2001 Annual Report EDAP TMS S.A.

EDAP TECHNOMED

Bringing New Horizons to Therapy

As filed with the Securities and Exchange Commission on May 7, 2002

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 20-F

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

or

☒ ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the Fiscal Year Ended December 31, 2001

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'Activités La Poudrette-Lamartine
4/6, rue du Dauphiné
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:
None

Securities for which there is a reporting obligation pursuant to Section 15(d) of the Act:
American Depositary Shares, each representing one Ordinary Share

Ordinary Shares, nominal value € 0.13 per share

Outstanding shares of each of the issuer's classes of capital or common stock as of December 31, 2001:

7,734,310 Ordinary Shares

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

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

Item 17 ☐ Item 18 ☒

[THIS PAGE INTENTIONALLY LEFT BLANK]

TABLE OF CONTENTS

[THIS PAGE INTENTIONALLY LEFT BLANK]

PRESENTATION OF FINANCIAL AND OTHER INFORMATION

Unless the context otherwise requires, references herein to "the Company" 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, 2001.

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 legal currency of The Republic of France, references to "euros" or "€" 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 € 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 = € 1.123, 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, 2001. See Item 3, "Key Information—Exchange Rates" for information regarding certain currency exchange rates and Item 11, "Quantitative and Qualitative Disclosures about Market Risk" for a discussion of the effects of fluctuations in currency exchange rates on the Company.

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

FORWARD-LOOKING INFORMATION

This Annual Report includes certain forward-looking statements, usually containing words such as "believe," "plan," "intend," "estimate," "expect" and "anticipate" or similar expressions, which reflect the Company's views about future events and financial performance. Actual events or results may differ materially from those projected in such forward-looking statements as a result of various factors that may be beyond the Company's control. These factors include, without limitation: the effects on the Company of the intense competition existing in the markets in which it operates; the uncertainty of market acceptance for the Company's HIFU devices; the clinical status of the Company's HIFU devices; the impact on the Company of government regulation, particularly relating to public healthcare systems and the commercial distribution of medical devices; dependence on the Company's strategic partners; reliance on patents, licenses and key proprietary technologies; product liability risk; risk of exchange rate fluctuations, particularly between the euro and the U.S. dollar and between the euro and the Japanese yen; and potential fluctuations in results of operations due to the cyclical nature of demand for medical devices. Readers should also consider the information contained in Item 3, "Key Information—Risk Factors" and Item 5, "Operating and Financial Review and Prospects," as well as the information contained in the Company's periodic filings with the Securities and Exchange Commission (including the Company's reports on Form 6-K), for further discussion of the risks and uncertainties that may cause such differences to occur.

PART I

Item 1. Identity of Directors, Senior Management and Advisors

Not applicable.

Item 2. Offer Statistics and Expected Timetable

Not applicable.

Item 3. Key Information

Selected Financial Data

The following table sets forth selected consolidated financial data for the periods indicated and is qualified by reference to, and should be read in conjunction with, the Consolidated Financial Statements and the Notes thereto appearing elsewhere in this Annual Report (the "Consolidated Financial Statements") and Item 5, "Operating and Financial Review and Prospects." The balance sheet data as of December 31, 2000 and 2001 and the income statement data for the years ended December 31, 1999, 2000 and 2001 set forth below have been derived from the Consolidated Financial Statements. The balance sheet data as of December 31, 1997 and 1998 and the income statement data for the years ended December 31, 1997 and 1998 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,	1997[2]	1998[2]	1999	2000	2001	2001[1]
	€	€	€	€	€	$
INCOME STATEMENT DATA						
Total revenues	33,086	20,668	19,881	27,252	23,965	21,340
Net sales	31,677	19,263	19,107	24,809	23,804	21,197
Gross profit	16,707	9,210	9,211	13,060	7,979	7,105
Operating expenses[3]	(17,438)	(18,721)	(16,869)	(16,795)	(13,093)	(11,659)
Income (loss) from operations	(731)	(9,511)	(7,658)	(3,735)	(5,114)	(4,554)
Income (loss) before income taxes	189	(9,636)	(6,487)	12,032	8,019	7,141
Income taxes	125	(181)	256	(323)	(882)	(785)
Net income (loss)	191	(9,817)	(6,231)	11,709	7,137	6,355
Net income (loss) per Share	0.03	(1.19)	(0.80)	1.50	0.92	0.82
Dividends per Share[4]	—	—	—	—	—	—
Weighted average shares outstanding used in diluted calculation	7,322	8,248	7,815	8,266	7,942	7,072
Diluted earnings per Share	0.03	(1.19)	(0.80)	1.42	0.90	0.80
BALANCE SHEET DATA						
Total current assets	40,828	32,856	23,897	39,881	45,927	40,897
Property, plant and equipment, net	2,881	1,719	3,089	1,825	2,233	1,988
Total current liabilities	13,463	14,559	13,953	10,185	11,916	10,611
Total assets	51,424	44,923	36,355	50,287	53,115	47,297
Long-term debt, less current portion[5]	1,518	7,053	6,344	3,478	304	271
Total shareholders' equity	34,182	22,363	15,424	34,679	38,909	34,647

(1) Translated for convenience of the reader at the Noon Buying Rate on December 31, 2001 of $1 = € 1.123. See "Presentation of Financial and Other Information" on page 1 of this Annual Report.

(2) 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 € 1 = FF 6.55957.

(3) The Company recorded a charge for impairment of long-lived assets of € 0.8 million in 1998.

(4) No dividends were paid with respect to fiscal years 1997 through 2000 and subject to approval at the annual shareholders' meeting to be held in June 2002, the Company does not anticipate paying any dividend with respect to fiscal year 2001. See Item 8, "Financial Information—Dividends and Dividends Policy."

(5) Long-term debt includes the long-term portion of capital lease obligations.

Exchange Rates

Fluctuations in the exchange rate between the euro and the dollar will affect the dollar amounts received by owners of ADSs on conversion by the Depositary of dividends, if any, paid on the Shares in the form of ADSs. Moreover, such fluctuations may affect the dollar price of the ADSs on Nasdaq and on Nasdaq Europe.

As of January 1, 1999, the conversion rate between the euro and the French franc was fixed irrevocably at € 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 periods and years indicated, the high, low, average and year-end Noon Buying Rates expressed in euros per $1.00. For the period 1997 through 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 € 1 = FF 6.55957 and expressed in euros per $1.00.

Year ended December 31,	High	Low	Average(1)	End of Period
	€	€	€	€
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
1997	0.97	0.79	0.89	0.92

(1) The average of the Noon Buying Rates on the last business day of each month during the period indicated. See "Presentation of Financial and Other 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
	€	€
October	1.12	1.09
November	1.14	1.11
December	1.14	1.11
January	1.16	1.11
February	1.16	1.14
March	1.16	1.13

On April 19, 2002, 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 = € 1.124.

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 derived only approximately 25% of its total revenues (including revenues from non-recurring sales of technology transfer services) for the year ended December 31, 2001 from these sales, compared to 36% of total revenues for the year ended December 31, 2000. Revenues from these sales are expected to represent only 6% to 7% of total revenues in 2002, as sales of technology transfer services have been completed. The Company's Extra-corporeal Shockwave Lithotripsy ("ESWL") line of products competes in a mature market that has experienced declining sales prices in recent years. 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. If the Company is not successful in its current negotiations with the FDA regarding the conditions under which it may re-submit the request, 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 believes this limitation would significantly hamper its ability to market the Ablatherm in the United States. See "—Uncertainty Relating to Clinical Trials; Clinical Status of Certain Products" and Item 4, "Information on the Company—Products—High-Intensity Focused Ultrasound—Clinical and Regulatory Status." There can be no assurance that the Company will be able to realize significant revenues from its HIFU products.

History of Operating Losses; Uncertainty of Future Profitability

The Company has incurred operating losses in each fiscal year since 1997 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. The Company incurred net losses of approximately € 9.8 million for the fiscal year 1998 and € 6.2 million for the fiscal year 1999. Although the Company had net income of € 11.7 million for the fiscal year 2000, net income for the fiscal year 2001 fell to € 7.1 million. In 2001, the Company recorded lower revenue and a higher operating loss compared to 2000 and expects that this trend may continue in the future as a result of the sale of its Prostatron business in October 2000. In addition, 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. See Item 5 "Operating and Financial Review and Prospects." There can be no assurance the Company will realize sufficient revenue to sustain or increase profitability in the future.

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—Products—High Intensity Focused Ultrasound—Competition" and "Extra-Corporeal Shockwave Lithotripsy—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.

Uncertainty Relating to Clinical Trials; Clinical Status of Certain Products

Before obtaining regulatory approvals for the commercial sale of any of its HIFU 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—Products—High Intensity Focused Ultrasound—Clinical and Regulatory Status."

The Company relies on scientific, technical and clinical data supplied by its academic collaborators in the evaluation and development of HIFU-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, or if the Company is otherwise unable to market them successfully, 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

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 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.

Government Regulation

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

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

Uncertainty Relating to Third-Party Reimbursement

The Company's success is dependent upon, among other things, the extent to which satisfactory reimbursement for the procedures performed with its devices can be obtained from healthcare payors in the United States and elsewhere. In the United States, the Company is dependent upon favorable decisions by 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 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, France. A significant interruption in the operations of the Company's sole facility could have a material adverse effect on the Company's business, financial condition and results of operations.

Dependence Upon Key Suppliers

The Company purchases the majority of the components used in its products from a number of suppliers but, for several components of its products, relies on a single source. In addition, the Company relies on single suppliers for certain services. If the supply of certain components or services were interrupted, the Company's manufacturing, marketing and selling of the relevant products would be delayed. These delays could be 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 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—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.

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 three 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 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 2001, approximately 57% of the Company's selling and general and administrative expenses and approximately 85% of the Company's research and development expenses were denominated in euros, while approximately 62% 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 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, 2001 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 American Depositary Shares ("ADSs") representing Ordinary Shares of the Company ("Shares").

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

Passive Foreign Investment Company Status

The Company expects to be a "passive foreign investment company" or "PFIC" for U.S. tax purposes in respect of the year 2002. Although the Company generally does not expect to be a PFIC in the long term, certain unfavorable U.S. tax rules apply to shareholders in companies that are PFICs in respect of even a single year. In order to minimize exposure to these rules, U.S. investors may wish to make a mark-to-market election. See Item 10, "Taxation—Taxation of 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 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 1,595,379 Urologix shares, including shares issued upon exercise of the warrants, as of March 31, 2002 the Company held 97,087 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").

The Company's legal name is EDAP TMS S.A. and its commercial name is EDAP TECHNOMED. The Company was incorporated on December 3, 1979 as a *société anonyme* organized under the laws of The Republic of France for 60 years from the date of incorporation. The Company's principal executive offices are located at Parc d'Activités la Poudrette-Lamartine, 4/6 rue du Dauphiné, 69120 Vaulx-en-Velin, France and its telephone number is +33 (0)4 72 15 31 50. The offices of EDAP Technomed, Inc., the Company's U.S. subsidiary, are located at 100 Pinnacle Way, Suite 100, Norcross GA 30071, and its telephone number is +1 (770) 446-9950.

Business Overview

EDAP TMS currently develops, produces and markets devices for the minimally invasive destruction of certain types of localized tumors using HIFU technology. 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 manufactured by the Company for the treatment of organ-confined prostate cancer, is approved for commercial distribution in the European Union and is undergoing clinical trials in the United States.

The Company also produces and markets devices for the treatment of urinary tract stones using ESWL technology. EDAP TMS had an installed base of 381 ESWL lithotripters worldwide as of December 31, 2001. ESWL lithotripters, which are widely used for the minimally-invasive treatment of urinary tract calculous disease, are designed to fragment urinary stones within the human body, thereby permitting their natural elimination. The Company currently manufactures three models of lithotripters: the LT02 and the SONOLITH Praktis, which are available for commercial distribution in the European Union, in Japan and in the United States, and the SONOLITH Vision, which is available for commercial distribution in the European Union.

Following the sale of the Prostatron business, EDAP TMS manufactures certain components of the Prostatron under the Supply Agreement and distributes the Prostatron in Japan and Italy under the Distribution Agreement.

In addition to selling HIFU and ESWL devices, the Company also generates revenues from the leasing of this equipment, as well as from the sale of disposables, spare parts and maintenance services.

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. The 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. See Item 5, "Operating and Financial Review and Prospects-Liquidity and Capital Resources."

See Note 21 of the Notes to the Consolidated Financial Statements for a breakdown of total sales and revenue during the past three fiscal years into geographical markets.

Business Strategy

The Company'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, production, marketing and distribution of minimally-invasive medical devices for urological and other indications, primarily using HIFU technology. The Company 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 Company's strategy to achieve that objective include:

Provide Minimally-Invasive Solutions to Prostate Cancer using HIFU. Building upon its established position in the ESWL market, the Company is striving to become a leading provider of minimally-invasive treatment alternatives for prostate cancer, the incidence of which the Company believes will increase as the male population ages in developed countries. The Company 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 Company's long-term growth strategy is to apply its HIFU technology toward the minimally-invasive treatment of indications beyond urological disorders. The Company 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 Company is working on various applications, such as gynecological tumors and thyroid tumors, where HIFU could provide an alternative to current invasive therapies. See "—Products—High-Intensity Focused Ultrasound."

