As filed with the Securities and Exchange Commission on May 19, 2000

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, 1999

or

☐ TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the Transition Period from to

0-29374
(Commission file number)

EDAP TMS S.A.
(Exact name of registrant as specified in its charter)

EDAP TMS S.A.
(Translation of registrant's name into English)

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:

American Depositary Shares, each representing one Ordinary Share

Ordinary Shares, nominal value FF 0.80 per share

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

None

Outstanding shares of each of the issuer's classes of capital or common stock as of December 31, 1999:

7,784,850 Ordinary Shares

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

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

Item 17 ☐ Item 18 ☒

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PRESENTATION OF FINANCIAL AND OTHER INFORMATION

Unless the context otherwise requires, references herein to "the Company" 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, 1999.

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 "ε" are to the legal currency of the countries of the European Monetary Union 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 ε1 = 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 is reporting its financial results in euros. For purposes of this Annual Report, the financial statements for fiscal years prior to 1999 were restated 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 = ε 1.0666, 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 April 20, 2000. The exchange rate used for convenience translations in this Annual Report differs from the rates used in the preparation of the Company's consolidated financial statements included in this Annual Report, and dollar amounts referred to herein may differ from corresponding actual dollar amounts that were translated into euros in the preparation of such financial statements. See Item 8, "Selected Financial Data—Exchange Rates" for information regarding certain currency exchange rates and Item 9A, "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®, Prostatron®, TUMT®, SONOLITH 2000®, and Ablatherm®. 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 certain of the Company's products, including the Prostatron and the Company's HIFU devices; the clinical status of certain of the Company's products, particularly its 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, such as the Siemens group; 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 1, "Description of Business—Risk Factors" and Item 9, "Management's Discussion and Analysis of Financial Condition and Results of Operations," 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. *Description of Business*

Overview

EDAP TMS develops, produces, markets and distributes a portfolio of minimally-invasive medical devices, primarily for the treatment of urological diseases. The Company currently produces and markets devices for the treatment of benign prostate hyperplasia (''BPH''), prostate cancer and urinary tract stones. The Company is also developing products for the minimally-invasive destruction of certain types of tumors.

EDAP TMS manufactures and sells the Prostatron, a medical device using transurethral microwave thermotherapy (''TUMT'') for the minimally-invasive treatment of BPH, a non-cancerous urological condition that affects an estimated 20 million men in the United States alone. In patients with BPH, the prostate becomes enlarged and obstructs the urethra, thereby restricting the normal flow of urine. The Prostatron uses microwaves to produce heat in order to destroy a well-defined area of diseased tissue within the prostate without damaging surrounding tissue and organs.

The Prostatron was the first medical device based on TUMT to receive a premarket approval (''PMA'') from the U.S. Food and Drug Administration (the ''FDA'') for commercial distribution in the United States. The Prostatron also meets the regulatory requirements for commercial distribution in the European Union (the ''EU'') and Japan. In addition, the Company received in April 2000 a PMA supplement from the FDA for a new version of the Prostatron's operating software, which reduces treatment time from approximately one hour to approximately thirty minutes. In addition to revenues from sales of the Prostatron, the Company also generates revenues from the leasing of Prostatrons to end-users on a cost-per-procedure basis and the sale of disposable parts and maintenance services for its worldwide installed base of Prostatrons.

EDAP TMS manufactures and distributes lithotripters based on extra-corporeal shockwave lithotripsy (''ESWL'') technology and had an installed base of 365 ESWL lithotripters worldwide as of December 31, 1999. 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, the SONOLITH 4000 and the SONOLITH Praktis, which are available for commercial distribution in the EU and Japan. The Company also generates revenues from the leasing of its ESWL lithotripters to end-users, as well as from the sale of spare parts and maintenance services for its worldwide installed base of lithotripters.

In addition, EDAP TMS is currently developing medical devices based on high-intensity focused ultrasound (''HIFU'') technology for the minimally-invasive destruction of certain types of tumors. 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 by the Company for the treatment of organ-confined prostate cancer, is approved for commercial distribution in the EU and is undergoing clinical trials in the United States.

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

Risk Factors

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, while in the BPH market and 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 the BPH market, the Company believes that the Prostatron competes not only against TUMT devices manufactured by other companies but also against the whole range of surgical and non-surgical BPH therapies. Traditional BPH therapies include "watchful waiting" and surgery. Surgical treatments for BPH typically use various means to completely remove the prostatic urethra along with a substantial portion of the diseased tissue within the prostate. The most common surgical procedure for the treatment of BPH is transurethral resection of the prostate ("TURP"). More recently, certain less-invasive surgical BPH treatments have been developed in an attempt to address the complications and side effects of TURP. The five most prevalent procedures are: (i) transurethral incision of the prostate ("TUIP"); (ii) transurethral vaporization of the prostate ("TVP"); (iii) laser assisted prostatectomy; (iv) interstitial laser coagulation therapy ("ILC"); and (v) radio frequency therapy ("RF"). The Indigo® laser from Indigo, Inc., an ILC-based device, has received 510(k) clearance for marketing in the United States. One device based on RF for the treatment of BPH, the TUNA® system developed by VidaMed, Inc., has also received 510(k) clearance, and United States Surgical Corp. ("U.S. Surgical") has announced that it is developing an RF-based device for the treatment of BPH. Drug therapies have also been introduced as an alternative to surgery. Drug therapy for the treatment of symptomatic BPH has been available in the EU since 1988, in Japan since 1989 and in the United States since 1992, and has grown significantly since. In the market for BPH treatments based on TUMT, the Company has a number of competitors worldwide, including Urologix, Inc. ("Urologix"), BSD Medical Corp. ("BSD"), Dornier Medizin Technik GmbH ("Dornier"), Bruker Spectrospin S.A. ("Bruker"), Olympus Optical Co. Ltd ("Olympus") and Prostalund Instruments AB ("Prostalund"). The TUMT device manufactured by Urologix obtained FDA approval in August 1997 and competes directly with the Prostatron, particularly in the United States.

In HIFU, the Company's devices, in particular the Ablatherm, competes with all current treatments for localized tumors, which include surgery, radiotherapy, brachytherapy and hormonotherapy. Other companies are working with HIFU for the minimally-invasive treatment of tumors in addition to the Company and Siemens, including Focus Surgery, Inc. ("Focus Surgery"), General Electric Medical Systems ("General Electric"), Toshiba Corporation ("Toshiba") and Karl Storz GmbH ("Storz"). See "Product Overview—The Prostatron—BPH—Competing BPH Therapies" and "—Competing TUMT Treatments," "Product Overview—Extra-Corporeal Shockwave Lithotripsy—Competition" and "Product Overview—High-Intensity Focused Ultrasound—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 of Market Acceptance of Certain Products

Notwithstanding any positive clinical results that the Company's products may have achieved in terms of safety and effectiveness and any marketing approvals that the Company may have obtained 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. See "—Uncertainty Relating to Third-Party Reimbursement." 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.

Compared with traditional BPH therapies such as "watchful waiting" and surgery, TUMT represents a relatively new procedure for the treatment of BPH. There can be no assurance that the Prostatron will gain significant additional market acceptance among physicians and patients.

