, can be used to offset income taxes due during the years following the year in which the carryback was recorded, or will be reimbursed by the French government.

Research and development tax credits can be used to offset income taxes due during the three years following the year in which the credits were recorded. Any balance of receivable at the end of this three-year period will be reimbursed by the French State.

**5 INVENTORIES**

Inventories consist of the following:

	<b>December 31,</b>	
	<b>2004</b>	<b>2003</b>
Components, spare parts	3,491	4,560
Work-in-progress	326	619
Finished goods	826	1,805
<b>Total gross inventories</b>	<b>4,643</b>	<b>6,984</b>
Less: provision for slow-moving inventory	(704)	(1,717)
<b>Total</b>	<b>3,939</b>	<b>5,267</b>

The allowance for slow moving inventory, which is classified as cost of sales ( COS ), amounted to 252 thousand, 569 thousand and 626 thousand for the years ended December 31, 2004, 2003 and 2002, respectively.



## EDAP TMS S.A. AND SUBSIDIARIES

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

**6 PROPERTY, PLANT AND EQUIPMENT, NET**

Property, plant and equipment, net, consist of the following:

	December 31,	
	2004	2003
Equipment	4,647	4,384
Furniture, fixture, and fittings and other	2,180	2,374
<b>Total gross value</b>	<b>6,827</b>	<b>6,758</b>
Less: accumulated depreciation	(4,020)	(3,855)
<b>Total</b>	<b>2,807</b>	<b>2,903</b>

Amortization expense related to property, plant and equipment amounted to 934 thousand, 867 thousand and 1,028 thousand for the years ended December 31, 2004, 2003 and 2002, respectively.

Capitalized costs of 1,058 thousand and 870 thousand are included in property, plant and equipment at December 31, 2004 and December 31, 2003, respectively. Accumulated amortization of these assets leased to third parties was 283 thousand and 66 thousand at December 31, 2004 and December 31, 2003, respectively.

Amortization expense on assets held under capital leases is included in total amortization expense and amounted to 217 thousand and 66 thousand for the years ended December 31, 2004 and 2003, respectively.

**7 GOODWILL AND OTHER INTANGIBLE ASSETS**

As discussed in Note 1-10, 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, 2004.

The Company completed the required annual impairment test in the fourth quarter of 2004. 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. 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.

**EDAP TMS S.A. AND SUBSIDIARIES****NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**  
**(in thousands of euro unless otherwise noted, except per share data)**

Other intangible assets consist of the following:

	<b>December 31,</b>	
	<b>2004</b>	<b>2003</b>
Licenses	419	460
Tradename and trademark	583	597
Patents	412	412
Organization costs	363	363
<b>Total gross value</b>	<b>1,777</b>	<b>1,832</b>
Less: accumulated amortization	(1,658)	(1,656)
<b>Total</b>	<b>119</b>	<b>176</b>

Amortization expenses related to other intangible assets amounted to 71 thousand, 77 thousand and 88 thousand, for the years ended December 31, 2004, 2003 and 2002, respectively.

For the two coming years, the annual estimated amortization expense for intangible assets will be approximately 70 thousand.

**8 TRADE ACCOUNTS AND NOTES PAYABLE**

Trade accounts and notes payable consist of the following:

	<b>December 31,</b>	
	<b>2004</b>	<b>2003</b>
Trade accounts payable	2,913	3,157
Notes payable	762	698
<b>Total</b>	<b>3,675</b>	<b>3,855</b>

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

## EDAP TMS S.A. AND SUBSIDIARIES

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

**9 DEFERRED REVENUES**

Deferred revenues consist of the following :

	December 31,	
	2004	2003
Deferred revenues on maintenance contracts	370	516
Deferred revenue on sale of devices	676	1,560
Deferral of the gain on sale-lease-back transactions	239	250
<b>Total</b>	<b>1,285</b>	<b>2,326</b>
Less long term portion <sup>(1)</sup>	442	633
<b>Current portion</b>	<b>843</b>	<b>1,693</b>

<sup>(1)</sup> Certain prior years amounts have been reclassified to conform the current year's presentation.