Products

Product Overview

Product	Procedure	Development Stage	Clinical and Regulatory Status
HIFU Devices			
Ablatherm	HIFU treatment of organ-confined prostate cancer	Commercial Production	Approved for distribution: European Union Japan: Request for approval made in April 2000 United States: Clinical trials as a salvage therapy ongoing
ESWL Devices			
LT02 lithotripter	Piezo-electric treatment of urinary stones	Commercial Production	Approved for distribution: European Union Japan
SONOLITH Praktis compact lithotripter	Electroconductive treatment of urinary stones	Commercial Production	Approved for distribution: European Union Japan United States
SONOLITH Vision	Electroconductive treatment of urinary stones	Commercial Production	Approved for distribution: European Union Japan: Request for approval made in November 2001 United States and Canada: Request for approval anticipated to be made in 2002

High-Intensity Focused Ultrasound

The Company is engaged in the development, manufacturing and marketing of medical devices based on HIFU for the minimally-invasive treatment of urological and other indications.

HIFU Technology

HIFU technology uses a high-intensity convergent ultrasound beam generated by high power transducers to produce heat. HIFU is intended to allow the surgeon to destroy a well-defined area of diseased tissue without damaging intervening tissue, thus eliminating the need for incisions, transfusions, general anesthesia and their resulting complications.

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. Integrated into the treatment module are a power generator for the piezo-applicator, a watt meter, a high-precision distance measurement unit, a cooling device, a temperature control unit, a roller pump, and power supply. Mounted on the module is a motorized and computer-driven treatment head. It is movable in three-dimensions and integrates a piezoelectric therapeutic applicator and a conventional diagnostic ultrasound scanner for treatment planning. The therapeutic applicator has the shape and size of a tablespoon and can twist in the rectal ampulla up to 45 degrees laterally to allow the isocentric motorized insertion of the transrectal ultrasound (TRUS) scanner.

After insertion of the endorectal probe, the physician visualizes the prostate and defines the area to be treated. The computer automatically calculates the optimum 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.

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 198,000 new cases of prostate cancer were diagnosed in 2001, and the Company 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 prostatic-specific antigen (''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 Company believes that its application could be expanded to other indications, such as certain localized thyroid, breast, gynecological, bladder, liver, brain, pancreatic and retroperitoneal tumors.

Clinical and Regulatory Status

The Company has conducted an extensive clinical trial for the Ablatherm in the European Union. This trial, the European Multicentric Study, involved a total of 652 patients suffering from localized prostate cancer and included six sites in France, Germany and The Netherlands.

The primary goals of the trial were to assess the safety and effectiveness of the Ablatherm. There are primarily two methods to evaluate the presence of cancerous tissue in the prostate. The first method is based on biopsies. A sextant biopsy is performed inside the prostate to reveal the presence of a tumor. The second method is based on a blood test, 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, six of which used a mobile machine. Patient enrolment was completed in a 11-month period with 115 patients included. Patient follow-up is planned for two additional years, with intermediate assessment at one year.

In addition, in January 1999, the Company 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 has initiated a trial in the United States to study the safety and effectiveness of the Ablatherm for the treatment of localized prostate cancer in 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). Three sites (Georgetown University Hospital, Baylor College in Houston and University of California at San Francisco) are currently conducting this trial. The trial will involve approximately 120 patients. 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.

In December 2001, the Company 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 has been denied by the FDA. The Company is currently in the process of discussing various options with its clinical investigators, counsel, and the FDA to determine necessary requirements to resubmit the protocol for approval. See Item 3, ''Key Information—Risk Factors—Dependence on HIFU Technology.''

In April 2000, the Company applied for an approval by the Japanese Minister of Health for the Ablatherm to be marketed in Japan.

Competition

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

The Company's HIFU devices compete with all current treatments for localized tumors, which include surgery, brachytherapy, radiotherapy, cryotherapy and hormonotherapy. The Company 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, Toshiba and Focus Surgery. Certain existing and potential competitors of the Company in HIFU may have substantially greater financial, research and development, sales and marketing and personnel resources than the Company and may have more experience in developing, manufacturing, marketing and supporting new products. The Company 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.

Extra-Corporeal Shockwave Lithotripsy ("ESWL")

The Company currently markets and sells three models of ESWL lithotripters: the LT02, which uses piezo-electric technology, the SONOLITH Praktis and the SONOLITH Vision, each of which uses electroconductive technology. EDAP TMS had an installed base of 381 ESWL lithotripters worldwide as of December 31, 2001. As of December 31, 2001, the European Union, Japan and the United States accounted for 37%, 27%, and 3%, respectively, of the total installed base of ESWL lithotripters of the Company.

Urinary Tract Calculous Disease and ESWL

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 Company 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 Company 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 Company 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 to the Company'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."

Products

The LT02 uses piezo-electric technology, with dual ultrasound and X-ray imaging systems. As the two imaging systems are in-line with the treatment head, switching between imaging modes can be done during the treatment without moving the patient, thereby reducing localization time and improving fragmentation control. 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 Company's ESWL customers are located worldwide and have historically been principally large hospitals and urology clinics and research institutions. In order to increase its penetration of the market segment of smaller hospitals and outpatient clinics, the Company developed the SONOLITH Praktis, a compact electroconductive lithotripter designed for smaller clinics.

Marketing Strategy

The Company offers the SONOLITH Praktis to mid-size hospitals, while the LT02 and the SONOLITH Vision are offered to large hospitals which can afford a fully dedicated and integrated lithotripter.

The disposable parts of the Company's lithotripters include the piezo-electric elements of the LT02 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 Company has retained sole marketing rights for those parts.

Competition

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

Regulatory Status

The SONOLITH Praktis is available for commercial distribution in the United States, the European Union and Japan. The SONOLITH Vision is available for commercial distribution in the European Union. A request for its approval was filed in Japan in November 2001 and the Company anticipates filing a request for approval in the United States and Canada in 2002. The Company received FDA approval of the LT02 in the United States in 1996 but is not currently marketing the LT02 in the United States. The LT02 is available for commercial distribution in the European Union and in Japan.

Research and Development

The Company's current research and development objectives in ESWL are to increase further cost-effectiveness and clinical efficacy of its products.

Sales and Distribution

The Company markets, sells and services its products through its own direct sales and service organization as well as through third-party distributors and agents. The Company established a direct sales and service force in France, Italy, the United States, Japan, South Korea and Malaysia and markets its products through agents and third-party distributors in several countries.

The Company's customers are located worldwide and have historically been principally public and private hospitals and urology clinics. The Company 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 Company represents a significant portion of the Company's installed base.

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

Patents and Intellectual Property

HIFU

As of December 31, 2001, the Company had obtained 47 patents covering key technologies relating to HIFU systems and associated software capabilities (including 24 in the United States, 18 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 Company 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 Company's proprietary rights in such technology. The Company'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 Company's ability to market HIFU systems.

ESWL

The Company'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 Diasonics Inc., the Company granted both companies a non-exclusive license to use its patented technology.

Manufacturing

The Company's policy is to subcontract the manufacture of the majority of the components for its devices and accessories, while performing the final assembly and quality control processes in-house to monitor and maintain its production standards. 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. The Company's policy is to conduct frequent quality audits of suppliers' manufacturing facilities. The Company's principal suppliers are located in France, Switzerland, Austria, the United Kingdom and the United States. Management believes that the relationships between the Company and its suppliers are good.

In addition, the Company's manufacturing operations 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. The Company's facilities are also subject to scheduled inspections by the FDA. The Company has obtained the ISO 9001 and EN 46001 certifications, which indicate compliance of the Company's manufacturing facilities with European Union standards for quality assurance, design and manufacturing process control. The Company 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.''

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 manufacturing and research and development activities. The Company is principally subject to regulation of medical devices and of the healthcare system.

Healthcare Regulation in the United States

The Company and its products are regulated in the United States by the FDA under a number of statutes including the Federal Food, Drug and Cosmetic Act (''FDC Act''). Pursuant to the FDC Act, the FDA regulates the preclinical and clinical testing, manufacturing, labeling, distribution, sale, marketing, advertising and promotion of medical devices in the United States. Medical devices are classified in the United States into one of three classes, Class I, II or III, on the basis of the controls reasonably necessary to ensure their safety and effectiveness. Class I devices are those whose safety and

effectiveness can be ensured through general controls, such as labeling, premarket notification (known as "510(k)") and adherence to FDA-mandated GMP. Class II devices are those whose safety and effectiveness can reasonably be ensured through the use of "special controls," such as performance standards, post-market surveillance, patient registries and FDA guidelines. Class III devices are those that must receive premarket approval ("PMA") by the FDA to ensure their safety and effectiveness. Except for the lithotripsy range of products, which has recently been 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.

Healthcare Regulation in the European Union

In the European Union, the Company has received the ISO 9001 and EN 46001 certifications, showing that the Company's procedures and manufacturing facilities comply with standards for quality assurance and manufacturing 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 to bear a CE Marking (subject to certain exceptions). The SONOLITH Praktis and SONOLITH Vision, the LT02, the Ablatherm and the Prostatron all 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.

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 and the Prostatron are all included on the MHW's list for reimbursement.

Organizational Structure

The following table sets forth our subsidiaries as of the date of this Annual Report:

Name of the Company	Jurisdiction of Establishment	Percentage Owned[1]
EDAP Technomed Inc.	United States	100%
EDAP Technomed Co. Ltd	Japan	100%
EDAP Technomed Sdn Bhd	Malaysia	100%
EDAP Technomed Srl	Italy	100%
Technomed Medical Systems S.A.	France	100%
HIFU S.A	France	100%

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

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 1,200 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 and EN 46001 certifications and specific GMP approval for the Prostatron.

The Company has another facility located in Marne-la-Vallée, on the outskirts of Paris. The facility comprises 3,500 square meters of office and factory space. The property is held under the terms of a financial lease, which entitles the Company to purchase the facility for a nominal sum in 2005. As a result of the decision to consolidate the manufacturing operations in Lyon, the Company does not currently use this facility and is attempting to sell the lease or to sublet the facility, subject to the lessor's agreement.

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

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, 1999, 2000 and 2001 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 fixed and determinable contract terms. For sales that do not immediately meet all of the criteria for recognition at the time of shipment or delivery (as the contract terms dictate) revenue is recognized when the contingency is resolved.

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

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 physician groups 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 € 0.8 million.

Litigation

The Company has been notified that it is a defendant in three legal proceedings associated with product liability matters. The Company does not believe that it is 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.

Deferred Tax Assets

As of December 31, 2001, the Company had approximately € 0.1 million of deferred tax assets principally related to the impact of temporary differences between the amounts of assets and liabilities reported for financial reporting purposes and such amounts as measured in accordance with tax laws.

The Company also has a history of operating loss carryforwards with various future expirations. However, it is the Company's policy to recognize a full valuation reserve against these deferred tax assets because the Company cannot be assured of future operating profits sufficient 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, 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 48% of such sales in 2001 and consisted primarily of sales of ESWL lithotripters. Net sales of spare parts, supplies and services in Japan represented approximately 32% of such sales in 2001 and related primarily to ESWL lithotripters, reflecting the fact that approximately 27% of the installed base of the Company's ESWL lithotripters is located in Japan. See Note 21 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 subsidies 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 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 € 0.3 million as of December 31, 2001. Research and

development expenses have amounted to € 3.4 million, € 4.0 million and € 3.1 million in 2001, 2000 and 1999, respectively, representing approximately 14%, 16% and 16% of total revenues in 2001, 2000 and 1999, respectively. Management expects the budget for research and development expenses for the foreseeable future to increase both in euro amount and as a proportion of total revenues to range from 15% to 20% of anticipated total revenues in each fiscal year, principally in connection with research and development in HIFU.

The Company did not record any non-recurring operating expenses in 2000 and 2001. In 1999, the Company recorded a non-recurring operating expense of € 0.3 million reflecting the costs of investigating the facts and circumstances underlying the recording of revenue on certain Prostatron sales in 1998 and 1999 and re-auditing its financial statements for 1998.

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 € 150,000 in 2000. See Note 16 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 group. As a result of that purchase of minority interest, the Company recorded € 3.2 million of goodwill, a € 0.12 million step-up in the historical carrying value of certain tangible assets of TMS and a € 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 € 1.49 million and charges for additional depreciation and amortization of fixed assets and intangible assets of € 29,000 and € 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 € 60,000.

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, the marketing and the 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 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 € 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 € 6.0 million or approximately 25% of total revenues in 2001. In 2002, as the technology transfers have been completed, revenues from sales under these agreements are expected to represent only 6% to 7% 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 and 2001, 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, 2001 approximately € 1.1 million or 12.5% of the Company's 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 € 15.7 million attributable to the sale of the Prostatron business.
- The Company recorded in 2001 non-recurrent net gains of € 12.2 million attributable to the sale of Urologix common stock.

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 € 27.3 million in 2000 to € 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.

The Company's net sales of medical devices increased 9.8% from € 9.8 million in 2000 to € 10.8 million in 2001, primarily due to a 9.5% increase in the number of EWSL 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 Company's new SONOLITH Praktis, a compact lithotripter launched in the European Union in October 1998. During 2001, the Company continued to manufacture Prostatron units on behalf of Urologix under the Supply Agreement. The Company experienced a 116.1% increase in the number of units sold in 2001 compared to 2000 and a decrease of 62.4% in average unit sale price as a result of the pricing terms under the Supply Agreement.

