

Edgar Filing: EDAP TMS SA - Form 20-F

EDAP TMS SA  
Form 20-F  
May 08, 2003

AS FILED WITH THE SECURITIES AND EXCHANGE COMMISSION ON MAY 8, 2003

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

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

For the Fiscal Year Ended December 31, 2002

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 -----	Name of each exchange on which registered -----
------------------------------	---

NONE

NONE

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

AMERICAN DEPOSITARY SHARES, EACH

REPRESENTING ONE ORDINARY SHARE

ORDINARY SHARES, NOMINAL VALUE

[e] 0.13 PER SHARE

Securities for which there is a reporting obligation pursuant to Section 15(d)  
of the Act:

NONE



# Edgar Filing: EDAP TMS SA - Form 20-F

## TABLE OF CONTENTS

	PAGE
Presentation of Financial and Other Information.....	1
Forward-looking Information.....	1
PART I	
ITEM 1. Identity of Directors, Senior Management and Advisors.....	2
ITEM 2. Offer Statistics and Expected Timetable.....	2
ITEM 3. Key Information.....	2
ITEM 4. Information on the Company.....	9
ITEM 5. Operating and Financial Review and Prospects.....	19
ITEM 6. Directors, Senior Management and Employees.....	29
ITEM 7. Major Shareholders and Related Party Transactions.....	35
ITEM 8. Financial Information.....	35
ITEM 9. The Offer and Listing.....	36
ITEM 10. Additional Information.....	39
ITEM 11. Quantitative and Qualitative Disclosures about Market Risk.....	51
ITEM 12. Not Applicable.....	52
PART II	
ITEM 13. Defaults, Dividends Arrearages and Delinquencies.....	53
ITEM 14. Material Modifications to the Rights of Security Holders and Use of Proceeds	53
ITEM 15. Controls and Procedures.....	53
ITEM 16A. Not Applicable.....	53
ITEM 16B. Not Applicable.....	53
ITEM 16C. Not Applicable.....	53
PART III	
ITEM 17. Financial Statements.....	53
ITEM 18. Financial Statements.....	53
ITEM 19. Exhibits.....	53

[THIS PAGE INTENTIONALLY LEFT BLANK]

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, 2002.

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 "French francs", " francs" or "FF" are to the

## Edgar Filing: EDAP TMS SA - Form 20-F

legal currency of The Republic of France, references to "euros" or "[e]" are to the legal currency of the countries of the European Monetary Union, including The Republic of France, and references to "dollars" or "\$" are to the legal currency of the United States of America. As of January 1, 1999, the conversion rate between the euro and the French franc was fixed irrevocably at [e] 1 = FF 6.55957, the exchange rate set by the Council of the European Union. Beginning with its financial statements for the fiscal year ended December 31, 1999, the Company has been reporting its financial results in euros. For purposes of this Annual Report, financial information for fiscal years prior to 1999 was converted from French francs to euros at the exchange rate set by the Council of the European Union for use as of January 1, 1999. 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 euros into dollars have been made at the rate of \$1.00 = [e] 0.9537, the rate derived from the noon buying rate in The City of New York for cable transfers in euros as certified for customs purposes by the Federal Reserve Bank of New York (the "Noon Buying Rate") on December 31, 2002. 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.

## Edgar Filing: EDAP TMS SA - Form 20-F

### 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, 2001 and 2002 and the income statement data for the years ended December 31, 2000, 2001 and 2002 set forth below have been derived from the Consolidated Financial Statements. The balance sheet data as of December 31, 1998 and 1999 and the income statement data for the years ended December 31, 1998 and 1999 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,	1998 (1)	1999	2000	2001	2002	2002 (2)
-----	-----	-----	-----	-----	-----	-----
	[e]	[e]	[e]	[e]	[e]	\$
	-----	-----	-----	-----	-----	-----
<b>INCOME STATEMENT DATA</b>						
Total revenues.....	20,668	19,881	27,252	23,965	19,961	20,929
Net sales.....	19,263	19,107	24,809	23,804	19,725	20,682
Gross profit.....	9,210	9,211	13,060	7,979	8,458	8,868
Operating expenses(3).....	(18,721)	(16,869)	(16,795)	(13,093)	(13,234)	(13,876)
Income (loss) from operations.....	(9,511)	(7,658)	(3,735)	(5,114)	(4,776)	(5,008)
Income (loss) before income taxes.....	(9,636)	(6,487)	12,032	8,019	(3,873)	(4,061)
Income taxes.....	(181)	256	(323)	(882)	(167)	(175)
Net income (loss).....	(9,817)	(6,231)	11,709	7,137	(4,040)	(4,236)
Net income (loss) per Share	(1.19)	(0.80)	1.50	0.92	(0.52)	(0.55)
Dividends per Share(4).....	---	---	---	---	---	---
Weighted average shares outstanding used in diluted calculation.....	8,248	7,815	8,266	7,942	7,771	7,771
Diluted earnings per Share.....	(1.19)	(0.80)	1.42	0.90	(0.52)	(0.54)
<b>BALANCE SHEET DATA</b>						
Total current assets.....	32,856	23,897	39,881	45,927	34,091	35,744
Property, plant and equipment, net.....	1,719	3,089	1,825	2,233	1,985	2,081
Total current liabilities.....	14,559	13,953	10,185	11,916	9,880	10,359
Total assets.....	44,923	36,355	50,287	53,115	39,787	41,717
Long-term debt, less current portion(5)	7,053	6,344	3,478	304	95	100
Total shareholders' equity.....	22,363	15,424	34,679	38,909	28,375	29,751

-----

## Edgar Filing: EDAP TMS SA - Form 20-F

- (1) Amounts have been converted from French francs into euros using the exchange rate set by the Council of the European Union for use as of January 1, 1999 of [e] 1 = FF 6.55957.
- (2) Translated for convenience of the reader at the Noon Buying Rate on December 31, 2002 of \$1 = [e] 0.9537. See "Presentation of Financial and Other Information" on page 1 of this Annual Report.
- (3) The Company recorded a charge for impairment of long-lived assets of [e] 0.8 million in 1998.
- (4) No dividends were paid with respect to fiscal years 1998 through 2001 and subject to approval of the annual shareholders' meeting to be held in June 2003, the Company does not anticipate paying any dividend with respect to fiscal year 2002. See Item 8, "Financial Information-Dividends and Dividend Policy."
- (5) Long-term debt includes the long-term portion of capital lease obligations.

2

### 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.

As of January 1, 1999, the conversion rate between the euro and the French franc was fixed irrevocably at [e] 1.00 = FF 6.55957. See "Presentation of Financial and Other Information" on page 1 of this Annual Report.

The following table sets forth, for each of the years indicated, the high, low, average and year-end Noon Buying Rates expressed in euros per \$1.00. For the year 1998, the high, low, average and year-end Noon Buying Rates for the French franc are shown converted into euros at the exchange rate set by the Council of the European Union for use as of January 1, 1999 of [e] 1 = FF 6.55957 and expressed in euros per \$1.00.

YEAR ENDED DECEMBER 31,	HIGH	LOW	AVERAGE (1)	END OF YEAR
-----	-----	-----	-----	-----
	[e]	[e]	[e]	[e]
	----	----	-----	-----
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
1999.....	0.97	0.85	0.94	0.99
1998.....	0.95	0.82	0.90	0.85

- 
- (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

## Edgar Filing: EDAP TMS SA - Form 20-F

Information" on page 1 of this Annual Report.

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

	HIGH	LOW
	----	----
	[e]	[e]
	----	----
October..	1.03	1.01
November.	1.01	0.99
December.	1.01	0.95
January..	0.97	0.92
February.	0.93	0.92
March....	0.94	0.90

On April 25, 2003, the latest practicable date before the filing of this Annual Report with the U.S. Securities and Exchange Commission, the Noon Buying Rate was \$1.00 = [e] 0.9058.

### RISK FACTORS

#### DEPENDENCE ON HIFU TECHNOLOGY

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 BPH, was one of the Company's three principal lines of medical devices. Although the Company continues to manufacture the Prostatron on behalf of Urologix, it only derived approximately 10% of its total revenues for the year ended December 31, 2002 from these sales, compared to 25% of total revenues (including revenues from non-recurring sales of technology transfer services) for the year ended December 31, 2001. Revenues from these sales are expected to represent no more than 10% of total revenues for the year ended December 31, 2003 and beyond. Meanwhile, the Company's Extra-corporeal 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 third 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 the early phase of its commercialization 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 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. The Company



## Edgar Filing: EDAP TMS SA - Form 20-F

may re-submit the request and has received from the FDA specific instruction on the expected protocol. If the Company chooses not to re-submit an IDE to the FDA it will not be able to market the Ablatherm in the United States as a primary therapy, but only, assuming successful completion of current clinical trials and FDA approval, as a salvage therapy where prior treatment has failed. The Company has begun the process of identifying a U.S. partner to assist in the approval process for re-submission of an IDE to the FDA. This process is ongoing and may not result in the identification of such a partner. The Company believes that these limitations would significantly hamper its ability to market the Ablatherm in the United States. The risks related to a FDA approved IDE study and the identification of a partner is specific to the U.S. market. See "----Uncertainty Relating to Clinical Trials; Clinical Status of Certain Products using HIFU Technology" and Item 4, "Information on the Company---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---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 no errors or omissions in such data that would materially adversely affect the development of such products.

The process of attempting to obtain 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 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 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 payors, which has not been provided for the

## Edgar Filing: EDAP TMS SA - Form 20-F

Company's HIFU products in any country, except Italy,

4

in which the products are currently sold, 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.

### 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 continue to 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. While the Company realized net income in 2000 and 2001, net income in 2000 reflected in large part the sale of the Prostatron business to Urologix and net income in 2001 reflected in large part gains on the sales of Urologix common stock by the Company. There can be no assurance 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 calculous disease, competition in that market comes principally from current manufacturers of lithotripters, including Siemens 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"), General Electric Medical Systems ("General Electric") and Toshiba Corporation ("Toshiba"). See Item 4 "Information on the Company---High Intensity Focused Ultrasound Division---HIFU Competition" and "---Urology Devices and Services Division: ESWL Competition."

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. The Company is currently experiencing ESWL declining revenues in its maintenance and service contract business and may not be able to offset these decreases with increases in other businesses.

5

#### 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 (Company)."

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 payors 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 payors. 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

## Edgar Filing: EDAP TMS SA - Form 20-F

reimbursement and, consequently, relevant approvals have to be sought in each member State. Failure to establish sufficient reimbursement from healthcare payors or adverse changes in governmental and private healthcare payors' 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 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, 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.

6

### 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 extended 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

## Edgar Filing: EDAP TMS SA - Form 20-F

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 proceedings 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---HIFU Division Patents and Intellectual Property", and "---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 seek to 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.

7

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

## Edgar Filing: EDAP TMS SA - Form 20-F

agreed to retain liability following the sale of the Prostatron business in October 2000. Additionally, the Company has been informed of an intent to commence legal action associated with a product liability claim, however, the Company has, as of the date of this report, not been included as a defendant in this action. 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.

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 2002, approximately 64% of the Company's selling and general and administrative expenses and approximately 94% of the Company's research and development expenses were denominated in euros, while approximately 51% of the Company's sales were denominated in currencies other than euros (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. No foreign exchange forward sale contracts were outstanding at December 31, 2002 and none are currently in place. In addition, since any dividends that may be declared by the Company will be denominated in euros, 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, cyclicity 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

8

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 U.S. holders of shares in companies that are considered passive foreign investment companies ("PFICs"). The unfavorable consequences of the rules can be alleviated by making the election described in Item 10 "Taxation---U.S. Investors---Passive Foreign Investment Company Rules." The Company believes it was a PFIC in the year 2002. It is uncertain whether the Company will be a PFIC in the year 2003. U.S. holders, therefore, should consider making a mark-to-market election. U.S. holders should consult their tax advisors regarding the potential consequences of PFIC treatment and the implications of the election as described in Item 10 "Taxation---U.S. Investors---Passive Foreign Investment Company Rules."

#### 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, a non-cancerous urological condition, 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. Following its sale of 1,676,979 Urologix shares, including shares issued upon exercise of the warrants, as of April 7, 2003 the Company held 15,487 Urologix shares, representing less than 1% of Urologix's total share capital. Additionally, the Company and Urologix entered into a supply agreement 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").

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 an Executive Board into a single Board of Directors. Additionally, two separate, fully consolidated, operating divisions were created: the High Intensity Focused Ultrasound ("HIFU") division and the

## Edgar Filing: EDAP TMS SA - Form 20-F

Urology Devices and Services ("UDS") division, with each division being headed by its own President.

The Company's legal name is EDAP TMS S.A. and the Company's commercial name is EDAP TECHNOMED. EDAP TMS S.A. was incorporated on December 3, 1979 as a societe 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'Activites la Poudrette-Lamartine, 4/6 rue du Dauphine, 69120 Vaulx-en-Velin, France and its telephone number is +33 (0)4 72 15 31 50. The offices of EDAP Technomed, Inc., the Company's U.S. subsidiary, are located at 100 Pinnacle Way, Suite 135, Norcross GA 30071, and its telephone number is +1 (770) 446-9950.

9

### 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 will allow it to expand its market share by optimizing worldwide distribution capabilities, all of which is coordinated through the Company's. 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 23 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 and geographical markets.

### 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	JURIDICTION OF ESTABLISHMENT	PERCENTAGE OWNED (1)
Technomed Medical Systems S.A.	France	100%
EDAP S.A.....	France	100%
EDAP Technomed Inc.....	United States	100%
EDAP Technomed Co. Ltd.....	Japan	100%
EDAP Technomed Sdn Bhd.....	Malaysia	100%
EDAP Technomed Srl.....	Italy	100%

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



## Edgar Filing: EDAP TMS SA - Form 20-F

through subsidiaries.

### 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 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.

#### 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, general anesthesia and their resulting complications. The Ablatherm, a HIFU-based device developed and marketed by the HIFU division for the treatment of organ-confined prostate cancer, is approved for commercial distribution in the European Union, Canada, South Korea and Russia, and is undergoing clinical trials in the United States. The HIFU division had an installed base of 16 Ablatherm machines worldwide as of December 31, 2002.

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.

#### 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

10

HIFU division believes that minimally-invasive treatments using HIFU could provide an alternative to current invasive therapies on the basis of reduced cost and minimized side effects 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 Extra-corporeal Shockwave Lithotripsy (ESWL) market of the UDS division, the HIFU division is striving to become a leading provider of minimally invasive treatment alternatives for prostate cancer, the incidence of which the HIFU division believes will increase as the male population ages in developed countries. The HIFU division believes that HIFU could represent an 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.
- \* Achieve Long-Term Growth by Expanding HIFU Applications Beyond Urology. The HIFU division's long-term growth strategy is to apply its HIFU technology toward the minimally-invasive treatment of indications beyond

## Edgar Filing: EDAP TMS SA - Form 20-F

urological disorders. 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."

### 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. There are clinical trials underway in the United States and requests for marketing clearance have been submitted to the appropriate regulatory agencies in Japan.

### HIFU DIVISION PRODUCT DEVELOPMENT PROGRAM

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 pre-defined 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 anesthesia.

### HIFU DIVISION PATENTS AND INTELLECTUAL PROPERTY

As of December 31, 2002, the HIFU division had obtained 54 patents covering key technologies relating to HIFU systems and associated software capabilities (consisting of 28 in the United States, 21 in the European Union and Japan and 5 in Israel), and has recently applied for additional patents covering certain other aspects of its HIFU technology in the European Union, the United States, Japan, Canada, Israel and Switzerland.

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 prosecuted, 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 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.

### HIFU DIVISION CLINICAL AND REGULATORY STATUS

The HIFU division has conducted an extensive clinical trial for the

## Edgar Filing: EDAP TMS SA - Form 20-F

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 Mark which allows the Company to market the Ablatherm in the European Union.

In 2000, 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.

In addition, in January 1999, the HIFU division obtained from the FDA an IDE to conduct clinical trials for the Ablatherm as a salvage therapy in the United States. Following receipt of the IDE, the Company initiated a trial in the United States to study the safety and effectiveness of the Ablatherm for patients who have experienced a local recurrence of their cancer after previous external beam radiation therapy failed (a patient population for which there are currently limited treatment options). The endpoints of the trial are primarily to show negative randomized sextant biopsies and secondarily to show low, stable PSA levels at least 12 months after treatment. The trial will involve approximately 120 patients.

In addition to three US sites (Georgetown University Hospital, Baylor College in Houston and Washington University in Saint Louis), the study will be extended to four European sites (University Hospital in Caen, France, La Pitie-Salpetriere University Hospital in Paris, France, University Hospital in Mannheim, Germany and University Hospital in Madrid, Spain).

In December 2001, the HIFU division submitted to the FDA a request for an additional IDE for the Ablatherm as a primary care in the localized prostate cancer indication. The proposed investigational plan was denied by the FDA. During 2002, the HIFU division conducted discussions with the FDA regarding the conditions under which it could re-submit the request and received specific instruction on the protocol the FDA would expect as a primary therapy. The HIFU division, after reviewing the recommendations of the FDA, began the process of identifying a U.S. partner to assist in the approval process in the United States. This process is ongoing and may not result in the identification of such a partner. See Item 3, "Key Information---Risk Factors---Dependence on HIFU Technology."

In June 2000, the HIFU division applied for an approval by the Japanese

## Edgar Filing: EDAP TMS SA - Form 20-F

Minister of Health for the Ablatherm to be marketed in Japan. The application is still under review.

### HIFU DIVISION MANUFACTURING

The HIFU division's policy is to subcontract the manufacture for its devices and accessories, including consumables. The HIFU division purchases all of the devices and accessories, including consumables, used in its marketing and sales functions from a single supplier, Technomed Medical Systems, part of the UDS division of the Company. It is the HIFU division's belief that, since its

12

only supplier is also a subsidiary of the same parent, there is no significant risk associated with the use of a single supplier. However, since the HIFU division does have its own independent quality system, it is its policy to conduct frequent quality audits of suppliers' manufacturing facilities.

### HIFU DIVISION QUALITY AND DESIGN CONTROL

The HIFU division has obtained the ISO 9001 (V2000), EN 46001 (V1996) 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 189,000 new cases of prostate cancer were diagnosed in 2002, and 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 been growing 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, gynecological, bladder, liver, brain, pancreatic and retroperitoneal tumors.

### 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.

## Edgar Filing: EDAP TMS SA - Form 20-F

The HIFU division's devices compete with all current treatments for localized tumors, which include surgery, brachytherapy, radiotherapy, cryotherapy and hormonotherapy. 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 General Electric, Insightec and Focus Surgery. Certain existing and potential competitors of the HIFU division may have substantially greater financial, research and development, 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 market for HIFU treatments will be the ability to make the substantial investments in research and development that will be required to bring the technology to market.

### 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 a direct marketing and sales force in France, Belgium, Germany and Italy, which currently represent EDAP's largest markets. Additionally, the HIFU division markets and sells its products through the Company's distribution platform in South Korea and Malaysia of the UDS division and further markets its products through agents and third-party distributors in several countries. In December 2002, the Company closed its direct sales and service office in the United States, therefore, the HIFU division has taken direct responsibility for the U.S. clinical trial.

13

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 and enable it to monitor the urological market, introduce new products and conduct trials under satisfactory conditions. No single customer of the HIFU division represents a significant portion of the division's installed base.

The HIFU division's marketing efforts include the organization of training programs for urologists worldwide.

### 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 US 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.

### 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 Extra Corporeal Shockwave Lithotripsy (ESWL) technology. ESWL uses extracorporeal shockwaves, which can be focused at urinary stones within the

## Edgar Filing: EDAP TMS SA - Form 20-F

human body, to fragment urinary stones, thereby permitting their natural elimination and preventing the need for incisions, transfusions, general anesthesia and 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 381 ESWL lithotripters worldwide as of December 31, 2002, with the European Union, Japan and the United States accounting for 37%, 25%, and 3%, respectively, of the total installed base of ESWL lithotripters of the division.

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 the Prostatron in Japan and Italy under the Distribution Agreement entered into with Urologix in October 2000.

Finally, 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 also manufactures certain components of the Prostatron. The UDS division, as an additional part of its contract manufacturing business, manufactures HIFU related devices and accessories, including consumables, 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, Prostatron devices (on behalf of Urologix) and HIFU devices (on behalf of the HIFU division). The key elements of the UDS division's strategy are:

14

- \* 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 consumables, accessories, services and replacement machines. The UDS division believes that a combination of continued investment in lowering end-user costs, 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 world-wide.