**10 OTHER ACCRUED LIABILITIES**

Other accrued liabilities consist of the following:

	December 31,	
	2004	2003
Provision for warranty costs <sup>(1)</sup>	660	694
Value added tax payable	273	269
Accruals for social expenses	301	151
Advance subsidies to be reimbursed	318	173
Advance to debtors	28	181
Others	236	259
<b>Total</b>	<b>1,816</b>	<b>1,727</b>

<sup>(1)</sup> Certain prior years amounts have been reclassified to conform the current year's presentation.

Changes in the provision for warranty costs are as follows:

December 31,	
2004	2003



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Beginning of year	694	901
Amount used during the year (payments)	(592)	(897)
New warranties	558	690
End of year	660	694

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## EDAP TMS S.A. AND SUBSIDIARIES

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

**11 LEASE OBLIGATIONS***11-1 Capital leases*

The Company leases certain of its equipment under capital leases. At December 31, 2004, this equipment consists of medical devices for an amount of 852 thousand and vehicles for an amount of 146 thousand. Future minimum lease payments under capital leases for the years ending December 31, are as follows:

	<b>December 31, 2004</b>
	<hr/>
2005	356
2006	355
2007	236
2008	87
2009	35
Total minimum lease payments	1,069
Less: amount representing interest	(72)
Present value of minimum lease payments	997
Less: current portion	(334)
	<hr/>
Long-term portion	663
	<hr/>

During 2002, the Company sold its administrative facility at Croissy-Beaubourg, France, which was held under a 12-year capital lease expiring in 2005 for which a 797.3 thousand impairment charge was recorded in the fourth quarter of 1998. The company recorded a 0.4 million gain on the transaction in 2002.

Interest paid under capital lease obligations was 19 thousand, 4 thousand, and 17 thousand for the years ended December 31, 2004, 2003, and 2002, respectively.

*11-2 Operating leases*

On June 30, 2004, following the reduction in headcount implemented early 2004, the Company reduced its rented office space and cancelled two lease contracts. As of December 31, 2004, operating leases having initial or remaining non-cancelable lease terms greater than one year consists of one lease for the facilities of TMS S.A. in Vaulx-en-Velin, France. This 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 this operating lease will amount to 223 thousand per year until 2006 or 446 thousand in the aggregate, or until the lease is otherwise canceled by the lessee.

Total rent expense under operating leases amounted to 899 thousand, 918 thousand and 1,290 thousand for the years ended December 31, 2004, 2003 and 2002, 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.



## EDAP TMS S.A. AND SUBSIDIARIES

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

**12 SHORT-TERM BORROWINGS**

As of December 31, 2004, short-term borrowings consist of loans in Japanese yen amounting to JPY20 million ( 143 thousand), JPY30 million ( 215 thousand) and JPY23 million ( 167 thousand) due to mature on March 30, May 30 and June 28, 2005, respectively, at an annual rate of 2.2%.

**13 LONG-TERM DEBT**

Long-term debt consists of the following:

	December 31,	
	2004	2003
Japanese yen term loan		67
Other financial debts	6	20
<b>Total</b>	<b>6</b>	<b>87</b>
Less current portion	(6)	(80)
<b>Total long-term portion</b>	<b>0</b>	<b>7</b>

Long-term debt as at December 31, 2004 matures as follows:

2005	6
2006	
<b>Total</b>	<b>6</b>

**14 OTHER LONG-TERM LIABILITIES**

Other long-term liabilities consist of the following:

	December 31,	
	2004	2003
Provision for retirement indemnities	379	404
Other	181	250
<b>Total</b>	<b>560</b>	<b>654</b>



## EDAP TMS S.A. AND SUBSIDIARIES

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

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 within the Company have defined benefit retirement indemnity plans in place. The provision for retirement indemnities at December 31, 2004 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.

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

	<b>Pension Benefits</b>		
	<b>2004</b>	<b>2003</b>	<b>2002</b>
Weighted average assumptions:			
Discount rate	4.50%	4.50%	4.50%
Rate of compensation increase	2.00%	2.50%	2.50%
Retirement age	65	63	63

**15 SHAREHOLDERS' EQUITY***15-1 Common stock*

As of December 31, 2004, EDAP TMS S.A.'s common stock consisted of 9,318,875 authorized shares with a par value of €0.13 each, of which 8,362,821 were issued and fully paid and 7,781,731 were outstanding.