Net sales of spare parts, supplies and services decreased 13.1% from € 15.0 million in 2000 to € 13.0 million in 2001, due to a 48.9% decrease in sales of its Prostatron disposable parts, reflecting the transfer of prostaprobe manufacturing to Urologix during 2001, and a 11.9% decrease in revenues from operating leases, with respect to lithotripters, Ablatherm and Prostatron units. A substantial portion of the Company's maintenance services are derived from the Company's Japanese operations. See "—Results of Operations—Overview."

Other revenues decreased from € 2.4 million in 2000 to € 0.2 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 € 14.2 million in 2000 to € 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 € 16.9 million in 2000 to € 13.1 million in 2001, mainly due to cost savings realized after the sale of the Prostatron business.

Research and development expenses decreased 13.6% from € 4.0 million in 2000 to € 3.4 million in 2001. This decrease is primarily due to the completion of Ablatherm clinical studies in Europe and the termination of research and development for TUMT. The remaining expenses are related to the continued research and development of HIFU technologies which the Company anticipates will increase in the future. See "—Results of Operations—Overview."

Selling expenses decreased 29.6% from € 6.0 million in 2000 to € 4.2 million in 2001, primarily due to the impact of decreased expenses following the Company's sale of the Prostatron business to Urologix. See "—Results of Operations—Sale of the Prostatron Business to Urologix." As a percentage of net sales, selling expenses decreased from 24.2% in 2000 to 17.7% in 2001.

General and administrative expenses decreased 2.3% from € 5.5 million in 2000 to € 5.3 million in 2001, and as a percentage of net sales, remained stable in 2000 and 2001.

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

Interest income (expense), net. Interest income (expense), net increased to income of € 0.7 million in 2001 from an expense of € 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 € 0.4 million in 2000 to € 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 € 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 € 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 € 7.1 million in 2001 compared with consolidated net income of € 11.7 million in 2000, as a result of the factors mentioned above.

Fiscal Year Ended December 31, 2000 Compared to Fiscal Year Ended December 31, 1999

Total revenues. The Company's total revenues increased 37.2% from € 19.9 million in 1999 to € 27.3 million in 2000, principally due to an increase in net sales of medical devices, as well as an increase in other revenues.

The Company's net sales of medical devices increased 75% from € 5.6 million in 1999 to € 9.8 million in 2000, primarily due to a 61% increase in the number of EWSL lithotripters sold in 2000 compared to 1999, partially offset by a 9% decrease in the average unit sale price of ESWL lithotripters in 2000 compared with 1999. The increase in the number of lithotripters sold in 2000 resulted principally from the successful launch in Japan of the Company's new SONOLITH Praktis, while the decrease in average unit sale price in 2000 reflected increased price competition. The Company also experienced a two-fold increase in the number of Prostatron units sold in 2000, partially offset by a 15% decrease in the average unit sale price reflecting the fact that, starting October 1, 2000, the Company's sales of Prostatron units represented sales to Urologix under the Supply Agreement at an agreed transfer price.

Net sales of spare parts, supplies and services increased 11.1% from € 13.5 million in 1999 to € 15.0 million in 2000, due to a 16.0% increase in sales of Prostatron disposable parts and a 71.3% increase in revenues from operating leases of both lithotripters and Prostatron units. A substantial portion of the

Company's maintenance services are derived from the Company's Japanese operations. See "—Results of Operations—Overview."

Other revenues increased from € 0.8 million in 1999 to € 2.5 million in 2000. This increase reflected principally the 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 32.7% from € 10.7 million in 1999 to € 14.2 million in 2000, and as a percentage of net sales increased from 55.8% in 1999 to 57.2% in 2000, 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 remained stable at € 16.8 million in 2000 versus € 16.9 million in 1999.

Research and development expenses increased 29.0% from € 3.1 million in 1999 to € 4.0 million in 2000. This increase reflected principally the restart of certain HIFU research and development projects which had been postponed as part of the Company's cost reduction program initiated in the second half of 1998. See "—Results of Operations—Overview."

Selling expenses decreased 4.8% from € 6.3 million in 1999 to € 6.0 million in 2000, primarily due to the impact of cost reductions following the Company's sale of the Prostatron business to Urologix. See "—Results of Operations—Sale of the Prostatron Business to Urologix." As a percentage of net sales, selling expenses decreased from 33% in 1999 to 24.2% in 2000.

General and administrative expenses increased 5.8% from € 5.2 million in 1999 to € 5.5 million in 2000, but as a percentage of net sales, decreased from 27.2% in 1999 to 22.1% in 2000.

Operating loss. As a result of the factors discussed above, the Company realized an operating loss of € 3.7 million in 2000, as compared to an operating loss of € 7.7 million in 1999.

Interest expense, net. Interest expense, net increased to € 0.5 million in 2000 from € 0.2 million in 1999, reflecting lower interest income due a decrease in cash and cash equivalents in the period up to the closing of the sale of the Prostatron business in 2000 compared with 1999.

Currency exchange gains. Net currency exchange gains decreased from € 1.4 million in 1999 to € 0.4 million in 2000, reflecting a lower increase in the value of the U.S. dollar and the Japanese yen against the euro in 2000 compared with 1999.

Net gain on sale of business. Net gain on sale of business was € 15.7 million in 2000 and was attributable to the sale of the Prostatron business.

Other income, net. Other income, net, remained stable in 2000 with € 0.1 million versus € 0.1 million in 1999.

Income taxes. The Company recorded corporate income tax of € 0.3 million in 2000, principally reflecting income tax with respect to the results of the Japanese subsidiary.

Net income. The Company realized consolidated net income (after minority interests) of € 11.7 million in 2000 compared with a consolidated net loss of € 6.2 million in 1999, 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, 2001.

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 € 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 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. During most of 1999, the Company experienced negative cash flows, which it financed using cash and cash equivalents on hand.

In 2001, net cash used in operating activities was € 3.4 million, compared with net cash provided by operating activities of € 30,000 in 2000 and net cash used in operating activities of € 2.5 million in 1999. In 2001, net cash used in operating activities reflected principally net income of € 7.1 million, elimination of € 12.0 million of expenses and benefits without effects on cash, an increase in trade accounts receivable of € 1.9 million and an increase in accrued expenses and other current liabilities of € 1.3 million. In 2000, net cash provided by operating activities reflected principally net income of € 11.7 million, a decrease in trade accounts receivable of € 3.3 million and a decrease in inventories of € 3.3 million, offset by a decrease in accrued expenses and other current liabilities of € 3.8 million and a non-cash item of € 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 1999, net use of cash in operating activities reflected principally the net loss of € 6.2 million in that year. In 1999, changes in net working capital items included a decrease of € 3.2 million in trade accounts and notes and other receivables, partially offset by a decrease in trade accounts and notes payable of € 0.5 million, in each case due to lower equipment sales volume. The Company also recorded an increase of € 0.5 million in allowances for doubtful accounts and slow moving inventories.

In 2001, net cash provided by investing activities was € 23.6 million, compared with net cash provided by investing activities of € 2.1 million in 2000 and net cash used in investing activities of € 1.8 million in 1999. In 2001 net cash provided by investing activities and reflected principally net proceeds from the sale of Urologix common stock of € 21.6 million and a decrease of € 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 € 3.7 million, partially offset by an increase of € 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 1999, net cash used in investing activities reflected principally acquisitions of fixed assets for € 2.1 million, including € 1.6 million of medical devices which were either the subject of an operating lease or used in clinical trials, partially offset by reimbursement of deposits and guarantees of € 0.3 million.

In 2001, net cash used in financing activities was € 4.1 million reflecting mainly early long-term debt repayment, compared to € 1.8 million in 2000, reflecting scheduled long-term debt repayments, and € 1.8 million in 1999, reflecting principally scheduled long-term debt repayments totaling € 1.6 million and repayment of short-term borrowings of € 0.2 million.

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 € 9.7 million as at 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 six ESWL lithotripters and three Ablatherms under such operating leases, and anticipates continuing to make these options available.

Contractual Obligations and Commercial Commitments (in thousands of euros)

	Payments Due by Period				
Contractual Obligations	**Total**	**Less than 1 year**	**1-3 years**	**4-5 years**	**After 5 years**
Long-Term Debt	928	624	304	—	—
Capital Lease Obligations	431	124	307	—	—
Operating Leases	534	267	267	—	—

New Accounting Standards

In June 2001, the FASB issued statement No. 141, "Business Combinations" ("SFAS 141") and statement No. 142, "Goodwill and Other Intangible Assets" ("SFAS 142"). SFAS 141 requires the use of the purchase method of accounting for all business combinations initiated after June 30, 2001. Under SFAS 142, goodwill will no longer be amortized on a straight line basis over its estimated useful life, but will be tested for impairment on an annual basis and whenever indicators of impairment arise. The goodwill impairment test, which is based on fair value, is to be performed on a reporting unit level. Under SFAS 142, intangible assets with indefinite lives will not be amortized. Instead, they will be carried at the lower cost or market value and tested for impairment at least annually. All other recognized intangible assets will continue to be amortized over their estimated useful lives.

SFAS 142 is effective for fiscal years beginning after December 15, 2001 although goodwill on business combinations consummated after July 1, 2001 will not be amortized. In addition, goodwill on prior business combinations will cease to be amortized. The Company will apply SFAS 142 beginning in the first quarter of 2002. Application of the non amortization provisions of SFAS 142 is expected to result in an increase in net income of € 119 thousand in 2002. The Company will test goodwill for impairment using two-step process prescribed in SFAS 142. The first step is a screen for potential impairment, while the second step measures the amount of the impairment, if any. The Company expects to perform the first of the required impairment tests of goodwill as of January 1, 2002 in the first quarter of 2002. Any impairment charge resulting from these transitional impairment tests will be reflected as cumulative effect of a change in accounting principle in the first quarter of 2002. The Company does not believe that the effect of these tests will be material to the earnings and financial positions of the Company.

In October 2001, the Financial Accounting Standards Board issued SFAS No. 144, "Accounting for the Impairment or Disposal of Long-Lived Assets." This Statement addresses the financial accounting and reporting for the impairment or disposal of long-lived assets and supersedes SFAS 121, and the accounting and reporting provisions of APB Opinion No. 30, "Reporting the Results of Operations-Reporting the Effects of Disposal of a Segment of a Business, and Extraordinary, Unusual and Infrequently Occurring Events and Transactions," for the disposal of a segment of a business (as previously defined in that Opinion). SFAS 144 also amends ARB No. 51, "Consolidated Financial Statements," to eliminate the exception to consolidation for a subsidiary for which control is likely to be temporary. The provisions of this Statement are effective for financial statements issued for fiscal years beginning after December 15, 2001. The Company has reviewed the provisions of this statement and does not believe its adoption will have a material impact on its results of operations or its financial position.

Research and Development, Patents and Licenses.

See Item 4, "Information on the Company—Extra-Corporeal Shockwave Lithotripsy—Research and Development" and "—High-Intensity Focused Ultrasound" and "—Operating Results—Summary."

Item 6. Directors, Senior Management and Employees

Executive Board and Senior Executive Officers

The following table sets forth the name, age and position of each of the members of the Executive Board and senior executive officers 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 his employment contract by the Company without cause, Mr. Eric Simon is entitled to receive a severance package of approximately € 0.4 million.

The Supervisory Board on February 18, 2000 reappointed the current members of the Executive Board for a period of three years ending on February 18, 2003.

Name	Age	Position
Eric Simon	41	President of the Executive Board and Chief Executive Officer
Antoine Tétard	37	Member of the Executive Board and Chief Operating Officer
François Lacoste	51	Member of the Executive Board and Vice President, Research and Development
Ian Vawter	30	Chief Financial Officer

Eric Simon — Eric Simon joined the Company in 1992 as Chief Financial Officer, became member of the Executive Board of EDAP TMS in October 1993, Chief Executive Officer of TMS in 1994 and President of the Executive Board and Chief Executive Officer of EDAP TMS in February 1998. Previously, Mr. Simon was International Finance Manager for Bouygues from 1985 to 1987, Head of Corporate Investment Banking at Tuffier, Ravier, Py, a French stockbroker, from 1987 to 1990, and Head of Options and Futures at EIFB, a subsidiary of the Union Européenne du CIC, a French credit institution, from 1990 to 1992. Mr. Simon holds an MBA in Finance from Paris Dauphine University and an MS in Civil Engineering from Ecole Supérieure des Travaux Publics, Paris.

Antoine Tétard — Antoine Tétard joined the Company in 1990 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. Mr. Tétard has been a member of the Executive Board since December 8, 2000. Previously, Mr. Tétard 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. Tétard holds an MBA from Institut Supérieur de Gestion, Paris.

François Lacoste — François Lacoste joined Technomed in 1988 as Vice President in charge of research and development and became member of the Executive Board of EDAP TMS in February 1996. Prior to 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.

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 Finances of the U.S. subsidiary 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, Massachussetts. Mr. Vawter holds a degree in

Business Management and Finance from Norwich University, Northfield, Vermont.