The HIFU devices that the Company is currently developing represent new therapies for the conditions that they are designed to treat, and there can be no assurance that, if introduced on the market, they will gain any significant degree of market acceptance among physicians and patients. In addition, the Company will initially limit the application of HIFU technology to the treatment of organ-confined prostate cancer and breast tumors.

Because the range of products currently marketed and sold by the Company is comprised of only three types of medical devices (the Company's ESWL lithotripters, the Prostatron and the Ablatherm), lack of market acceptance by physicians or patients for any of those therapies could 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 EU and Japan, third-party reimbursement is generally conditioned upon decisions by national health authorities. In the EU, there is no single procedure for obtaining reimbursement and, consequently, relevant approvals have to be sought in each member State. The Prostatron procedure is currently reimbursed by Medicare in all States of the United States and many private healthcare providers are reimbursing the procedure throughout the United States as long as it is performed as an outpatient hospital procedure The Prostatron procedure is currently reimbursed by public and private healthcare systems in Japan, but not in larger EU member States, with the exception of Italy. 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. See "Third-Party Reimbursement."

Uncertainty Relating to Clinical Trials; Clinical Status of Certain Products

Before obtaining regulatory approvals for the commercial sale of any of its products under development, the Company must demonstrate through preclinical studies and clinical trials that the product is safe and efficacious for use in each indication. The results from preclinical testing and early clinical trials may not be predictive of 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.

The Company relies on scientific, technical and clinical data supplied by its academic collaborators in the evaluation and development of potential products, including HIFU-related devices such as the Ablatherm. 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 approvals is unpredictable, often lengthy and requires the expenditure of substantial resources. There can be no assurance that the Company's products currently in the

clinical testing stage, in particular its HIFU devices, will prove to be effective or safe, or will be approved by appropriate regulatory authorities. If the Company's products currently in the clinical testing stage 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 for at least several years, if at all. See "Product Overview—High-Intensity Focused Ultrasound—Clinical Status" and "—Government Regulation."

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 testing 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. See "—Uncertainty Relating to Clinical Trials; Clinical Status of Certain Products" above and "—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.

As the Prostatron uses radio-frequency energy and accordingly emits radio waves, the Company is subject to international and national regulations governing the use of radio-frequency bandwidths. The band currently used by the Prostatron falls within a bandwidth authorized for use by medical devices subject in the United States to a 24 dB noise limit mandated by the U.S. Federal Communications Commission ("FCC"). Any medical device exceeding this limit must be electronically shielded to lower emissions to an acceptable level. Measured at their source, Prostatrons exceed the 24 dB limit. In a number of cases, however, Prostatrons are installed in environments (such as large hospitals) which prevent the 24 dB noise limit from being exceeded. In 1995, the Company requested a waiver from the FCC, which would have allowed the Prostatron to exceed the legal noise limit. This request was rejected in 1998. The FCC has, however, authorized the Company to continue its current practice, which consists of testing the noise emission of each newly-installed Prostatron, and electronically shielding only those machines which are found to exceed the legal noise limit. Although the tests are inexpensive to perform, the necessity of electronically shielding some Prostatrons is an additional expense which may adversely affect the marketing of, and the revenues generated by, the Prostatron in the United States. See "—Government Regulation—Regulation of Radio-Frequency Bands."

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. See "—Manufacturing."

Manufacturing

The Company's manufacturing operations must comply with regulations established by regulatory agencies in the United States, the EU and other countries, and in particular with the good manufacturing practices ("GMP") mandated by the FDA and the EU 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. See "—Manufacturing."

Substantially all of the Company's assembly of its 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. See Item 2, "Description of Property."

Dependence on Outside Parties and Risks Associated with Collaborative Arrangements

To date, the Company is party to collaborative arrangements for the development, commercialization and marketing of certain of its products worldwide. For instance, the Company depends on Siemens AG (together with other companies of the Siemens group, "Siemens") to fund portions of the Company's product development program in HIFU. There can be no assurance that the Company's existing or future collaborative arrangements will be scientifically or commercially successful. The success of any of such arrangements is dependent in part upon each collaborative partner's commitment and timely performance of its obligations, which are factors beyond the Company's control. Each of the Company's collaborative arrangements is subject to termination under various circumstances, and any such termination might adversely affect the Company's ability to develop, commercialize, market or distribute certain of its products. The Company is currently engaged in negotiations with Siemens regarding the costs of the development program for the Ablatherm after year-end 1999. If these negotiations are unsuccessful, Siemens may not continue to fund part of this program. There can be no assurance that the Company's collaborative partners will not be pursuing alternative technologies, developing alternative products or marketing competing products, either on their own or in collaboration with others, including the Company's competitors. See "Business Strategy" and "Collaborative Partners."

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. In December 1999, the European patent office revoked the Company's European patent relating to the Prostatron. See "Patents and Intellectual Property—The Prostatron" for further discussion of this action. 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.

The Company owns patents covering several of its technologies and has additional patent applications pending in the United States, the EU, Japan and elsewhere. See "Patents and Intellectual Property." 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. See "Patents and Intellectual Property."

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. The Company is a party to a product liability action in the United States. See "Product Liability and Insurance." 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. See "Product Liability and Insurance."

Internal Accounting Controls

Following the departure of the former President of the Company's U.S. subsidiary in October 1999, the Company discovered side letters from the Company's U.S. subsidiary setting forth conditions to certain Prostatron orders and guaranteeing end-user payment to a third-party lessor of medical equipment, in violation of the Company's revenue recognition policies. These side letters were not disclosed to the Company's management, and the Company therefore was not aware of them at the time the revenue from these transactions was recognized. No such problems were found in orders from Company customers outside the United States. Following a review of the transactions, the Company decided to restate its audited consolidated annual financial statements for the year ended December 31, 1998 and unaudited consolidated quarterly financial statements for the three months ended March 31, June 30 and September 30, 1999, the six months ended June 30, 1999 and the nine months ended September 30, 1999. See Item 9, "Management's Discussion and Analysis of Financial Condition and Results of Operations."

The Company has made changes to its system of accounting controls as a result of the circumstances described above. A committee of the Supervisory Board was established 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. The Company's sales force also underwent training on the terms and application of the Company's revenue recognition policy. Finally, management initiated a quarterly review of financial statements and key revenue-generating transactions. However, there can be no assurance that the Company's internal accounting controls will be sufficient to prevent similar events from occurring in the future.

Any failure of the Company's internal accounting controls could have a material adverse effect on the Company's financial condition and results of operations.

Nasdaq Delisting Proceedings

On December 22, 1999, following the announcement by the Company of its intention to proceed with the restatement of its consolidated financial statements, the Nasdaq Stock Market, Inc. ("Nasdaq") initiated proceedings to delist the ADSs from Nasdaq. See Item 5, "Nature of Trading Market" for a description of these proceedings. While to date the Company has filed in a timely manner all the materials required to be filed by Nasdaq as a condition to the continued listing of the ADSs on Nasdaq, and such listing has been provisionally continued, Nasdaq is currently reviewing these materials and as of the date of this Annual Report has not notified the Company of its final decision in this matter. In the event that Nasdaq delists the ADSs, there would likely be a material adverse effect on the marketability and price of the ADSs.