## Edgar Filing: EDAP TMS SA - Form 20-F

\* 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 leading 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), EN 46001 (V1996) and ISO 13485 (V1996) certified facilities allow the UDS division 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 lithotripters disposable parts, 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 those parts.

PRODUCT	PROCEDURE	DEVELOPMENT STAGE	CLINICAL AND REGULATORY STATUS
SONOLITH Praktis compact lithotripter	Electroconductive treatment of urinary stones	Commercial Production	Approved for distribution: European Union Japan United States Canada
SONOLITH Vision	Electroconductive treatment of urinary stones	Commercial Production	Approved for distribution: European Union Japan Canada
LT02 lithotripter	Piezo-electric treatment of urinary stones	Discontinued	Approved for distribution: European Union United States Japan

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

## Edgar Filing: EDAP TMS SA - Form 20-F

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 December 31, 2002, the UDS division had obtained 27 patents covering key technologies relating to ESWL systems and associated software capabilities (consisting of 10 in the United States, 15 in the European Union and Japan and 2 in Israel).

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 Dasonics Inc., TMS granted both companies a non-exclusive license to use its patented technology. The UDS division's ongoing research and development objectives in ESWL are to increase further 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 anticipates filing a request for commercial distribution approval of the SONOLITH Vision in the United States in 2003. The UDS division continues to provide consumables, 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 extra-corporeal 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



## Edgar Filing: EDAP TMS SA - Form 20-F

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 Dornier, Siemens and Storz.

### 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

16

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, opting instead to use third-party distributors and agents in North America.

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 Prostatron devices for Urologix and the Ablatherm on behalf of the HIFU division. 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 ISO9001, ISO46001, EN13485 International standards and FDA approved manufacturing facility.

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 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 in a more economic manner- perform final assembly, 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

## Edgar Filing: EDAP TMS SA - Form 20-F

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 Technomed Medical Systems' ("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 traceability and retention, among other things. TMS's facilities are also subject to scheduled inspections by the FDA. TMS has obtained the ISO 9001, EN 46001 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 2,345 square meters of office space and 3,000 square meters of factory space 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 has ISO 9001, EN 46001 and ISO13485 certifications and specific GMP approval for the Prostatron.

17

The Company had another facility located in Marne-la-Vallee, on the outskirts of Paris, which was sold in October 2002. As a result the Company recorded a net gain on the disposal of these assets of [e] 0.4 million that year. The Company does not anticipate incurring any additional charges related to this financial lease agreement.

In addition, the Company rents office and/or warehouse facilities in Atlanta, Kuala Lumpur, Rome, Seoul, Fukuoka, Osaka and Tokyo.

### 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,

## Edgar Filing: EDAP TMS SA - Form 20-F

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 good manufacturing processes ("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), EN 46001 (V1996) and ISO 13485 (V1996) certifications, showing that the Company complies with standards for quality assurance, 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 have to comply with the requirement of the above mentioned 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 greater degree of supervision. All of the devices currently marketed by the Company are Class IIb devices.

## Edgar Filing: EDAP TMS SA - Form 20-F

### HEALTHCARE REGULATION IN JAPAN

The import and sale of medical devices in Japan is regulated by the MHW. 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 import and sale of such devices by the importer and specific licenses for each device. The Company's Japanese subsidiary has obtained a general license and has also obtained a specific license to import those of the Company's products that are approved in Japan. The MHW 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 MHW 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 MHW'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, 2000, 2001 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" on page 1 of 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

## Edgar Filing: EDAP TMS SA - Form 20-F

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.

19

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.

### 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' credit worthiness 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 account 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

The Company, on an annual basis, 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, 2001, the Company's inventory of one product was in excess of its current requirements based on the transfer of manufacturing of this product to Urologix pursuant to the agreements dated October 1, 2000. As a result, the Company recorded a full depreciation of these inventories at December 31, 2001 with a charge of [e] 0.8 million. 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

## Edgar Filing: EDAP TMS SA - Form 20-F

31, 2002 with a charge of [e] 0.6 million.

### LITIGATION

The Company has been notified that it is currently a defendant in four legal proceedings, two associated with product liability matters and two claiming fraud related to the sale of medical equipment. The Company has also been informed of an intent to commence legal action associated with a product liability claim, however, the Company has, as of the date of this report, not been included as a defendant in this action. Additionally, the Company has settled a claim alleging failure to make license payments brought against one of its subsidiaries. The cost of settling this claim, [e] 0.3 million, was included in the consolidated financial statements of the Company dated December 31, 2002. The Company does not believe that it is currently a party to any legal proceeding that will have a material adverse effect on its consolidated financial position. It is possible, however, 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.

20

### DEFERRED TAX ASSETS

As of December 31, 2002, the Company had approximately [e] 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 enough 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.

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.

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,

## Edgar Filing: EDAP TMS SA - Form 20-F

as well as from operating leases of the Company's medical devices.

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 25.7% of such sales in 2002 and consisted primarily of sales of ESWL lithotripters. Net sales of spare parts, supplies and services in Japan represented approximately 38.2% of such sales in 2002 and related primarily to ESWL lithotripters, reflecting the fact that approximately 25% of the installed base of the Company's ESWL lithotripters is located in Japan. See Note 23 of the Notes to the Consolidated Financial Statements. Sales in Japan are effected through EDAP Technomed Co. Ltd., the Company's wholly-owned Japanese subsidiary.

Other revenues consists principally of license fee and royalty payments from third parties with respect to the Company's intellectual property and operating subsidiaries from French governmental agencies. See Note 14 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, selling expenses, general and administrative expenses, depreciation and amortization and non-cash charges for impairment of long-lived assets.

Research and development expenses include all costs related to the development of new technologies and products and the enhancement of existing products, including the costs of organizing clinical trials and of obtaining patents and regulatory approvals. The Company does not capitalize any of its research and development expenses, except for the expenses relating to the production of

21

machines to be used in clinical trials, which are amortized over a three-year period equivalent to the clinical trial period. The net book value of these machines, which have alternative future uses as equipment or components for future research, amounted to [e] 0.3 million as of December 31, 2002.

Research and development expenses have amounted to [e] 3.2 million, [e] 3.4 million and [e] 4.0 million in 2002, 2001 and 2000, respectively, representing approximately 16%, 14% and 16 % of total revenues in 2002, 2001 and 2000, respectively. Management expects the budget for research and development expenses for the foreseeable future to range from 15% to 20% of anticipated total revenues in each fiscal year, principally in connection with research and development in HIFU.

In 2002, the Company recorded a non-recurring operating expense of [e] 1.2 million reflecting mainly the costs associated with restructuring the Company into two separate operating units. The Company did not record any non-recurring operating expenses in 2001 or 2000. See Note 15 of the Notes to the

## Edgar Filing: EDAP TMS SA - Form 20-F

### Consolidated Financial Statements.

The Company benefited in 2000 from tax credits for research and development expenses. Pursuant to French tax law, the amount of such tax credits in any given year is equal to half of the amount of the increase in research and development expenses in such year over the average of such expenses for the two previous years, subject to certain adjustments. Research tax credits amounted to [e] 150,000 in 2000. See Note 18 of the Notes to the Consolidated Financial Statements.

In December 1996, the Company acquired the 20% minority interest in TMS which was previously held outside the Company. As a result of that purchase of minority interest, the Company recorded [e] 3.2 million of goodwill, a [e] 0.12 million step-up in the historical carrying value of certain tangible assets of TMS and a [e] 0.41 million step-up in the historical carrying value of certain identifiable intangible assets of TMS, which are amortized over 25, eight and five years, respectively. Following the sale of the Company's Prostatron business to Urologix in October 2000, the Company recorded additional amortization in fiscal year 2000 to write off the portion of the remaining goodwill and carrying value of these assets related to the Prostatron business, resulting in 2000 in an amortization charge for goodwill of [e] 1.49 million and charges for additional depreciation and amortization of fixed assets and intangible assets of [e] 29,000 and [e] 76,000, respectively. In December 1997, the Company purchased the 49.9% minority interest held by Nippon Eurotec in EDAP Technomed Co. Ltd, the Company's wholly-owned Japanese subsidiary. The yearly impact of the amortization over 25 years of the goodwill recorded as a result of that transaction is [e] 60,000. However, pursuant to the Financial Accounting Standard Board issuance of SFAS No. 142, "Goodwill and Other Intangible Assets," the Company no longer amortizes its goodwill, in a straight-line method over its estimated useful life, instead it now tests its goodwill for impairment on an annual basis and/or whenever indicators of impairment arise. The Company did not record any charge, in 2002, for the impairment of goodwill.

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 increased expenses in connection with the development, marketing and commercial launch of HIFU applications, including the Ablatherm. See "---Liquidity and Capital Resources." Such increased expenses will be offset only partially in the near future by revenues arising from sales of HIFU devices.

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

### SALE OF THE PROSTATRON BUSINESS TO UROLOGIX

In October 2000, the Company sold its Prostatron business to Urologix. See



## Edgar Filing: EDAP TMS SA - Form 20-F

Item 4, "Information on the Company" and Item 10, "Additional Information--- Material Contracts." The principal effects of the sale of the Prostatron business on the Company's results of operations are summarized below:

- 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. Sales of Prostatron units and spare parts, maintenance services and disposable parts for the Prostatron amounted to [e] 8.7 million, or approximately 36% of total revenues, in 2000. Following the sale of the Prostatron business, the Company continues 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 (including from sales of technology transfer services under these agreements) amounted to [e] 6.0 million, or approximately 25% of total revenues in 2001. In 2002, revenues from sales under the Supply Agreement and the Distribution Agreement decreased significantly to [e] 2.1 million, or approximately 10% of total revenues. During 2003, as the Supply Agreement and the Distribution Agreement are due to terminate, revenues from sales under these agreements are expected to represent significantly less than 10% of total revenues. In addition, the Company's margins on the manufacturing and distribution of the Prostatron on behalf of Urologix on the terms agreed in these agreements are lower compared to periods prior to the sale of the business. For instance, while the Company generated 25% of its total revenues in 2001 from sales under the Supply Agreement and the Distribution Agreement, these sales generated only 6% of operating income in that year.
- The Company has experienced in 2000, 2001 and 2002, and expects to continue to experience for so long as the Supply Agreement and the Distribution Agreement are in effect, an increase in cost of sales as a percentage of total revenues reflecting lower margins on the manufacturing and distribution of the Prostatron on behalf of Urologix on the terms agreed in these agreements compared to periods prior to the sale of the business.
- As of December 31, 2002, approximately [e] 1.6 million or 17.3% of the Company's net accounts receivable were attributable to Urologix. The Company currently estimates that its accounts receivable attributable to Urologix are significantly lower. However, to the extent that accounts receivable from Urologix increase again during the term of the Supply Agreement and the Distribution Agreement, any failure by Urologix to meet its obligations to the Company could adversely affect its results of operations and cash flows. See "---Liquidity and Capital Resources."
- The Company recorded in 2000 non-recurrent net gains on sale of business of [e] 15.7 million attributable to the sale of the Prostatron business.
- The Company recorded non-recurrent net gains of approximately [e] 1.5 million and [e] 12.2 million in 2002 and 2001, respectively, attributable to the sale of Urologix common stock.

FISCAL YEAR ENDED DECEMBER 31, 2002 COMPARED TO FISCAL YEAR ENDED DECEMBER 31, 2001

## Edgar Filing: EDAP TMS SA - Form 20-F

Total revenues. The Company's total revenues decreased 16.7% from [e] 24.0 million in 2001 to [e] 20.0 million in 2002, principally due to a decrease in TUMT revenues in 2002 compared to 2001 relating to a decrease in Prostatron manufacturing in 2002 compared to 2001, and the transfer of Protaprobe (a Prostatron disposable part) manufacturing to a third-party acting on behalf of Urologix in the latter part of 2001, as further described by division below.

HIFU division. The Company's total revenues increased, in its HIFU division, 111.8% from [e] 1.6 million in 2001 to [e] 3.4 million in 2002 (including [e] 0.0 million and [e] 0.3 million of internal segment revenues in 2001 and 2002, respectively), principally due to an increase in both the sale of HIFU medical devices and HIFU related spare parts, supplies and services.

23

The HIFU division's net sales of medical devices increased 69.5% from [e] 1.1 million in 2001 to [e] 1.9 million in 2002, primarily due to the fact that 2002 represented the first full fiscal year in which the division's main product, the Ablatherm, was approved for distribution in the European Union.

Net sales of HIFU related spare parts, supplies and services increased 156.3% from [e] 0.5 million in 2001 to [e] 1.2 million in 2002, primarily due the fact that 2002 represented the first full fiscal year in which the division's products were approved for distribution in the European Union.

Other HIFU related revenue increased from [e] 15 thousand in 2001 to [e] 35 thousand in 2002, primarily related to an increase in subsidies received.

UDS division. The Company's total revenues decreased, in its UDS division, 20.9 % from [e] 23.3 million in 2001 to [e] 18.4 million in 2002 (including [e] 0.9 million and [e] 1.6 million of internal segment revenues in 2001 and 2002, respectively), principally due to the decrease in Prostatron manufacturing in 2002 compared to 2001 and the transition of Prostaprobe manufacturing to a third-party on behalf of Urologix in the latter part of 2001.

The UDS division's net sales of medical devices decreased 12.0% from [e] 9.6 million in 2001 to [e] 8.5 million in 2002, primarily due to a decrease in Prostatron manufacturing revenue in 2002 as compared to 2001 offset by a 30.4% increase in the number of ESWL lithotripters sold in 2002 compared to 2001. The increase in the number of lithotripters sold in 2002 resulted principally from successful penetration of the Japanese market with the Company's new SONOLITH Praktis, a compact lithotripter launched in the European Union in October 1998. During 2002, the UDS division continued to manufacture Prostatron units on behalf of Urologix under the Supply Agreement. The UDS division experienced a 33.0% decrease in the number of units sold in 2002 compared to 2001.

Net sales of UDS related spare parts, supplies and services decreased 35.1% from [e] 12.6 million in 2001 to [e] 8.2 million in 2002, primarily related to the transfer of Prostaprobe manufacturing to Urologix in the latter part of 2001. A substantial portion of the UDS division's maintenance services are derived from its Japanese operations. See "---Results of Operations--- Overview."

Other UDS related revenue increased from [e] 146 thousand in 2001 to [e] 201 thousand in 2002 primarily related to an increase in royalties received.

Cost of sales. Cost of sales decreased 28.0% from [e] 16.0 million in 2001 to [e] 11.5 million in 2002, and as a percentage of net sales decreased from

## Edgar Filing: EDAP TMS SA - Form 20-F

67.2% in 2001 to 58.3% in 2002, due to a reduced proportion of sales of Prostatron units and disposable parts at a lower gross margin under the Supply Agreement and an increase in gross margin on sales of ESWL lithotripters and Ablatherms. See "---Results of Operations---Sale of the Prostatron Business to Urologix."

Operating expenses. Operating expenses increased 1.1% from [e] 13.1 million in 2001 to [e] 13.2 million in 2002, mainly due to [e] 1.2 million in one-time charges related to the restructuring of the Company into two separate operating units during the course of 2002 and as further described, by division, below.

HIFU division research and development expenses increased 11.6 % from [e] 1.4 million in 2001 to [e] 1.5 million in 2002, primarily due to the ongoing research into HIFU technologies. The Company anticipates these expenses to increase in the future. See "---Results of Operations---Overview."

UDS division research and development expenses decreased 35.0% from [e] 0.6 million in 2001 to [e] 0.4 million in 2002. This decrease is primarily due to the termination of research and development for TUMT. The remaining expenses are related to the continued research and development of ESWL technologies. The Company anticipates these expenses to remain consistent in the future. See "---Results of Operations---Overview."

HIFU division selling expenses increased 33.4% from [e] 0.6 million in 2001 to [e] 0.7 million in 2002, 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 increase in the future as it enters new markets with the Ablatherm. As a percentage of net sales, HIFU division related selling expenses decreased from 35.5% in 2001 to 24.3% in 2002.

UDS division selling expenses decreased 7.5% from [e] 2.2 million in 2001 to [e] 2.0 million in 2002, primarily due to continued control of expenses following the Company's sale of the Prostatron business to Urologix. The Company anticipates that these expenses will remain consistent in the

24

future. See "---Results of Operations---Sale of the Prostatron Business to Urologix." As a percentage of net sales, selling expenses increased from 9.7% in 2001 to 13.4% in 2002, primarily due to the decrease in TUMT related revenues.

General and administrative expenses, at the consolidated level, decreased 13.1% from [e] 5.3 million in 2001 to [e] 4.6 million in 2002, mainly as a result of cost cutting measures, including reductions in headcount, at several of the Company's subsidiaries. As a percentage of net sales, general and administrative expenses remained stable in 2001 and 2002. The holding company continues to manage these expenses so that the expenses at each of the divisions remains consistent with each individual business and revenue levels.

Operating loss. As a result of the factors discussed above, the Company realized an operating loss of [e] 4.8 million in 2002, as compared to an operating loss of [e] 5.1 million in 2001.

As a result of the factors discussed above, the Company realized an operating loss, in its HIFU division, of [e] 3.4 million in 2002 and 2001; realized an operating income, in its UDS division, of [e] 0.6 million in 2002, as compared to an operating loss of [e] 0.5 million in 2001; and realized an operating loss, directly related to the holding company EDAP TMS S.A. (the

## Edgar Filing: EDAP TMS SA - Form 20-F

holding company segment is purely an expense segment and will therefore always show an operating loss), of [e] 1.9 million in 2002, as compared to an operating loss of [e] 1.3 million in 2001.

Interest income (expense), net. Interest income (expense), net decreased to income of [e] 0.5 million in 2002 compared to an income of [e] 0.7 million in 2001, 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 decreased from a gain of [e] 0.2 million in 2001 to a loss of [e] 1.0 million in 2002, reflecting a significant decrease in the value of the U.S. dollar and the Japanese yen against the euro in 2002 compared with 2001.

Other income, net. Other income, net was [e] 1.5 million in 2002 compared to [e] 12.3 million in 2001. The gain in 2002 was attributable to net gains on the sale in 2002 of Urologix common stock received as part of the sale of the Prostatron business in 2000. The decrease of 88.0% between 2001 and 2002 was primarily due to a decrease in value of the common shares of Urologix on the open market, offset by the gain on sale of the common shares.

Income taxes. The Company recorded corporate income tax of [e] 0.2 million in 2002, principally reflecting income tax with respect to the results of various subsidiaries and net capital gains on the sale of shares of Urologix.

Net income. The Company realized consolidated net loss of [e] 4.0 million in 2002 compared with consolidated net income of [e] 7.1 million in 2001, as a result of the factors mentioned above.

FISCAL YEAR ENDED DECEMBER 31, 2001 COMPARED TO FISCAL YEAR ENDED DECEMBER 31, 2000

Total revenues. The Company's total revenues decreased 12.1% from [e] 27.3 million in 2000 to [e] 24.0 million in 2001, principally due to a decrease in other revenues in 2001 compared to 2000 relating to a one-time recognition of non-recurring license revenue in 2000 as a result of the sale of the Prostatron business to Urologix, as further described by division below.

HIFU division. The Company's total revenues increased, in its HIFU division, 108.9% from [e] 0.8 million in 2000 to [e] 1.6 million in 2001, principally due to an increase in both the sale of HIFU medical devices and HIFU related spare parts, supplies and services.

The HIFU division's net sale of medical devices increased 81.6% from [e] 0.6 million in 2000 to [e] 1.1 million in 2001, primarily due to the fact that 2000 represented the first partial fiscal year in which the division's main product, the Ablatherm, was approved for distribution in the European Union.

Net sales of HIFU related spare parts, supplies and services increased 217.8% from [e] 0.1 million in 2000 to [e] 0.4 million in 2001, primarily due to the fact that 2001 represented the first partial fiscal year in which the division's products were approved for distribution in the European Union.

Other HIFU related revenue increased from [e] 4 thousand in 2000 to [e] 15 thousand in 2001 primarily related to an increase in subsidies received.