Supervisory Board

The following table sets forth the names of the members of the Supervisory Board and the background of the members of the Supervisory Board who are individuals:

Philippe Chauveau, President of the Supervisory Board, Age: 66	Philippe Chauveau was appointed as a member of the Company's Supervisory Board in January 1997 and became Chairman of the Board in April 1997. Mr. Chauveau is Chairman of the Board of Scynexis Inc., member of the Executive Board of Directorship France S.A. and member of the Board of Technomed Medical Systems S.A. Most recently, he was Research and Development Vice-President at AT&T Bell Laboratories. Before 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.
Siemens France S.A., represented by Holger Schmidt, Age: 36	Siemens France S.A. was appointed as a member of the Company's Supervisory Board in December 2001.
Christian Baillet, Age: 51	Christian Baillet was appointed as a member of the Company's Supervisory Board in October 1993. He is a Managing Director and Board member of Quilvest Group, Board member of Viel et Compagnie, Compagnie Financière Tradition, and C.A. Holding. From 1976 to 1978, Mr. Baillet was an International Financial Consultant for CITICORP New York. In 1978, he joined Bemberg Group and became Chief Financial Officer of the Luxembourg holding company Quilvest and Chief Executive Officer of its two main financial subsidiaries, Banque Privée Quilvest and Société Internationale de Finances. In June 1994, he became Director and Chief Executive Officer of Quilvest. He holds an engineering degree from Ecole Centrale de Lyon, a Master of Science from the University of Lyon and an MBA from the Wharton School of Business of the University of Pennsylvania.
Bernard Péjouan, Age: 69	Pr. Bernard Péjouan Ph.D was appointed as a member of the Company's Supervisory Board in April 1997. He is a Board member of the French National Academy of Pharmacy. Mr. Péjouan held various responsibilities in Groupe Roche-Nicholas until 1972 when he joined Merck & Co. Group as Chief Executive Officer of MSD Laboratoires in France and Executive Director of MSD International.
Yves Robert, Age: 74	Yves Robert was appointed as a member of the Company's Supervisory Board in April 1999. From 1954 to 1968, Mr. Robert occupied several executive positions in the Pechiney Group in New York. In 1968, he became President and Chief Executive Officer of Howmet Corp., a diversified metals manufacturing company listed on the New York Stock Exchange. In 1970, he became Chairman and Chief Executive Officer of Howmedica, Inc., a manufacturer of medical and dental products. Following the sale of the company to Pfizer Inc., Mr. Robert joined Continental Grain, a privately owned trading company, as Executive Vice President and Director. He remained at Continental Grain until 1979, when he rejoined Pechiney as head of trading operations. In 1986, he became associated with Alex Brown & Co., specializing in the health care sector in New York and London. Mr. Robert is now retired.

On April 27, 2000, the Supervisory Board decided to appoint two members of the Supervisory Board, namely Messrs. Philippe Chauveau and Bernard Péjouan, to a committee of the Supervisory Board to review the Company's annual financial statements with the assistance of the Company's

auditors, and to review internal accounting controls and investigate financial matters as appropriate or necessary.

On December 8, 2000, the Supervisory Board appointed four members of the Supervisory Board, namely Messrs. Philippe Chauveau, Bernard Péjouan, Yves Robert and Christian Baillet, to a "Remuneration Committee" of the Supervisory Board to review the Company's Executive Board compensation and to propose any change to Executive Board compensation to the Supervisory Board, which under French law is the competent body to approve any such change.

On December 17, 2001, on Siemens France's request, the Supervisory Board agreed to replace Dr. Frank Anton with Mr. Holger Schmidt, representing Siemens France S.A. as a permanent member of the Board.

Compensation and Options

Aggregate compensation paid by the Company and its subsidiaries to members of the Executive Board and the Supervisory Board as a group paid or accrued for services in all capacities for the fiscal year 2001 was approximately € 0.8 million. No amount was set aside or accrued by the Company to provide pension, retirement or similar benefits for members of the Executive Board and the Supervisory Board as a group in respect of the year 2001.

As of December 31, 2001, Members of the Executive Board held an aggregate of 316,000 options (266,000 of which were granted in 2001) to purchase or to subscribe to new shares of the Company's common stock, with a weighted average exercise price of € 2.22. Of these options, 10,000 expire on December 31, 2004, 40,000 expire on March 31, 2009, 86,885 expire on March 31, 2001 and 179,115 expire on September 25, 2011.

Scientific Advisory Board

The Company has assembled a Scientific Advisory Board comprised of five 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:

Peter T. Scardino	Professor and Chairman, Department of Urology, Sloan-Kettering Hospital (New York). Dr. Scardino is a member of the American Board of Urology and was elected to the Institute of Medicine of the National Academy of Sciences in 1996. He is a member of the Editorial Boards of the journals "The Prostate," "Urologic Oncology" and "Urology." Dr. Scardino has published more than 100 articles in peer-reviewed journals and has presented approximately 150 papers at scientific meetings, mainly in the field of research in prostate cancer. He received his M.D. from the Duke University School of Medicine, North Carolina.

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.
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 München-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.
Jean J.M.C.H. de la Rosette	Director of the Minimal Invasive Urology Center of the department of Urology, University Hospital Nijmegen. 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, 1999, the Company employed 163 individuals on a full-time basis, of whom 42 were employed in sales and marketing, 31 in manufacturing, 35 in service, 21 in research and development and 34 in administration. Of the Company's employees, 91 were located in France, 35 in Japan, 20 in the United States, 7 in Malaysia, 5 in Italy and 2 in South Korea.

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

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, 2002, 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, and Mr. Eric Simon, President of the Executive Board and Chief Executive Officer of EDAP TMS, owned 282,500 Shares representing 3.4% of the total share capital and (after subtracting treasury stock which under French law carries no voting rights) 3.6% of the voting rights of the Company. Mr. Simon has not been granted any stock options. Mr. Antoine Tétard,

member of the Executive Board, 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 Executive Board or Supervisory Board 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 Executive Board and the Supervisory Board members hold a total of 1,614,829 Shares representing 19.3% of the total share capital and (after subtracting treasury stock which under French law carries no voting rights) 20.8% of the voting rights of the Company.

On March 21, 2002, an option was exercised for the subscription of 47,421 new shares. The Executive Board held a meeting on March 21, 2002 to approve the corresponding increase of the capital, from € 1,081,002.00 to € 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 € 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, 2001, the duration of stock option contracts was as follows:

Number of Shares granted	Until expiration (years)
10,000	3
47,125	6
119,000	7
62,425	8
95,885 (of which 86,885 are options to subscribe to new shares)	9
387,115 (of which 80,000 are options to subscribe to new shares)	10

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

	2001		2000		1999	
	Options	Weighted average exercise price	Options	Weighted average exercise price	Options	Weighted average exercise price
Outstanding on January 1	303,675	3,53	501,550	3.91	583,500	3.99
Granted	474,000	2,02	35,000	2.39	86,425	2.75
Exercised	—	—	—	—	—	—
Forfeited	(56,125)	3,66	(232,875)	3.81	(168,375)	3.81
Expired	—	—	—	—	—	—
Outstanding on December 31	721,550	2,53	303,675	3.53	501,550	3.91
Exercisable on December 31	271,160	3,03	149,750	3.78	83,965	3.78
Shares available on December 31 for share purchase options that may be granted	26,425					

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, 2001:

		Outstanding stock options		Exercisable stock options	
Exercise prices	Options	Weighted average remaining contractual life	Weighted average exercise price	Options	Weighted average exercise price
€ 3.81	196,125	6,1	3.81	162,875	3.81
€ 2.74	10,000	8.0	2.74	7,500	2,74
€ 2.39	29,000	6.7	2.39	5,000	2.39
€ 2.08[(1)]	387,115	9.9	2.08	—	—
€ 1.83	12,425	7.2	1.83	8,900	1.83
€ 1.76[(2)]	86,885	9,3	1.76	86,885	1.76
€ 1.76 to € 3.8	721,550	7.9	2.53	271,160	3.03

(1) All the 387,115 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 = € 1.085).

(2) All the 86,885 options were granted on April 2, 2001 with an exercice price expressed in U.S. dollars ($1.561) based on the noon buying rate on April 2, 2001 ($1 = € 1.13).

On March 21, 2002, a member of the Executive Board exercised his option to subcribe to 47,421 new Shares at an exercise price of $1.56, or € 1.76. The capital of the Company was therefore increased from € 1,081,002.00 to € 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, 2002, 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 943,000 Shares representing 11.3% of the total share capital of the Company and (after subtracting treasury stock, which under French law carries no voting rights) 12.1% 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.

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 Chairman of the Company's Supervisory Board, is the general manager and a significant shareholder. Timco provides advice and assistance to the Company in connection with the Company's shareholder relations policy. The Company paid Timco an annual fee of € 54,882 for its services during each of the years 1999, 2000 and 2001. In accordance with French company law, the continuation of the agreement during the fiscal year 2001 will be submitted for ratification to the Company's shareholders at the annual shareholders' meeting in June 2002.

Item 8. Financial Information

Consolidated Financial Statements

See Item 18, ''Financial Statements''.

Export Sales

See Note 21 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 three 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 believes that the patients' claims against the Company are without merit. In addition, if the claims against the Company are successful, the Company believes any potential damages assessed against it would be covered by insurance and/or by a contribution obligation of the physicians and/or the organization which provided services with the product. However, these product liability claims could have a material adverse impact on the Company.

Dividends and Dividend Policy

The payment and amount of dividends depend on the earnings and financial condition of the Company and such other factors that the Company's Executive Board (Directoire) deems relevant. Dividends are subject to recommendation by the Executive Board 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 1997 through 2000. Subject to the approval of the shareholders' meeting to be held on or before June 30, 2002, the Company does not anticipate paying any dividends with respect to fiscal year 2001.

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, 2001.

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 the Nasdaq Europe, formerly known as the European Association of Securities Dealers Automated Quotation System ("Nasdaq Europe"), 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.

As of March 31, 2002, 8,362,821 Shares were issued, including 7,781,731 outstanding and 581,090 treasury Shares. At the same date, there were 7,090,002 ADSs, each representing one Share, all of which were held of record by ten registered holders in the United States (including The Depositary Trust Company).

Trading Markets

The following tables set forth, for the years 1997 through 2002, the reported high and low sales prices of the ADSs on Nasdaq and Nasdaq Europe:

	Nasdaq	
	High	Low
	(in dollars)	
1997 (beginning August 6)	9.50	6.25
1998	7.25	1.31
1999	2.66	0.63
2000	3.13	0.50
2001	3.43	0.59
2002 (through March 31)	2.49	1.62

	Nasdaq Europe	
	High	Low
	(in dollars)	
1997 (beginning August 6)	8.75	7.50
1998	7.25	1.44
1999	2.38	1.05
2000	3.03	0.70
2001	3.40	0.64
2002 (through March 31)	2.25	1.70

The following tables set forth, for the years 2000 and 2001 and the first quarter of 2002, 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)	
2000		
First Quarter	3.13	1.13
Second Quarter	2.75	1.00
Third Quarter	2.06	0.88
Fourth Quarter	1.94	0.50
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

	Nasdaq Europe	
	High	Low
	(in dollars)	
2000		
First Quarter	3.03	1.10
Second Quarter	2.80	1.38
Third Quarter	1.85	1.00
Fourth Quarter	1.53	0.70
2001		
First Quarter	1.85	0.64
Second Quarter	3.40	1.65
Third Quarter	2.40	1.30
Fourth Quarter	2.25	1.00
2002		
First Quarter	2.25	1.70

The following tables set forth, for the most recent six months (from October 2001 through March 2002), the reported high and low sale prices of the ADSs on Nasdaq and Nasdaq Europe for each month:

	Nasdaq	
	High	Low
	(in dollars)	
2001		
October	2.05	1.22
November	2.03	1.31
December	2.31	1.56
2002		
January	2.49	2.03
February	2.43	2.05
March	2.28	1.62

	Nasdaq Europe	
	High	Low
	(in dollars)	
2001		
October	2.25	1.20
November	1.65	1.45
December	2.25	1.00
2002		
January	2.25	1.70
February	2.10	2.00
March	2.00	1.85

Item 10. Additional Information

Memorandum and Articles of Association

Set forth below is a brief summary of significant provisions of the Company's Articles of Association and applicable French law. 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. 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, or the French Commercial Code.

Corporate Purpose

Pursuant to Article 2 of the Articles of Association, the purpose of the Company is:

- 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, related to property and real estate which may be connected directly or indirectly, in whole or in part, to the Company's purpose or to any other similar or related purposes which may favor the extension or development of said purpose.

Executive Board and Supervisory Board

The Company's affairs are managed by an Executive Board (*Directoire*) and by the President of the Executive Board. The Executive Board may be composed of up to five members. The Executive Board is currently composed of three members. Members of the Executive Board are appointed by the Supervisory Board to serve terms not exceeding three years and may be re-appointed for consecutive terms. They may resign at any time and their functions as members of the Executive Board may be terminated at any time by the voting shareholders at a general meeting. In case of removal without cause, members of the Executive Board may be entitled to damages. Under French law, only individuals may be appointed members of the Executive Board.

The Executive Board is vested with the fullest powers to act in any circumstance on the Company's behalf, within the scope of the Company's purpose and subject to those powers expressly attributed by law to shareholder meetings or to the Supervisory Board. A majority of the members present or represented (or if only two members are present or represented, unanimity) is required for the Executive Board to take action. The President of the Executive Board may cast a decisive vote in case of deadlock. The President of the Executive Board, who is appointed by the Supervisory Board, is vested with the power to act in any circumstance on the Company's behalf and to represent the Company with respect to third parties, within the scope of the Company's corporate purpose and subject to those powers expressly attributed by law to shareholders' meetings or to the Supervisory Board.

There is no requirement for members of the Executive Board to own any shares of the Company. The age limit for members of the Executive Board is 70 years old.

The Supervisory Board on February 18, 2000 appointed each of the current members of the Executive Board for a term of three years ending on February 18, 2003. See Item 6, ''Directors, Senior Management and Employees.''