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 1999, approximately 65% of the Company's general and administrative expenses and approximately 80% of the Company's research and development expenses were denominated in euros, while approximately 72% of the Company's sales were denominated in currencies other than euros (primarily the U.S. dollar and the Japanese yen). The Company's operating profitability could be materially adversely affected by large fluctuations in the rate of exchange between the euro and such other currencies. For instance, a decrease in the value of the U.S. dollar or the Japanese yen against the euro would have a negative impact 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 impact of movements in exchange rates on the Company's results of operations. No foreign exchange forward sale contracts were outstanding at December 31, 1999 or are currently in place. See Item 9A, "Quantitative and Qualitative Disclosures about Market Risk." 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"). See Item 8, "Selected Financial Data—Exchange Rates."

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. See Item 9, "Management's Discussion and Analysis of Financial Condition and Results of Operations" and "—Government Regulation."

No Dividends Anticipated in Future

The Company has not paid any dividends on its Shares since 1994 and does not anticipate paying any dividends for the foreseeable future. Declaration of dividends on the Shares will depend upon, among other things, future earnings, if any, the operating and financial condition of the Company, its capital requirements and general business conditions. See Item 8, "Selected Financial Data—Dividends and Dividend Policy."

Business Strategy

The Company's business strategy is to capitalize on 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. The key elements of the Company's strategy to achieve that objective include:

Provide Minimally-Invasive Solutions to Urological Disorders. Building upon its established position in the ESWL market, the Company is striving to become a leading provider of minimally-invasive treatment alternatives for BPH and prostate cancer, the incidence of which the Company believes will increase as the male population ages in developed countries.

Expand Prostatron Usage and Customer Base. The Company focuses on (i) developing usage of the Prostatron installed base by providing increased customer assistance and (ii) broadening the customer base for the Prostatron. The Company's marketing strategy for broadening its customer base is to increase its penetration of its traditional customer market segment, which is comprised of larger hospitals and urology clinics and research institutions, while also expanding into the segment of smaller hospitals and urology clinics and individual urologists.

In an effort to target smaller hospitals and urology clinics and individual urologists, the Company implemented in 1999 a new marketing strategy for the Prostatron in the United States which includes expanding the leasing of the Prostatron, either by selling Prostatron units to a third-party financial institution specializing in leasing capital goods equipment which in turn leases the units to end-users on a cost-per-procedure basis or by leasing Prostatron units directly to end-users on a cost-per-procedure basis. The Company is also focusing on this market segment by providing the Prostatron for treatment on a mobile basis, which permits smaller hospitals and outpatient clinics to have access to the Prostatron procedure in a more cost-effective manner. The Company believes that due to the advent of more stringent healthcare cost control policies in developed countries, the number of non-surgical procedures not requiring a hospital environment that are performed by individual urologists and smaller urology clinics will grow in the next two to three years, to the extent third-party reimbursement can be obtained for such procedures. See "Product Overview—The Prostatron—Marketing Strategy."

Achieve Long-Term Growth by Expanding Applications Beyond Urology. The Company's long-term growth strategy is to apply its technology toward the minimally-invasive treatment of indications beyond urological disorders. The Company believes that minimally-invasive treatments could provide an alternative to current invasive therapies on the basis of reduced cost and minimized side effects for a number of different indications. Capitalizing upon its technological expertise in developing minimally-invasive treatments for urological disorders, the Company is developing in collaboration with Siemens an innovative method of destroying localized tumors without damaging surrounding tissue and organs based on HIFU technology. Having initially focused its development efforts in HIFU on the treatment of organ-confined prostate cancer, the Company is expanding the application of HIFU to non-urological indications, such as breast tumors. The Company believes that HIFU could represent an alternative to surgery, radiotherapy, brachytherapy and hormonotherapy for the treatment of organ-confined prostate cancer and to surgery and radiotherapy for the treatment of breast tumors, in both cases without the cost, in-patient hospitalization and adverse side effects associated with those therapies. Based upon the incidence rates and overall healthcare costs for those indications, the Company believes that HIFU technology, if it can be developed commercially, will represent an opportunity to capture a significant share of the market for minimally-invasive treatments for organ-confined prostate cancer and breast tumors. See "Product Overview—High-Intensity Focused Ultrasound."

Collaborative Partners

In February 1998, the Company entered into a cooperation agreement with Bard for the co-marketing and sale of the Prostatron in the United States. Bard is a leading provider of urological diagnostic and interventional devices in the United States, with a focus on urological drainage, endourology, continence and prostate disease management. The cooperation with Bard provides the Company with access to Bard's existing customer base ranging across all market segments from large hospitals and urology clinics to individual urologists. In October 1999, the cooperation agreement with Bard, under which Bard acted as exclusive agent for the marketing and sale of the Prostatron and its disposable parts in the United States, was replaced by a new agreement. Pursuant to the new agreement, Bard will continue to market and sell the Prostatron in the United States on behalf of the Company on a

non-exclusive basis. Bard is entitled to receive a commission on any sales of Prostatrons generated by it. In September 1998, the Company and Siemens entered into an agreement for the distribution by the Company in the United States of Siemens' Modularis® and Multiline® lithotripters, both of which have received FDA approval. This distribution agreement was terminated in December 1999.

In January 1997, the Company and Siemens entered into an agreement relating to a joint research and development program for HIFU. This agreement (the "Development Agreement") provides for cooperation between the Company and Siemens on two HIFU research and development programs. One program concerns the Ablatherm, an ultrasound-guided device for the treatment of organ-confined prostate cancer which is in the clinical testing stage in the United States and is available for commercial distribution in the EU. In return for funding 50% of the costs of this program, Siemens was granted a non-exclusive right to market the Ablatherm. The other program relates to the development of a HIFU-based device equipped with a magnetic resonance imaging ("MRI") guidance system for the treatment of breast cancer. The arrangements for the commercial distribution of those products are subject to agreement by the Company and Siemens at a later stage. Any patents resulting from the joint development work will be filed in the name of, and will be owned by, the Company, but Siemens will have a free and perpetual license to use such patents. As of the date hereof, one patent resulting from the joint development work was filed. The results of the non-patented development work under both programs is the jointly owned intellectual property of both parties. See "Product Overview—High Intensity Focused Ultrasound—Product Development Program."

The Company is currently engaged in negotiations with Siemens regarding the costs of the development program for the Ablatherm after year-end 1999. If these negotiations are unsuccessful, Siemens may not continue to fund part of this program.

Siemens also purchased Shares currently representing 11.6% of the Company's share capital and 12.8% of voting rights.