UDS division. The Company's total revenues decreased, in its UDS division,

## Edgar Filing: EDAP TMS SA - Form 20-F

13.7% from [e] 27.0 million in 2000 to [e] 23.3 million in 2001 (including [e] 0.5 million and [e] 0.9 million of internal segment revenues in 2000 and 2001, respectively), principally due to a decrease in other revenues in 2001 compared to 2000 relating to a one-time recognition of non-recurring license revenue in 2000 as a result of the sale of the Prostatron business to Urologix.

The UDS division's net sales of medical devices increased 5.0% from [e] 9.2 million in 2000 to [e] 9.6 million in 2001, primarily due to a 9.5% increase in the number of ESWL lithotripters sold in 2001 compared to 2000. The increase in the number of lithotripters sold in 2001 resulted principally from the successful launch in Japan of the UDS division's new SONOLITH Praktis. During 2001, the UDS division continued to manufacture Prostatron units on behalf of Urologix under the Supply Agreement. The UDS division experienced a 116.1% increase in the number of units sold in 2001 compared to 2000 and a decrease of 62.4% in average sale price as a result of the pricing terms under the Supply Agreement.

Net sales of UDS related spare parts, supplies and services decreased 15.4% from [e] 14.9 million in 2000 to [e] 12.6 million in 2001, due to a 48.9% decrease in sales of its Prostatron disposable parts, reflecting the transfer of Prostatprobe manufacturing to Urologix during 2001, and a 11.9% decrease in revenues from operating leases, with respect to lithotripters and Prostatron units. A substantial portion of the Company's maintenance services is derived from the Company's Japanese operations. See "---Results of Operations -- Overview".

Other UDS related revenue decreased from [e] 2.4 million in 2000 to [e] 0.1 million in 2001. Other revenues in 2000 reflected principally the one-time recognition of non-recurring license revenues, which previously had been deferred, due to the sale of a license relating to Prostatron technology as part of the sale of the Prostatron business to Urologix in October 2000.

Cost of sales. Cost of sales increased 12.6% from [e] 14.2 million in 2000 to [e] 16.0 million in 2001, and as a percentage of net sales increased from 57.2% in 2000 to 67.2% in 2001, due to lower gross margins on Prostatron units and disposable parts manufactured under the Supply Agreement. See "---Results of Operations--Sale of the Prostatron Business to Urologix."

Operating expenses. Operating expenses decreased 22.0% from [e] 16.9 million in 2000 to [e] 13.1 million in 2001, mainly due to cost savings realized after the sale of the Prostatron business and as further described, by division, below.

HIFU division research and development expenses increased 48.1% from [e] 0.9 million in 2000 to [e] 1.4 million in 2001, primarily due to the ongoing research into HIFU technologies. The Company anticipates these expenses to increase in the future. See "---Results of Operations -- Overview".

UDS division research and development expenses decreased 25.2% from [e] 0.8 million in 2000 to [e] 0.6 million in 2001. This decrease is primarily due to the termination of research and development for TUMT. The remaining expenses are related to the continued research and development of ESWL technologies. The Company anticipates these expenses to remain consistent in the future. See "---Results of Operations -- Overview".

HIFU division selling expenses increased 12.4% from [e] 0.5 million in 2000 to [e] 0.6 million in 2001, primarily due to the increase in sales activities after the commercialization of the division's primary product the Ablatherm, in the European Union, in the latter part of 2001. The Company anticipates that these expenses will increase in the future as it enters new markets with the Ablatherm. As a percentage of net sales, HIFU division related selling expenses decreased from 65.5% in 2000 to 35.5% in 2001.

## Edgar Filing: EDAP TMS SA - Form 20-F

UDS division selling expenses decreased 30.4% from [e] 3.1 million in 2000 to [e] 2.2 million in 2001, primarily due to continued control of expenses following the Company's sale of the Prostatron business to Urologix. The Company anticipates that these expenses will remain constant in the future. See "---Results of Operations -- Sale of the Prostatron Business to Urologix." As a percentage of net sales, selling expenses decreased from 12.9% in 2000 to 9.7% in 2001.

26

General and administrative expenses, at the consolidated level, decreased 2.3% from [e] 5.5 million in 2000 to [e]5.3 million in 2001. As a percentage of net sales, general and administrative expenses remained stable in 2000 and 2001. The holding company continues to manage these expenses so that the expenses at each of the divisions remains consistent with each individual business and revenue levels.

Operating loss. As a result of the factors discussed above, the Company realized an operating loss of [e] 5.1 million in 2001, as compared to an operating loss of [e] 3.7 million in 2000.

As a result of the factors discussed above, the Company realized an operating loss, in its HIFU division, of [e] 3.4 million in 2001, as compared to an operating loss of [e] 3.3 million in 2000; realized an operating loss, in its UDS division, of [e] 0.5 million in 2001, as compared to operating income of [e] 1.3 million 2000; and realized an operating loss, directly related to the holding company EDAP TMS S.A. (the holding company segment is purely an expense segment and will therefore always show an operating loss), of [e] 1.3 million in 2001 and 2000.

Interest income (expense), net. Interest income (expense), net increased to income of [e] 0.7 million in 2001 from an expense of [e] 0.5 million in 2000, reflecting greater interest income received by the Company on its short-term cash investment due to larger cash balances during the year.

Currency exchange gains, net. Net currency exchange gains decreased from [e] 0.4 million in 2000 to [e] 0.2 million in 2001, reflecting a lower increase in the value of the U.S. dollar and the Japanese yen against the euro in 2001 compared with 2000.

Other income, net. Other income, net was [e] 12.3 million in 2001 and was attributable to net gains on the sale of Urologix common stock received as part of the sale of the Prostatron business in 2000.

Income taxes. The Company recorded corporate income tax of [e] 0.9 million in 2001, principally reflecting income tax with respect to the results of the Japanese subsidiary and net capital gains on the sale of shares of Urologix.

Net income. The Company realized consolidated net income (after minority interests) of [e] 7.1 million in 2001 compared with consolidated net income of [e] 11.7 million in 2000, 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, 2002.

## Edgar Filing: EDAP TMS SA - Form 20-F

### 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.

The Company anticipates that cash flow in future periods will be mainly derived from ongoing operations and the collection of current receivables. In the event of a shortfall the Company has a [e] 1.0 million line of credit with its bank. The Company does not have any other commercial commitments nor does it employ any off-balance sheet financing. 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 due to operating difficulties or adverse market conditions, would reduce the availability of funds to the Company.

In 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. In 2001, the Company's cash flow was positive due, in large part, to the sale of Urologix common stock. In 2000, the Company's cash flow remained stable.

27

In 2002, net cash used in operating activities was [e] 8.0 million, compared with net cash used in operating activities of [e] 3.4 million in 2001 and net cash provided by operating activities of [e] 30,000 in 2000. In 2002, net cash used in operating activities reflected principally a net loss of [e] 4.0 million, elimination of [e] 0.9 million of expenses and benefits without effects on cash, a decrease in trade accounts receivable of [e] 0.3 million, a decrease in trade accounts payable of [e] 1.4 million and a decrease in accrued expenses and other current liabilities of [e] 0.9 million. In 2001, net cash used in operating activities reflected principally net income of [e] 7.1 million, elimination of [e] 12.0 million of expenses and benefits without effects on cash, an increase in trade accounts receivable of [e] 1.9 million and an increase in accrued expenses and other current liabilities of [e] 1.3 million. In 2000, net cash provided by operating activities reflected principally net income of [e] 11.7 million, a decrease in trade accounts receivable of [e] 3.3 million and a decrease in inventories of [e] 3.3 million, offset by a decrease in accrued expenses and other current liabilities of [e] 3.8 million and a non-cash item of [e] 15.7 million representing the net gain on the sale of the Prostatron business. Changes in trade accounts receivable, inventories and accrued expenses and other current liabilities in 2000 reflected the transfer to Urologix of current assets and liabilities relating to the Prostatron business.

In 2002, net cash provided by investing activities was [e] 5.1 million, compared with net cash provided by investing activities of [e] 23.6 million in 2001 and net cash provided by investing activities of [e] 2.1 million in 2000. In 2002, net cash provided by investing activities reflected principally net proceeds from the sale of Urologix common stock of [e] 5.5 million, a decrease of [e] 0.9 million in restricted cash equivalents and an investment of [e] 1.5 million in property, plant, equipment, the acquisition of intangible assets and

## Edgar Filing: EDAP TMS SA - Form 20-F

capitalized assets produced by the Company. In 2001 net cash provided by investing activities and reflected principally net proceeds from the sale of Urologix common stock of [e] 21.6 million and a decrease of [e] 3.5 million in restricted cash released after repayment of a term loan. In 2000, net cash provided by investing activities reflected principally net proceeds from the sale of the Prostatron business of [e] 3.7 million, partially offset by an increase of [e] 1.0 million in restricted cash resulting from the deposit in an escrow account of a portion of the cash proceeds of the sale of the Prostatron business to secure indemnification obligations under the asset purchase agreement.

In 2002, net cash used in financing activities was [e] 0.3 million reflecting mainly scheduled long-term debt repayment totaling [e] 0.6 million, scheduled payments made under capital leases totaling [e] 0.3 million and offset by an increase in short-term borrowings totaling [e] 0.7 million, compared to [e] 4.1 million in 2001, reflecting mainly early long-term debt repayment, and [e] 1.8 million in 2000, reflecting scheduled long-term debt repayments.

The Company currently expects to make significant expenditures over the next several years, particularly in connection with clinical trials for HIFU devices and marketing expenses relating to HIFU devices. The Company anticipates that cash flows from operations, together with the proceeds of the sale of any or all of its investments available for sale, which amounted to [e] 5.5 million as of December 31, 2002 and [e] 21.6 million as of December 31, 2001, will provide it with sufficient resources to meet its expenditure requirements for approximately three years. In addition, to the extent that any opportunities for the sale of non-strategic assets become available, the Company may seek to exploit those opportunities.

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. In an effort to increase availability of its equipment, the Company implemented in 1999 a new marketing strategy which includes expanding the leasing of its medical devices, by leasing devices directly to end-users on a cost-per-procedure basis, or on a monthly, quarterly or yearly basis. Such operating leases generate a smaller immediate contribution to total revenues than sales. The Company currently leases five ESWL lithotripters and one Ablatherm under such operating leases, and anticipates continuing to make these options available.

28

### CONTRACTUAL OBLIGATIONS AND COMMERCIAL COMMITMENTS (IN THOUSANDS OF EUROS)

CONTRACTUAL OBLIGATIONS	PAYMENTS DUE BY PERIOD				
	TOTAL	LESS THAN 1 YEAR	1-3 YEARS	4-5 YEARS	AFTER 5 YEARS
Short-Term Debt.....	482	482	---	---	---
Long-Term Debt.....	497	---	497	---	---
Capital Lease Obligations	---	---	---	---	---
Operating Leases.....	1,400	350	700	350	---



## Edgar Filing: EDAP TMS SA - Form 20-F

### NEW ACCOUNTING PRONOUNCEMENTS

In June 2001, the Financial Accounting Standards Board issued SFAS 143, "Accounting for Asset Retirement Obligations" (SFAS 143). SFAS 143 requires the fair value of a liability for an asset retirement obligation be recognized in the period in which it is incurred if a reasonable estimate of fair value can be made. The associated asset retirement costs are capitalized as part of the carrying amount of the long-lived asset. An entity shall measure changes in the liability for an asset retirement obligation due to passage of time by applying an interest method of allocation to the amount of the liability at the beginning of the period. That amount shall be recognized as an increase in the carrying amount of the liability and as an expense classified as an operating item in the statement of income. SFAS 143 will become effective for EDAP TMS beginning on January 1, 2003. The Company does not expect that adoption of SFAS 143 will have a material impact on its financial position, results of operations or cash flows.

In June 2002, the Financial Accounting Standards Board issued SFAS No. 146, "Accounting for Costs Associated with Exit or Disposal Activities" (SFAS 146). The Statement requires companies to recognize costs associated with exit or disposal activities when they are incurred rather than at the date of a commitment to an exit or disposal plan. The Statement replaces EITF Issue No. 94-3, "Liability Recognition for Certain Employee Termination Benefits and Other Costs to Exit an Activity (including Certain Costs Incurred in a Restructuring)." The Company is required to apply this Statement prospectively to exit or disposal activities initiated after December 31, 2002, with earlier application encouraged. The Company does not expect that adoption of SFAS 146 will have a material impact on its financial position, results of operations or cash flows.

On November 25, 2002, the Financial Accounting Standards Board announced the issuance of Interpretation No. 45, "Guarantor's Accounting and Disclosure Requirements for Guarantees, Including Indirect Guarantees of Indebtedness of Others", which expands on the accounting guidance of Statements No. 5, 57, and 107 and incorporates without change the provisions of FASB Interpretation No. 34, which has been superseded by this Interpretation. Given observed differences in practice, this Interpretation clarifies the requirements for a guarantor's accounting and interim and annual financial statement disclosures of certain guarantees issued and outstanding. It also clarifies that a guarantor is required to recognize, at the inception of a guarantee, a liability for the fair value of the obligation undertaken in issuing the guarantee. This Interpretation does not prescribe a specific approach for subsequently measuring the guarantor's recognized liability over the term of the related guarantee. The incremental disclosure requirements in this Interpretation are effective for financial statements of interim or annual periods ending after December 15, 2002. The initial recognition and initial measurement provisions of this Interpretation are applicable to guarantees issued or modified after December 31, 2002. The Company is currently reviewing this interpretation to measure the potential impact on its results of operations and financial position.

In December 2002, the Financial Accounting Standards Board issued FASB Statement No. 148, Accounting for Stock-Based Compensation -- Transition and Disclosure ("SFAS 148"). This Statement amends FASB Statement No. 123, Accounting for Stock-Based Compensation ("SFAS 123"), to provide alternative methods of transition to SFAS 123's fair value method of accounting for stock-based employee compensation. It also amends the disclosure provisions of SFAS 123 to require prominent disclosure in the summary of significant account policies of the effects of an entity's accounting policy with respect to stock-based employee compensation on reported net income and earnings per share in

## Edgar Filing: EDAP TMS SA - Form 20-F

annual financial statements. SFAS 148's amendment of the transition and annual disclosure requirements are effective for fiscal years ending after December 15, 2002. Refer to Note 1.16 for disclosures related to stock based compensation. The Company intends to continue to account for stock-based compensation based on the provisions of APB Opinion No. 25.

### RESEARCH AND DEVELOPMENT, PATENTS AND LICENSES.

See Item 4, "Information on the Company---HIFU Division Patents and Intellectual Property" and "UDS Division Patents and Intellectual Property."

### 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 [e] 0.6 million.

NAME	AGE	POSITION
Philippe Chauveau	67	Chairman of the Board of Directors and Chief Executive Officer
Ian Vawter	31	Chief Financial Officer
Antoine Tetard	38	President, HIFU Division
Hugues de Bantel	33	President, UDS Division
Francois Lacoste	52	Vice-President, Research & Development

**Philippe Chauveau** Philippe Chauveau was appointed as a member of the Supervisory Board in January 1997, became Chairman of the Supervisory Board in April 1997 and became Chief Executive Officer of the Company in July 2002. Mr. Chauveau is Chairman of the Board of Scynexis Inc., a member of the Board of Technomed Medical Systems S.A. and a member of the Board of EDAP S.A. Most recently, he was Research and Development Vice-President at AT&T Bell Laboratories. Before joining AT&T, he held senior positions at Apple Computer and ITT Industries in Europe and in the United States. He graduated from Trinity College with an MBA in Economics.

**Ian Vawter** Ian Vawter joined the Company in 1997 as an accountant for the Company's U.S. subsidiary, EDAP Technomed Inc. and after holding various financial positions within the subsidiary, became Vice President of Finance of EDAP Technomed Inc. in February 2000. In August 2001, Mr. Vawter was appointed Chief Financial Officer of the Company. Previously, Mr. Vawter worked in investment banking in Boston, Massachusetts. Mr. Vawter holds a degree in Business Management and Finance from Norwich University, Northfield,

## Edgar Filing: EDAP TMS SA - Form 20-F

Vermont.

Antoine Tetard joined the Company in 1991 as area sales manager and became Vice President in charge of Japanese operations in 1996, President of U.S. and Japanese operations in January 2000 and General Manager and Chief Operating Officer of the Company in November 2000. He was appointed President of EDAP S.A. on November 6, 2002. Previously, Mr. Tetard worked for Bongard, a French manufacturer of "turnkey" bakeries, first as manager of the U.S. subsidiary and then as an area sales manager for the European Union and North America. Mr. Tetard holds an MBA from Institut Supérieur de Gestion, Paris.

30

Hugues de Bantel joined the Company in 1996, and since then has served as Asia Pacific Area Manager, Manager of EDAP Technomed Malaysia from its founding in 1997 and, since April 1997, President of EDAP Technomed Japan. He was appointed President of TMS S.A. on November 6, 2002. 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 Supérieure de Commerce, Rouen (France).

Francois Lacoste joined Technomed in 1988 as Vice President in charge of research and development. Prior to joining Technomed, Mr. Lacoste worked in the engineering department of Perkin-Elmer (Connecticut), a life science and analytical instrument systems manufacturer, and from 1984 to 1988 was in charge of various research and development projects in electronics, optics and lasers for Alcatel, a major French industrial company. Mr. Lacoste holds a Ph.D in Physics from Rio de Janeiro University and an MS in Optics from Ecole Supérieure d'Optique de Paris.

### 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:

Philippe Chauveau See biography in Senior Executive Officers

Pierre Beysson was appointed as a member of the Board of Directors in September 2002. Pierre Beysson is the Chief Financial Officer of Compagnie des Wagons-Lits, the on-board train service division of Accord, a multinational Hotel and Business Services Group. Prior to joining Compagnie des Wagons-Lits, he held senior financial positions with Nixdorf Computers, Trane, AM International and FMC. Mr. Pierre Beysson was trained as a CPA, has auditing experience and holds an MBA from Harvard Business School.

Dr. Karim Fizazi was appointed as a member of the Company's Board of Directors in November 2002. He is an Assistant Professor in Medical Oncology at Institut Gustave Roussy (IGR) in Villejuif, France. He was visiting Assistant Professor, Genitourinary Medical Oncology Department, MD ANDERSON Cancer Center in

## Edgar Filing: EDAP TMS SA - Form 20-F

Houston, Texas, for 18 months. His medical residency included time at the Institut Curie in Paris.

Olivier Missoffe was appointed as a member of the Company's Board of Directors in November 2002. He is Chairman and CEO of Societe Services et Sante (SES), a services and support provider to hospitals and clinics. He is advisor to the Executive Board of the French healthcare group "Generale de Sante". He was Chief Executive Officer of the Company until 1998.

Dr. Bernard Pejouan was appointed as a member of the Company's Supervisory Board of Directors in April 1997 and became a member of the Company's Board of Directors in July 2002. He is a member of the French National Academy of Pharmacy. Dr. Pejouan held various responsibilities in Groupe Roche-Nicholas until 1972 when he joined Merck & Co. Group as Chairman and Chief Executive Officer of MSD Laboratoires in France and Executive Director of MSD International.

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.

Siemens France S.A., represented by Holger Schmidt,  
Age: 37

31

Pr. 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 Departement at the Institut Mutualiste Monsouris (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.

On December 17, 2002, the Board of Directors decided that the whole Board of Directors will act as a "Remuneration 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.

### COMPENSATION AND OPTIONS

Aggregate compensation paid by the Company and its subsidiaries to Senior Executive Officers and to the Board of Directors as a group paid or accrued for services in all capacities for the fiscal year 2002 was approximately [e] 0.9 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 2002.

As of December 18, 2002, the shareholders of two of the Companies 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. The total number of subscription options granted, if exercised, would represent 6% of the respective share capital of TMS S.A. and

## Edgar Filing: EDAP TMS SA - Form 20-F

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, 2002, Senior Executive Officers held an aggregate of 293,579 options to purchase or to subscribe to new Shares of the Company's common stock, with a weighted average exercise price of [e] 2.32. Of these options, 10,000 expire on December 31, 2004, 6,000 expire on December 31, 2008, 40,000 expire on March 31, 2009, 39,464 expire on March 31, 2011 and 198,115 expire on September 25, 2011.