The Executive Board is placed under the control and supervision of a Supervisory Board (*Conseil de Surveillance*). Members of the Supervisory Board are elected, and may be removed, only by the voting shareholders at a general meeting. The Supervisory Board must be composed of a minimum of three and a maximum of 24 members. The Supervisory Board is currently composed of five members. A member of the Supervisory Board cannot be appointed as a member of the Executive Board. A member of the Supervisory Board may under certain conditions enter into an employment contract with the Company, provided that the number of members of the Supervisory Board in the employment of the Company may not exceed one third of the members of the Supervisory Board. None of the current members of the Supervisory Board is an employee or an officer of the Company.

Each member of the Supervisory Board must own at least one share of the Company for as long as he serves as such. The age limit for members of the Supervisory Board is 80 years old.

In the case of a vacancy resulting from the resignation or death of a member of the Supervisory Board, the remaining members may fill the vacancy by appointing a new member of the Board, subject to ratification by the shareholders at the next ordinary general meeting, unless the Supervisory Board consists of less than three members as a result of such vacancy.

The term of the current members of the Supervisory Board expires upon approval of the financial statements of the Company for the year ended December 31, 2003. See Item 6. ''Directors, Senior Management and Employees.''

The Supervisory Board has the authority to make any investigations and verifications it deems necessary, review quarterly reports on the Company's affairs which must be prepared by the Executive Board and inspect and verify the Company's annual accounts.

The Supervisory Board must submit to the shareholders at the annual general meeting a report containing its observations on the annual report and accounts of the Company.

The Supervisory Board also has a number of specific powers, including the power to appoint members of the Executive Board and determine their compensation, to appoint the President of the Executive Board, to make a proposal to the shareholders for the revocation of members of the Executive Board and to approve certain agreements between the Company and an interested member of the Executive Board or the Supervisory Board or a managing director.

Under French law, any transaction directly or indirectly between the Company and a member of its Executive Board or Supervisory Board that cannot reasonably be considered in the ordinary course of business of the Company and is not at arm's-length is subject to the Supervisory Board's prior consent. An interested member of the Supervisory Board cannot take part in the Supervisory Board's vote on the transaction. Any transaction concluded without the prior consent of the Supervisory Board can be nullified if it caused prejudice to the Company. The interested member of the Executive Board or Supervisory Board can be held liable on this basis. The statutory auditor must be informed of the transaction by the President of the Supervisory Board and must prepare a report to be submitted to the shareholders for approval at their next meeting. The interested member of the Executive Board or Supervisory Board, if also a shareholder, cannot vote his shares at the meeting. If the transaction is not ratified by the shareholders at a shareholders' meeting, it will remain enforceable by third parties as against the Company, but the Company may in turn hold the interested member of the Executive Board or the Supervisory Board and possibly the other members of the Executive Board liable for any damages it may suffer as a result. In addition, in this case, the transaction may be canceled if it is fraudulent. Moreover, certain transactions between a corporation and a member of its Executive Board or Supervisory Board who is a natural person are prohibited under French law.

Transactions directly or indirectly between the Company and a managing director of the Company would be subject to the procedures described in the preceding paragraph.

Dividend and Liquidation Rights

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 share capital. The legal reserve is distributable only upon the liquidation of the Company.

The shareholders of the Company may, upon recommendation of the Executive Board, 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 resolved by the shareholders, reserves which are available for distribution under French law and the Company's Articles of Association may be distributed as dividends, subject to certain limitations.

If the Company has made distributable profits since the end of the preceding fiscal year (as shown on an interim income statement certified by the Company's auditors), the Executive Board has the authority, subject to French law, without the approval of shareholders, to distribute dividends to the extent of such distributable profits. Historically, the Company has not paid interim dividends.

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 approving the distribution of dividends, or in the case of interim dividends, on the date of the Executive Board 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. See "—Dividends." The actual dividend payment date is decided by the shareholders in an ordinary general meeting or by the Executive Board in the absence of such a decision by the shareholders. The payment of the dividends must occur within nine months of 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 assets of the Company 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

The share capital of the Company may be increased only with the approval of the shareholders entitled to vote at an extraordinary general meeting, following a recommendation of the Executive Board. Increases in share capital may be effected either by the issuance of additional shares (including the creation of a new class of shares) or by an increase in the nominal value of existing shares. Additional shares may be issued for cash or for assets contributed in kind, upon the conversion of debt securities previously issued by the Company, by capitalization of reserves, or, subject to certain conditions, in satisfaction of indebtedness incurred by the Company. 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 the outstanding ordinary shares.

The share capital of the Company may be decreased only with the approval of the shareholders entitled to vote at an extraordinary general meeting. Share capital may be reduced either by decreasing the nominal value of the shares or by reducing the number of outstanding shares. The conditions under which the share capital may be reduced will vary depending upon whether 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

Pursuant to French law, the Company may not acquire its own shares except (a) to reduce its share capital under certain circumstances with the approval of the shareholders at an extraordinary general meeting, (b) to provide shares for distribution to employees under a profit-sharing or stock option plan and (c) after obtaining approval from the shareholders at an ordinary general meeting, to make purchases for stabilization of quotations on a French regulated stock exchange. The amounts to be repurchased under (b) and (c) may not, in either case, result in the Company holding more than 10% of the 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 it has to transfer any shares in excess of this 10% threshold within the year following the date it became a holder thereof.

Attendance and Voting at Shareholders' Meetings

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

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

The Executive Board is required to convene an annual ordinary general meeting of shareholders, which must be held within six months of the end of the Company's fiscal year, for approval of the annual accounts. Other ordinary or extraordinary meetings may be convened at any time during the year. Meetings of shareholders may be convened by the Executive Board or, if the Executive Board 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 shareholder(s) holding at least 10% of the Company's share capital or by an interested party under certain circumstances. The notice calling a meeting must state the agenda for such meeting.

French law provides that, at least 15 days before the date set for any general meeting on first notice, and at least six days before the date set for any general meeting on second notice, notice of the meeting must be sent by mail to all holders of properly registered shares who have held such shares for more than one month prior to the date of the notice. A preliminary written notice *(avis de réunion)* must be sent to each shareholder who has requested to be notified in writing 35 days before the date set for any ordinary or extraordinary general meeting. Shareholders holding shares of at least equal to a defined percentage of the share capital of the Company, which varies depending on the absolute amount of the share capital, 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 Depositary for the ADSs.

Attendance and exercise of voting rights at ordinary general meetings and extraordinary general meetings of shareholders 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 reflected 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 meeting of shareholders will vote the Shares with respect to which such blank proxy has been given in favor of all resolutions proposed by the Executive Board 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 any other extraordinary general meeting.

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

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

Under French law, shareholders can nominate individuals for election to the Supervisory Board at a shareholders' meeting. If 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 shareholder's meeting includes the election of members of the Supervisory Board, any shareholder may nominate a candidate for election to the Supervisory Board at the shareholders' meeting, even if the shareholder has not followed established nomination procedures. Under French law, shareholders cannot elect a new member of the Supervisory Board at a general shareholders' meeting if the agenda for the meeting does not include the election of Supervisory Board members, unless such nomination is necessary to fill a vacancy due to the previous removal 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

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

Form of Shares

The Company's Articles of Association provide that shares can be held only in registered form.

Holding of Shares

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

Stock certificates evidencing shares, in a manner comparable to that in the United States, are not issued by French companies, but the Company may issue or cause to be issued confirmations 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

Under French law, there is no limitation on the right of non-French residents or non-French security holders to own, or where applicable, vote securities of a French company. A non-resident of France must file a *déclaration administrative*, or administrative notice, with French authorities in connection with the acquisition of a controlling interest in any French company. Under existing administrative rulings, ownership, by a non-resident of France or a French corporation which is itself controlled by a foreign national, of 20 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).

Certain Exemptions

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 corporate governance requirements of the Nasdaq Stock Market, including the requirements concerning audit committees and independent directors.

Enforceability of Civil Liabilities

EDAP TMS is a *société anonyme*, or limited liability corporation, organized under the laws of The Republic of France. The majority of the directors and executive officers of EDAP TMS reside in The Republic of France. All or a substantial portion of the assets of such persons and of the Company are located outside the United States. As a result, it may not be possible for investors to effect service of process within the United States upon such persons or to enforce, either inside or outside the United States, judgments against such persons obtained in U.S. courts or to enforce in U.S. 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 may preclude or restrict the obtaining of evidence in France or from French persons in connection with such actions.

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. See Note 12 of the Notes to the Consolidated Financial Statements.

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 facilties are located in Vaulx-en-Velin, on the outskirts of Lyons. The premises comprise 1,200 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.

Exchange Controls

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

Under French law, there is no limitation on the right of non-French residents or non-French security holders to own, or where applicable, vote securities of a French company. A non-resident of France must file a *déclaration administrative*, or administrative notice, with French authorities in connection with the acquisition of a controlling interest in any French company. Under existing administrative rulings, ownership, by a non-resident of France or a French corporation which is itself controlled by a foreign national, of 20 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.

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 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. The *avoir fiscal* applicable to corporate investors generally is equal to 15% of the dividend. Dividends paid to non-residents normally are subject to a 25% French withholding tax and 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).

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

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 précompte, which is payable by the distributing corporation. The *précompte* generally is 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 15% may claim an additional payment equal to 70% of the *précompte* actually paid in cash by the distributing corporation, net of applicable withholding tax. These additional payments are considered 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 obtain from the French tax authorities a payment equal to 100% of the *précompte* actually paid in cash by the distributing corporation, net of applicable withholding tax.

Taxation on Sale or Disposition of Shares or ADSs

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 held not more than 25% of the dividend rights (*droits aux bénéfices 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.

A 1% registration duty (subject to a maximum of € 3,049 per transfer) applies to certain transfers of shares or ADSs in 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. French tax law does not specify whether a company listed on a non-French securities exchange would be considered a "listed company" for purposes of these rules. The Company, based on the advice of its counsel, believes that it should be considered a listed company.

Estate and Gift Tax

France imposes estate and gift tax on shares or ADSs of a French company that are acquired by inheritance or gift. The tax applies without regard to the 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 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.

The Company expects to be a "passive foreign investment company" or "PFIC" for U.S. tax purposes in respect of the year 2002. In order to minimize exposure to unfavorable U.S. tax rules applicable to PFICs, U.S. holders may wish to make a mark-to-market election. See "—Passive Foreign Investment Company Rules."

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.

Holders 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 payment equal to the *avoir fiscal*, less a 15%

withholding tax. French tax will be withheld at 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 15% of the amount of a dividend. A U.S. holder that is an individual generally will be entitled to an *avoir fiscal* refund at the 50% rate.

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 *précompte* 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 70% of the *précompte* actually paid in cash by the Company, less a 15% withholding tax. Pension funds and certain other tax-exempt U.S. holders generally will be entitled to receive 30/85 of 70% of the *précompte* 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 12.75, consisting of the *avoir fiscal* of 15, less a 15% withholding tax on that amount (equal to 2.25); in the event that the dividend distribution triggers payment by the Company of the *précompte*, such U.S. holder may also obtain from the French tax authorities an additional payment equal to 70% of the *précompte* 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 *précompte* 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 *précompte* the Company actually pays in cash. Such holders should consult their own tax advisers concerning *précompte* refunds.

The gross amount of dividend, *avoir fiscal* and *précompte* 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. 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) or, if the holder is not the owner of all such rights, providing certain information concerning other owners.

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. The Depositary will arrange for the filing with the French tax authorities of all certificates and applications completed by U.S. holders of ADSs and returned to the Depositary in time for prompt filing with the French tax authorities. If the certificate or application is not filed prior to a dividend payment, then holders may claim 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 *précompte* and U.S. pension funds and certain other tax-exempt U.S. holders that are entitled to a partial refund of the *précompte* 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-Résidents* (9, rue d'Uzès, 75094 Paris Cedex 2).

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

Unfavorable U.S. tax rules apply to companies that are considered passive foreign investment companies (''PFICs''). The Company will be classified as a PFIC in a particular taxable year if either:

- 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 expects to be classified as a PFIC in the year 2002.

If the Company is a PFIC in respect of any year, then a U.S. holder who holds shares during that year and does not make a mark-to-market election will be subject to a special tax at ordinary income tax rates on certain dividends received from the Company and on gains realized on the sale of Shares or

ADSs (“excess distributions”) in all subsequent years, without regard to whether the Company was a PFIC in the year the excess distribution was received. The amount of this tax will be increased by an interest charge to compensate for tax deferral, calculated as if the excess distributions had been earned ratably over the period the U.S. holder held its Shares or ADSs. 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 rules 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 would be taxed as ordinary income in the year of sale.

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

U.S. holders should consult their own tax advisers regarding the U.S. federal income tax considerations discussed above and should carefully consider whether to make a mark-to-market 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.

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 Commissions’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

A uniform 10% strengthening in the value of the euro as of December 31, 2001 relative to the U.S. dollar and the Japanese yen would have resulted in a decrease in income before taxes and minority interests of approximately € 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 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 is exposed to foreign currency exchange rate risk because a significant portion of its costs are denominated in currencies other than those in which it earns revenues. In 2001, approximately 57% of the Company's selling and general and administrative expenses and approximately 85% of the Company's research and development expenses were denominated in euros. During the same period, only 38% of the Company's sales were denominated in euros, the remainder being denominated primarily in U.S. dollars and Japanese yen.

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, 2001.