*15-2 Preemptive 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.

*15-3 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 €23,967 thousand and €24,517 thousand at December 31, 2004 and 2003, respectively. Dividend distributions, if any, will be made in euros. The Company has no plans to distribute dividends in the foreseeable future.

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

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

***15-4 Treasury stock***

As of December 31, 2004, the 581,090 shares of treasury stock consisted of (i) 177,750 shares acquired on December 2, 1996 for 707 thousand, (ii) 352,800 shares acquired between August and December 1998 for 1,016 thousand, and (iii) 50,540 shares acquired in June and July 2001 for 153 thousand. All 581,090 shares of treasury stock have been acquired to cover outstanding stock options (see Note 15-5).

***15-5 Stock-option plans***

As of December 31, 2004, EDAP TMS S.A. sponsored seven 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.

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 expire 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.

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

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**  
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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 expire 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). To conform to the terms of the 1998 option plan discussed above, on March 15, 1999, the Board of Directors also amended the terms of 122,250 of certain options granted in 1997 and authorizing certain employees to subscribe to new Shares, modifying their contract into options to purchase Shares at an exercise price of 3.81 instead of 6.97; exercise and vesting conditions remained the same. The Board also amended the terms of 20,125 Share purchase options granted in 1997, modifying the exercise price to 3.81, without modifying exercise and vesting conditions.

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.

On June 24, 1999, the shareholders of EDAP TMS S.A. authorized the Board of Directors to grant up to 68,540 options to purchase pre-existing Shares and 86,885 options to subscribe to new Shares, at a fixed exercise price to be set by the Supervisory Board. Conforming to this plan, on February 21, 2000, the Board of Directors granted 26,000 options to French employees meeting certain tenure criteria. The exercise price was fixed at U.S.\$2.20 ( 2.39) per Share. Of the 26,000 options, 16,000 options were to begin vesting two years after the date of grant and were fully vested as of March 1, 2003; shares acquired pursuant to the options cannot be sold prior to five years from the date of grant. The options expire on February 28, 2010 (i.e. ten years after the date of grant) or when employment with the Company ceases, whichever occurs earlier. The 10,000 remaining options granted on February 21, 2000, were to begin vesting on date of grant and were fully vested on January 1, 2003; shares acquired pursuant to the options cannot be sold prior to five years from the date of grant. The options expired on December 31, 2004 or when employment with the Company ceased, whichever occurred earlier.

On April 2, 2001, the Board of Directors granted 86,885 options to subscribe to new Shares to a Member of the Management Board meeting certain tenure criteria. The exercise price was fixed at \$1.561 ( 1.76) per share. Options began vesting at the date of grant and expire on March 31, 2011 (i.e. ten years 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 euro unless otherwise noted, except per share data)**

On December 18, 2000, the Board of Directors decided to grant 9,000 options to one employee of the Company at an exercise price of \$2.20 ( 2.39) 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. Shares acquired pursuant to the options cannot be sold prior to five years from the date of grant. The options expire on December 31, 2010 (i.e., ten years and three months after the date of grant) or when employment with the Company ceases, whichever occurs earlier.

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 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.

## EDAP TMS S.A. AND SUBSIDIARIES

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

A summary of stock option activity to purchase or to subscribe to Shares under these plans is as follows:

	2004		2003		2002	
	Options	Weighted average exercise price ( )	Options	Weighted average exercise price ( )	Options	Weighted average exercise price ( )
Outstanding on January 1, 2004	391,262	2.68	654,341	2.58	721,550	2.53
Granted	325,000	2.19	0	-	26,425	2.02
Exercised	0	-	0	-	(47,421)	1.76
Forfeited	(136,000)	2.34	(263,079)	2.43	(46,213)	2.37
Expired	-	-	-	-	-	-
Outstanding on December 31, 2004	580,262	2.49	391,262	2.68	654,341	2.58
Exercisable on December 31, 2004	219,547	2.99	272,442	2.94	353,324	3.00
Share purchase options available for grant on December 31	15,000	-	0	-	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, 2004:

Exercise price ( )	Outstanding options			Exercisable options		
	Options	Weighted average remaining contractual life	Weighted average exercise price ( )	Options	Weighted average exercise price ( )	
3.81	117,625	3.5	3.81	117,625	3.81	
2.60	225,000	9.2	2.60	0	0	
2.08 <sup>(1)</sup>	113,000	7.0	2.08	84,500	2.08	
2.02 <sup>(2)</sup>	14,425	7.5	2.02	7,210	2.02	
1.83	10,212	4.5	1.83	10,212	1.83	
1.28	100,000	9.2	1.28	0	0	
1.28 to 3.81	580,262	5.3	2.49	219,547	2.99	

<sup>(1)</sup> All the 113,000 options were granted on September 25, 2001 with an exercise price expressed in U.S. dollars (\$1.92) and converted here into euros based on the noon buying rate on September 25, 2001 (\$1 = 1.085).

<sup>(2)</sup> All the 14,425 options were granted on June 18, 2002 with an exercise price expressed in U.S. dollars (\$1.92) and converted here into 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 euro unless otherwise noted, except per share data)**

The Company applies Accounting Principles Board Opinion No. 25, *Accounting for Stock-Based Compensation* (APB 25), and its related interpretations in accounting for its employee stock options. Under APB 25 and its related interpretations, the options granted or modified in 2004, 2002 and 2001 did not result in recording any compensation expense, additional compensation expense or reversal of compensation expense. Options granted in 2004 recorded a compensation expense amounting 14 thousand.

**16 NET SALES**

Net sales consist of the following:

	2004	2003	2002
Medical devices	11,922	8,557	10,527
Disposables	1,901	1,850	1,505
CPPs	1,422	562	476
Leases	1,564	1,462	1,233
Spare parts & services	5,320	5,599	5,985
<b>Total sales</b>	<b>22,129</b>	<b>18,030</b>	<b>19,725</b>
Warrants granted	(174)		
<b>Total net sales</b>	<b>21,955</b>	<b>18,030</b>	<b>19,725</b>

**Warrants**

On February 25, 2004, the Company entered into a distribution agreement with HealthTronics granting it, among other things, (i) the right to begin clinical trials in the U.S. with the Ablatherm, (ii) the right to seek PMA for the Ablatherm from the FDA and (iii) exclusive Ablatherm distribution rights in the United States, when and if a PMA is granted. Under the terms of the distribution agreement, the Company also agreed to grant HealthTronics 1 million warrants on January 28, 2005, each which will entitle HealthTronics to purchase a share of the Company at a price of U.S.\$1.50 upon their vestiture. The distribution agreement allows HealthTronics to exercise specified numbers of warrants as it meets various specified milestones set out in the distribution agreement, some of which relate to HealthTronics' commitment to purchase a specified number of lithotripter units and others which relate to completion of various stages of the clinical trials and the regulatory process leading to the PMA for the Ablatherm. In accordance with EITF 96-18, the company accounts for the warrants issued to HealthTronics under the distribution agreement based upon the fair value of the warrants, measured at the date of milestone achievement, as there is no performance obligation from HealthTronics. The related amount, which is a non-cash charge, is then recorded as a reduction of revenue.

The non-cash charge, amounting 174,000, was calculated at the fair value using the Black & Scholes pricing model based on the following assumptions:

Risk-Free Interest Rate (%): 3.30,  
Strike (U.S.\$): 1.50,  
Volatility (%): 85,  
Assets (U.S.\$): 3.00,  
Dividend (%): 0.

This non-cash charge of 174,000 recorded for 2004 related to a series of warrants is linked to HealthTronics' purchase of four lithotripters in 2004, in accordance with the terms of the agreement.



## EDAP TMS S.A. AND SUBSIDIARIES

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

**17 OTHER REVENUES**

Other revenues consists of the following:

	<b>2004</b>	<b>2003</b>	<b>2002</b>
Royalties	163	124	97
Grants and others	45	319	139
<b>Total</b>	<b>208</b>	<b>443</b>	<b>236</b>

TMS S.A. and EDAP S.A. received grants of 25 thousand in 2004 and 75 thousand in 2003 and TMS S.A. received grants of 81 thousand in 2002, from the French Ministry of Research and Development.