### SCIENTIFIC ADVISORY BOARD

The Company has assembled a Scientific Advisory Board comprised of four individuals who are leaders in the field of medical research of urological disorders. Members of the Scientific Advisory Board review the Company's research and development and operations activities and are available for consultation with the Company's management and staff relating to their respective areas of expertise. Several of the members of the Scientific Advisory Board meet more frequently, on an individual basis, with the Company's management and staff to discuss the Company's ongoing research and development projects. The members of the Scientific Advisory Board are reimbursed for their expenses and the time spent in connection with their services. Members of the Scientific Advisory Board are expected to devote only a small portion of their time to the business of the Company.

The names and background of the current members of the Scientific Advisory Board are set forth below:

John H. Lynch            Professor and Chief of Urology, Georgetown University (Washington D.C.). Dr. Lynch is a member of the American Board of Urology, the CME Advisory Board and the Education Council of the American Urology Association. Dr. Lynch is a reviewer of "Journal of Urology" and "Urology." He received his M.D. from the Georgetown University School of Medicine.

32

Guy Vallancien        Professor of Urology and Chief of the Urology Department at the Institut Mutualiste Montsouris (Paris, France). Dr. Vallancien is a member of the Executive Committee of the French Urological Association and a member of the European and International Urological Association. He is a member of the Lecturer Committees of "Journal of Urology" and "Urology" and he has published more than 300 articles in the field of urology and oncology. He received his M.D. from Necker University Hospital (Paris).

Christian Chaussy    Chairman of the Urology Division of University-associated Municipal Hospital Munchen-Harlaching. Dr. Chaussy is the President of the German Lithotripsy Society. He is a member of the German Urological Society, the European Society for organ transplantation and the Max-Planck Society. He is a member of the Editorial Boards of "Journal of Endourology" and "Newsletter on Endourology & ESWL." He is the author or co-author of more than 250 articles and publications principally on ESWL and renal surgery. He received his M.D. from University of Munich Medical School.

## Edgar Filing: EDAP TMS SA - Form 20-F

Jean J.M.C.H. de la Rosette Chairman of the Urology Department at the Academic Medical Center, Amsterdam. Dr. de la Rosette is the Chairman of the European Society of Urotechnology, Chairman of the BPH - Guidelines Committee of the EAU HealthCare Office, Board member of the Society of Endourology and member of the WHO prostate cancer working party. Dr de la Rosette is Section Editor of "European Urology" and reviewer of the "Journal of Urology", "Urology" and "European Urology". He has published more than 250 articles in the field of minimal invasive urology. He received his M.D. from University Hospital Nijmegen.

### EMPLOYEES

As of December 31, 2000, the Company employed 149 individuals on a full-time basis, of whom 29 were employed in sales and marketing, 33 in manufacturing, 34 in service, 20 in research and development, 9 in regulatory and 24 in administration. Of the Company's employees, 94 were located in France, 33 in Japan, 9 in the United States, 6 in Malaysia, 5 in Italy and 2 in South Korea.

As of December 31, 2001, the Company employed 144 individuals on a full-time basis, of whom 25 were employed in sales and marketing, 27 in manufacturing, 39 in service, 15 in research and development, 13 in regulatory and 25 in administration. Of the Company's employees, 93 were located in France, 30 in Japan, 8 in the United States, 6 in Malaysia, 5 in Italy and 2 in South Korea.

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 research and development, 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.

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, 2003, 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. As of March 31, 2003, Mr. Antoine Tetard, President of EDAP S.A., has the right to subscribe to and purchase 238,579 Shares representing 2.9% of the total share capital and (after subtracting treasury stock which under French law carries no voting rights) 3.1% 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.

As a whole, the Board of Directors and the Senior Executive Officers of the Company hold a total of 1,408,005 Shares representing 16.8% of the total share capital and (after subtracting treasury stock which under French law carries no voting rights) 18.1% of the voting rights of the Company.

On March 21, 2002, a Senior Executive Officer of the Company exercised an option to subscribe to 47,421 new Shares. The Executive Board at the time held a meeting on March 21, 2002 to approve the corresponding increase of the

## Edgar Filing: EDAP TMS SA - Form 20-F

capital of the Company, from [e] 1,081,002.00 to [e] 1,087,166.73, and to modify the by-laws accordingly. See Item 6, "Options to Purchase or Subscribe for Securities" below.

### OPTIONS TO PURCHASE OR SUBSCRIBE FOR SECURITIES

The Company currently sponsors four stock purchase and 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 [e] 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.

All of the Shares that may be purchased through the exercise of stock options are currently held as treasury stock.

On December 31, 2002, the duration of stock option contracts was as follows:

NUMBER OF SHARES GRANTED	UNTIL EXPIRATION (YEARS)
10,000.....	2
47,125.....	5
115,000.....	6
51,212.....	7
48,464 (of which 39,464 are options to subscribe to new shares).	8
356,115 (of which 80,000 are options to subscribe to new shares)	9
26,425.....	9.5

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

2002	2001	2000
WEIGHTED	WEIGHTED	WEIGHTED
AVERAGE	AVERAGE	AVERAGE
EXERCISE	EXERCISE	EXERCISE

Edgar Filing: EDAP TMS SA - Form 20-F

	OPTIONS	PRICE	OPTIONS	PRICE	OPTIONS	PRICE
	-----	-----	-----	-----	-----	-----
Outstanding on January 1 .....	721,550	2.53	303,675	3.53	501,550	3.91
Granted .....	26,425	2.02	474,000	2.02	35,000	2.39
Exercised .....	(47,421)	1.76	---	---	---	---
Forfeited .....	(46,213)	2.37	(56,125)	3.66	(232,875)	3.81
Expired .....	---	---	---	---	---	---
Outstanding on December 31 .....	654,341	2.58	721,550	2.53	303,675	3.53
Exercisable on December 31 .....	353,324	3.00	271,160	3.03	149,750	3.78

34

	2002		2001		2000	
	WEIGHTED	WEIGHTED	WEIGHTED	WEIGHTED	WEIGHTED	WEIGHTED
	AVERAGE	AVERAGE	AVERAGE	AVERAGE	AVERAGE	AVERAGE
	EXERCISE	EXERCISE	EXERCISE	EXERCISE	EXERCISE	EXERCISE
	OPTIONS	PRICE	OPTIONS	PRICE	OPTIONS	PRICE
	-----	-----	-----	-----	-----	-----
Shares available on December 31 for share purchase options that may be granted.....	0	---	26,425	---	0	---

The following table summarizes information about stock options to purchase Shares already held by the Company as Treasury shares, or to subscribe to new Shares, at December 31, 2002:

EXERCISE PRICES	OPTIONS	OUTSTANDING STOCK OPTIONS		EXERCISABLE STOCK OPTIONS	
		WEIGHTED AVERAGE REMAINING CONTRACTUAL LIFE	WEIGHTED AVERAGE EXERCISE PRICE	WEIGHTED AVERAGE EXERCISE PRICE	WEIGHTED AVERAGE EXERCISE PRICE
-----	-----	-----	-----	-----	-----
[e] 3.81.....	192,125	6.0	3.81	192,125	3.81
[e] 2.39.....	29,000	5.7	2.39	21,750	2.39
[e] 2.08 (1).....	356,115	9.0	2.08	89,029	2.08
[e] 2.02 (2).....	26,425	9.5	2.02	---	---
[e] 1.83.....	11,212	6.1	1.83	10,956	1.83
[e] 1.76 (3).....	39,464	8.3	1.76	39,464	1.76
[e] 1.76 to [e] 3.81	654,341	7.4	2.58	353,324	3.00



## Edgar Filing: EDAP TMS SA - Form 20-F

- 
- (1) All the 356,115 options were granted on September 25, 2001 with an exercise price expressed in U.S. dollars (\$1.92) based on the noon buying rate on September 25, 2001 (\$1 = [e] 1.085).
  - (2) All the 26,425 options were granted on June 18, 2002 with an exercise price expressed in U.S. dollars (\$1.92) based on the noon buying rate on June 18, 2002 (\$1 = [e] 1.0545).
  - (3) All the 39,464 options were granted on April 2, 2001 with an exercise price expressed in U.S. dollars (\$1.561) based on the noon buying rate on April 2, 2001 (\$1 = [e] 1.13).

On March 21, 2002, a Senior Executive Officer exercised his option to subscribe to 47,421 new Shares at an exercise price of \$1.56, or [e] 1.76. The capital of the Company was therefore increased from [e] 1,081,002.00 to [e] 1,087,166.73.

### ITEM 7. MAJOR SHAREHOLDERS AND RELATED PARTY TRANSACTION

#### 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, 2003, 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 Benson Associates LLC owned 1,091,200 Shares representing 13.0% of the total share capital of the Company and (after subtracting treasury stock, which under French law carries no voting rights) 14.0% of voting rights. The Shares owned by these persons do not carry special voting rights.

To the Company's knowledge, there has been one significant change in percentage of ownership over the past three years: Heartland Advisors Inc., that held 1,364,100 Shares, representing 16.4% of the total share capital of the Company and 17.5% of the voting rights, sold all of the Shares it owned in the last quarter of 2000.

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.

35

As of March 31, 2003, 8,362,821 Shares were issued, including 7,781,731 outstanding and 581,090 treasury Shares. At the same date, there were 7,072,088 ADSs, each representing one Share, all of which were held of record by seventeen registered holders in the United States (including The Depository Trust Company).

#### RELATED PARTY TRANSACTIONS

In August 1997, the Company entered into an agreement with Timco S.A.R.L. ("Timco"), a French company of which Mr. Chauveau, the Company's Chairman of the Board of Directors and Chief Executive Officer, is the general manager and a significant shareholder. Timco provided advice and assistance to the Company

## Edgar Filing: EDAP TMS SA - Form 20-F

in connection with the Company's shareholder relations policy. From August 1997 to August 2002, Mr. Chauveau was Chairman of the Supervisory Board but not an employee of EDAP TMS S.A.

As approved by the Company's shareholders at the annual shareholders meetings for years 2000 and 2001, the Company paid Timco an annual fee of [e] 54,882 for its services during each of the years 2000 and 2001. Coinciding with the appointment of Mr. Chauveau as Chairman of the new single Board of Directors, as well as Mr. Chauveau becoming an employee of EDAP TMS S.A., the Company terminated the agreement with Timco in August 2002. For year 2002, the Company paid Timco a fee of [e] 43,759. In accordance with French company law, the continuation of the agreement during the fiscal year 2002 will be submitted for ratification to the Company's shareholders at the annual shareholders' meeting in June 2003.

### ITEM 8. FINANCIAL INFORMATION

#### CONSOLIDATED FINANCIAL STATEMENTS

See Item 18, "Financial Statements".

#### EXPORT SALES

See Note 23 of the Notes to the Consolidated Financial Statements, which includes disclosure relating to the total amount of export 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, for which it has agreed to retain liability following the sale of the Prostatron business in October 2000. The Company has also been informed of an intent to commence legal action associated with a product liability claim by a patient claiming to have been injured in the course of a Prostatron procedure performed after the sale of the Prostatron business in October 2000, for which the Company may be able to claim indemnification, if at such a time the Company is included as a defendant in this action. 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.

The Company has also been notified that it is currently a defendant in two actions claiming fraud related to the sale of medical equipment. One of these actions is in the United States and one is in Japan. The Company believes that the claims are baseless and without merit and the Company is confident in its defenses and will defend itself vigorously in a court of law. However, there is no guarantee that a satisfactory outcome will occur and therefore these claims could have a material adverse impact on the Company.

Additionally, the Company settled a claim, in March 2003, alleging failure to make license payments brought against one of its subsidiaries. The cost of settling this claim, [e] 0.3 million, was included in the consolidated financial statements of the Company dated December 31, 2002.

## Edgar Filing: EDAP TMS SA - Form 20-F

### 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 shareholder's ordinary general meeting. Dividends, if any, would be paid in euros 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 (as defined herein).

Dividends paid to holders of ADSs or Shares who are not resident of France generally will be subject to French withholding tax at a rate of 25%. Holders of Shares 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, an additional payment (net of withholding tax) representing all or part of the French avoir fiscal, or tax credit, under conditions provided for in the relevant treaty under French law. See Item 10, "French Taxation---Taxation of Dividends on Shares." Prospective purchasers of ADSs should consult their own advisers with respect to the tax consequences of an investment in ADSs.

No dividends were paid with respect to fiscal years 1998 through 2001. Subject to the approval of the shareholders' meeting to be held on or before June 30, 2003, the Company does not anticipate paying any dividends with respect to fiscal year 2002.

### 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, 2002.

### 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 the Nasdaq Europe for the delisting of its ADSs effective on April 25, 2002.

#### TRADING MARKETS

The following tables set forth, for the years 1998 through 2003, the reported high and low sales prices of the ADSs on Nasdaq and Nasdaq Europe (through to April 25, 2002 for Nasdaq Europe)

Edgar Filing: EDAP TMS SA - Form 20-F

	NASDAQ	
	HIGH	LOW
	----	----
	(IN DOLLARS)	
	-----	-----
1998.....	7.25	1.31
1999.....	2.66	0.63
2000.....	3.13	0.50
2001.....	3.43	0.59
2002.....	2.49	1.15
2003 (through March 31).....	1.93	1.20

37

	NASDAQ EUROPE	
	HIGH	LOW
	----	----
	(IN DOLLARS)	
	-----	-----
1998.....	7.25	1.44
1999.....	2.38	1.05
2000.....	3.03	0.70
2001.....	3.40	0.64
2002 (through April 25).....	2.25	1.59

The following tables set forth, for the years 2001 and 2002 and the first quarter of 2003, as applicable, the reported high and low sales prices of the ADSs on Nasdaq and Nasdaq Europe, for each full financial quarter:

	NASDAQ	
	HIGH	LOW
	----	----
	(IN DOLLARS)	
	-----	-----
2001		
First Quarter.....	2.13	0.59
Second Quarter.....	3.43	1.50
Third Quarter.....	2.89	1.15
Fourth Quarter.....	2.31	1.22
2002		
First Quarter.....	2.49	1.62
Second Quarter.....	2.05	1.25
Third Quarter.....	2.20	1.18
Fourth Quarter.....	1.60	1.15
2003		
First Quarter.....	1.93	1.20

	NASDAQ EUROPE	
	HIGH	LOW
	(IN DOLLARS)	
2001		
First Quarter.....	3.03	1.10
Second Quarter.....	2.80	1.38
Third Quarter.....	1.85	1.00
Fourth Quarter.....	1.53	0.70
2002		
First Quarter.....	2.25	1.70
Second Quarter (through April 25) (1)	2.00	1.59
Third Quarter.....	Not traded	Not traded
Fourth Quarter.....	Not traded	Not traded
2003		
First Quarter	Not traded	Not traded

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

38

The following table sets forth, for the most recent six months (from October 2002 through March 2003), the reported high and low sale prices of the ADSs on Nasdaq for each month:

	NASDAQ	
	HIGH	LOW
	(IN DOLLARS)	
2002		
October.....	1.45	1.15
November.....	1.60	1.20
December.....	1.46	1.15
2003		
January.....	1.78	1.20
February.....	1.86	1.61
March.....	1.93	1.42

ITEM 10. ADDITIONAL INFORMATION

MEMORANDUM AND ARTICLES OF ASSOCIATION

## Edgar Filing: EDAP TMS SA - Form 20-F

Set forth below is a brief summary of significant provisions of the Company's articles of association 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, or articles of association. 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 Article II of the French Code de Commerce, as amended, of the French Commercial Code.

The Company's articles of association were last updated in July 2002 in order formally to comply with new French Rules on Economic Regulation (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 shares, obligations or other securities, mergers, holding companies, groups, alliances or partnerships;
- the management of such financial interests;
- the direction, management, supervision 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. They opted for a management by a Board of Directors instead of an Executive Board controlled by a Supervisory Board.

The Board of Directors is currently composed of seven members appointed by the shareholders, on July 30, 2002, for a period of 3 years. (See Item 6, "Senior Management, Directors and Employees").

Each Director must own at least one share during his/her term of office. However there is no minimal obligation if the Director, at the same time, has an employment contract with the Company.

If, at the time of his/her appointment, the Director does not own the requested number of shares or if during his/her term, he/she no longer owns the requested number of shares, he/she is considered to have automatically

## Edgar Filing: EDAP TMS SA - Form 20-F

resigned, if he/ she has failed to comply with the shareholding requirement within three months.

The general shareholders meeting has appointed the Directors for a 3 year term of office (in accordance with Article L.225-18 of the French Commercial Code, the articles of association stipulate that the Directors can be appointed up to six years, the maximum duration allowed by French Law), one year being calculated as the period in between two consecutive annual ordinary general shareholders meetings. The tenure of a Director terminates at the end of the ordinary general shareholders meeting that meets to vote upon the accounts of the then preceding fiscal year and is held in the year during which the office of said Director comes to an end. The Directors may always be re-elected; their election may also be revoked at any time at the shareholders meeting.

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

In case of death or resignation of one or more Director, the Board of Directors may make provisional appointments to fill vacancies, even 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 remain nonetheless 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 correspond to the business in which the Company is engaged. 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 can not exceed one third of the Directors then in office or five members.

Directors cannot be more than seventy years old. In case one of the Directors reaches this limit during his/her office, 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 activities and supervises their execution. 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 business of the Company and make any decisions in accordance with such business.

### THE CHAIRMAN OF THE BOARD

The Board of Directors must elect one of its members as Chairman of the Board, who must be an individual person. The Board of Directors determines the duration of the office of the Chairman; it cannot exceed that of his/her office as a Director. The Board of Directors may revoke the election as Chairman at any time. The remuneration of the Chairman is decided by the Board of Directors.

## Edgar Filing: EDAP TMS SA - Form 20-F

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 confirming 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 within the framework of criminal proceedings which might be taken against the Company.

40

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 may be appointed. Subject to this provision, the Chairman of the Board may also be re-elected.

### THE CHIEF EXECUTIVE OFFICER

The general management of the Company is performed, under the responsibility of a person bearing the title of Chief Executive Officer, and who may be either the Chairman of the Board or another individual elected by the Board of Directors. 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 30, 2002, the Board of Directors appointed Mr. Philippe Chauveau as Chief Executive Officer, for the period of his term as a member of the Board of Directors.

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 contrary to the corporate purposes, unless it is proven that the third party knew such act overcame 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 knowledge.

The remuneration of the Chief Executive Officer is decided by the Board of Directors. Appointment as 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 an Executive 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 would automatically be considered to have resigned. However, his/her tenure is extended until the next Board of Directors meeting, during which his/her



## Edgar Filing: EDAP TMS SA - Form 20-F

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.

41

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 auditors), the Board of Directors has the authority, subject to French law, without the approval of shareholders, to distribute 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 holdings of shares. Dividends are payable to holders of shares outstanding on the date of the shareholder 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 holders of shares 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 registered 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 registered capital may be effected either by the issuance of additional shares

## Edgar Filing: EDAP TMS SA - Form 20-F

(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. Share dividends may be distributed in lieu of payment of cash dividends, as described above under "Dividend and Liquidation Rights (French law)" permits different classes of shares to have liquidation, voting and dividend rights different from those of the outstanding ordinary shares.

The registered capital of the Company may be decreased only with the approval of the shareholders entitled to vote at an extraordinary general meeting. Registered 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 holders of shares 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 registered 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 generally prohibited by French law from holding shares of the Company and, in the event it becomes a holder of shares, it may not hold more than 10% of the shares then issued and has to transfer any shares in excess of this 10% threshold within the year following the date it became a holder thereof.

42

### 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 registered 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 from the end of the Company's fiscal year, for approval of the annual accounts. Other ordinary or

## Edgar Filing: EDAP TMS SA - Form 20-F

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 (Comite 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 reunion) must be sent to each shareholder who has requested to be notified in writing more than 25 days before the date set for any ordinary or extraordinary general meeting. Shareholders holding shares for an amount at least equal to a defined percentage of the registered capital of the Company, which, under French law, varies depending upon the absolute amount of the registered capital (3.35% on December 31, 2002), 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. Holders of shares 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, shares held by entities controlled directly or indirectly by the Company are not 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 the shares, with respect to which such blank proxy has been given, 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 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

## Edgar Filing: EDAP TMS SA - Form 20-F

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-third 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.

### PREFERENTIAL SUBSCRIPTION RIGHTS (FRENCH LAW)

Holders of shares 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.

## Edgar Filing: EDAP TMS SA - Form 20-F

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 as to holdings of shares 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 declaration administrative, or administrative notice, with French authorities in connection with the acquisition of a controlling interest in any French company. Under existing

44

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 registered 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, including the requirements concerning audit committees and independent directors.