Product Overview

Product	Procedure	Development Stage	Clinical and Regulatory Status
TUMT Devices			
Prostatron	TUMT treatment of BPH	Commercial production	Approved for distribution: United States EU Japan
Prostatron Operating Software			
60-minute protocol	60-minute TUMT treatment of moderate to severe BPH obstruction	Commercial production	Approved for distribution: United States EU Japan
30-minute protocol	30-minute TUMT treatment of BPH	Commercial production	Approved for distribution United States EU
ESWL Devices			

Product	Procedure	Development Stage	Clinical and Regulatory Status
LT02 Lithotripter	Piezo-electric treatment of urinary stones	Commercial Production	Approved for distribution: United States EU Japan
SONOLITH 4000 Lithotripter	Electroconductive treatment of urinary stones	Commercial Production	Approved for distribution: EU Japan
SONOLITH Praktis compact Lithotripter	Electroconductive treatment of urinary stones	Commercial Production	Approved for distribution: EU Japan
HIFU Devices			
Ablatherm	HIFU treatment of organ-confined prostate cancer	Commercial Production	Approved for distribution: EU Request for approval in Japan made in April 2000 Clinical testing ongoing in the United States
MRI-guided HIFU device	HIFU treatment of breast tumors	Prototype	In clinical trials in the EU

The Prostatron

The Prostatron, a medical device using TUMT for the minimally-invasive treatment of BPH, was the first such device to obtain FDA approval. The Prostatron also meets the regulatory requirements for commercial distribution in the EU and Japan. The Prostatron uses microwaves to produce heat in order to destroy a well-defined area of diseased tissue within the prostate without damaging surrounding tissue and organs. The urethral and treatment surface is preserved from damage from excessive heat by conductive cooling produced by water circulating within the applicator. The Prostatron procedure does not require general anesthesia because the energy is precisely directed to the target area, no rigid urethral instrumentation is used and the treatment session is of short duration. With the previous generation of the Prostatron's operating software, the Prostatron procedure takes approximately one hour per patient. The Company has developed a version of the Prostatron's operating software that shortens treatment time to approximately 30 minutes. The new version of the Prostatron's operating software is authorized for commercial distribution in the EU and was approved by the FDA in the United States in April 2000. The Company is currently reviewing the regulatory status of the new version of the Prostatron's operating software in Japan with a view to determining whether it may be made available for commercial distribution in Japan under existing regulatory approvals or whether a new approval must be obtained. The Company is in the process of upgrading the Prostatron's installed base by installing the new 30-minute operating software on Prostatrons located in countries where it may legally do so.

The Prostatron has two principal components, the microwave delivery system and the treatment and control module. The microwave delivery system consists of a disposable urethral catheter and a rectal probe. The urethral catheter is water-cooled and contains a microwave antenna and a fiberoptic thermosensor. The rectal probe contains three additional fiberoptic thermosensors, designed to monitor temperature and give feedback to the control system to prevent damage to the rectal wall. The treatment and control module consists of a microwave generator, a cooling system, a fiberoptic temperature measurement system and a computer which monitors the temperature, power output and safety systems.

The challenge in providing effective microwave therapy relates to producing and maintaining adequately high temperatures in the diseased tissue while at the same time preventing excessive thermal exposure of the urethra and the rectum, as well as the internal and external urinary sphincters, for varying prostate sizes and degrees of BPH severity.

BPH

BPH is a non-cancerous urological condition in which the prostate enlarges and restricts the urethra. The prostate is a walnut-size gland surrounding the male urethra (the channel that carries urine from the bladder out of the body) that is located just below the bladder and adjacent to the rectum. The prostate produces seminal fluid and plays a key role in sperm preservation and transportation. As men reach middle age, the prostate often expands, compressing or impinging upon the urethra, thereby restricting the normal passage of urine. Symptoms associated with BPH, which include frequency of urination during the day and night, stopping and starting of flow during urination, weak flow of urine, sudden urgency to urinate, sensation of incompleteness in emptying of the bladder and difficulty in starting urination, affect the quality of life of millions of sufferers worldwide. BPH can also lead to irreversible bladder or kidney damage.

Evidence of BPH typically begins to appear in men in their 50s, and by age 70, the quality of life of many men is negatively affected by BPH symptoms. Because BPH is an age-related disorder, its incidence increases as the population ages, occurring in approximately 50% of men aged 50 and 80% of those aged 80. The Company believes that the increase in the number of men suffering from BPH is likely, in turn, to bring BPH to the forefront of men's health issues and result in greater public awareness of the disease and its treatments.

According to industry sources, approximately 20 million men are suffering from BPH in the United States. According to industry sources, of those BPH sufferers in the United States seeking treatment, approximately 40% are currently taking oral drugs, while the others seek surgical treatments such as TURP or less-invasive surgical alternatives. Total annual expenditures related to TURP are estimated to be approximately $5 billion in the United States alone.

Levels of BPH severity range from primarily symptomatic patients, through moderately to severely obstructed patients, to patients with complete obstruction. There are principally two methods to evaluate and monitor the severity of BPH conditions. The first method is based on determination of obstruction by measuring the urinary "peak-flow rate," a ratio of the volume of urine voided to duration of voiding expressed in milliliters per second. A second method is based on a qualitative assessment of the symptoms which a patient experiences from BPH, which primarily relate to changes in urination and the impact of BPH on quality of life. Systems for evaluating and monitoring BPH symptom severity include the American Urological Association symptom score, the Madsen symptom score and the international prostate symptom score. See "Product Overview—The Prostatron."

Competing BPH Therapies

The Company estimates that the Prostatron competes not only against TUMT devices manufactured by other companies but against the whole range of surgical and non-surgical BPH therapies. Traditional BPH therapies include "watchful waiting" and surgery. More recently, certain less-invasive techniques have been developed in an attempt to address the complications and side effects of surgery, and drug therapies have also been introduced as an alternative to watchful waiting and surgery. The Company believes, however, that there are still significant unmet needs in the market for BPH treatments, due to the fact that many of the current therapies either are limited in their effectiveness or are associated with undesirable complications and costs.

Watchful Waiting. Historically, many men suffering from mild to moderate symptoms of BPH have elected for watchful waiting instead of active treatment, which the Company believes has been due primarily to a lack of understanding of the disease and limitations of existing therapies. For many BPH sufferers, watchful waiting represents only a temporary option due to the significant impact BPH has on a patient's quality of life. The Company believes that many healthcare payors have encouraged watchful waiting or drug therapy over surgical intervention due in large part to the costs and potential complications of surgical treatments.

Surgical Treatments. Surgical treatments for BPH typically use various means to completely remove the prostatic urethra along with a substantial portion of the diseased tissue within the prostate. The most common surgical procedure for the treatment of BPH is TURP, whereby a rigid scope is inserted into the patient's urethra through which the surgeon passes an electrosurgical loop that is used to remove the urethra and the diseased tissue within the prostate. The TURP procedure requires general or spinal anesthesia and almost always requires post-treatment hospitalization, yet it has been the established standard for treating BPH since the 1940s. The Company believes that the numerous post-operative complications associated with TURP deter many prospective patients. This has led to a decline in the number of TURPs performed in the United States from an estimated total of 500,000 per year in the early 1990s to an estimated total of 140,000 in 1998, as drug therapy and less-invasive and minimally-invasive treatments for BPH have become available. The growth in the number of patients undergoing drug therapies despite their limited effectiveness also indicates that an increasing number of BPH patients are looking for less invasive and less risky alternatives to surgery. While clinical studies have shown TURP to be effective, a significant number of patients experience serious complications. Virtually all patients experience a burning sensation upon urination that lasts for up to three weeks following the procedure. Other complications include retrograde ejaculation (the reverse flow of semen), infection, impotence, excessive hemorrhaging requiring transfusion or immediate surgery, total urinary incontinence, urethral stricture (resulting in a complete inability to urinate) and the TURP syndrome (resulting in mental confusion, nausea, visual disturbance and cardiac arrythmias). The incidence of those complications, as well as treatment outcome, depend to a large extent on the experience of the surgeon performing the TURP. Another surgical technique is open surgery, or adenomectomy, where the entire prostate gland is removed. It is performed mainly in EU countries, is limited to large prostates (usually over 60g) and requires general anesthesia and an average hospital stay of nine days.