**18 OPERATING EXPENSES**

In 2004, following the Company's decision in 2003 to reduce headcount in both division (discussed below), the Company recorded non-recurring expenses of 0.3 million, including 0.2 million of employee termination expenses. In 2003, after an extensive review of the businesses, with consideration of the current economic situation and in order to maintain the competitiveness of the Company, EDAP TMS S.A. implemented a reduction in headcount in its two French operational divisions. The reductions represented a decrease of 22% of the French-based workforce. The Company recorded non-recurring expenses of 2.1 million, including 1.8 million of employee termination expenses and 0.2 million of legal and various expenses linked to this reorganization. The balance of the provision as of December 31, 2003 amounted to 2.0 million. This provision was used in 2004, for an amount of 1.7 million of employee termination expenses and 0.2 million of legal and various expenses linked to this reorganization. The balance of the provision amounted to 0.1 million as of December 31, 2004.

Operating expenses also included an additional 0.1 million related to other non-recurring expenses, not directly linked to the reorganization.

In 2002, following the Company's decision to restructure and reorganize its activities into two operating divisions, the Company recorded non-recurring expenses of 1.2 million, including 0.8 million of employee termination expenses, 0.2 million of legal expenses linked to this reorganization and 0.2 million related to various non-recurring expenses.

**19 INTEREST (EXPENSE) INCOME, NET**

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

	<b>2004</b>	<b>2003</b>	<b>2002</b>
Interest income	146	284	502
Interest expense	(75)	(107)	(47)
<b>Total</b>	<b>71</b>	<b>177</b>	<b>455</b>



## EDAP TMS S.A. AND SUBSIDIARIES

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

**20 OTHER INCOME (LOSS), NET**

Other income (loss), net, consists of the following:

	<b>2004</b>	<b>2003</b>	<b>2002</b>
Net gain (loss) on sale of Urologix common stock		(123)	1,669
Other (loss)/income, net	(74)	(95)	(194)
<b>Total</b>	<b>(74)</b>	<b>(218)</b>	<b>1,475</b>

The net gain on sale of Urologix Common Stock in 2002 reflected the net gain on the sale of Urologix Common Stock during the year.

**21 INCOME TAXES***21-1 Income before income taxes*

Income (loss) before income taxes is comprised of the following:

	<b>2004</b>	<b>2003</b>	<b>2002</b>
France	(361)	(8,509)	(3,633)
Other countries	(510)	(581)	(240)
<b>Total</b>	<b>(871)</b>	<b>(9,090)</b>	<b>(3,873)</b>

*21-2 Income tax expense*

Income tax (expense)/benefit consists of the following:

	<b>2004</b>	<b>2003</b>	<b>2002</b>
Current income tax expense:			
France	6	(22)	(59)
Other countries	(29)	(78)	(91)
<b>Sub-total current income tax expense</b>	<b>(23)</b>	<b>(100)</b>	<b>(150)</b>
Deferred income tax (expense) benefit:			
France	(255)	149	(1)
Other countries		65	(16)
<b>Sub-total deferred income tax (expense) benefit</b>	<b>(255)</b>	<b>214</b>	<b>(17)</b>



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Total	(278)	114	(167)
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## EDAP TMS S.A. AND SUBSIDIARIES

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

*21-3 Deferred income tax:*

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 effect of temporary differences which give rise to significant deferred tax assets (liabilities) are as follows:

	<b>December 31,</b>	
	<b>2004</b>	<b>2003</b>
Elimination of intercompany profit in inventory	199	288
Other items	413	411
Net operating loss carryforwards	5,707	5,433
Total deferred tax assets	6,319	6,133
Capital leases treated as operating leases for tax	(4)	(1)
Exit tax	(161)	
Other items	(88)	(85)
Total deferred tax liabilities	(253)	(86)
Net deferred tax assets	6,066	6,047
Valuation allowance for deferred tax assets	(5,989)	(5,715)
Deferred tax assets, net of allowance	77	332