### ENFORCEABILITY OF CIVIL LIABILITIES (FRENCH LAW)

EDAP TMS is a societe 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 resides 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. courts 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

## Edgar Filing: EDAP TMS SA - Form 20-F

may preclude or restrict the obtaining of evidence in France or from French persons in connection with such actions.

### 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 declaration 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 percent 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 owning and disposing of Shares and 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 that date.

45

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 ownership or disposition of Shares or ADSs. It 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 capital of the Company.

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. HOLDERS OF ADSS, INCLUDING THOSE WHO ARE NOT U.S. RESIDENTS, SHOULD CONSULT THEIR OWN TAX ADVISORS CONCERNING THE CONSEQUENCES OF OWNERSHIP AND DISPOSITION OF ADSS.

### TAXATION OF DIVIDENDS ON SHARES

In France, dividends are paid out of after-tax income. However, French residents are entitled to a tax credit, known as the avoir fiscal, in respect of dividends they receive from French companies. Individuals are entitled to an avoir fiscal equal to 50% of the dividend itself. The avoir fiscal applicable to corporate investors generally is equal to 10% of the dividend. Dividends paid to non-residents normally are subject to a 25% French withholding tax and

## Edgar Filing: EDAP TMS SA - Form 20-F

are not eligible for the benefit of the *avoir fiscal*. However, non-resident holders that are entitled to and comply with the procedures for claiming benefits under an applicable tax treaty may be subject to a reduced rate of withholding tax, and may be entitled to benefit from a refund of the *avoir fiscal*, as described below.

France has entered into tax treaties with certain countries under which qualifying residents are entitled to obtain from the French tax authorities a reduction (generally to 15%) of the French dividend withholding tax and a refund of the *avoir fiscal* (net of applicable withholding tax).

Whenever a non-resident holder, prior to the payment of a dividend, establishes his/her/its entitlement to treaty benefits, then French tax will generally be withheld at the reduced rate provided under the treaty.

Dividends paid out of profits that have not been taxed at the ordinary corporate rate, or were earned and taxed more than five years before the distribution, are subject to an equalization tax called the *precompte*, which is payable by the distributing corporation. The *precompte* is generally equal to one-half of the amount of the dividend paid to the shareholder prior to deduction of withholding tax. Corporate investors entitled under a tax treaty to a refund of the *avoir fiscal* at a rate of 10% may claim an additional payment equal to 80% of the *precompte* actually paid in cash by the distributing corporation, net of applicable withholding tax. These additional payments are considered as an increase to the *avoir fiscal*.

When a tax treaty does not provide for a refund of the *avoir fiscal*, or when a non-resident investor is not entitled to such a refund but is otherwise entitled to the benefits of the tax treaty, then a qualifying investor may generally obtain from the French tax authorities a payment equal to 100% of the *precompte* actually paid in cash by the distributing corporation, net of applicable withholding tax.

In September 2002, the French government announced a proposed reform to the French tax treatment of dividends, which is expected to be included in the draft Finance Law for 2004 that will be submitted to the French Parliament in September 2003. The proposed reform contemplates the implementation of a new regime to avoid the double taxation of dividends and the elimination of the *avoir fiscal* and *precompte*. This proposed reform, if adopted, may affect the right of eligible holders to obtain a tax credit payment from the French Treasury with respect to dividends paid in 2003 or thereafter.

### TAXATION ON SALE OR DISPOSITION OF SHARES OR ADS

Holders that are not resident in 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 the dividend rights (*droits aux benefices sociaux*) of the Company, directly or indirectly, at any time during the preceding five years, are not subject to any French income tax or capital gains tax on the sale or disposition of Shares or ADSs.

46

A 1% registration duty (subject to a maximum of [e] 3,049 per transfer) applies to transfers of shares or ADSs in certain French companies. The 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

## Edgar Filing: EDAP TMS SA - Form 20-F

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 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 countries may be exempted from such tax or obtain a tax credit.

### TAXATION OF U.S. INVESTORS

The following is a summary of the material French and U.S. federal income tax consequences of the 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 it is (1) the beneficial owner of the Shares or ADSs (and the dividends paid with respect thereto); (2) 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; (3) not also a resident of France for French tax purposes; and (4) 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.

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 U.S. holders that do not hold Shares or ADSs 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, 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.

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

In general, for U.S. federal income tax purposes, and for purposes of the Treaty, U.S. holders of ADSs will be treated as holding the Shares represented by such ADSs.

### DIVIDENDS

As discussed in more detail under "---French Taxation," dividends paid by French companies to non-residents of France generally are subject to French withholding tax at a 25% rate, and are not eligible for the benefit of the *avoir fiscal*.

However, under the Treaty, U.S. holders can claim the benefit of a reduced dividend withholding tax rate of 15%. U.S. holders are also entitled to a



## Edgar Filing: EDAP TMS SA - Form 20-F

payment equal to the avoir fiscal, less a 15% withholding tax, although as discussed above, the avoir fiscal is currently the subject of a significant reform proposal. The proposed reform contemplates the implementation of a new regime to avoid the double taxation of dividends and the elimination of the avoir fiscal and precompte. This proposed reform, if adopted, may affect the right of U.S. holders to obtain a tax credit payment from the French Treasury with respect to dividends paid in 2003 or thereafter. French tax will be withheld at

47

the 15% rate if the holder has established before the date of payment that it is a resident of the United States under the Treaty and, if it is not an individual, that it is the owner of all the rights relating to the full ownership of Shares represented by ADSs (including, but not limited to, dividend rights). A U.S. holder generally will be entitled to receive a refund of the avoir fiscal only if the holder (or its partners, beneficiaries or grantors, if the holder is a partnership, estate or trust) is subject to U.S. federal income tax on the avoir fiscal payment and the dividend to which it relates.

The refund of the avoir fiscal will not be made available until after the close of the calendar year in which the dividend is paid. A U.S. holder that is a corporation generally will be entitled to an avoir fiscal refund of 10% of the amount of a dividend while a U.S. holder that is an individual generally will be entitled to an avoir fiscal refund at the 50% rate, in both cases less a 15% withholding tax.

Pension funds and certain other tax-exempt U.S. holders are entitled to a reduced withholding tax rate of 15%, and to a payment at least equal to 30/85 of the avoir fiscal generally payable to a corporation, net of a 15% withholding tax.

U.S. holders that are not entitled to receive a payment in respect of the avoir fiscal at the 50% rate (i.e., corporations and certain tax-exempt investors) will be entitled to receive an additional payment from the French tax authorities if the Company is liable for the precompte equalization tax (discussed under "-French Taxation," above) in respect of a dividend distribution. Corporate holders generally will be entitled to receive a payment equal to 80% of the precompte actually paid in cash by the Company, less a 15% withholding tax. The additional payment is considered an increase to the avoir fiscal, and will also not be made available until after the close of the calendar year in which the dividend is paid.

Thus, for example, if the Company pays a dividend of 100 to an individual U.S. holder, the holder initially will receive 85, but will be entitled to an additional payment of 42.50, consisting of the avoir fiscal of 50 less a 15% withholding tax on that amount (equal to 7.50). If the Company pays a dividend of 100 to a U.S. holder that is a corporation, such U.S. holder initially will receive 85, but will generally be entitled to an additional payment of 8.5, consisting of the avoir fiscal of 10, less a 15% withholding tax on that amount; in the event that the dividend distribution triggers payment by the Company of the precompte, such U.S. holder may also obtain from the French tax authorities an additional payment equal to 80% of the precompte that the Company actually pays in cash, less a 15% withholding tax.

U.S. holders not entitled to a refund of the avoir fiscal generally may obtain from the French tax authorities a refund of the entire precompte actually paid in cash by the Company in respect of a dividend, less a 15% French withholding tax. Pension funds and certain other tax-exempt U.S. holders are also entitled to certain refunds in respect of the precompte the Company

## Edgar Filing: EDAP TMS SA - Form 20-F

actually pays in cash. Such holders should consult their own tax advisers concerning precompte refunds.

The gross amount of dividend, avoir fiscal and precompte payments that a U.S. holder receives (prior to the deduction of French withholding tax) generally will be subject to U.S. federal income taxation as foreign source dividend income. Such dividends will not be eligible for the dividends received deduction generally allowed to U.S. corporations. French withholding tax at the 15% Treaty rate will be treated as a foreign income tax that, subject to generally applicable limitations under U.S. law, is eligible for credit against a holder's U.S. federal income tax liability or, at the holder's election, may be deducted in computing taxable income. For foreign tax credit purposes, dividends paid by the Company generally will constitute passive income or, in the case of certain U.S. holders, financial services income. Foreign tax credits will not be allowed for withholding taxes imposed in respect of certain short-term or hedged positions in securities or in respect of arrangements in which a U.S. holder's expected economic profit, after non-U.S. taxes, is insubstantial. U.S. holders should consult their own advisers concerning the implications of these rules in the light of their particular circumstances.

Dividends paid in euros 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 ADSs, by the Depositary, regardless of whether the payment is in fact converted into U.S.

48

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

In order to claim Treaty benefits, a U.S. holder must complete and deliver to the French tax authorities either (i) the simplified certificate described below; or (ii) an application for refund on French Treasury form RF 1A EU-No. 5052. A simplified certificate must state that (i) the holder is a U.S. resident within the meaning of the Treaty; (ii) the holder does not maintain a permanent establishment or fixed base in France with which the holding giving rise to the dividend is effectively connected; (iii) the holder owns all the rights attached to the full ownership of the Shares or ADSs, including dividend rights; and (iv) the holder meets all the requirements of the Treaty for obtaining the benefit of the reduced rate of withholding tax and the refund of the avoir fiscal. If a holder that is not an individual submits an application for refund on form RF 1A EU-No. 5052, the application must be accompanied by an affidavit attesting that the holder is the owner of all the rights attached to the full ownership of the Shares or ADSs (including dividend rights).

In the case of Shares or ADSs held by a partnership or a trust, claims for Treaty benefits and related attestations are made by the partners, beneficiaries or grantors that may have to supply certain additional documentation.

To be eligible for Treaty benefits, pension funds and certain other tax-exempt U.S. holders must comply with the filing requirements described above and certain additional documentation requirements.

Copies of the simplified certificate and the application for refund will be provided by the Depositary to any U.S. holder of ADSs upon request. Copies are also available from the U.S. Internal Revenue Service. If the certificate or application is not filed prior to a dividend payment, then holders may claim

## Edgar Filing: EDAP TMS SA - Form 20-F

withholding tax and avoir fiscal refunds by filing an application for refund before December 31 of the year following the year in which the dividend was paid.

U.S. holders that are not entitled to a refund of the avoir fiscal but are entitled to a full refund of the precompte and U.S. pension funds and certain other tax-exempt U.S. holders that are entitled to a partial refund of the precompte must apply for such a refund by filing French Treasury form RF 1B EU-No. 5053 before the end of the year following the year in which the dividend was paid. This form, together with instructions, is available from the U.S. Internal Revenue Service or at the Centre des Impôts des Non-Residents (9, rue d'Uzes, 75094 Paris Cedex 2).

The avoir fiscal or partial avoir fiscal and any French withholding tax refund will not be paid before January 15 following the end of the calendar year in which the dividend is paid.

### 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 holder generally is subject to taxation at a maximum rate of 20%. A U.S. holder's ability to offset capital losses against ordinary income is limited.

Deposits and withdrawals of Shares in exchange for ADSs will not result in the realization of gain or loss for U.S. federal income tax purposes.

### 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%.

The Company's holdings of assets that are considered passive for this purpose have been reduced significantly since 2002. However, such holdings still remain substantial, and it is possible that the Company will be treated as a PFIC in respect of 2003. If the Company is a PFIC in respect of any year, then a U.S. holder who holds Shares or ADSs during that year and does not make a mark-to-market election 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

## Edgar Filing: EDAP TMS SA - Form 20-F

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 the 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.

### U.S. INFORMATION REPORTING AND BACKUP WITHHOLDING

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.

### MATERIAL CONTRACTS

The Company entered into and closed an Asset Purchase Agreement with Urologix under which the Company sold its Transurethral Microwave Thermotherapy product line and related patents and technologies to Urologix. The assets sold included the Company's equipment used in the Company's TUMT business, raw materials, spare parts and a portion of the inventory of finished products, U.S. third party accounts and notes receivables (with some exceptions), books and records, sales and promotional literature, designated assumed customer and supply contracts, patents, trademarks and other intellectual property, product approvals, clearances and permits, computer software and firmware used in the TUMT business and all goodwill of the Company with respect to the TUMT business. The assets acquired by Urologix excluded, among other things, cash, certain inventories and contracts, and real property.

Under the Asset Purchase Agreement and related documents, the Company received total consideration of \$7,988,000 in cash, 1,365,000 shares of Urologix common stock and a five-year warrant to purchase 327,466 shares of Urologix common stock at a price of \$7.725 per share. Urologix agreed to assume approximately \$1.5 million in lease obligations related to equipment located at customer sites and issued a promissory note to pay the Company \$575,000 on December 30, 2003. Of the total amount paid to the Company, \$2,250,000 in cash and 97,097 shares of Urologix

common stock were placed into an escrow account to secure indemnification obligations and compliance by the Company of certain of the representations, warranties and undertakings. The Company set off \$370,000 of intercompany debt against the cash portion of the consideration. The agreement is dated as of October 1, 2000. The Company was required by this agreement to purchase ten Prostatron units from Urologix, of which nine were expected to be obsolete.

The Company entered into a Supply Agreement with Urologix in connection with the Asset Purchase Agreement. The Supply Agreement, dated October 1, 2000, obligates the Company to manufacture the Prostatron control modules used in conjunction with the microwave thermotherapy products and to supply these products to Urologix at the prices set forth in the agreement. In addition, the Company agreed to provide Urologix with information about the manufacture and assembly processes. The term of this agreement is three years.

The Company is a party to a commercial lease agreement for its corporate headquarters and research and development and manufacturing facilities are located in Vaulx-en-Velin, on the outskirts of Lyons. The premises comprise 2,345 square meters of office space and 3,000 square meters of factory space. The lease has a term of nine years and is renewable at the leasee's option. The Company believes that the terms of the lease reflect commercial practice and market rates.

#### 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 thereto, 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 prescribed 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. As a foreign private issuer, the Company is not currently required to make filings with the Commission by electronic means, although it may elect to do so. Any filings the Company makes electronically will be available to the public over the Internet at the Commission's web site at <http://www.sec.gov>.

#### 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 use any other derivative instruments, such as foreign currency options, interest rate swaps and forward rate agreements, to manage market risks, nor does it hold or issue derivative or other financial instruments for trading purposes.

#### EXCHANGE RATE RISK

##### REVENUES AND EXPENSES IN FOREIGN CURRENCIES

The Company is exposed to foreign currency exchange rate risk because a

## Edgar Filing: EDAP TMS SA - Form 20-F

significant portion of its costs are denominated in currencies other than those in which it earns revenues. In 2002, approximately 64% of the Company's selling and general and administrative expenses and approximately 94% of the Company's research and development expenses were denominated in euros. During the same period, only 49% of the Company's sales were denominated in euros, 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, 2002 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 [e] 50 thousand for the year ended December 31, 2002, compared to a decrease of approximately [e] 1.8 million for the year ended December 31, 2001. 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

51

above, changes in exchange rates also affect the volume of sales. This sensitivity analysis of the effects of changes in currency exchange rates does not factor in a potential change in sales levels or any offsetting gains on forward sale contracts.

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. The Company had no forward sale contracts in place at December 31, 2002.

### FINANCIAL INSTRUMENTS AND INDEBTEDNESS

The Company regularly assesses its exposure related to any financial instruments that it may be utilizing during the normal course of business. At December 31, 2002 the Company was not utilizing any such financial instruments and therefore has no material exposure to risks related to financial instruments including, but not limited to, exchange and interest rate exposure.

In the prior years, the Company also had exchange rate exposures with respect to indebtedness denominated in U.S. dollars and Japanese yen. Approximately [e] 0.9 million of the indebtedness of the Company at December 31, 2001 was denominated in Japanese yen, and none in U.S. dollars, compared to [e] 3.9 million denominated in U.S. dollars and [e] 0.8 million denominated in Japanese yen at December 31, 2000. In addition, at December 31, 2001, the Company had approximately [e] 16.6 million and [e] 0.6 million of financial assets denominated in U.S. dollars and in Japanese yen, respectively, principally representing investments available for sale and the cash balances of its U.S. and Japanese subsidiaries at such date, compared with [e] 22.7 million and [e] 1.6 million at December 31, 2000, respectively.

The potential immediate loss to the Company that would have resulted from a hypothetical 10% decrease in the exchange rate of the U.S. dollar against the euro had been approximately [e] 1.5 million at December 31, 2001 compared with [e] 1.7 million as of December 31, 2000. The exposure at December 31, 2001 and at December 31, 2000 resulted from the Company's move from a net borrowing position in U.S. dollar financial instruments in 1999 to a net lending position at December 31, 2000 as a result of the Urologix transaction.

The potential immediate loss to the Company that would have resulted from a hypothetical 10% decrease in the exchange rate of the Japanese yen against the

## Edgar Filing: EDAP TMS SA - Form 20-F

euro had not been material to the Company as at December 31, 2001.

This sensitivity analysis assumes an unfavorable 10% fluctuation in the exchange rates affecting the foreign currencies in which financial assets and liabilities (based on principal amounts outstanding as of December 31, 2001 (or December 31, 2000 with respect to information given as of that date) are denominated from such rates as of December 31, 2001 (or December 31, 2000 with respect to information given as of that date), and assumes the same exchange rate movement within each category (e.g., U.S. dollar-denominated financial assets and liabilities and Japanese yen-denominated financial assets and liabilities). As consistently and simultaneously unfavorable movements in all relevant exchange rates are unlikely, these assumptions may overstate the impact of exchange rate fluctuations on such financial instruments.

### EQUITY PRICE RISK

The Company was exposed to equity price risk as a consequence of holding shares of common stock and warrants to purchase shares of common stock of Urologix, which it received in partial consideration for the sale by the Company to Urologix of its Prostatron business in October 2000. These securities represented approximately 43% of the Company's consolidated assets at December 31, 2000, approximately 18% at December 31, 2001 and less than 1% at December 31, 2002. Consequently, the Company believes that this exposure is no longer material.

### ITEM 12. DESCRIPTION OF SECURITIES OTHER THAN EQUITY SECURITIES

Not Applicable.

52

## PART II

### ITEM 13. DEFAULTS, DIVIDENDS 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.

## Edgar Filing: EDAP TMS SA - Form 20-F

ITEM 16A.

Not Applicable.

ITEM 16B.

Not Applicable.

ITEM 16C.

Not Applicable.

### PART III

ITEM 17. FINANCIAL STATEMENTS.

Not Applicable.

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

EXHIBIT NUMBER DESCRIPTION

- |     |  |
|-----|--|
| 1   | By-laws (statuts) of EDAP TMS S.A. as amended as of July 30, 2002 (together with an English translation thereof).  |
| 4.1 | Asset Purchase Agreement, dated as of October 1, 2000, among Urologix, Inc., EDAP TMS S.A., Technomed Medical Systems, S.A. and EDAP Technomed Inc.(1)   |
| 4.2 | Supply Agreement, dated as of October 1, 2000, among Urologix, Inc., EDAP TMS S.A., Technomed Medical Systems, S.A. and EDAP Technomed Inc.(1)   |
| 4.3 | Registration Rights Agreement, dated as of October 1, 2000, among EDAP TMS S.A., Technomed Medical Systems, S.A., EDAP Technomed Inc. and Urologix, Inc.(2)  |
| 4.4 | Commercial Leases dated October 1, 2002 and Amendment No. 1 dated October 15, 2002, between Maison Antoine Baud and EDAP TMS SA, EDAP SA and Technomed Medical Systems SA. (together with an English translation thereof). |
| 8   | List of subsidiaries of EDAP TMS S.A. as of March 31, 2003.  |
| 12  | Annual certification pursuant to Section 906 of the Sarbanes Oxley Act of 2002.  |

-----

- (1) Previously filed with certain confidential portions omitted under Rule 24b-2 under the Securities Exchange Act of 1934.  
(2) Previously filed.