Less Invasive Surgical BPH Treatments. Certain less-invasive surgical BPH treatments have been developed in an attempt to address the complications and side effects of TURP. The five most prevalent procedures are: (i) TUIP; (ii) TVP; (iii) laser assisted prostatectomy; (iv) interstitial laser coagulation therapy ("ILC"); and (v) radio frequency therapy ("RF").

TUIP is a surgical procedure performed under general or spinal anesthesia, whereby a surgical cutting tool is passed through a cystoscope in the urethra to make one or two incisions in the prostatic urethra near the bladder neck, thereby reducing urethral obstruction. TVP is a surgical procedure performed under general or spinal anesthesia, similar to a TURP, except that the electrosurgical cutting tool is a cylinder (roller ball) rather than a loop. Laser assisted prostatectomy includes two similar procedures: visual laser removal, or ablation, of the prostate ("V-LAP") and contact laser ablation of the prostate ("C-LAP"), in which a laser fiber catheter is guided through a cystoscope and used to remove and coagulate the prostatic urethra and prostatic tissue. While the first clinical studies suggest that these alternative surgical treatments are effective in reducing some side effects associated with a TURP, such as reduced risk of blood loss, they still remove the urethra, require general or regional anesthesia and are performed in an operating room. In addition, these procedures are still at an early clinical stage and further studies are required for a full assessment of their results. ILC and RF present certain common features. In those procedures, a rigid scope is inserted into the patient's urethra and either needle electrodes or laser fibers pierce the urethra and are advanced into the lobes of the prostate. RF or laser energy is delivered, destroying surrounding tissue. As with TURP, the incidence of the complications resulting from the procedure, as well as treatment outcome, depend to a large extent on the experience of the surgeon performing the procedure. These procedures are designed to be performed using local anesthesia. One device based on ILC for the treatment of BPH, the Indigo laser, has received 510(k) clearance from the FDA for marketing in the United States. The TUNA device from VidaMed, Inc., which is an RF device, has also received 510(k) clearance. U.S. Surgical has started clinical studies for an RF device for the treatment of BPH. See "Government Regulation—Healthcare Regulation in the United States."

HIFU technology has also been applied to the treatment of BPH. Focus Surgery has developed and manufactures the Sonablate SB-200™, a HIFU-based device for the treatment of BPH which is authorized for commercial distribution in the EU and Japan. Based on its experience with HIFU systems, the Company believes that the relationship of effectiveness to side effects using HIFU technology is not optimal for the treatment of BPH. See "Product Overview—High-Intensity Focused Ultrasound."

Drug Therapy. Drug therapy for the treatment of symptomatic BPH has been available in the EU since 1988, in Japan since 1989 and in the United States since 1992, and has grown significantly since. The Company

believes the increasing acceptance of drug therapy in the United States in the period since FDA approval is due to extensive drug company marketing resulting in increased consumer awareness and the desire of consumers for effective treatments which have less severe complications and side effects than currently available surgical procedures. The Company believes that drug therapy has had a similar incidence on BPH treatment patterns in the EU. Drug therapy may require daily administration for the duration of the patient's life. Drug therapy has long-term side effects which, although less significant than those associated with surgery, include impotence and decreased libido, dizziness, headache and asthenia. Although drug therapy for BPH is used by millions of patients and has expanded significantly in recent years, its effect is not curative. Consequently, patients often require more definitive treatment, sometimes after only one year of drug therapy.

Competing TUMT Treatments

A number of companies are developing competing TUMT systems for the treatment of symptomatic BPH, including Urologix, BSD, Dornier, Bruker, Olympus and Prostalund. The Targis® System manufactured by Urologix and Dornier's UroWave® obtained FDA approval in August 1997 and May 1998, respectively. However, in January 1999, the Company obtained a permanent injunction against Dornier, preventing it from making, using, offering to sell or selling the UroWave in the United States. See "Patents and Intellectual Property." Prostalund has obtained an Investigational Device Exemption ("IDE") from the FDA, permitting it to undertake clinical trials in the United States. The Company is not aware of any other FDA filings for TUMT devices.

In the market for TUMT treatments, the Company competes on the basis of a number of factors, including: (i) the cost-effectiveness of the procedure and its ability to provide effective and lasting treatment while limiting side effects; (ii) physician and patient acceptance; and (iii) third party reimbursement policies. An important factor in the market for TUMT treatments is the timing of the commercialization of competitive products. The speed with which the Company can develop products, complete clinical testing and regulatory approval processes and obtain reimbursement acceptance is a critical factor in such timing. Competition in the market for TUMT treatments is intense. Increased competition has subjected the selling price of the Prostatron to downward pressure in the past few years, and the Company expects this trend to continue in the future. See "Risk Factors—Competition and Technological Advances" and Item 9, "Management's Discussion and Analysis of Financial Condition and Results of Operations."

Marketing Strategy

The Company's marketing strategy focuses on developing usage of the Prostatron installed base and broadening the Prostatron customer base. The Company's strategy to increase usage of the Prostatron installed base is to provide increased customer assistance, such as technical support, assistance in obtaining reimbursement for treatments from Medicare and private insurance carriers, and assistance in communicating with potential patients via advertising. In addition, the Company will attempt to increase its penetration of its traditional customer market segment, which is comprised of larger hospitals and urology clinics and research institutions, while also broadening its customer base to include the market segment of the smaller hospitals and mobile providers and increasing its marketing effort vis-à-vis individual urologists.

In an effort to target smaller hospitals and urology clinics and individual urologists, the Company implemented in 1999 a new marketing strategy for the Prostatron in the United States. Under this new strategy, the Company focuses on expanding the leasing of the Prostatron to smaller hospitals and urology clinics and individual urologists, which often are unable or reluctant to make the significant investment of purchasing Prostatrons due to limited financial resources or a relatively small number of BPH patients, either by selling Prostatron units to a third-party financial institution specializing in leasing capital goods equipment which in turn leases the units to end-users on a cost-per-procedure basis (a "financing lease") or by leasing Prostatron units directly to end-users on a cost-per-procedure basis (an "operating lease"). In a financing lease, the lessee has the option to purchase from the financial institution the leased equipment at a nominal price at the end of the lease term, but the Company is under no obligation vis-à-vis that institution or the lessee to repurchase the equipment. In an operating lease, the Company places the equipment with an end-user and retains title to the equipment. The end-user pays the Company a "per procedure" fee, which includes the costs of disposable parts supplied to the end-user and a component reflecting the depreciation cost with respect to the equipment.