Base net operating loss carryforwards of 1,826 thousand, 2,637 thousand, 1,910 thousand, 583 thousand and 9,585 thousand as of December 31, 2004 are available at EDAP Technomed Inc., TMS S.A., EDAP S.A., Edap Technomed Italia S.R.L. and EDAP TMS S.A., respectively. This net operating loss generates deferred tax assets of 5,707 thousand. Realization of these assets is contingent on future taxable earnings in the applicable tax jurisdictions. As of December 31, 2004, 5,283 thousand out of these 5,707 thousand net operating loss carry-forwards have no expiration date. The remaining tax loss carry-forwards expire in years 2005 through 2011. In accordance with SFAS No. 109, a valuation allowance is recorded as realization of those amounts is not considered as probable.

Deferred taxes have not been provided on the undistributed earnings of domestic subsidiaries as these earnings, with the exception of the earnings of TMS S.A., which benefited from the tax exemption, can be distributed tax-free to EDAP TMS S.A. The tax exempted earnings of TMS S.A. 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.

The Company recorded a corporate income tax benefit of 0.3 million in 2004, principally reflecting income tax with respect to the results of various subsidiaries and an exceptional exit tax in France of 2.5% (which was enacted in compensation for the phase-out of capital gains tax on participation shares). The Company has booked a deferred tax liability amounting to 161 thousand related to this exit tax, which will be paid in two equal installments in 2006 and 2007, pursuant to the Amended Finance Law of 2004, dated December 30, 2004.



## EDAP TMS S.A. AND SUBSIDIARIES

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

*21-4 Effective tax rate*

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

	<b>2004</b>	<b>2003</b>	<b>2002</b>
French statutory rate	34.30%	34.30%	34.30%
Income of foreign subsidiaries taxed at different tax rates	1.90%	0.10%	0.40%
Effect of net operating loss carryforwards and valuation			
Allowances	(31.4%)	(23.50%)	(25.00%)
Non deductible entertainment expenses	(2.60%)	(0.30%)	(0.20%)
Other	(34.10%)	(9.30%)	(13.80%)
Effective tax rate	(31.9%)	(1.30%)	(4.30%)

**22 COMMITMENTS AND CONTINGENCIES***22-1 Commitments*

The Company currently has commitments regarding its operating leases as described in Note 11- 2.

*22-2 Litigation*

The Company is involved in a number of claims and lawsuits considered normal in its business, including employee litigation and product liability matters. While it is not possible to predict the outcome of legal actions brought against the Company, the Company believes that the liability resulting from the pending claims and suits would not have a material adverse effect on the results of its operations, cash flows, or financial position as of December 31, 2004, and for the year then ended.

**23 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, 2004 and 2003.

## EDAP TMS S.A. AND SUBSIDIARIES

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

	December 31,		December 31,	
	2004 Recorded Value	2004 Estimated Fair Value	2003 Recorded Value	2003 Estimated Fair Value
Assets:				
Cash and cash equivalents	9,398	9,398	10,429	10,429
Trade accounts and notes receivable, net	7,722	7,722	8,000	8,000
Liabilities:				
Short-term borrowings	525	525	222	222
Trade accounts payable	2,913	2,913	3,262	3,262
Notes payable	762	762	698	698
Long-term debt	6	6	7	6

The recorded amount of cash and cash equivalents, 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.

Fair value of long-term debt is estimated based on borrowing rates currently available to the Company for loans with similar terms and maturities.

#### 24 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 0.7 and 0.5 million as of December 31, 2004 and 2003. Ultimate losses may vary from the current estimates, and any adjustments are reported in earnings in the periods in which they become known.

In 2004 and 2003, the Company did not generate significant revenue with a single customer. As of December 31, 2002, approximately 1.6 million or 17.3% of the Company's net accounts receivable were attributable to a single customer.

## EDAP TMS S.A. AND SUBSIDIARIES

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

**25 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, 2004, the Company had an option to hedge against Japanese yen for an amount of JPY210 million (i.e. 1,550 thousand), expiring on December 2005 and an option to hedge against US\$ for an amount of US\$300 thousand (i.e. 220 thousand), expiring on May 2005. The fair value of these derivatives was not material as of December 31, 2004.