## Edgar Filing: EDAP TMS SA - Form 20-F

### 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.

\s\ Philippe Chauveau  
By: \_\_\_\_\_  
Philippe Chauveau  
Chairman and Chief Executive Officer

Dated: May 8, 2003

\s\ Ian Vawter  
By: \_\_\_\_\_  
Ian Vawter  
Chief Financial Officer

Dated: May 8, 2003

54

### ANNUAL CERTIFICATION PURSUANT TO SECTION 302 OF SARBANES-OXLEY ACT OF 2002

I, Philippe Chauveau, Chairman and Chief Executive Officer of EDAP TMS S.A., certify that:

1. I have reviewed this annual report on Form 20-F of EDAP TMS S.A.;
2. Based on my knowledge, this annual report does not contain any untrue

## Edgar Filing: EDAP TMS SA - Form 20-F

- statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this annual report;
3. Based on my knowledge, the financial statements, and other financial information included in the annual report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this annual report;
  4. The registrant's other certifying officers and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-14 and 15d-14) for the registrant and we have:
    - a) Designed such disclosure controls and procedures to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this annual report is being prepared;
    - b) Evaluated the effectiveness of the registrant's disclosure controls and procedures as of a date within 90 days prior to the filing date of this annual report (the "Evaluation Date"); and
    - c) Presented in this annual report our conclusions about the effectiveness of the disclosure controls and procedures based on our evaluation as of the Evaluation Date;
  5. The registrant's other certifying officers and I have disclosed, based on our most recent evaluation, to the registrant's auditors and the audit committee of registrant's board of directors (or persons performing the equivalent function):
    - a) All significant deficiencies in the design or operation of internal controls which could adversely affect the registrant's ability to record, process, summarize and report financial data and have identified for the registrant's auditors any material weaknesses in internal controls; and
    - b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal controls; and
  6. The registrant's other certifying officers and I have indicated in this annual report whether or not there were significant changes in internal controls or in other factors that could significantly affect internal controls subsequent to the date of our most recent evaluation, including any corrective actions with regards to significant deficiencies and material weaknesses.

\s\ Philippe Chauveau  
By: \_\_\_\_\_  
Philippe Chauveau  
Chairman and Chief Executive Officer

## Edgar Filing: EDAP TMS SA - Form 20-F

Dated: May 8, 2003

55

### ANNUAL CERTIFICATION PURSUANT TO SECTION 302 OF SARBANES-OXLEY ACT OF 2002

I, Ian Vawter, Chief Financial Officer of EDAP TMS S.A., certify that:

1. I have reviewed this annual report on Form 20-F of EDAP TMS S.A.;
2. Based on my knowledge, this annual report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this annual report;
3. Based on my knowledge, the financial statements, and other financial information included in the annual report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this annual report;
4. The registrant's other certifying officers and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-14 and 15d-14) for the registrant and we have:
  - a) Designed such disclosure controls and procedures to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this annual report is being prepared;
  - b) Evaluated the effectiveness of the registrant's disclosure controls and procedures as of a date within 90 days prior to the filing date of this annual report (the "Evaluation Date"); and
  - c) Presented in this annual report our conclusions about the effectiveness of the disclosure controls and procedures based on our evaluation as of the Evaluation Date;
5. The registrant's other certifying officers and I have disclosed, based on our most recent evaluation, to the registrant's auditors and the audit committee of registrant's board of directors (or persons performing the equivalent function):
  - a) All significant deficiencies in the design or operation of internal controls which could adversely affect the registrant's ability to record, process, summarize and report financial data and have identified for the registrant's auditors any material weaknesses in internal controls; and

Edgar Filing: EDAP TMS SA - Form 20-F

- b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal controls; and
- 6 The registrant's other certifying officers and I have indicated in this annual report whether or not there were significant changes in internal controls or in other factors that could significantly affect internal controls subsequent to the date of our most recent evaluation, including any corrective actions with regards to significant deficiencies and material weaknesses.

\s\ Ian Vawter  
By: \_\_\_\_\_  
Ian Vawter  
Chief Financial Officer

Dated: May 8, 2003

INDEX TO FINANCIAL STATEMENTS

INDEX TO FINANCIAL STATEMENTS

Index to Financial Statements.....

AUDITED CONSOLIDATED FINANCIAL STATEMENTS FOR EDAP TMS S.A. AND SUBSIDIARIES FOR THE YEARS ENDED  
DECEMBER 31, 2002, 2001 AND 2000

Report of Independent Auditors.....

Consolidated Balance Sheets as of December 31, 2002 and 2001.....

Consolidated Statements of Income for the years ended December 31, 2002, 2001 and 2000.....

Consolidated Statements of Comprehensive Income for the years ended December 31, 2002, 2001 and  
2000.....

Consolidated Statements of Shareholders' Equity for the years ended December 31, 2002, 2001 and  
2000.....

Consolidated Statements of Cash Flows for the years ended December 31, 2002, 2001 and 2000.....

Notes to Consolidated Financial Statements.....

F-1

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, 2002 and 2001, 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, 2002. 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 auditing standards generally accepted in the 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. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes 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, 2002 and 2001, and the consolidated results of their operations and their cash flows for each of the three years in the period ended December 31, 2002 in conformity with accounting principles generally accepted in the United States.

ERNST & YOUNG (Audit)

\s\ Jean-Luc Desplat  
Represented by: \_\_\_\_\_  
Jean-Luc Desplat

April 22, 2003  
Lyon, France

F-2

EDAP TMS S.A. AND SUBSIDIARIES  
 CONSOLIDATED BALANCE SHEETS  
 AS OF DECEMBER 31, 2002 AND 2001  
 (IN THOUSANDS OF EUROS UNLESS OTHERWISE NOTED)

ASSETS	NOTES	2002	2001
<hr/>			
CURRENT ASSETS			
Cash and cash equivalents.....		15,755	19,361
Investments available for sale.....	2	82	9,686
Trade accounts and notes receivable, net of allowance of [e] 862 in 2002 and [e] 917 in 2001.....	3	9,222	8,828
Other receivables.....	4	1,974	2,007
Inventories.....	5	6,566	5,598
Deferred income taxes.....	18-2	105	111
Prepaid expenses.....		387	336
		<hr/>	<hr/>
Total current assets.....		34,091	45,927
Property, plant and equipment, net.....	6	1,985	2,233
Intangible assets.....	7	228	104
Goodwill, net of accumulated amortization of [e] 2,359 in 2002 and 2001	7	2,412	2,412
Net assets held for sale.....		---	245
Restricted cash equivalents.....		---	890
Deposits and other non-current assets.....		1,071	1,304
		<hr/>	<hr/>
Total assets.....		39,787	53,115
		=====	=====
LIABILITIES AND SHAREHOLDERS' EQUITY			
CURRENT LIABILITIES			
Short-term borrowings.....	10	482	---
Trade accounts and notes payable.....	8	5,167	6,511
Deferred maintenance contract income.....		1,134	965
Social security and other payroll withholdings taxes.....		600	618
Employee compensation absences.....		751	431
Income taxes payables.....		43	693
Others accrued liabilities.....		1,229	1,972
Current portion of obligations under capital leases.....	9	---	102
Current portion of long-term debt.....	11	402	624
		<hr/>	<hr/>
Total current liabilities.....		9,880	11,916
Obligations under capital leases	9	---	229

Edgar Filing: EDAP TMS SA - Form 20-F

Long-term debt.....	11	95	304
Other provisions and long-term liabilities.....	12	1,509	1,757
Total liabilities.....		11,412	14,206
Commitments and contingent liabilities	19		
SHAREHOLDERS' EQUITY			
Common stock, [e] 0.13 par value, 9,318,875 shares authorized; 8,315,400 shares issued; 7,781,731 and 7,734,310 shares outstanding at December 31, 2002 and 2001, respectively.....	13	1,087	1,081
Additional paid-in capital.....		19,811	19,811
Retained earnings.....	13	11,787	15,827
Cumulative other comprehensive income.....		(2,513)	3,987
Treasury stock, at cost; 581,090 shares at December 31, 2002 and 2001	13	(1,797)	(1,797)
		-----	-----
Total shareholders' equity.....		28,375	38,909
		-----	-----
Total liabilities and shareholders' equity.....		39,787	53,115
		=====	=====

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

F-3

EDAP TMS S.A. AND SUBSIDIARIES

CONSOLIDATED STATEMENTS OF INCOME  
FOR THE YEARS ENDED DECEMBER 31, 2002, 2001 AND 2000  
(IN THOUSANDS OF EUROS UNLESS OTHERWISE NOTED)

	NOTES	2002	2001	2000
	-----	-----	-----	-----
Net sales of medical devices.....		10,527	10,760	9,796
Net sales of spare parts, supplies and services...		9,198	13,044	15,013
		-----	-----	-----
Net sales.....		19,725	23,804	24,809
Other revenues.....	14	236	161	2,443
		-----	-----	-----
Total revenues.....		19,961	23,965	27,252
Cost of sales (exclusive of items shown separately below).....		(11,503)	(15,190)	(14,192)
One time cost of sales provision.....		---	(796)	---
		-----	-----	-----
Gross profit.....		8,458	7,979	13,060
Research and development expenses.....		(3,186)	(3,430)	(3,971)
Selling expenses.....		(4,023)	(4,223)	(6,002)
General and administrative expenses.....		(4,647)	(5,348)	(5,476)
Depreciation and amortization.....		(137)	(92)	(1,346)
Non recurring operating expenses.....	15	(1,241)	---	---
		-----	-----	-----
Operating loss.....		(4,776)	(5,114)	(3,735)
Interest income (expense), net.....	16	455	694	(494)
Currency exchange gains, net.....		(1,027)	166	406
Net gain on sale of business.....		---	---	15,742
Other income, net.....	17	1,475	12,273	113
		-----	-----	-----

Edgar Filing: EDAP TMS SA - Form 20-F

Income (loss) before taxes.....		(3,873)	8,019	12,032
Income tax (expense) credit.....	18	(167)	(882)	(323)
		-----	-----	-----
Net (loss) income.....		(4,040)	7,137	11,709
		=====	=====	=====
Basic earnings per share.....	1-15	(0.52)	0.92	1.50
Weighted average shares outstanding used in basic calculation.....	1-15	7,771,467	7,760,044	7,784,850
Diluted earnings per share.....	1-15	(0.52)	0.90	1.42
Weighted average shares outstanding used in diluted calculation.....	1-15	7,833,514	7,941,869	8,266,361

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

F-4

EDAP TMS S.A. AND SUBSIDIARIES

CONSOLIDATED STATEMENTS OF COMPREHENSIVE INCOME  
FOR THE YEARS ENDED DECEMBER 31, 2002, 2001 AND 2000  
(IN THOUSANDS OF EUROS UNLESS OTHERWISE NOTED)

	2002	2001	2000
	-----	-----	-----
Net (loss) income.....	(4,040)	7,137	11,709
Other comprehensive income:			
Unrealized (loss) gain on investments.....	(109)	5,949	8,656
Foreign currency translation adjustments.....	(442)	(123)	(1,108)
	-----	-----	-----
Comprehensive (loss) income, net of tax.....	(4,591)	12,963	19,257
	=====	=====	=====



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

F-5

EDAP TMS S.A. AND SUBSIDIARIES

CONSOLIDATED STATEMENTS OF SHAREHOLDERS' EQUITY  
FOR THE YEARS ENDED DECEMBER 31, 2002, 2001 AND 2000  
(IN THOUSANDS OF EUROS UNLESS OTHERWISE NOTED)

	NUMBER OF SHARES	COMMON STOCK	ADDITIONAL PAID-IN CAPITAL	RETAINED EARNINGS	DEFERRED COMPEN- SATION	CUMULATIVE OTHER COMPRE- HENSIVE INCOME	TREA- SU- RE
Balance as of December 31, 1999 .....	7,784,850	1,060	19,811	(1,619)	--	(730)	(3)
Net income.....				11,709			
Translation adjustment.....						(1,109)	
Unrealized gain on investments available for sale .....						8,656	
Capital decrease.....		(46)		(1,330)			1
Balance as of December 31, 2000 .....	7,784,850	1,014	19,811	8,760	---	6,817	(1)
Net income.....				7,137			
Translation adjustment.....						(123)	
Acquisition of treasury shares .....	(333,540)						
Sale of treasury shares.....	283,000						
Change in unrealized gain on investments available for sale .....						(2,707)	
Capital conversion into euros .....		67		(67)			
Balance as of December 31, 2001 .....	7,734,310	1,081	19,811	15,827	---	3,987	(1)
Net income.....				(4,040)			

Edgar Filing: EDAP TMS SA - Form 20-F

Translation adjustment.....						(442)	
Increase of shares / Capital increase .....	47,421	6					
Sale of treasury shares							
Change in unrealized gain / loss on investments available for sale .....						(6,058)	
Balance as of December 31, 2002 .....	7,781,731	1,087	19,811	11,787		(2,513)	(1)
	=====	=====	=====	=====	=====	=====	=====

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

F-6

EDAP TMS S.A. AND SUBSIDIARIES

CONSOLIDATED STATEMENTS OF CASH FLOWS  
FOR THE YEARS ENDED DECEMBER 31, 2002, 2001 AND 2000  
(IN THOUSANDS OF EUROS UNLESS OTHERWISE NOTED)

	2002	2001	2000
	-----	-----	-----
<b>CASH FLOWS FROM OPERATING ACTIVITIES</b>			
Net (loss) income.....	(4,040)	7,137	11,137
Elimination of expenses and benefits without effect on cash:			
Depreciation and amortization.....	1,116	1,103	1,103
Change in allowances for doubtful accounts & slow-moving inventories.....	(595)	(820)	(820)
Change in long-term provisions.....	(248)	(189)	(189)
Cancellation of government grants.....	---	---	---
Net capital loss on disposal of assets.....	386	---	---
Deferred tax charge/(benefit).....	6	131	131
Net (loss) gain on sale of assets.....	(2)	(8)	(8)
Net (loss) gain on sale of business.....	---	---	(15)
Net (loss) gain on sale of investments available for sale.....	(1,535)	(12,242)	(12,242)
	-----	-----	-----
	(872)	(12,025)	(13,139)
Increase/Decrease in operating assets and liabilities, net of effects from sale of business:			
(Decrease)/Increase in trade accounts and notes and other receivables.....	(306)	(1,933)	3,933
Decrease/(Increase) in inventories.....	(428)	559	3,933
Decrease/(Increase) in prepaid expenses.....	(50)	18	
(Decrease)/Increase in trade accounts and notes payable.....	(1,382)	1,503	
(Decrease)/Increase in accrued expenses, other current liabilities and minority interests.....	(884)	1,340	(3,933)

Edgar Filing: EDAP TMS SA - Form 20-F

	(3,050)	1,487	2
NET CASH (USED IN)/PROVIDED BY OPERATING ACTIVITIES.....	(7,962)	(3,401)	
CASH FLOWS FROM INVESTING ACTIVITIES			
Acquisitions of property, plant and equipment.....	(859)	(847)	
Acquisitions of intangible assets.....	(210)	(82)	
Capitalized assets produced by the Company.....	(377)	(570)	
Net proceeds from sale of assets.....	15	12	
Net proceeds from sale of business.....	---	---	3
Proceeds from sale of investments available for sale.....	5,521	21,619	
Reimbursement of loans granted.....	---	20	
Change in restricted cash equivalents.....	890	3,481	
Reimbursement of deposits and guarantees.....	105	---	
NET CASH PROVIDED BY (USED IN) INVESTING ACTIVITIES.....	5,086	23,633	2
CASH FLOW FROM (USED IN) FINANCING ACTIVITIES			
Acquisition of treasury shares.....	---	(74)	
Repayment of long term borrowings.....	(624)	(3,784)	(1)
Repayment of obligations under capital leases.....	(331)	(96)	
Increase/(decrease) in bank overdrafts and short-term borrowings.....	699	(177)	
NET CASH USED IN FINANCING ACTIVITIES.....	(256)	(4,131)	(1)
Net effect of exchange rate changes on cash.....	(474)	(128)	
NET INCREASE/(DECREASE) IN CASH AND CASH EQUIVALENTS.....	(3,606)	15,973	
Cash and cash equivalents at beginning of year.....	19,361	3,388	3
CASH AND CASH EQUIVALENTS AT END OF YEAR.....	15,755	19,361	3

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

F-7

EDAP TMS S.A. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS  
(IN THOUSANDS OF EUROS UNLESS OTHERWISE NOTED, EXCEPT PER SHARE DATA)

1---SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

1-1 NATURE OF OPERATIONS

EDAP TMS S.A. and its subsidiaries ("the Company") are engaged in the development, production, marketing 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, the United States and Asia.

The Company purchases the majority of the components used in its products

## Edgar Filing: EDAP TMS SA - Form 20-F

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 were 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 accounting principles generally accepted in the United States (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. ("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 significant intercompany transactions and balances are eliminated in consolidation.

### 1-4 REVENUE RECOGNITION

For equipment 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 equipment, revenue is recognized when title to the machine 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 equipment, revenue is recognized when the contingency is resolved. The Company provides training and a one-year warranty upon installation. The Company accrues for the estimated training and warranty costs at the time of sale.

Revenues related to services and maintenance contracts are recognized when the services are rendered. Billings or cash receipts in advance of services due under maintenance contracts are recorded as deferred revenue.

### 1-5 CASH EQUIVALENTS

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

F-8

EDAP TMS S.A. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS  
(IN THOUSANDS OF EUROS UNLESS OTHERWISE NOTED, EXCEPT PER SHARE DATA)

## Edgar Filing: EDAP TMS SA - Form 20-F

### 1-6 INVENTORIES

Inventories are valued at the lower of manufacturing cost, which is principally comprised of components and labor costs, or market (net realizable value). Cost is determined on a first-in, first-out basis for components and spare parts and by specific identification for finished goods (medical devices). The Company establishes reserves for inventory estimated to be obsolete, unmarketable or slow-moving inventory on a case by case basis, equal to the difference between the cost of inventory and estimated market value based upon assumptions about future demand, technology change and market conditions.

### 1-7 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 cost per procedure transactions. This equipment is depreciated over a period of three years.

### 1-8 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.

### 1-9 GOODWILL AND OTHER INTANGIBLE ASSETS

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 n8 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.

Prior to the adoption of SFAS 142, goodwill was amortized over 25 years. Goodwill amortization expense amounted to [e] 119 thousand for the year ended December 31, 2001 and [e] 1,653 thousand, including an exceptional amortization expense of [e] 1,444 thousand following the sale of the TUMT business in October 2000, for the year ended December 31 2000.

Other intangible assets consist primarily of purchased patents relating to lithotripters, purchased licenses, a purchased tradename and trademark. The basis for valuation of these assets is historical acquisition cost. Organization costs represent out-of-pocket expenses incurred for setting up certain foreign subsidiaries. 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:

## Edgar Filing: EDAP TMS SA - Form 20-F

Patents.....	5 years
Licenses.....	5 years
Tradename and trademark.....	7 years
Organization costs.....	3 years

F-9

### EDAP TMS S.A. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS  
(IN THOUSANDS OF EUROS UNLESS OTHERWISE NOTED, EXCEPT PER SHARE DATA)

#### 1-10 WARRANTY COSTS

The Company generally provides customers a warranty with each product 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.

#### 1-11 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.

#### 1-12 RESEARCH AND DEVELOPMENT COSTS

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

#### 1-13 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, 2002, 2001 and 2000 were not material to the consolidated financial statements.

#### 1-14 TRANSLATION OF FOREIGN CURRENCIES

Translation of the financial statements of consolidated companies

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

## Edgar Filing: EDAP TMS SA - Form 20-F

the year; and

- \* translation gains and losses are recorded in a separate component of shareholders' equity.

Translation of balance sheet items denominated in foreign currencies

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.

### 1-15 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.

F-10

### EDAP TMS S.A. AND SUBSIDIARIES

#### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (IN THOUSANDS OF EUROS UNLESS OTHERWISE NOTED, EXCEPT PER SHARE DATA)

A reconciliation of the numerators and denominators of the basic and diluted EPS calculations for the years ended December 31, 2002 and 2001 is as follows:

	FOR THE YEAR ENDED DEC. 31, 2002			FOR THE YEAR ENDED DEC.	
	INCOME IN EUROS (NUMERATOR)	SHARES (DENOMINATOR)	PER-SHARE AMOUNT	INCOME IN EUROS (NUMERATOR)	SHARES (DENOMINATOR)
<b>BASIC EPS</b>					
Income available to common Shareholders.....	(4,039,835)	7,771,467	(0.52)	7,137,000	7,760,044
Effect of dilutive securities:					
Stock options.....		62,047			181,825
<b>DILUTED EPS</b>					
Income available to common shareholders	(4,039,835)	7,833,514	(0.52)	7,137,000	7,941,869
+ assumed conversions.....					