In an effort to target smaller hospitals and urology clinics, the Company is also providing the Prostatron for treatment on a mobile basis in the United States. In a mobile configuration, the Prostatron is installed on a truck and transported from one site to another, making the treatment available to patients at different sites on a rotating basis and, as a result, permitting smaller hospitals and urology clinics to have more cost-effective access to the Prostatron procedure. The Company has sold mobile Prostatron units to a range of providers of mobile services and intends to continue to exploit opportunities to do so in the future. The Company believes that due to the advent of more stringent healthcare cost control policies in developed countries, the number of non-surgical procedures not requiring a hospital environment that are performed by individual urologists and smaller urology clinics will grow in the next two to three years, to the extent third-party reimbursement can be obtained for such procedures.

The Company is subject to certain limitations on the use of the Prostatron in the United States that result from the regulations applicable to the use of radio-frequency bands. Those limitations could have an adverse impact on the marketing of the Prostatron in the United States as an office-based procedure, for which mobility and compactness of the device are critical. See "Government Regulation—Regulation of Radio-Frequency Bands."

The current price of the Prostatron in the markets in which it is sold ranges from $150,000 to $250,000, depending on the model, while the price of its catheters depends on volumes purchased.

Extra-Corporeal Shockwave Lithotripsy

EDAP TMS also manufactures and distributes ESWL lithotripters, and had an installed base of 365 ESWL lithotripters worldwide as of December 31, 1999. The Company currently markets and sells three models of ESWL lithotripters: the LT02, which uses piezo-electric technology, and the SONOLITH 4000 and SONOLITH Praktis, both of which use electroconductive technology. Based on information obtained from its distributors, the Company believes that it has the third largest installed base of ESWL lithotripters worldwide. As of December 31, 1999, the EU, Japan and the United States accounted for 30%, 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. The consequences of 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 about 15 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 (treating less than 200 patients per year) and hospitals in developing countries. The Company believes that after a period of fast growth in the mid-1980s, the market for lithotripters in developed countries is now mature and has become primarily a replacement and maintenance market. In developing countries, the Company believes that despite recent economic difficulties in certain emerging markets, the market for lithotripters still offers growth potential, but demand in public hospitals is driven primarily by the availability of subsidies and government-sponsored export credits.

The Company believes that in developed countries, 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 in developed countries 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. The Company also intends to continue to exploit opportunities to sell new ESWL lithotripters in developing countries, particularly in Asia. See Item 9, "Management's Discussion and Analysis of Financial Condition and Results of Operations."

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 4000 and the SONOLITH Praktis 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 has developed a compact electroconductive lithotripter designed for smaller clinics, the SONOLITH Praktis.

Marketing Strategy

The Company believes that physicians accustomed to using a certain type of technology will select a replacement machine based on a similar technology. Consequently, in the EU and Japan, where both types of lithotripter are used, the Company is marketing both the SONOLITH 4000 and the LT02. In addition, in the EU and Japan, the Company markets the SONOLITH Praktis, which is intended to increase the Company's penetration of the market segment of smaller hospitals and outpatient clinics. Although the LT02 is approved for commercial distribution in the United States, the Company is not currently marketing it there.

The disposable parts of the Company's lithotripters include the piezo-electric elements of the LT02 and the electrodes of the SONOLITH 4000 and the SONOLITH Praktis, which need to be replaced approximately every year and approximately every 10 treatments, respectively. Such 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 9, "Management's Discussion and Analysis of Financial Condition and Results of Operations." The Company's major competitors in developed countries are Dornier, Siemens and Storz.

Regulatory Status

The Company received FDA approval of the LT02 in the United States in December 1996 but is not currently marketing the LT02 in the United States. Although an IDE for the SONOLITH 4000, which permits the Company to undertake clinical trials in the United States, was granted by the FDA in June 1996, the Company is not currently conducting any such trials. The SONOLITH 4000, the SONOLITH Praktis and the LT02 are available for commercial distribution in the EU 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 and to continue to develop more compact products.

High-Intensity Focused Ultrasound

The Company is engaged in the development of medical devices based on HIFU for the minimally-invasive treatment of urological and other indications. The Company and Siemens have established a framework for the joint development of two devices based on HIFU. One program concerns the Ablatherm, an ultrasound-guided device for

the treatment of organ-confined prostate cancer. The Company has received approval for commercial distribution of the Ablatherm in the EU and is conducting clinical trials of the Ablatherm in the United States. The other program relates to the development of an MRI-guided device for the treatment of breast tumors.

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. Consequently, many procedures currently requiring a hospital stay could be performed on an outpatient basis without the need for anesthesia.

While most of its HIFU research and development activities have been performed in-house, the Company has entered into collaborative arrangements with the French National Health Research Institute *(Institut National des Sciences et de la Recherche Médicale* ("INSERM")) principally with respect to fundamental research in acoustics. In exchange for its research services, INSERM will receive royalties on any sales of HIFU devices by the Company. The collaboration with INSERM provides the Company with access to INSERM's extensive research and development resources.

Product Development Program

Under the Development Agreement, the Company and Siemens collaborate on two HIFU research and development programs and share the costs of both programs.

One program concerns the Ablatherm. The Company is actively pursuing the development of the Ablatherm with a view to completing the clinical trials ongoing in the United States and obtaining the necessary approvals initially in Japan and later in the United States.

The second joint HIFU product development program between the Company and Siemens concerns a device equipped with an MRI guidance system primarily for breast cancer. Siemens was primarily responsible for developing a prototype of such device and the Company was involved in the determination of specification requirements. The Company is primarily responsible for performing and organizing animal and clinical trials, which began in the EU in 1999 in collaboration with the *Deutsches Krebsforschungscentrum* (the "DKFZ"), the German center for cancer research.

Any patents resulting from the joint development work will be filed in the name of, and will be owned by, the Company, but Siemens will have a free and perpetual license to use such patents. Both parties will share the costs of the filing of any such patents. Subject to certain conditions relating to prior notice and approval, the parties will also share the costs, as well as any benefits, of any legal action taken by the Company to protect the intellectual property covered by such patents. As of the date hereof, one patent resulting from the joint development work with respect to the Ablatherm was filed. The results of the non-patented development work under both programs is the jointly-owned intellectual property of both parties, except to the extent that they arise out of intellectual property of one party predating the Development Agreement. See "Collaborative Partners."

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 210,000 new cases of prostate cancer were diagnosed in 1998. A new, more effective diagnostic method for prostate cancer, the "PSA test," was recently introduced and there is growing public awareness of the disease in developed countries. 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.

Breast tumors are a very common condition among women. The number of new cases diagnosed is expected to increase, due primarily to early detection policies. The Company believes that HIFU therapy has the potential initially to complement the standard treatment for malignant breast tumors, i.e., radiotherapy or surgery and to become the treatment of choice for small tumors at a later stage. 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, bladder, liver, brain, pancreatic and retroperitoneal tumors.