Financial Instruments

The Company also has exchange rate exposures with respect to indebtedness denominated in U.S. dollars and Japanese yen. Approximately € 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 € 3.9 million denominated in U.S. dollars and € 0.8 million denominated in Japanese yen at December 31, 2000. In addition, at December 31, 2001, the Company had approximately € 16.6 million and € 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 € 22.7 million and € 1.6 million at December 31, 2000, respectively.

The potential immediate loss to the Company that would result from a hypothetical 10% decrease in the exchange rate of the U.S. dollar against the euro would be approximately € 1.5 million at December 31, 2001 compared with € 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 result from a hypothetical 10% decrease in the exchange rate of the Japanese yen against the euro would not be 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.

Interest Rate Risk

The Company is subject to market risk deriving from changes in interest rates which may affect the cost of its financing, the return on its floating-rate financial assets and the fair market value of its fixed-

rate financial assets. At December 31, 2001, the Company had approximately € 0.9 million in loans and financing outstanding, all of which bore interest at fixed rates. This represents a decrease from € 4.7 million at December 31, 2000. The decrease in outstanding indebtedness principally reflected early repayments of U.S. dollar denominated long-term debt in 2001. The Company invests its excess liquidity (€ 19.4 million at December 31, 2001 compared with € 3.6 million at December 31, 2000) mainly in short-term floating-rate financial instruments. Fixed-rate financial instruments are segregated from floating-rate financial instruments in evaluating the potential impact of changes in applicable interest rates.

The Company assesses market risk exposure for fixed-rate financial instruments on the basis of the impact of a hypothetical interest rate change on the fair market value of such instruments and for floating-rate financial instruments on the basis of the impact of a hypothetical interest rate change on future earnings. The potential loss in fair market value of fixed-rate financial assets and liabilities held at December 31, 2001 and December 31, 2000 resulting from a hypothetical, instantaneous and unfavorable change of 100 basis points in the interest rate applicable to such financial instruments would not be material. The insignificant exposure is primarily due to the reduction in the Company's outstanding indebtedness in 2001 and 2000 compared to 1999, including fixed-rate indebtedness.

A hypothetical and instantaneous change of 100 basis points in interest rates applicable to floating-rate financial assets and liabilities held at December 31, 2001 and at December 31, 2000 would not result in a material loss of future earnings over one year. The Company believes that this decrease in risk is also attributable to the reduction in indebtedness from December 31, 1999 to December 31, 2000 and December 31, 2001.

The above sensitivity analyses are based on the assumption of an unfavorable 100 basis point movement in the interest rates applicable to each homogeneous category of financial assets and liabilities (based on principal amounts at December 31, 2001 (or December 31, 2000 with respect to information given as of that date)) from such rates as at December 31, 2001 (or December 31, 2000 with respect to information given as of that date). A homogeneous category is defined according to the currency in which financial asset and liabilities are denominated and assumes the same interest rate movement within each homogeneous category (e.g., French franc, US dollars, Japanese yen). As a result, the Company's interest rate risk sensitivity model may overstate the impact of interest rate fluctuations for such financial instruments as consistently unfavorable movements of all interest rates are unlikely.

Equity Price Risk

The Company is 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, and approximately 18% at December 31, 2001.

Item 12. Description of Securities Other than Equity Securities

Not Applicable.

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. Reserved

Item 16. Reserved

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 Articles of Association (*statuts*) of EDAP TMS S.A. as amended as of March 21, 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 Lease dated November 27, 1995 between SCI Oliverianne 3 and Technomed Medical Systems (together with an English translation thereof).[2]

8 List of subsidiaries of EDAP TMS S.A. as of March 31, 2002.

---

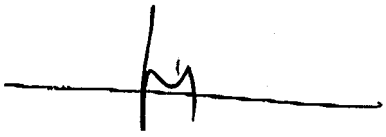
(1) Previously filed with certain confidential portions omitted under Rule 24b-2 under the Securities Exchange Act of 1934.

(2) Previously filed.

SIGNATURES

Pursuant to the requirements of Section 12 of the Securities Exchange Act of 1934, the registrant certifies that it meets all of the requirements of filing on Form 20-F and has duly caused this annual report to be signed on its behalf by the undersigned, thereunto duly authorized.

EDAP TMS S.A.
(Registrant)



By: /s/ ERIC SIMON
Eric Simon
Chief Executive Officer

Dated: May 7, 2002

INDEX TO FINANCIAL STATEMENTS

Audited Consolidated Financial Statements for EDAP TMS S.A. and Subsidiaries for the Years Ended December 31, 2001, 2000 and 1999

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 subsidiaries as of December 31, 2001 and 2000, and the consolidated statements of income, comprehensive income, shareholders' equity and cash flows for each of the three years in the period ended December 31, 2001. 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 subsidiaries at December 31, 2001 and 2000, and the consolidated results of their operations and their cash flows for each of the three years in the period ended December 31, 2001 in conformity with accounting principles generally accepted in the United States.

ERNST & YOUNG Audit

Represented by
Jean-Luc Desplat

April 2, 2002
Lyon, France

EDAP TMS S.A. AND SUBSIDIARIES

CONSOLIDATED BALANCE SHEETS
As of December 31, 2001 and 2000
(in thousands of euros unless otherwise noted)

ASSETS	Notes	2001	2000
Current assets			
Cash and cash equivalents		19,361	3,388
Investments available for sale	2	9,686	21,651
Trade accounts and notes receivable, net of allowance of € 917 in 2001 and € 1,163 in 2000	3	8,828	5,773
Other receivables	4	2,007	2,883
Inventories	5	5,598	5,590
Deferred income taxes	18-2	111	242
Prepaid expenses		336	354
Total current assets		45,927	39,881
Property, plant and equipment, net	6	2,233	1,825
Intangible assets	7	104	189
Goodwill, net of accumulated amortization of € 2,359 in 2001 and € 2,240 in 2000		2,412	2,531
Net assets held for sale		245	245
Restricted cash equivalents		890	4,371
Deposits and other non-current assets		1,304	1,245
Total assets		53,115	50,287
LIABILITIES AND SHAREHOLDERS' EQUITY			
Current liabilities			
Short-term borrowings		—	171
Trade accounts and notes payable	8	6,511	5,045
Accrued expenses and other current liabilities	9	4,679	3,302
Current portion of obligations under capital leases	10	102	96
Current portion of long-term debt	11	624	1,571
Total current liabilities		11,916	10,185
Obligations under capital leases	10	229	331
Long-term debt	11	304	3,147
Other provisions and long-term liabilities	12	1,757	1,945
Total liabilities		14,206	15,608
Commitments and contingent liabilities	19		
Shareholders' equity			
Common stock, € 0.13 par value, 9,318,875 shares authorized; 8,315,400 shares issued; 7,734,310 and 7,784,850 shares outstanding at December 31, 2001 and 2000, respectively	13	1,081	1,014
Additional paid-in capital		19,811	19,811
Retained earnings	13	15,827	8,760
Cumulative other comprehensive income		3,987	6,817
Treasury stock, at cost; 581,090 and 530,550 shares at December 31, 2001 and 2000, respectively	13	(1,797)	(1,723)
Total shareholders' equity		38,909	34,679
Total liabilities and shareholders' equity		53,115	50,287

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

EDAP TMS S.A. AND SUBSIDIARIES

CONSOLIDATED STATEMENTS OF INCOME
For the years ended December 31, 2001, 2000 and 1999
(in thousands of euros unless otherwise noted)

	Notes	2001	2000	1999
Net sales of medical devices		10,760	9,796	5,613
Net sales of spare parts, supplies and services		13,044	15,013	13,494
Net sales		23,804	24,809	19,107
Other revenues	14	161	2,443	774
Total revenues		23,965	27,252	19,881
Cost of sales (exclusive of items shown separately below)		(15,190)	(14,192)	(10,670)
One time cost of sales provision		(796)	—	—
Gross profit		7,979	13,060	9,211
Research and development expenses		(3,430)	(3,971)	(3,133)
Selling expenses		(4,223)	(6,002)	(6,314)
General and administrative expenses		(5,348)	(5,476)	(5,220)
Depreciation and amortization		(92)	(1,346)	(1,864)
Non recurring operating expenses		—	—	(338)
Operating loss		(5,114)	(3,735)	(7,658)
Interest income (expense), net	16	694	(494)	(240)
Currency exchange gains, net		166	406	1,357
Net gain on sale of business		—	15,742	—
Other income, net	17	12,273	113	54
Income (loss) before taxes		8,019	12,032	(6,487)
Income tax (expense) credit	18	(882)	(323)	256
Net income (loss)		7,137	11,709	(6,231)
Basic earnings per share	1-14	0.92	1.50	(0.80)
Weighted average shares outstanding used in basic calculation	1-14	7,760,044	7,784,850	7,815,272
Diluted earnings per share	1-14	0.90	1.42	(0.80)
Weighted average shares outstanding used in diluted calculation	1-14	7,941,869	8,266,361	7,815,272

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

EDAP TMS S.A. AND SUBSIDIARIES

CONSOLIDATED STATEMENTS OF COMPREHENSIVE INCOME
For the years ended December 31, 2001, 2000 and 1999
(in thousands of euros unless otherwise noted)

	2001	2000	1999
Net income (loss)	7,137	11,709	(6,231)
Other comprehensive income:			
Unrealized gain on investments	5,949	8,656	—
Foreign currency translation adjustments	(123)	(1,108)	(681)
Comprehensive income (loss), net of tax	12,963	19,257	(6,912)

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

EDAP TMS S.A. AND SUBSIDIARIES

CONSOLIDATED STATEMENTS OF SHAREHOLDERS' EQUITY
For the years ended December 31, 2001, 2000 and 1999
(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	Treasury stock	Total
Balance as of December 31, 1998	7,819,650	1,060	19,811	4,612	(22)	(49)	(3,049)	22,363
Amortization of deferred Compensation					22			22
Net income				(6,231)				(6,231)
Translation adjustment						(681)		(681)
Acquisition of treasury shares	(34,800)						(49)	(49)
Balance as of December 31, 1999	7,784,850	1,060	19,811	(1,619)	—	(730)	(3,098)	15,424
Net income				11,709				11,709
Translation adjustment						(1,109)		(1,109)
Unrealized gain on investments available for sale						8,656		8,656
Capital decrease		(46)		(1,330)			1,375	—
Balance as of December 31, 2000	7,784,850	1,014	19,811	8,760	—	6,817	(1,723)	34,679
Net income				7,137				7,137
Translation adjustment						(123)		(123)
Acquisition of treasury shares	(333,540)						(930)	(930)
Sale of treasury shares	283,000						853	853
Change in unrealized gain on investments available for sale						(2,707)		(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	(1,797)	38,909

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

EDAP TMS S.A. AND SUBSIDIARIES

CONSOLIDATED STATEMENTS OF CASH FLOWS
For the years ended December 31, 2001, 2000 and 1999
(in thousands of euros unless otherwise noted)

	2001	2000	1999
Cash flows from operating activities			
Net income (loss)	7,137	11,709	(6,231)
Elimination of expenses and benefits without effect on cash:			
Depreciation and amortization	1,103	1,345	1,791
Change in allowances for doubtful accounts & slow-moving inventories	(820)	(118)	550
Change in long-term provisions	(189)	586	(311)
Cancellation of government grants	—	—	(366)
Net capital loss on disposal of assets	—	19	17
Deferred tax charge/(benefit)	131	72	(207)
Minority interests in consolidated subsidiaries	—	—	(3)
Stock compensation expense	—	—	22
Net gain on sale of assets	(8)	—	—
Net gain on sale of business	—	(15,742)	—
Net gain on sale of investments available for sale	(12,242)	—	—
	(12,025)	(13,838)	1,493
Increase/Decrease in operating assets and liabilities, net of effects from sale of business:			
(Decrease)/Increase in trade accounts and notes and other receivables	(1,933)	3,273	3,160
Decrease/(Increase) in inventories	559	3,279	25
Decrease/(Increase) in prepaid expenses	18	37	(103)
(Decrease)/Increase in trade accounts and notes payable	1,503	(663)	(462)
(Decrease)/Increase in accrued expenses, other current liabilities and minority interests	1,340	(3,767)	(410)
	1,487	2,159	2,210
Net cash (used in)/provided by operating activities	(3,401)	30	(2,528)
Cash flows from investing activities			
Acquisitions of property, plant and equipment	(847)	(456)	(497)
Acquisitions of intangible assets	(82)	(26)	(15)
Capitalized assets produced by the Company	(570)	(211)	(1,581)
Net proceeds from sale of assets	12	—	—
Net proceeds from sale of business	—	3,732	—
Proceeds from sale of investments available for sale	21,619	—	—
Reimbursement of loans granted	20	—	—
Increase in deposits and guarantees	—	—	(10)
Change in restricted cash equivalents	3,481	(972)	—
Reimbursement of deposits and guarantees	—	—	336
Net cash provided by (used in) investing activities	23,633	2,067	(1,767)
Cash flow from (used in) financing activities			
Acquisition of treasury shares	(74)	—	(49)
Repayment of long term borrowings	(3,784)	(1,876)	(1,594)
Repayment of obligations under capital leases	(96)	(91)	(85)
Increase/(decrease) in bank overdrafts and short-term borrowings	(177)	159	(22)
Net cash used in financing activities	(4,131)	(1,808)	(1,750)
Net effect of exchange rate changes on cash	(128)	(162)	511
Net increase/(decrease) in cash and cash equivalents	15,973	127	(5,534)
Cash and cash equivalents at beginning of year	3,388	3,261	8,795
Cash and cash equivalents at end of year	19,361	3,388	3,261

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

1—SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

1-1 Nature of operations

EDAP TMS S.A. and its subsidiaries (''the Group'') are engaged in the development, production, marketing and distribution of a portfolio of minimally-invasive medical devices for the treatment of urological diseases. The Group 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 Group purchases the majority of the components used in its products from a number of suppliers but for some components, relies on a single source. Delay would be caused if the supply of these components or other components 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 Group's business, financial position and results of operation.