## Edgar Filing: EDAP TMS SA - Form 20-F

### 1-16 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 designate 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.

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

### 1-17 EMPLOYEE STOCK OPTION PLANS

At December 31, 2002, the Company has four stock-based employee compensation plans, which are described more fully in Note 26. 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 cost 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.

F-11

### EDAP TMS S.A. AND SUBSIDIARIES

#### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (IN THOUSANDS OF EUROS UNLESS OTHERWISE NOTED, EXCEPT PER SHARE DATA)

	YEAR ENDED DECEMBER 31		
	2002	2001	2000
Net income (loss), as reported .....	(4,040)	7,137	11,709
Add: Stock-based employee compensation expense included in reported net income (loss), net of related tax effects.....	---	---	---
Deduct: Total stock-based employee compensation expense determined under fair value based method for all awards, net of related tax effects.....	(129)	(141)	(116)
Pro forma net income (loss) .....	(4,169)	6,996	11,593



## Edgar Filing: EDAP TMS SA - Form 20-F

Earnings per share:

Basic, as reported .....	(0.52)	0.92	1.50
Basic, pro forma .....	(0.54)	0.90	1.48
Diluted, as reported .....	(0.52)	0.90	1.42
Diluted, pro forma .....	(0.54)	0.88	1.40

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:

	YEAR ENDED DECEMBER 31		
	2002	2001	2000
Weighted-average expected life (years).....	5	5	5
Expected volatility rates.....	54.16%	79.54%	101.00%
Expected dividend yield.....	---	---	---
Risk-free interest rate.....	4.25%	5%	5%
Weighted-average exercise price.....	2.02	2.08	2.23
Weighted-average fair value of options granted during the year..	0.90	2.23	2.17

### 1-18 NEW ACCOUNTING PRONOUNCEMENTS

In June 2001, the Financial Accounting Standards Board issued SFAS 143, "Accounting for Asset Retirement Obligations" (SFAS 143). SFAS 143 requires the fair value of a liability for an asset retirement obligation be recognized in the period in which it is incurred if a reasonable estimate of fair value can be made. The associated asset retirement costs are capitalized as part of the carrying amount of the long-lived asset. An entity shall measure changes in the liability for an asset retirement obligation due to passage of time by applying an interest method of allocation to the amount of the liability at the beginning of the period. That amount shall be recognized as an increase in the carrying amount of the liability and as an expense classified as an operating item in the statement of income. SFAS 143 will become effective for EDAP TMS beginning on January 1, 2003. The Company does not expect that adoption of SFAS 143 will have a material impact on its financial position, results of operations or cash flows.

In June 2002, the Financial Accounting Standards Board issued SFAS No. 146, "Accounting for Costs Associated with Exit or Disposal Activities" (SFAS 146). The Statement requires companies to recognize costs associated with exit or disposal activities when they are incurred rather than at the date of a commitment to an exit or disposal plan. The Statement replaces EITF Issue No. 94-3, "Liability Recognition for Certain Employee Termination Benefits and Other Costs to Exit an Activity (including Certain Costs Incurred in a Restructuring)". The Company is required to apply this Statement prospectively to exit or disposal activities initiated after December 31, 2002, with earlier application encouraged. The Company does not expect that adoption of SFAS 146 will have a material impact on its financial position, results of operations or cash flows.

# Edgar Filing: EDAP TMS SA - Form 20-F

## EDAP TMS S.A. AND SUBSIDIARIES

### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (IN THOUSANDS OF EUROS UNLESS OTHERWISE NOTED, EXCEPT PER SHARE DATA)

On November 25, 2002, the Financial Accounting Standards Board announced the issuance of Interpretation No. 45, "Guarantor's Accounting and Disclosure Requirements for Guarantees, Including Indirect Guarantees of Indebtedness of Others", which expands on the accounting guidance of Statements No. 5, 57, and 107 and incorporates without change the provisions of FASB Interpretation No. 34, which has been superseded by this Interpretation. Given observed differences in practice, this Interpretation clarifies the requirements for a guarantor's accounting and interim and annual financial statement disclosures of certain guarantees issued and outstanding. It also clarifies that a guarantor is required to recognize, at the inception of a guarantee, a liability for the fair value of the obligation undertaken in issuing the guarantee. This Interpretation does not prescribe a specific approach for subsequently measuring the guarantor's recognized liability over the term of the related guarantee. The incremental disclosure requirements in this Interpretation are effective for financial statements of interim or annual periods ending after December 15, 2002. The initial recognition and initial measurement provisions of this Interpretation are applicable to guarantees issued or modified after December 31, 2002. The Company is currently reviewing this interpretation to measure the potential impact on its results of operations and financial position.

In December 2002, the Financial Accounting Standards Board issued FASB Statement No. 148, Accounting for Stock-Based Compensation -- Transition and Disclosure ("SFAS 148"). This Statement amends FASB Statement No. 123, Accounting for Stock-Based Compensation ("SFAS 123"), to provide alternative methods of transition to SFAS 123's fair value method of accounting for stock-based employee compensation. It also amends the disclosure provisions of SFAS 123 to require prominent disclosure in the summary of significant account policies of the effects of an entity's accounting policy with respect to stock-based employee compensation on reported net income and earnings per share in annual financial statements. SFAS 148's amendment of the transition and annual disclosure requirements are effective for fiscal years ending after December 15, 2002. The Company intends to continue to account for stock-based compensation based on the provisions of APB Opinion No. 25.

#### 2---SALE OF THE PROSTATRON BUSINESS

##### 2-1 SALE OF PROSTATRON BUSINESS

In October 2000, the Company sold its Prostatron business to Urologix 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 have been exercised) on the date of the closing of the transaction. Additionally, the Company and Urologix entered into a supply agreement 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").

The sale of the Prostatron business included the transfer of all the rights, title and interest of the Company in the assets, properties, rights and goodwill which were used in the Prostatron business (including inventories, receivables, equipment, contracts, patents, trademarks and product approvals)

## Edgar Filing: EDAP TMS SA - Form 20-F

as well as the liabilities related to these transferred assets.

The Company recorded in 2000 non-recurrent net gain of [e] 15.7 million attributable to the sale of the assets of the Prostatron business.

### 2-2 INVESTMENTS AVAILABLE FOR SALE

Investments at December 31, 2001 consist of 425,000 Urologix, Inc. shares at a cost per share of \$ 7.725. These securities were received as part of the consideration for the sale of the Company's Prostatron business to Urologix in October 2000. These securities are deemed by management to be available for sale and are reported at fair value with net unrealized gains or losses reported within shareholders' equity.

F-13

### EDAP TMS S.A. AND SUBSIDIARIES

#### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

(IN THOUSANDS OF EUROS UNLESS OTHERWISE NOTED, EXCEPT PER SHARE DATA)

For the year ended December 31, 2001 unrealized gains amounted to [e] 5.9 million and represent the difference between the market value of the Urologix shares as of December 31, 2001 (\$20.05) and the negotiated value per the sales agreement (\$ 7.725).

The Company recorded, in 2001, a non-recurrent net gain of [e] 12.2 million attributable to the sale of Urologix Common Stock.

Investments at December 31, 2002 consist of 25,987 Urologix, Inc. shares at a cost per share of \$ 7.725. These securities were received as part of the consideration for the sale of the Company's Prostatron business to Urologix in October 2000. These securities are deemed by management to be available for sale and are reported at fair value with net unrealized gains or losses reported within shareholders' equity.

For the year ended December 31, 2002 unrealized losses amounted to [e] 0.1 million and represent the difference between the market value of the Urologix shares as of December 31, 2002 (\$3.31) and the negotiated value per the sales agreement (\$ 7.725).

The Company recorded, in 2002, a non-recurrent net gain of [e] 1.7 million attributable to the sale of Urologix Common Stock.

The carrying amount of the Company's investments is shown in the table below:

	COST	UNREALIZED GAINS AND LOSSES	FAIR VALUE
	-----	-----	-----
Urologix, Inc. common stock.....	191	(109)	82
Investments available for sale.....	191	(109)	82

Edgar Filing: EDAP TMS SA - Form 20-F

3---TRADE ACCOUNTS AND NOTES RECEIVABLE, NET

	DECEMBER 31,	
	2002	2001
	-----	-----
Trade accounts and notes receivable.....	10,084	9,745
Less: allowance for doubtful accounts.....	(862)	(917)
	-----	-----
Total.....	9,222	8,828
	=====	=====

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

F-14

EDAP TMS S.A. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS  
(IN THOUSANDS OF EUROS UNLESS OTHERWISE NOTED, EXCEPT PER SHARE DATA)

4---OTHER RECEIVABLES

Other receivables consist of the following:

	DECEMBER 31,	
	2002	2001
	-----	-----
Tax loss carryback receivable from the French State.....	578	609
Value-added taxes receivable from the French State.....	693	671
Research and development tax credit receivable from the French State.....	150	313
Other receivables from the French State.....	58	153
Others.....	495	261
	-----	-----
Total.....	1,974	2,007
	=====	=====

The receivable for tax losses carried back to prior years, which was recorded in 1997 and 1998, can be used to offset income taxes due during the five years following the year in which the carryback was recorded. Any balance of receivable at the end of this five-year period will be reimbursed by the

## Edgar Filing: EDAP TMS SA - Form 20-F

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 government.

### 5---INVENTORIES

Inventories consist of the following:

	DECEMBER 31,	
	2002	2001
Components, spare parts.....	5,225	5,494
Work-in-progress.....	722	551
Finished goods.....	2,147	1,621
	8,094	7,666
Total gross inventories.....	8,094	7,666
Less: provision for slow-moving inventory.....	(1,528)	(2,068)
	6,566	5,598
Total.....	6,566	5,598

### 6---PROPERTY, PLANT AND EQUIPMENT

Property, plant and equipment consist of the following:

	DECEMBER 31,	
	2002	2001
Equipment.....	3,507	4,269
Furniture, fixture, and fittings and other.....	2,256	2,686
	5,763	6,954
Total gross value.....	5,763	6,954
Less: accumulated depreciation.....	(3,778)	(4,722)
	1,985	2,233
Total.....	1,985	2,233

F-15

EDAP TMS S.A. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS  
(IN THOUSANDS OF EUROS UNLESS OTHERWISE NOTED, EXCEPT PER SHARE DATA)

## Edgar Filing: EDAP TMS SA - Form 20-F

Depreciation expense related to property, plant and equipment amounted to [e] 1,028 thousand and [e] 825 thousand for the years ended December 31, 2002 and 2001, respectively.

### 7---GOODWILL AND OTHER INTANGIBLE ASSETS

As discussed in Note 1-9, 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 segments --- 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 segments have similar economic characteristics and thus do not represent separate reporting units.

The Company completed the required annual impairment test in the fourth quarter of 2002. 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 units book value, which resulted in no goodwill impairment.

Had SFAS 142 been effective January 1, 2000, net income (loss) and earnings (loss) per share would have been reported as follows:

	YEAR ENDED DECEMBER 31		
	2002	2001	2000
Net income (loss), as reported.....	(4,040)	7,137	11,709
Add: Goodwill amortization.....	---	119	1,653
Pro forma net income (loss).....	(4,040)	7,256	13,362
	=====	=====	=====
Earnings per share:			
Basic, as reported .....	(0.52)	0.92	1.50
Basic, pro forma .....	(0.52)	0.94	1.72
Diluted, as reported .....	(0.52)	0.90	1.42
Diluted, pro forma .....	(0.52)	0.91	1.62

Other intangible assets consist of the following:

	DECEMBER 31,	
	2002	2001
Licenses.....	434	255
Tradename and trademark.....	630	661
Patents.....	412	412
Organization costs.....	363	360

Edgar Filing: EDAP TMS SA - Form 20-F

Total gross value.....	1,839	1,688
Less: accumulated amortization.....	(1,611)	(1,584)
Total.....	228	104
	=====	=====

Amortization expenses related to other intangible assets amounted to [e] 88 thousand and [e] 159 thousand, for the years ended December 31, 2002 and 2001, respectively.

F-16

EDAP TMS S.A. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

(IN THOUSANDS OF EUROS UNLESS OTHERWISE NOTED, EXCEPT PER SHARE DATA)

For the three coming years, the annual estimated amortization expense for intangible assets is approximately [e] 90 thousand.

8---TRADE ACCOUNTS AND NOTES PAYABLE

Trade accounts and notes payable consist of the following:

	DECEMBER 31,	
	2002	2001
	-----	-----
Trade accounts payable.....	4,198	5,439
Notes payable.....	969	1,072
Total.....	5,167	6,511
	=====	=====

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

9---LEASE OBLIGATIONS

9-1CAPITAL LEASES

The following assets held under capital leases have been classified as assets held for sale at December 31, 2002 and 2001 (see Note 19):

	DECEMBER 31,	
	2002	2001
	-----	-----

## Edgar Filing: EDAP TMS SA - Form 20-F

	----	
	-----	
Land and buildings.....	---	2,208
Less: accumulated depreciation and impairment reserve.....	---	(1,963)
	----	
	-----	
Total.....	---	245
	====	=====

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 [e] 797.3 thousand impairment charge was recorded in the fourth quarter of 1998. The company recorded a [e] 0.4 million gain on the transaction in 2002. The Company does not use this facility any more.

Interest paid for capital lease obligations was [e] 17 thousand, [e] 28 thousand and [e] 33 thousand for the years ended December 31, 2002, 2001 and 2000, respectively.

Depreciation expense on assets held under capital leases is included in total depreciation expense for the years ended December 31, 2002, 2001 and 2000.

### 9-2OPERATING LEASES

Operating leases having initial or remaining non-cancelable lease terms greater than one year consist principally of three leases for the facilities of EDAP TMS S.A., TMS S.A. and EDAP S.A. in Vaulx-en-Velin, France. These lease contracts have a lease term of nine years expiring at the option of the lessee at the end of a first four-year period, then a two-year and finally a three-year period, through 2011 (i.e., in 2006, 2008 or 2011). Future minimum lease payments for these three operating leases will amount to [e] 350 thousand per year until 2006 or [e] 1,400 thousand in the aggregate, or until otherwise canceled by the lessee.

Total rent expense under operating leases amounted to [e] 1,290, [e] 1,113 thousand and [e] 1,374 thousand for the years ended December 31, 2002, 2001 and 2000, respectively.

F-17

## EDAP TMS S.A. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS  
(IN THOUSANDS OF EUROS UNLESS OTHERWISE NOTED, EXCEPT PER SHARE DATA)

### 10---SHORT-TERM DEBT

As of December 31, 2002, the short-term debt consists of a loan in Japanese yen amounting to JPY 60 million ([e] 482 thousand), due to mature on June 15, 2003, at a rate of 2.375%.

### 11---LONG-TERM DEBT

Long-term debt consists of the following:



Edgar Filing: EDAP TMS SA - Form 20-F

	DECEMBER 31,	
	2002	2001
	-----	-----
Japanese yen term loan.....	458	867
Other financial debts.....	39	61
	-----	-----
Total.....	497	928
Less current portion.....	(402)	(624)
	-----	-----
Total long-term portion.....	95	304
	=====	=====

The Japanese yen five-year unsecured term loan had an initial principal of JPY 150 million, bears interest at a fixed rate of 2.48%, calls for repayment of principal in eight semi-annual instalments of JPY 15 million beginning February 23, 1999 and one installment of JPY 30 million on February 24, 2003, and calls for semi-annual payments of interest in advance beginning February 23, 1998.

Long-term debt as at December 31, 2002 matures as follows:

2003.....	402
2004.....	87
2005.....	8
	---
Total.....	497
	===

12---OTHER PROVISIONS AND LONG-TERM LIABILITIES

	DECEMBER 31,	
	2002	2001
	-----	-----
Provision for warranty costs.....	901	1,185
Provision for retirement indemnities.....	424	277
Other.....	184	295
	-----	-----
Total.....	1,509	1,757
	=====	=====

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 companies within the Company have defined benefit retirement indemnity plans in place. The provision for retirement indemnities at December 31, 2002 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.

## Edgar Filing: EDAP TMS SA - Form 20-F

This provision has been calculated taking into account the estimated payment at retirement (discounted to the current date), turnover and salary increases.

F-18

### EDAP TMS S.A. AND SUBSIDIARIES

#### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

(IN THOUSANDS OF EUROS UNLESS OTHERWISE NOTED, EXCEPT PER SHARE DATA)

#### 13---SHAREHOLDERS' EQUITY

##### 13-1 COMMON STOCK

As of December 31, 2002, EDAP TMS S.A.'s common stock consists of 9,318,875 authorized shares with a par value of [e] 0.13 each, of which 8,362,821 were issued and fully-paid and 7,781,731 were outstanding.

##### 13-2 RETAINED EARNINGS

Distributable statutory retained earnings amount to [e] 33,308 thousand and [e] 42,927 thousand at December 31, 2002 and 2001.

##### 13-3 TREASURY STOCK

As of December 31, 2002, the 581,090 shares of treasury stock consists of (i) 177,750 shares acquired on December 2, 1996 for [e] 707 thousand, (ii) 352,800 shares acquired between August and December 1998 for [e] 1,016 thousand, and (iii) 50,540 shares acquired in June and July 2001 for [e] 153 thousand. All 581,090 shares of treasury stock have been acquired to cover outstanding stock options (see Note 26). On July 29, 2001, the Company sold 283,000 shares on the Nasdaq Europe, these shares corresponded to shares purchase options initially allocated to employees of the Company who left the Company, renouncing therefore to their stock purchase options. The Company bought all 283,000 shares back on the same day for [e] 774 thousand. This operation was to conform to French law requesting that treasury shares, held to cover stock option plans, should be allocated to employees within one year of their purchase.

#### 14---OTHER REVENUE

Other revenue consists of the following:

	2002	2001	2000
	----	----	-----
Royalties.....	97	70	2,406
Subsidies and others.....	139	91	37
	----	----	-----
Total.....	236	161	2,443
	====	====	=====

TMS S.A. and EDAP S.A. received [e] 81 thousand in subsidies in 2002 and TMS S.A. only received [e] 30 thousand and [e] 37 thousand in subsidies in 2001 and

## Edgar Filing: EDAP TMS SA - Form 20-F

2000, respectively, from the French Ministry of Research and Development.

### 15---OPERATING EXPENSES

Operating expenses include bad debt expense of [e] 51 thousand, [e] 127 thousand and [e] 111 thousand for 2002, 2001 and 2000, respectively. These operating expenses also include allowance for slow moving inventory of [e] 624 thousand, [e] 1,124 thousand and [e] 1,035 thousand for 2002, 2001 and 2000, respectively.

Following the Company's decision to restructure and reorganize the activities of the Company into two operating divisions, during year 2002, the Company recorded [e] 1.2 million of non-recurring expenses, including [e] 0.8 million of termination expenses, [e] 0.2 million legal expenses linked to this reorganization and [e] 0.2 million related to various non-recurring expenses.

F-19

### EDAP TMS S.A. AND SUBSIDIARIES

#### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (IN THOUSANDS OF EUROS UNLESS OTHERWISE NOTED, EXCEPT PER SHARE DATA)

### 16---INTEREST (EXPENSE) INCOME, NET

	2002	2001	2000
	----	----	----
Interest income.....	502	991	228
Interest expense.....	(47)	(297)	(722)
	----	----	----
Total.....	455	694	(494)
	====	====	====

### 17---OTHER INCOME, NET

	2002	2001	2000
	-----	-----	-----
Net gain on sale of Urologix common stock.....	1,669	12,242	---
Net gain on sale of business.....	---	---	15,742
Other (loss)/income, net.....	(194)	31	113
	-----	-----	-----
Total.....	1,475	12,273	15,855
	=====	=====	=====

The net gain on sale of business in 2000 reflected the net gain on the sale to Urologix of the Prostatron business, on October 1, 2000 (see Note 2.1).

The net gain on sale of Urologix Common Stock in 2001 and 2002 reflected the

## Edgar Filing: EDAP TMS SA - Form 20-F

net gain on the sale of Urologix Common Stock during the year (see Note 2.2).