Clinical and Regulatory Status

The Company received a CE Marking for the Ablatherm in June 1999. In April 2000, the Company also applied for an approval by the Japanese Minister of Health for the Ablatherm.

Clinical trials for the Ablatherm are ongoing at three sites in the United States, in collaboration with Georgetown University, Baylor University and the University of California at San Francisco. The costs of these trials are shared by the Company and Siemens under the Development Agreement and have been agreed to with respect to costs through year-end 1999. The Company is currently engaged in negotiations with Siemens regarding the costs of these trials after year-end 1999. If these negotiations are unsuccessful, Siemens may not continue to fund part of the Ablatherm development program.

Early clinical results indicate that HIFU can destroy internal localized tumors. In addition, the treatment presents several advantages over other therapies, as it is minimally invasive, requires only a short hospital stay, can be easily repeated and does not prevent other, more invasive, forms of treatment to be applied in case of failure. However, follow-up over a longer period of time and on a larger patient population will be required to determine the long-term effectiveness of the HIFU procedure. There can be no assurance that equivalent results will be achieved over a longer follow-up period or on a larger patient population or that the results of clinical trials will be sufficient to obtain required United States or foreign regulatory approvals or physician acceptance of the HIFU procedure.

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. Other therapies for prostate cancer include brachytherapy, a therapy that involves the implantation of radioisotopes into the prostate gland, external beam radiotherapy, cryotherapy and hormonotherapy.

The primary current therapy for breast tumors is surgery, in association with radiotherapy and chemotherapy for malignant breast tumors. Those therapies also carry side effects that can seriously affect a patient's quality of life.

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 in addition to the Company and Siemens, including General Electric, Toshiba and Storz. See "—The Prostatron—Competing BPH Therapies." 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.

Third-Party Reimbursement

The Company believes that third-party reimbursement is essential to physician and patient acceptance of its products. In the United States, most medical procedures are reimbursed by a variety of third-party payors, including Medicare and private insurers. HCFA, the regulatory agency that manages the Medicare public healthcare program, may establish national coverage policies for Medicare carriers. Alternatively, if HCFA has set no policy with respect to a given procedure, local Medicare carriers determine whether to reimburse that procedure, and if so, in what amount. Private third-party healthcare payors in the United States usually base their reimbursement policies on HCFA's decisions and also on their own investigation of the cost-effectiveness and safety of such procedures.

Outside the United States, reimbursement approvals must be sought on an individual country basis, including in the EU, where to date there is no single procedure for obtaining third-party reimbursement. The main types of reimbursement systems in those markets are government-sponsored healthcare and private insurance. Most EU member States have government-sponsored healthcare systems. In some EU member States, such as the United Kingdom, Norway and Sweden, the costs of medical procedures accepted for reimbursement by the public healthcare system are borne directly by hospitals. New devices are brought into the system through negotiations between departments at individual hospitals at the time of budgeting. In others, such as France, costs are borne in whole or in part by the patient, who is reimbursed in whole or in part through the public healthcare system. Supplemental insurers may provide additional reimbursement when a fraction of the costs only is covered by the public healthcare system.

In the United States, the Prostatron obtained a reimbursement code (CPT) from the American Medical Association in September 1996. The new code became effective in January 1998. In April 2000, HCFA set a national policy with respect to the Prostatron, which will become effective on July 1, 2000. In the meantime, the procedure is being reimbursed by local Medicare carriers (based on written guidelines or on a case-by-case basis) in all States and the District of Columbia. Many private healthcare providers throughout the United States are also reimbursing the procedure. In Japan, TUMT was approved for third-party reimbursement by the Ministry of Health and Welfare ("MHW") in 1996. In the EU, there is no blanket reimbursement policy for the Prostatron in any member State, with the exception of Italy. Reimbursement can currently be obtained from certain private insurers in Germany. In France, the Prostatron procedure is currently not reimbursed. However, the French Urological Association *(Association Française d'Urologie)* submitted a report on TUMT to the French National Health Insurance Agency *(Caisse Nationale d'Assurance Maladie*, or "CNAM") in early 1998, and the CNAM has appointed an investigator to evaluate the cost-effectiveness of the procedure. Reimbursement approval by the CNAM is effective throughout the French public healthcare system and is necessary for any additional reimbursement by supplemental insurers. In Italy, the Ministry of Health has included TUMT in a category of treatments for BPH which are approved for reimbursement subject to a maximum amount. Each region sets its own limit for reimbursement, which may be lower, although not higher, than that approved by the Ministry of Health. However, the Italian healthcare system is currently in transition toward a partially hospital-based system, under which reimbursement levels will vary from hospital to hospital. In the United Kingdom, the Prostatron procedure is made available in two hospitals belonging to the National Health Service. BUPA, the leading private healthcare carrier in the United Kingdom, is currently reimbursing the TUMT procedure. In Norway, Denmark and Sweden, public hospitals routinely perform TUMT procedures and include the costs of such procedures within their overall budgets. In the Netherlands, the Ministry of Health is currently evaluating the procedure in order to determine whether it should be approved for reimbursement. There is no reimbursement policy for the Prostatron in any other EU member State.

Lithotripsy has been approved for reimbursement by both public and private healthcare payors in the United States, the EU and Japan for the treatment of calculi located in the kidney and upper and middle urinary tract.

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, the United States, Japan, Italy, South Korea and Malaysia and markets its products through agents and third-party distributors in several countries. The Company has entered into certain arrangements with Bard for the marketing and sale of the Prostatron. See "Product Overview—The Prostatron—Marketing Strategy."

In September 1998, the Company and Siemens entered into an agreement for the distribution by the Company in the United States of Siemens' Modularis and Multiline lithotripters. See "Collaborative Partners." This agreement was terminated in December 1999.

The Company's customers are located worldwide and have historically been principally large hospitals, urology clinics and research institutions. 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. The programs extend over two days and, in the United States, have been approved by the FDA.

Patents and Intellectual Property

The Prostatron

The Company holds significant proprietary rights in a number of key technologies with respect to the Prostatron. The Company has obtained six patents in the United States, five in the EU and one in Japan concerning such technologies. The Company has applied for additional patent coverage in Europe, Canada and Japan. The main patents in the United States, the EU and Japan protect the Company's Prostatron technology relating to the urethral probe incorporating an antenna and a cooling device, which the Company believes is critical to the safe and effective operation of a TUMT device. See "Product Overview—The Prostatron."

In January 1999, the United States District Court for the District of Eastern Wisconsin granted a permanent injunction against Dornier, pursuant to which Dornier is forbidden to make, use, offer to sell or sell its UroWave TUMT device in the United States. The Company and Dornier also entered into a settlement agreement, in which Dornier agreed to respect the terms of the injunction and undertook to pay the Company's legal fees.