1-2 Management estimates

The preparation of financial statements in conformity with generally accepted accounting principles 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 HIFU S.A. Edap Technomed Sdn Bhd was incorporated in early 1997. Edap Technomed Co. Ltd. was created in late 1996. HIFU 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 Group provides training and a one-year warranty upon installation. The Group 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.

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). Appropriate consideration is given to deterioration, obsolescence and other factors in evaluating net realizable value.

1-7 Property, plant and equipment

Property, plant and equipment is stated at historical cost. Depreciation of property, plant and equipment is calculated by the straight-line method over the estimated useful life of the assets concerned, 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. The Group applies Statement of Accounting Standards (SFAS) No. 121, ''Accounting for the Impairment of Long-Lived Assets and for Long-Lived Assets to Be Disposed Of'' and records a provision for impairment if the carrying values of property, plant and equipment exceed estimated future cash flows.

1-8 Intangible assets and goodwill

Intangible assets consist primarily of purchased patents relating to lithotripters, purchased licenses, a purchased tradename and trademark and goodwill. 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 intangible assets is calculated by the straight-line method over the shorter of the contractual or estimated useful life of the assets concerned, as follows:

Patents	5 years
Licenses	5 years
Tradename and trademark	7 years
Organization costs	3 years
Goodwill	25 years

The Group provides for intangible assets if undiscounted estimated future cash flows are not sufficient to recover the recorded amount. If a provision is necessary, the Group would write down the value of the intangible assets to the value of the discounted future cash flows and also evaluate the remaining estimated useful life of the assets as appropriate.

1-9 Warranty costs

The Group 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.

1-10 Deferred income taxes

The Group 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.

1-11 Research and development costs

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

1-12 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, 2001, 2000 and 1999 were not material to the consolidated financial statements.

1-13 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, Edap Technomed Italia S.R.L., and Edap Technomed Co. Ltd.) are as follows:

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

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.

1-14 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 Group. The dilutive effects of the Group'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.

(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, 2001 and 2000 is as follows:

	For the year ended Dec. 31, 2001			For the year ended Dec. 31, 2000		
	Income in euros (Numerator)	Shares (Denominator)	Per-Share Amount	Income in euros (Numerator)	Shares (Denominator)	Per-Share Amount
Basic EPS						
Income available to common Shareholders	7,137,000	7,760,044	0.92	11,709,000	7,784,850	1.50
Effect of dilutive securities:						
Stock options		180,825			481,511	
Diluted EPS						
Income available to common shareholders						
+ assumed conversions	7,137,000	7,940,869	0.90	11,709,000	8,266,361	1.42

1-15 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 Group's financial position, results of operations or cash flows.

1-16 New accounting standards

In June 2001, the FASB issued statement No. 141, "Business Combinations" ("SFAS 141") and statement No. 142, "Goodwill and Other Intangible Assets" ("SFAS 142"). SFAS 141 requires the use of the purchase method of accounting for all business combinations initiated after June 30, 2001. Under SFAS 142, goodwill will no longer be amortized on a straight line basis over its estimated useful life, but will be tested for impairment on an annual basis and whenever indicators of impairment arise. The goodwill impairment test, which is based on fair value, is to be performed on a reporting unit level. Under SFAS 142, intangible assets with indefinite lives will not be amortized. Instead, they will be carried at the lower cost or market value and tested for impairment at least annually. All other recognized intangible assets will continue to be amortized over their estimated useful lives.

SFAS 142 is effective for fiscal years beginning after December 15, 2001 although goodwill on business combinations consummated after July 1, 2001 will not be amortized. In addition, goodwill on prior business combinations will cease to be amortized. The Company will apply SFAS 142 beginning in the first quarter of 2002. Application of the non amortization provisions of SFAS 142 is expected to result in an increase in net income of € 119 thousand in 2002. The Company will test goodwill for

impairment using two-step process prescribed in SFAS 142. The first step is a screen for potential impairment, while the second step measures the amount of the impairment, if any.

The Company expects to perform the first of the required impairment tests of goodwill as of January 1, 2002 in the first quarter of 2002. Any impairment charge resulting from these transitional impairment tests will be reflected as cumulative effect of a change in accounting principle in the first quarter of 2002. The Company does not believe that the effect of these tests will be material to the earnings and financial positions of the Company.

In October 2001, the Financial Accounting Standards Board issued SFAS No. 144, ''Accounting for the Impairment or Disposal of Long-Lived Assets''. This Statement addresses the financial accounting and reporting for the impairment or disposal of long-lived assets and supersedes SFAS 121, and the accounting and reporting provisions of APB Opinion No. 30, ''Reporting the Results of Operations-Reporting the Effects of Disposal of a Segment of a Business, and Extraordinary, Unusual and Infrequently Occurring Events and Transactions'', for the disposal of a segment of a business (as previously defined in that Opinion). SFAS 144 also amends ARB No. 51, ''Consolidated Financial Statements'', to eliminate the exception to consolidation for a subsidiary for which control is likely to be temporary. The provisions of this Statement are effective for financial statements issued for fiscal years beginning after December 15, 2001. The Company has reviewed the provisions of this statement and does not believe its adoption will have a material impact on its results of operations or its financial position.

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 holds 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) as well as the liabilities related to these transferred assets.

The Company recorded in 2000 non-recurrent net gain of € 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.

For the year ended December 31, 2001 unrealized gains amounted to € 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 € 12.2 million attributable to the sale of Urologix common stock.

(in thousands of euros unless otherwise noted, except per share data)

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	3,737	5,949	9,686
Investments available for sale	3,737	5,949	9,686

3—TRADE ACCOUNTS AND NOTES RECEIVABLE, NET

	December 31,	
	2001	2000
Trade accounts and notes receivable	9,745	6,936
Less: allowance for doubtful accounts	(917)	(1,163)
Total	8,828	5,773

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

4—OTHER RECEIVABLES

	December 31,	
	2001	2000
Tax loss carryback receivable from the French State	1,609	1,464
Value-added taxes receivable from the French State	671	525
Research and development tax credit receivable from the French State	313	490
Other receivables from the French State	153	150
Others	261	255
Total	2,007	2,883

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 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.

(in thousands of euros unless otherwise noted, except per share data)

5—INVENTORIES

	December 31,	
	2001	2000
Components, spare parts and work-in-progress	6,045	6,928
Finished goods	1,621	1,297
Total gross inventories	7,666	8,225
Less: provision for slow-moving inventory	(2,068)	(2,635)
Total	5,598	5,590

6—PROPERTY, PLANT AND EQUIPMENT

	December 31,	
	2001	2000
Equipment	4,269	3,475
Furniture, fixture, and fittings and other	2,686	2,447
Total gross value	6,954	5,922
Less: accumulated depreciation	(4,722)	(4,097)
Total	2,233	1,825

7—INTANGIBLE ASSETS

	December 31,	
	2001	2000
Licenses	255	173
Tradename and trademark	661	698
Patents	412	412
Organization costs	360	360
Total gross value	1,688	1,643
Less: accumulated amortization	(1,584)	(1,454)
Total	104	189

(in thousands of euros unless otherwise noted, except per share data)

8—TRADE ACCOUNTS AND NOTES PAYABLE

	December 31,	
	2001	2000
Trade accounts payable	5,439	4,407
Notes payable	1,072	638
Total	6,511	5,045

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

9—ACCRUED EXPENSES AND OTHER CURRENT LIABILITIES

	December 31,	
	2001	2000
Deferred maintenance contract income	965	796
Social security and other payroll withholding taxes	618	589
Employee compensated absences	431	355
Income taxes payable	693	208
Others	1,972	1,003
Total	4,679	3,302

10—LEASE OBLIGATIONS

10-1 Capital leases

The following assets held under capital leases have been classified as assets held for sale at December 31, 2001 and 2000 (see Note 19):

	December 31,	
	2001	2000
Land and buildings	2,208	2,208
Less: accumulated depreciation and impairment reserve	(1,963)	(1,963)
Total	245	245

The above consists of the Group's administrative facility at Croissy-Beaubourg, France under a 12-year capital lease expiring in 2005 for which a € 797.3 thousand impairment charge was recorded in the fourth quarter of 1998 (see Note 19).

Future minimum lease payments under capital leases in effect at December 31, 2001 are as follows (in thousands of euros):

	Future minimum lease payments	Less interest Portion	Net present value of future minimum lease payments
2002	124	(22)	102
2003	124	(16)	109
2004	124	(9)	116
Thereafter	6	(2)	5
Total	379	(48)	331
Less current portion	(124)	22	(102)
Total long-term portion	255	(26)	229

Interest paid for capital lease obligations was € 28 thousand, € 33 thousand and € 39 thousand for the years ended December 31, 2001, 2000 and 1999, respectively.

Depreciation expense on assets held under capital leases is included in total depreciation expense for the years ended December 31, 2001, 2000 and 1999.

10-2 Operating leases

Operating leases having initial or remaining non-cancelable lease terms greater than one year consist principally of a lease for the production facility of TMS S.A. in Vaulx-en-Velin, France which has a lease term of nine years expiring at the option of the lessee at the end of each three-year period through 2003 (i.e., in 2000 or 2003). Future minimum lease payments for this operating lease will amount to € 267 thousand per year until 2003 or € 534 thousand in the aggregate, or until otherwise canceled by the lessee.

Total rent expense under operating leases amounted to € 1,113 thousand, € 1,374 thousand and € 1,200 thousand for the years ended December 31, 2001, 2000 and 1999, respectively.

11—LONG-TERM DEBT

Long-term debt consists of the following:

	December 31,	
	2001	2000
U.S. dollar term loan	—	3,875
Japanese yen term loan	867	843
Other financial debts	61	843
Total	928	4,718
Less current portion	(624)	1,571
Total long-term portion	304	3,147

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 instalment of JPY 30 million on February 24, 2003, and calls for semi-annual payments of interest in advance beginning February 23, 1998.

(in thousands of euros unless otherwise noted, except per share data)

Long-term debt as at December 31, 2001 matures as follows:

2002	624
2003	278
2004	16
2005	10
Total	928

12—OTHER PROVISIONS AND LONG-TERM LIABILITIES

	December 31,	
	2001	2000
Provision for warranty costs	1,185	657
Provision for retirement indemnities	277	275
Other	295	1,013
Total	1,757	1,945

Pension, post-retirement, and post-employment benefits for most of the Group's employees are sponsored by European governments. The Group's liability with respect to these plans is mostly limited to specific payroll deductions. In addition to government-sponsored plans, certain companies within the Group have defined benefit retirement indemnity plans in place. The provision for retirement indemnities at December 31, 2001 represents an accrual for lump-sum retirement indemnity payments to be paid at the time an employee retires. The largest part of this liability relates to employees in France. This provision has been calculated taking into account the estimated payment at retirement (discounted to the current date), turnover and salary increases.

Other provisions in 2000 consisted primarily of a € 725 thousand provision for Prostatron units which the Company is obligated to buy from Urologix as part of the Asset Purchase Agreement. The company estimates that these units will be obsolete and therefore has provided for the expected loss on sale.

13—SHAREHOLDERS' EQUITY

13-1 Common stock

As of December 31, 2001, EDAP TMS S.A.'s common stock consists of 9,318,875 authorized shares with a par value of € 0.13 each, of which 8,315,400 were issued and fully-paid and 7,734,310 were outstanding.

13-2 Retained earnings

Distributable statutory retained earnings amount to € 42,927 thousand and € 39,400 thousand at December 31, 2001 and 2000.

13-3 Treasury stock

As of December 31, 2001, the 581,090 shares of treasury stock consists of (i) 177,750 shares acquired on December 2, 1996 for € 707 thousand, (ii) 352,800 shares acquired between August and December 1998 for € 1,016 thousand, and (iii) 50,540 shares acquired in June and July 2001 for € 153 thousand. All 581,090 shares of treasury stock have been acquired to cover outstanding stock options (see Note 24). 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 Group who left the

(in thousands of euros unless otherwise noted, except per share data)

Company, renouncing therefore to their stock purchase options. The Company bought all 283,000 shares back on the same day for € 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

	2001	2000	1999
Royalties	70	2,406	298
Subsidies and others	91	37	476
Total	161	2,443	774

TMS S.A. received € 30 thousand, € 37 thousand and € 476 thousand in subsidies in 2001, 2000 and 1999, respectively, from the French Ministry of Research and Development. Subsidies in 1999 include the € 366 thousand waiver of a loan from the French Government agency ANVAR.

15—OPERATING EXPENSES

Operating expenses include bad debt expense of € 127 thousand, € 111 thousand, and € 592 thousand for 2001, 2000, and 1999, respectively. These operating expenses also include allowance for slow moving inventory of € 1,124 thousand, € 1,035 thousand and € 330 thousand for 2001, 2000, and 1999, respectively.

16—INTEREST (EXPENSE) INCOME, NET

	2001	2000	1999
Interest income	991	228	564
Interest expense	(297)	(722)	(804)
Total	694	(494)	(240)

17—OTHER INCOME, NET

	2001	2000	1999
Net gain on sale of Urologix common stock	12,242	—	—
Net gain on sale of business	—	15,742	—
Other income, net	31	113	54
Total	12,273	15,855	54

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.