### 18---INCOME TAXES

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

	2002	2001	2000
	----	----	----
Current income tax provision:			
France .....	(59)	(35)	(5)
Other countries .....	(91)	(723)	(399)
	----	----	----
Sub-total current income tax provisions.....	(150)	(758)	(404)
	----	----	----
Research and development tax credit.....	---	0	150
Sub total current income tax.....	(150)	(758)	(254)
Deferred income tax (provision) credit.....	(17)	(124)	(69)
	----	----	----
Total.....	(167)	(882)	(323)
	====	====	====

F-20

### EDAP TMS S.A. AND SUBSIDIARIES

#### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

(IN THOUSANDS OF EUROS UNLESS OTHERWISE NOTED, EXCEPT PER SHARE DATA)

#### 18-1 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:

	DECEMBER 31,	
	2002	2001
	-----	-----
Elimination of intercompany profit in inventory.....	264	256
Provision for impairment of long-lived assets.....	---	292
Other items.....	283	287
Operating loss carryforwards.....	3,295	2,326
	-----	-----
Total deferred tax assets.....	3,842	3,161
Capital leases treated as operating leases for tax.....	---	(257)

## Edgar Filing: EDAP TMS SA - Form 20-F

Other items.....	(161)	(175)
	-----	-----
Total deferred tax liabilities.....	(161)	(432)
Net deferred tax assets.....	3,681	2,729
Valuation allowance for deferred tax assets.....	(3,576)	(2,618)
	-----	-----
Deferred tax assets, net of allowance.....	105	111
	=====	=====

Net operating loss carryforwards of [e] 555 thousand, [e] 829 thousand, [e] 991 thousand, [e] 241 thousand and [e] 678 thousand as of December 31, 2002 are available at EDAP Technomed Inc., TMS S.A., EDAP S.A., Edap Technomed Italia S.R.L. and EDAP TMS S.A., respectively. Realization of these assets is contingent on future taxable earnings in the applicable tax jurisdictions. As of December 31, 2002, [e] 660 thousand out of these [e] 3,295 thousand net operating loss carry-forwards have no expiration date. The remaining tax loss carryforwards expire in years 2003 through 2016. In accordance with SFAS No. 109, a 100% valuation allowance is recorded as realization of these amounts, as well as other net deferred tax assets existing at EDAP TMS S.A. and certain subsidiaries, is not considered more likely than not.

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 discussed in Note 18-1, 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.

F-21

### EDAP TMS S.A. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS  
(IN THOUSANDS OF EUROS UNLESS OTHERWISE NOTED, EXCEPT PER SHARE DATA)

#### 18-2 EFFECTIVE TAX RATE

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

	2002	2001	2000
	-----	-----	-----
French statutory rate.....	34.3%	35.3%	36.7%
Research and development tax credit.....	0%	0%	(1.2%)

## Edgar Filing: EDAP TMS SA - Form 20-F

Non deductible amortization of goodwill and other intangibles.....	0%	0.8%	5.2%
Income of foreign subsidiaries taxed at different tax rates.....	0.4%	(0.5%)	(13.6%)
Effect of net operating loss carryforwards and valuation allowances	(25.0%)	(23.0%)	(31.8%)
Non deductible entertainment expenses.....	(0.2%)	0.2%	0.2%
Other.....	(13.8%)	(1.8%)	7.2%
Effective tax rate.....	(4.3%)	11%	2.7%

### 19---COMMITMENTS AND CONTINGENCIES

#### 19-1 COMMITMENTS

The Company currently has commitments regarding its operating leases as described in Note 9.

#### 19-2 LITIGATIONS

The Company is involved in a number of claims and lawsuits considered normal in its business, including employee litigations 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, 2002, and for the year then ended.

### 20---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, 2002 and 2001.

	DECEMBER 31,		DECEMBER 31,	
	2002	2002	2001	2001
	RECORDED	ESTIMATED	RECORDED	ESTIMATED
	VALUE	FAIR VALUE	VALUE	FAIR VALUE
	-----	-----	-----	-----
<b>ASSETS:</b>				
Cash and cash equivalents.....	15,755	15,755	19,361	19,361
Trade accounts and notes receivable, net.....	9,222	9,222	8,828	8,828
Restricted cash equivalents.....	---	---	890	890
Investments available for sale.....	82	82	9,686	9,686
<b>LIABILITIES:</b>				
Short-term borrowings.....	699	699		
Trade accounts payable.....	4,198	4,198	5,439	5,439
Notes payable.....	969	969	1,072	1,072
Long-term debt.....	23	21	304	290

The recorded amount of cash and cash equivalents, investments available for sale, trade accounts and notes receivable (drafts), short-term borrowings, and

## Edgar Filing: EDAP TMS SA - Form 20-F

trade accounts and notes payable (drafts) are a reasonable estimate of their fair value due to the short-term maturities of these instruments.

F-22

### EDAP TMS S.A. AND SUBSIDIARIES

#### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (IN THOUSANDS OF EUROS UNLESS OTHERWISE NOTED, EXCEPT PER SHARE DATA)

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

#### 21---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 [e] 0.9 million as of December 31, 2002 and 2001. Ultimate losses may vary from the current estimates, and any adjustments are reported in earnings in the periods in which they become known.

The Company generated approximately 14.0% of revenues and corresponding accounts receivable from sales to a single customer. As of December 31, 2002 approximately [e] 1.6 million or 17.3% of the Company's net accounts receivable were attributable to this customer; and [e] 1.1 million or 12.5% of the Company's net accounts receivable were attributable to this same customer, as of December 31, 2001.

#### 22---FOREIGN CURRENCY TRANSACTIONS

The Company generates a significant percentage of its revenues, and of its operating expenses, in currencies other than Euros. 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. The Company did not deem it necessary to engage in hedging activities in the years ended December 31, 2002 and 2001, thus there are no such financial instruments outstanding at December 31, 2002 and 2001.

#### 23---SEGMENT AND GEOGRAPHIC INFORMATION

## Edgar Filing: EDAP TMS SA - Form 20-F

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 HIFU division; and the Urological Devices and Services division. The following tables set forth the key income statement figures, by segment, for fiscal years 2000, 2001 and 2002 and the key balance sheet figures, by segment, for fiscal years 2001 and 2002.

Previously, the Company reported operating segments by geographic region. This geographic presentation is being provided, for information purposes, however, may not be included in future segment presentation.

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.

F-23

### EDAP TMS S.A. AND SUBSIDIARIES

#### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

(IN THOUSANDS OF EUROS UNLESS OTHERWISE NOTED, EXCEPT PER SHARE DATA)

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:

	2002	2001	2000
	-----	-----	-----
Segment operating (loss) profit.....	(4,776)	(5,114)	(3,735)
Interest income (expense), net.....	455	694	(494)
Currency exchange (losses) gains, net.....	(1,027)	166	406
Other income, net.....	1,475	12,273	15,855
Income tax (expense) credit.....	(167)	(882)	(323)
	-----	-----	-----
Consolidated income before taxes.....	(4,040)	7,137	11,709
	=====	=====	=====

External revenue by segment and by product and service noted below is computed based on the geographic segment which invoices the related external sale, which is generally the same geographic zone in which the segment is located, except for France, which invoices most other countries where local Company subsidiaries are not present.



F-24

## EDAP TMS S.A. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS  
(IN THOUSANDS OF EUROS UNLESS OTHERWISE NOTED, EXCEPT PER SHARE DATA)

A summary of the Company's former operating segments by geographical areas is presented below:

	2002	2001	2000
	-----	-----	-----
France.....	4,525	4,258	2,788
United States.....	403	---	1,276
Japan.....	2,679	5,192	4,147
Other geographical areas.....	3,512	1,310	1,585
	-----	-----	-----
External sales of medical devices.....	11,120	10,760	9,796
	-----	-----	-----
France.....	2,877	5,652	3,408
United States.....	180	132	3,489
Japan.....	3,579	4,171	5,364
Other geographical areas.....	2,755	3,090	2,752
	-----	-----	-----
External sales of spare parts, supplies and services...	9,390	13,045	15,013
	-----	-----	-----
France.....	(3,945)	(3,209)	(2,464)
United States.....	(1,165)	(1,773)	(2,338)
Japan.....	(136)	(70)	676
Other geographical areas.....	469	(62)	391
	-----	-----	-----
Operating (loss) profit.....	(4,776)	(5,114)	(3,735)
	-----	-----	-----
France.....	28,379	28,971	17,787
United States.....	1,792	13,914	22,198
Japan.....	4,227	4,368	5,795
Other geographical areas.....	5,389	4,861	4,507
	-----	-----	-----
Segment assets.....	39,788	53,115	50,287
	-----	-----	-----
France.....	1,352	1,747	1,320
United States.....	41	72	45
Japan.....	134	183	277
Other geographical areas.....	459	336	372
	-----	-----	-----
Long-lived assets.....	1,985	2,337	2,014
	=====	=====	=====

F-25

## EDAP TMS S.A. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS  
(IN THOUSANDS OF EUROS UNLESS OTHERWISE NOTED, EXCEPT PER SHARE DATA)

A summary of the Company's operations by business unit is presented below for years ending December 31, 2002, 2001 and 2000:

	HIFU DIVISION	UDS DIVISION	EDAP TMS	CONSOLI- DATION	TOTAL CONSOLIDATED
	-----	-----	-----	-----	-----
2002					
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
Total Revenues.....	3,376	18,419	---	(1,835)	19,961
Total COS.....	(1,877)	(11,461)	---	1,835	(11,503)
Gross margin.....	1,499	6,959	---	---	8,458
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)
Total expenses.....	(4,898)	(6,390)	(1,946)	---	(13,234)
Operating income (loss).....	(3,399)	569	(1,946)	---	(4,776)
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

F-26

## EDAP TMS S.A. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS  
(IN THOUSANDS OF EUROS UNLESS OTHERWISE NOTED, EXCEPT PER SHARE DATA)

	HIFU DIVISION	UDS DIVISION	EDAP TMS	CONSOLI- DATION	TOTAL CONSOLIDATED
	-----	-----	-----	-----	-----
2001					
External sales of medical devices	1,115	9,645	---	---	10,760
External sales of spares parts, supplies & services.....	464	12,580	---	---	13,044
Internal segment revenues.....	0	912	---	(912)	---
Other revenues.....	15	146	---	---	161
Total Revenues.....	1,594	23,283	---	(912)	23,965
Total COS.....	(947)	(15,951)	---	912	(15,986)
Gross margin.....	647	7,332	---	---	7,979
R&D.....	(1,373)	(583)	---	---	(1,956)
Clinical trials.....	(529)	(90)	---	---	(619)
Regulatory.....	(330)	(525)	---	---	(855)
Marketing.....	(518)	(986)	---	---	(1,504)
Selling.....	(560)	(2,159)	---	---	(2,720)
G&A.....	(704)	(3,482)	(1,253)	---	(5,440)
Total expenses.....	(4,014)	(7,826)	(1,253)	---	(13,093)
Operating income (loss).....	(3,367)	(494)	(1,253)	---	(5,114)
Assets.....	12,146	33,852	12,445	(5,328)	53,114
Capital expenditures.....	429	961	27	---	1,417
Long lived assets.....	1,112	1,029	26	---	2,167
Goodwill.....	645	1,767	---	---	2,412

F-27

## EDAP TMS S.A. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS  
(IN THOUSANDS OF EUROS UNLESS OTHERWISE NOTED, EXCEPT PER SHARE DATA)

	HIFU DIVISION	UDS DIVISION	EDAP TMS	CONSOLI- DATION	TOTAL CONSOLIDATED
	-----	-----	-----	-----	-----
2000					
External sales of medical devices.....	614	9,182	---	---	9,796
External sales of spares parts, supplies & services.....	146	14,867	---	---	15,013
Internal segment revenues.....	0	503	---	(503)	---
Other revenues.....	4	2,439	---	---	2,443
	-----	-----	-----	-----	-----
Total Revenues.....	763	26,992	---	(503)	27,252
	-----	-----	-----	-----	-----
Total COS.....	(514)	(14,181)	---	503	(14,192)
	-----	-----	-----	-----	-----
Gross margin.....	249	12,811	---	---	13,060
	-----	-----	-----	-----	-----
R&D.....	(927)	(779)	---	---	(1,706)
Clinical trials.....	(742)	(100)	---	---	(842)
Regulatory.....	(293)	(676)	---	---	(969)
Marketing.....	(460)	(1,944)	---	---	(2,404)
Selling.....	(498)	(3,100)	---	---	(3,598)
G&A.....	(626)	(4,943)	(1,253)	---	(6,822)
	-----	-----	-----	-----	-----
Total expenses.....	(3,546)	(11,542)	(1,253)	---	(16,341)
	-----	-----	-----	-----	-----
Operating income (loss).....	(3,297)	1,270	(1,253)	---	(3,281)
	-----	-----	-----	-----	-----

## 24---VALUATION ACCOUNTS

	ALLOWANCE FOR DOUBTFUL ACCOUNTS	SLOW-MOVING INVENTORY
	-----	-----
Restated balance as of December 31, 1999.....	1,664	2,252
	-----	-----
Charges to costs and expenses.....	111	2,035
Deductions: write-off of bad debts provided in prior periods....	(658)	(1,731)
Translation adjustment.....	46	79
	-----	-----

## Edgar Filing: EDAP TMS SA - Form 20-F

Restated balance as of December 31, 2000.....	1,163	2,635
Charges to costs and expenses.....	128	1,124
Deductions: write-off of bad debts provided in prior periods....	(375)	(1,697)
Translation adjustment.....	1	6
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

F-28

### EDAP TMS S.A. AND SUBSIDIARIES

#### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

(IN THOUSANDS OF EUROS UNLESS OTHERWISE NOTED, EXCEPT PER SHARE DATA)

#### 25---SUPPLEMENTAL DISCLOSURES OF CASH FLOW INFORMATION

Interest and income taxes paid are as follows:

	2002	2001	2000
Income taxes paid (refunds received).....	112	(784)	344
Interest paid.....	2	198	863
Interest received.....	278	198	863

#### 26---STOCK OPTION PLANS

EDAP TMS S.A. currently sponsors four stock purchase and 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 [e] 6.97 per share. The authorization to grant the options expires 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 are exercisable as of the date of grant and the right to exercise the remaining 75% of the options vests at the rate of 25% each January 1 following the date of grant. The options expire five years after the date of grant. On October 29, 1998, the Board of Directors amended the terms of 124,125 of the purchase options to conform the terms of the 1998 option plan discussed below.

On May 14, 1998, the shareholders of EDAP TMS S.A. authorized the Board of

## Edgar Filing: EDAP TMS SA - Form 20-F

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 modification of 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 [e] 3.81 per share for 152,000 options and [e] 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 begin vesting two years after the date of grant and are 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 the terms to the terms of the 1998 stock option plan.

Conforming to 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 [e] 3.81 per share for 11,000 options and [e] 1.83 per share for 13,000 options. The options begin vesting two years after the date of grant and are fully vested as of January 1, 2002 (i.e. four 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 [e] 3.81 and 20,000 options at an exercise price of [e] 2.74.

F-29

### EDAP TMS S.A. AND SUBSIDIARIES

#### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (IN THOUSANDS OF EUROS UNLESS OTHERWISE NOTED, EXCEPT PER SHARE DATA)

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 begin vesting two years after the date of grant and are fully vested as of June 1, 2002 (i.e. three years and two & 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, fifty percent of the options are exercisable as of the date of grant and the right to exercise the remaining fifty percent of the options vests at the rate of 25% each January 1 following the date of grant. The options expire on December 31, 2003 (i.e. four years and nine months after the date of grant). To conform to the terms of the 1998

## Edgar Filing: EDAP TMS SA - Form 20-F

option plan discussed here 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 [e] 3.81 instead of [e] 6.97 --- exercise and vesting conditions remains the same. The Board also amended the terms of 20,125 share purchase options granted in 1997 modifying the exercise price to [e] 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 [e] 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 begin vesting two years after the date of grant and are 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 \$ 2.20 ([e] 2.39) per share. Of the 26,000 options, 16,000 options begin vesting two years after the date of grant and are 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 begin vesting on date of grant and are fully vested on January 1, 2003, corresponding option expires on December 31, 2004 or when employment with the Company ceases, whichever occurs earlier. On April 2, 2001, the Board of Directors granted 86,885 options to subscribe to new shares to a Member of the Executive Board meeting certain tenure criteria. The exercise price was fixed at \$ 1.561 ([e] 1.76) per share. Options begins 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. 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 ([e] 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 begin vesting two years after the date of grant and are 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

F-30

EDAP TMS S.A. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

(IN THOUSANDS OF EUROS UNLESS OTHERWISE NOTED, EXCEPT PER SHARE DATA)

## Edgar Filing: EDAP TMS SA - Form 20-F

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 \$ 1.92 ([e] 2.08) per share. Options begin vesting one year after the date of grant and are 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 Executive 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 \$ 1.561 ([e] 1.76). The capital of the Company has then been increased from [e] 1,081 thousand to [e] 1,087 thousand and the number of shares issued increased from 8,315,400 to 8,362,821.

On June 18, 2002, conforming to 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 \$ 1.92 ([e] 2.02) per share. Options begin vesting one year after the date of grant and are 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 options to be potentially purchased through the exercise of stock options are currently held as treasury stock.

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

	2002		2001		2000	
	OPTIONS	WEIGHTED AVERAGE EXERCISE PRICE	OPTIONS	WEIGHTED AVERAGE EXERCISE PRICE	OPTIONS	WEIGHTED AVERAGE EXERCISE PRICE
Outstanding on January 1	721,550	2.53	303,675	3.53	501,550	3.53
Granted.....	26,425	2.02	474,000	2.02	35,000	2.02
Exercised.....	(47,421)	1.76	---	---	---	---
Forfeited.....	(46,213)	2.37	(56,125)	3.66	(232,875)	3.66
Expired.....	---	---	---	---	---	---
Outstanding on December 31.....	654,341	2.58	721,550	2.53	303,675	3.53
Exercisable on December 31.....	353,324	3.00	271,160	3.03	149,750	3.03
Shares available on December 31 for share purchase options that may be granted.....	0		26,425		0	



EDAP TMS S.A. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS  
(IN THOUSANDS OF EUROS UNLESS OTHERWISE NOTED, EXCEPT PER SHARE DATA)

The following table summarizes information about stock options to purchase shares already held by the Company as Treasury shares, or to subscribe to new Shares, at December 31, 2002:

EXERCISE PRICES	OPTIONS	OUTSTANDING STOCK OPTIONS		EXERCISABLE STOCK OPTIONS	
		WEIGHTED AVERAGE REMAINING CONTRACTUAL LIFE	WEIGHTED AVERAGE EXERCISE PRICE	OPTIONS	WEIGHTED AVERAGE EXERCISE PRICE
[e] 3.81.....	192,125	6.0	3.81	192,125	3.81
[e] 2.39.....	29,000	5.7	2.39	21,750	2.39
[e] 2.08 (1).....	356,115	9.0	2.08	89,029	2.08
[e] 2.02 (2).....	26,425	9.5	2.02	---	---
[e] 1.83.....	11,212	6.1	1.83	10,956	1.83
[e] 1.76 (3).....	39,464	8.3	1.76	39,464	1.76
[e] 1.76 to [e] 3.81.....	654,341	7.4	2.58	353,324	3.00

- (1) All the 356,115 options were granted on September 25, 2001 with an exercise price expressed in U.S. dollars (\$1.92) based on the noon buying rate on September 25, 2001 (\$1 = [e] 1.085).
- (2) All the 26,425 options were granted on June 18, 2002 with an exercise price expressed in U.S. dollars (\$1.92) based on the noon buying rate on June 18, 2002 (\$1 = [e] 1.0545).
- (3) All the 39,464 options were granted on April 2, 2001 with an exercise price expressed in U.S. dollars (\$1.561) based on the noon buying rate on April 2, 2001 (\$1 = [e] 1.13).

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. Accordingly, the options granted in 1997 resulted in recording deferred compensation expense of [e] 255 thousand. Based on the vesting provisions of the plan, [e] 178 thousand of this compensation was expensed in 1997, [e] 55 thousand was expensed in 1998 and [e] 22 thousand in 1999. Under APB 25 and its related interpretations, the options granted or modified in 1999, 2000 and 2001 did not result in recording any compensation expense, additional compensation expense or reversal of compensation expense.

F-32