**26 SEGMENT INFORMATION**

In July of fiscal year 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. The following tables set forth the key income statement figures, by segment for fiscal years 2004, 2003 and 2002 and the key balance sheet figures, by segment, for fiscal years 2004 and 2003.

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 and its related amortization are not allocated to individual segments. A reconciliation of segment operating profit or loss to consolidated net income is as follows:

	2004	2003	2002
Segment operating (loss) profit	(830)	(8,121)	(4,776)
Interest income (expense), net	71	177	455
Currency exchange (losses) gains, net	(38)	(928)	(1,027)
Other income, net	(74)	(218)	1,475
Income tax (expense) credit	(278)	114	(167)
<b>Consolidated net income</b>	<b>(1,149)</b>	<b>(8,976)</b>	<b>(4,040)</b>

## EDAP TMS S.A. AND SUBSIDIARIES

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**  
(in thousands of euro 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, 2004, 2003 and 2002:

	<b>HIFU Division</b>	<b>UDS Division</b>	<b>EDAP TMS</b>	<b>Consolidation</b>	<b>Total consolidated</b>
<b>2004</b>					
External sales of medical devices	3,733	8,189			11,922
External sales of spares parts, Supplies & services	2,915	7,291			10,206
Internal segment revenues	287	1,905		(2,192)	
Total sales	6,935	17,385		(2,192)	22,128
Warrants granted		(174)			(174)
Total net sales	6,935	17,211		(2,192)	21,954
Other revenues	34	174			208
Total revenues	6,969	17,385		(2,192)	22,162
<b>Total COS</b>	<b>(3,749)</b>	<b>(12,119)</b>		<b>2,192</b>	<b>(13,676)</b>
<b>Gross margin</b>	<b>3,220</b>	<b>5,266</b>			<b>8,486</b>
<b>R&amp;D</b>	<b>(492)</b>	<b>(329)</b>			<b>(821)</b>
Clinical trials	(325)	(15)			(340)
Regulatory		(362)			(362)
Marketing	(279)	(454)			(733)
Selling	(996)	(1,674)			(2,670)
G&A	(659)	(2,221)	(1,193)		(4,073)
Non recurring	(82)	(27)	(208)		(317)
<b>Total expenses</b>	<b>(2,833)</b>	<b>(5,082)</b>	<b>(1,401)</b>		<b>(9,316)</b>
<b>Operating income (loss)</b>	<b>387</b>	<b>184</b>	<b>(1,401)</b>		<b>(830)</b>
<b>Assets</b>	<b>7,162</b>	<b>20,334</b>	<b>6,645</b>	<b>(6,256)</b>	<b>27,885</b>
Capital expenditures	287	844	2		1,133
Long-lived assets	969	1,816	22		2,806
Goodwill	645	1,767			2,412

## EDAP TMS S.A. AND SUBSIDIARIES

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

	<b>HIFU Division</b>	<b>UDS Division</b>	<b>EDAP TMS</b>	<b>Consolidation</b>	<b>Total consolidated</b>
<b>2003</b>					
External sales of medical devices	1,148	7,364			8,512
External sales of spares parts, supplies & services		1,709	7,809		9,518
Internal segment revenues	3	1,967		(1,970)	
Other revenues	99	342	2		443
Total revenues	2,959	17,482	2	(1,970)	18,473
<b>Total COS</b>	<b>(2,056)</b>	<b>(12,771)</b>		<b>1,733</b>	<b>(13,094)</b>
<b>Gross margin</b>	<b>903</b>	<b>4,711</b>		<b>(237)</b>	<b>5,379</b>
R&D	(1,523)	(313)			(1,836)
Clinical trials	(651)				(651)
Regulatory	(171)	(412)			(583)
Marketing	(944)	(322)			(1,266)
Selling	(1,079)	(1,883)			(2,962)
G&A	(747)	(2,005)	(1,353)		(4,105)
Non recurring	(1,590)	(463)	(44)		(2,097)
<b>Total expenses</b>	<b>(6,705)</b>	<b>(5,398)</b>	<b>(1,397)</b>		<b>13,500</b>
<b>Operating income (loss)</b>	<b>(5,802)</b>	<b>(687)</b>	<b>(1,395)</b>	<b>(237)</b>	<b>(8,121)</b>
Assets	9,432	21,050	5,238	(3,810)	31,910
Capital expenditures	635	1,138	25		1,798
Long-lived assets	1,334	1,541	28		2,903
Goodwill	645	1,767			2,412