The net gain on sale of Urologix common stock in 2001 reflected the net gain on the sale of Urologix Common Stock during the year.

(in thousands of euros unless otherwise noted, except per share data)

18—INCOME TAXES

Income tax (provision)/benefit	2001	2000	1999
Current income tax provision	(758)	(404)	55
Research and development tax credit	0	150	1
Sub total current income tax	(758)	(254)	56
Deferred income tax (provision) credit	(124)	(69)	200
Total	(882)	(323)	256

18-1 Current income tax:

Refundable income taxes and a tax benefits of € 109 thousand has been recorded by EDAP TMS S.A. in 1998, on the basis of tax losses amounting to € 327 thousand.

18-2 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,	
	2001	2000
Elimination of intercompany profit in inventory	256	298
Provision for impairment of long-lived assets	292	292
Other items	287	300
Operating loss carryforwards	2,326	4,176
Total deferred tax assets	3,161	5,066
Capital leases treated as operating leases for tax	(257)	(223)
Other items	(175)	(133)
Total deferred tax liabilities	(432)	(356)
Net deferred tax assets	2,729	4,710
Valuation allowance for deferred tax assets	(2,618)	(4,468)
Deferred tax assets, net of allowance	111	242

Net operating loss carryforwards of € 301 thousand, € 1,607 thousand, € 241 thousand and € 177 thousand as of December 31, 2001 are available at EDAP Technomed Inc., TMS 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. These tax loss carryforwards expire in years 2001 through 2015. 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.

The net decrease in the operating loss carryforwards for year 2001 reflects the utilization of these carryforwards against the taxable earnings of the Company in 2000. The net decrease in the valuation allowance for deferred tax assets of € 4,339 thousand in 2000 was also related to the utilization of operating loss carryforwards. The net increase in the valuation allowance for deferred tax assets for the

(in thousands of euros unless otherwise noted, except per share data)

year ended December 31, 1999 was € 1,363 million and related primarily to the valuation allowance established for additional net operating loss carryforwards recognized by the Company in this year.

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.

18-3 Effective tax rate

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

	2001	2000	1999
French statutory rate	35.3%	36.7%	41.7%
Research and development tax credit	0%	(1.2%)	0%
Income taxed at capital gains rate	0%	0%	0.8%
Carryback of tax losses to prior years	0%	0%	0%
Non deductible compensation expenses	0%	0%	(0.5%)
Non deductible amortization of goodwill and other intangibles	0.8%	5.2%	(1.9%)
Income of foreign subsidiaries taxed at different tax rates	(0.5%)	(13.6%)	(7.9%)
Effect of net operating loss carryforwards and valuation allowances	(23.0%)	(31.8%)	34.2%)
Non deductible entertainment expenses	0.2%	0.2%	0.4%
Other	1.8%	7.2%	6.3%
Effective tax rate	11%	2.7%	3.9%

19—COMMITMENTS AND CONTINGENCIES

The Group has a number of commitments including operating and capital leases as described in Note 10. It is also a party to various commercial disputes, including employee claims. The Group is also subject to product warranty and liability costs. Provision has been made for probable losses in accordance with SFAS No. 5.

(in thousands of euros unless otherwise noted, except per share data)

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. The estimated fair value amounts have been determined by the Group using available market information and appropriate valuation methodologies. The estimates of fair values of the Group's financial instruments are compared below to the recorded amounts at December 31, 2001 and 2000.

	December 31,		December 31,	
	2001 Recorded Value	2001 Estimated Fair Value	2000 Recorded Value	2000 Estimated Fair Value
Assets:				
Cash and cash equivalents	19,361	19,361	3,388	3,388
Trade accounts and notes receivable, net	8,828	8,828	5,773	5,773
Restricted cash equivalents	890	890	4,371	4,371
Investments available for sale	9,686	9,686	21,651	21,651
Liabilities:				
Short-term borrowings	—	—	172	172
Trade accounts payable	5,439	5,439	4,407	4,407
Notes payable	1,072	1,072	638	638
Long-term debt	304	290	3,147	2,650

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

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

Concentration of credit risk

Financial instruments which potentially subject the Group 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 Group 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 Group has procedures in effect to monitor the creditworthiness of its customers. The Group 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 Group reviewed individual customer balances considering current and historical loss experience and general economic conditions in determining the allowance for doubtful accounts receivable of € 0.9 million and € 1,163 million as of December 31, 2001 and 2000, respectively. 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 25% of its 2001 revenues from a single customer. As of December 31, 2001 approximately € 1.1 million or 12.5% of the Company's accounts receivable were attributable to this customer. No customer accounted for more than 10% of net sales in 2000.

Foreign Currency Transactions

The Group generates a significant percentage of its revenues, and of its operating expenses, in currencies other than French francs. The Group's operating profitability could be materially adversely affected by large fluctuations in the rate of exchange between the French Franc and such other

(in thousands of euros unless otherwise noted, except per share data)

currencies. The Group 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 Group's results of operations. The Group did not deem it necessary to engage in hedging activities in the years ended December 31, 2001 and 2000, thus there are no such financial instruments outstanding at December 31, 2001 and 2000.

21—SEGMENT AND GEOGRAPHIC INFORMATION

The operating segments of the Group are the following: France, USA, Japan and other areas.

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

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

	2001	2000	1999
Segment operating (loss) profit	(5,114)	(3,735)	(7,658)
Interest income (expense), net	694	(494)	(240)
Currency exchange (losses) gains, net	166	406	1,357
Other income, net	12,273	15,855	54
Income tax (expense) credit	(882)	(323)	256
Consolidated income before taxes	7,137	11,709	(6,231)

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 Group subsidiaries are not present.

(in thousands of euros unless otherwise noted, except per share data)

A summary of the Group's operating segments is presented below:

	2001	2000	1999
France	4,258	2,788	612
United States	—	1,276	1,213
Japan	5,192	4,147	2,875
Other geographical areas	1,310	1,585	913
External sales of medical devices	10,760	9,796	5,613
France	5,652	3,408	2,739
United States	132	3,489	3,330
Japan	4,171	5,364	4,874
Other geographical areas	3,090	2,752	2,551
External sales of spare parts, supplies and services	13,045	15,013	13,494
France	3,912	7,524	6,499
United States	15	—	3
Japan	28	188	59
Other geographical areas	182	108	6
Inter-segment revenues	4,137	7,820	6,567
France	(557)	(452)	(500)
United States	(38)	(379)	(373)
Japan	(156)	(104)	(122)
Other geographical areas	(188)	(125)	(66)
Depreciation and amortization	(938)	(1,060)	(1,061)
France	(3,209)	(2,464)	(3,175)
United States	(1,773)	(2,338)	(5,143)
Japan	(70)	676	626
Other geographical areas	(62)	391	34
Operating (loss) profit	(5,114)	(3,735)	(7,658)
France	28,971	17,787	19,491
United States	13,914	22,198	7,633
Japan	4,368	5,795	5,833
Other geographical areas	4,861	4,507	3,398
Segment assets	53,115	50,287	36,355
France	1,142	304	704
United States	65	—	1,204
Japan	82	68	16
Other geographical areas	128	295	153
Capital expenditure	1,417	667	2,077
France	1,747	1,320	1,868
United States	72	45	1,566
Japan	183	277	358
Other geographical areas	336	372	187
Long-lived assets	2,337	2,014	3,979

(in thousands of euros unless otherwise noted, except per share data)

22—VALUATION ACCOUNTS

	Allowance for doubtful accounts	Slow-moving inventory
Balance as of December 31, 1998	1,389	1,977
Charges to costs and expenses	592	330
Deductions: write-off of bad debts provided in prior periods	(361)	(58)
Translation adjustment	44	3
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
Restated balance as of December 31, 2000	1,664	2,252
Charges to costs and expenses	836	7,373
Deductions: write-off of bad debts provided in prior periods	(2,457)	(11,133)
Translation adjustment	5	43
Restated balance as of December 31, 2001	6,013	13,566

23—SUPPLEMENTAL DISCLOSURES OF CASH FLOW INFORMATION

Interest and income taxes paid:

	2001	2000	1999
Income taxes paid (refunds received)	(784)	344	324
Interest paid	198	863	744

24—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 € 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 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 € 3.81 per share for 152,000 options and € 1.83 per share for 175,000 options; both exercise prices were not less than the average stock market price of the shares over the 20 business days preceding the date of grant and also exceeded the market price of the shares on the date of grant. The options 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 Group 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 € 3.81 per share for 11,000 options and € 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 Group ceases, whichever occurs earlier. On March 15, 1999, the Board of Directors granted 60,000 options to certain employees of the Group, 40,000 options were granted with an exercise price of € 3.81 and 20,000 options at an exercise price of € 2.74. Exercise prices corresponding to options granted on these two dates were not less than the average stock market price of the shares over the 20 business days preceding the date of grant. Among these options granted on March 15, 1999: 50,000 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 Group 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 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 € 3.81 instead of € 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 € 3.81, without modifying exercise and vesting conditions. On September 27, 1999, the Board of Directors decided to grant 2,425 options to certain employees of the company at an exercise price of € 1.83 which is not less than the average stock market price of the shares over the 20 business days preceding the date of grant. The options 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 Group 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 (€ 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 Group 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 Group 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 (€ 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 Group 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 (€ 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 Group ceases, whichever occurs earlier.

On June 12, 2001, the shareholders of EDAP TMS S.A. authorized the Board of Directors to grant up to 300,000 options to purchase pre-existing Shares and 80,000 options to subscribe to new shares, at a fixed exercise price to be set by the Supervisory Board. Conforming this plan, on September 25, 2001, the Board of Directors granted 307,115 options to purchase shares (among which 33,540 options were related to the plan authorized by the Shareholders on June 24, 1999) and granted 80,000 options to subscribe to new shares, to employees of the Group meeting certain tenure criteria. The exercise price was fixed at $ 1.92 (€ 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 Group 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 (€ 1.76). The capital of the Company has then been increased from € 1,081 thousand to € 1,087 thousand and the number of shares issued increased from 8,315,400 to 8,362,821.

All options to be potentially purchased through the exercise of stock options are currently held as treasury stock.

(in thousands of euros unless otherwise noted, except per share data)

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

	2001		2000		1999	
	Options	Weighted average exercise price	Options	Weighted average exercise price	Options	Weighted average exercise price
Outstanding on January 1	303,675	3,53	501,550	3.91	583,500	3.99
Granted	474,000	2,02	35,000	2.39	86,425	2.75
Exercised	—	—	—	—	—	—
Forfeited	(56,125)	3,66	(232,875)	3.81	(168,375)	3.81
Expired	—	—	—	—	—	—
Outstanding on December 31	721,550	2,53	303,675	3.53	501,550	3.91
Exercisable on December 31	271,160	3,03	149,750	3.78	83,965	3.78
Shares available on December 31 for share purchase options that may be granted	26,425					

The following table summarizes information about stock options to purchase shares of EDAP already held by the Company as Treasury shares, or to subscribe to new Shares, at December 31, 2001:

	Outstanding stock options			Exercisable stock options	
Exercise prices	Options	Weighted average remaining contractual life	Weighted average exercise price	Options	Weighted average exercise price
€ 3.81	196,125	6,1	3.81	162,875	3.81
€ 2.74	10,000	8.0	2.74	7,500	2,74
€ 2.39	29,000	6.7	2.39	5,000	2.39
€ 2.08[(1)]	387,115	9.9	2.08	—	—
€ 1.83	12,425	7.2	1.83	8,900	1.83
€ 1.76[(2)]	86,885	9,3	1.76	86,885	1.76
€ 1.76 to € 3.81	721,550	7.9	2.53	271,160	3.03

(1) All the 387,115 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, 200($1 = € 1.085).

(2) All the 86,885 options were granted on April 2, 2001 with an exercice price expressed in U.S. dollars ($1.561) based on the noon buying rate on April 2, 2001 ($1 = € 1.13).

The Group 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 € 255 thousand. Based on the vesting provisions of the plan, € 178 thousand of this compensation was expensed in 1997, € 55 thousand was expensed in 1998 and € 22 thousand in 1999. Under APB 25 and

(in thousands of euros unless otherwise noted, except per share data)

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.

Compensation expense for the options granted in 2001, 2000 and 1999 determined based upon the fair value of the options on the date of grant consistent with the methodology prescribed under SFAS No. 123 would have amounted to approximately € 141 thousand, € 116 thousand and € 89 thousand, respectively. Had SFAS No. 123 been applied, compensation expense would have been increased and net results would have been decreased by € 141 thousand (€ 0.018 per Basic and Diluted Share), € 116 thousand (€ 0.0154 per Basic and Diluted Share) and € 89 thousand (€ 0.011 per Basic Share and € 0.014 per Diluted Share) in 2001, 2000 and 1999, respectively, with no impact on income taxes.

Information used to calculate the fair value of options granted in 2001, 2000 and 1999 is as follows:

	2001	2000	1999
Weighted-average fair value per option	2.23	2.17	1.24
Valuation assumptions, using the Black-Scholes option pricing model:			
Weighted-average market value/fair value of share	2.25	1.10	1.56
Weighted-average exercise price	2.08	2.23	3.21
Expected option term (years)	5.0	5.0	5.0
Expected volatility	79.54%	101.00%	66.80%
Expected dividend yield	0%	0%	0%
Risk-free interest rate	5.0%	5.0%	4.0%