## EDAP TMS S.A. AND SUBSIDIARIES

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

	<b>HIFU Division</b>	<b>UDS Division</b>	<b>EDAP TMS</b>	<b>Consolidation</b>	<b>Total consolidated</b>
<b>2002</b>					
External sales of medical devices	1,890	8,486			10,376
External sales of spares parts, Supplies & services	1,189	8,160			9,349
Internal segment revenues	262	1,573		(1,835)	
Other revenues	35	201			236
<b>Total revenues</b>	<b>3,376</b>	<b>18,419</b>		<b>(1,835)</b>	<b>19,961</b>
<b>Total COS</b>	<b>(1,877)</b>	<b>(11,461)</b>		<b>(1,835)</b>	<b>(11,503)</b>
<b>Gross margin</b>	<b>1,499</b>	<b>6,959</b>			<b>8,458</b>
R&D	(1,532)	(379)		69	(1,842)
Clinical trials	(550)				(550)
Regulatory	(440)	(518)		164	(794)
Marketing	(690)	(783)		63	(1,410)
Selling	(747)	(1,996)		129	(2,614)
G&A	(939)	(2,236)	(1,183)	(426)	(4,784)
Non recurring		(478)	(762)		(1,240)
<b>Total expenses</b>	<b>(4,898)</b>	<b>(6,390)</b>	<b>(1,946)</b>		<b>(13,234)</b>
<b>Operating income (loss)</b>	<b>(3,399)</b>	<b>569</b>	<b>(1,946)</b>		<b>(4,776)</b>
Assets	13,712	25,859	5,656	(5,439)	39,788
Capital expenditures	440	787	8		1,235
Long-lived assets	1,024	954	7		1,985
Goodwill	645	1,767			2,412

## EDAP TMS S.A. AND SUBSIDIARIES

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

**27 VALUATION ACCOUNTS**

	<b>Allowance for doubtful accounts</b>	<b>Slow-moving inventory</b>
Restated balance as of December 31, 2001	917	2,068
Charges to costs and expenses	51	624
Deductions: write-off of bad debts provided in prior periods	(106)	(1,144)
Translation adjustment		(20)
Restated balance as of December 31, 2002	862	1,528
Charges to costs and expenses	41	569
Deductions: write-off of bad debts provided in prior periods	(377)	(380)
Restated balance as of December 31, 2003	526	1,717
Charges to costs and expenses	204	252
Deductions: write-off of bad debts provided in prior periods	(25)	(1,265)
Restated balance as of December 31, 2004	705	704

**28 SUPPLEMENTAL DISCLOSURES OF CASH FLOW INFORMATION**

Interest and income taxes paid are as follows:

	<b>2004</b>	<b>2003</b>	<b>2002</b>
Income taxes paid (refunds received)	(82)	(560)	112
Interest paid	19	21	2
Interest received	120	223	278
Non-cash transactions:			
	<b>2004</b>	<b>2003</b>	<b>2002</b>
Capital lease obligations incurred	998	792	

**29 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 the Company medical devices installed in Korea for an amount of 63 thousand, 33 thousand and 53 thousand, for 2004, 2003 and 2002 respectively.

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Dae You is also acting as an agent to promote the Company's medical devices in South Korea, and receives commissions on sales.

Dae You also purchased medical devices from the Company and operates them in partnership with hospitals or clinics for an amount of 401 thousand, 309 thousand and 285 thousand in 2004, 2003 and 2002 respectively.

As of December 31, 2004, there were no receivables nor payables recorded for Dae You. As of December 31, 2003, receivables amounted to 104 thousand and there were no payables.

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