The Company was recently involved in unsuccessful legal proceedings in France to defend certain of its patents for the Prostatron. In 1992, the Company sued Bruker in the French courts for infringement of its French patent concerning its urethral probe technology and lost. Bruker's defense was based on prior art relating to a rectal probe incorporating a cooling system and a microwave generator. In 1994 and 1996, the Company was awarded additional patents with respect to that technology in the EU, Japan and the United States and, on the basis of those rulings, appealed the 1992 judgment in the French courts. In October 1997, the Paris Court of Appeals confirmed the 1992 judgment in favor of Bruker. The Court of Appeals invalidated the Company's French patent and ordered the Company to pay ε 30,500 of damages and legal costs and expenses. Based on the advice of its intellectual property counsel, the Company believes that it may rely on its EU patent, the scope of which includes its urethral probe technology, to enforce its intellectual property rights with respect to that technology in EU member States other than France.

The Company was awarded an EU patent covering Prostatron-related technology in November 1995. Oppositions were filed by a number of competitors. In December 1999, the patent was revoked by the European patent office. At the time of the filing of the EU patent, the Company had also filed additional patent applications with the European patent office that included a more restrictive definition of the claims at issue and their potential application (referred to as "divisional applications"). The European patent office is currently reviewing these divisional applications. Based on the advice of its intellectual property counsel, the Company believes that these divisional applications, if granted, will give the Company a basis to enforce its intellectual property rights in the Prostatron technology covered by the recently revoked EU patent.

In July 1996, the Company and Urologix agreed to settle a dispute concerning the Company's claim that Urologix's Targis System infringed one of the Company's patents relating to the Prostatron's technology. As part of that settlement, the Company granted to Urologix a non-exclusive license to use certain elements of the technology covered by the patent at issue. In July 1996, the Company also granted a non-exclusive license for the same patent to another competitor of the Company, Boston Scientific. Those license agreements are expected to provide

ongoing royalty income to the Company and, the Company believes, indicate industry recognition of the value of the Company's proprietary methods and devices.

BSD holds a U.S. patent which is relevant to certain aspects of the Prostatron's technology. BSD entered into an agreement for the non-exclusive license of such patent to the Company and the Company pays royalties to BSD in connection therewith.

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 4000 and the SONOLITH Praktis. 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.

HIFU

As of December 31, 1999, the Company had obtained 47 patents covering key technologies relating to HIFU systems and associated software capabilities (including 23 in the United States, 19 in the EU and Japan and 1 in Israel), and has recently applied for additional patents covering certain other aspects of its HIFU technology in the EU, 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. See "Risk Factors—Patents, Licenses and Proprietary Technologies."

Manufacturing

The Company's policy is to subcontract the manufacture of the majority of the components for its machines, 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. The only components that the Company manufactures itself are piezo-electric elements for the LT02 lithotripter and Prostatron probes.

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 EU standards for quality assurance 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 EU."

Government Regulation

Government regulation in the Company's major markets, in particular the United States, the EU 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. Additionally, the Company is subject to certain FCC regulations concerning the use of radio-frequency bands.

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 approval of a PMA by the FDA to ensure their safety and effectiveness. 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 approval of an IDE from the FDA prior to commencing human clinical trials in the United States in support of the PMA.

Advertising and promotional activities in the United States are subject to regulation by the FDA and, in certain instances, by the Federal Trade Commission. The FDC Act also regulates the Company's quality control and manufacturing procedures by requiring the Company to demonstrate and maintain compliance with current GMP regulations. The Company's manufacturing facilities are in compliance with GMP regulations.

Healthcare Regulation in the EU

In the EU, 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 EU, the Company's products are also subject to legislation implementing the EU 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 EU have to comply with the requirement to bear a CE Marking (subject to certain exceptions). The Prostatron and the Prostatron Praktis, the SONOLITH 4000 and the SONOLITH Praktis, the LT02 and the Ablatherm 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 Prostatron, the LT02, the SONOLITH 4000 and the SONOLITH Praktis are all included on the MHW's list for reimbursement.

Regulation of Radio-Frequency Bands

The Prostatron is subject to the regulations governing the allocation of radio-frequency bands as it uses radio-frequency energy and therefore emits radio waves. The allocation of radio-frequency bandwidths to specific categories of users is regulated at the international level by the Radio Regulations (the "Radio Regulations") established within the International Telecommunication Union and adopted by the World Radio Administrative Conferences. The Radio Regulations are completed by regulations adopted at the national level by national telecommunications administrations. Under the Radio Regulations, the world is divided into three regions for purposes of the allocation of radio-frequency bandwidths. Region 1 includes Europe, the former USSR and Africa. Region 2 is comprised of the American continent and Region 3 includes Asia and Australasia. The radio-frequency band used by the Prostatron is 1296 MHz. The 1260-1300 MHz bandwidth is allocated, in order of priority, to radiolocation and amateur radio services in the three Regions. Under the Radio Regulations, scientific and medical equipment may operate outside the bandwidth designated for use by this equipment, provided that telecommunications administrations may take steps to prevent radiation from such equipment causing harmful interference to other services. No limitations restricting the use of the Prostatron have currently been imposed in Regions 1 and 3. By contrast, in the United States, users of the 1260-1300 MHz bandwidth other than those to whom it has been allocated in priority are prohibited by the FCC from exceeding a 24dB limit on noise emission. Measured at their source, Prostatrons exceed the 24 dB limit. In a number of cases, however, Prostatrons are installed in environments (such as large hospitals) which prevent the 24 dB noise limit from being exceeded. In 1995, the Company requested a waiver from the FCC, which would have allowed the Prostatron to exceed the legal noise limit. This request was rejected in 1998. The FCC has, however, authorized the Company to continue its current practice, which consists of testing the noise emission of each newly-installed Prostatron and electronically shielding only those machines which are found to exceed the legal noise limit. Although the tests are inexpensive to perform, the necessity of electronically shielding some Prostatrons may have an adverse impact on the marketing of the Prostatron in the United States as an office-based device, for which mobility and compactness of the device are critical. See "Risk Factors—Government Regulation."

Product Liability and Insurance

The business of the Company entails the risk of product liability claims. To date the Company has only experienced one such claim, in an action brought against the Company and other parties by a patient claiming to have been injured in the course of the Prostatron procedure. The Company believes based on advice from counsel that the patient's claim against the Company is without merit. In addition, if the claim against the Company is successful, the Company believes any potential damages assessed against it would be covered by insurance and/or by a contribution obligation of the doctor who provided services with the product. However, product liability could have a material adverse impact on the Company. The Company maintains separate product liability insurance policies for the United States and the rest of the world, with coverage in an annual aggregate maximum amount of $10 million and FF 40 million, respectively. The Company evaluates its insurance requirements on an ongoing basis.

Employees

As of March 31, 2000, the Company employed 160 individuals on a full-time basis, of whom 40 were employed in sales and marketing, 38 in manufacturing, 36 in services, 20 in research and development and 26 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. Management considers labor relations to be good. Employee benefits are in line with those specified by applicable government regulations.

Item 2. ***Description of Property***

The Company has one principal facility, which is located in Vaulx-en-Velin, on the outskirts of Lyons, 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 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 Lyons, 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 3. ***Legal Proceedings***

The Company's policy is to vigorously defend its patents and other intellectual property. A description of certain legal actions regarding the products is given in Item 1, "Description of Business—Patents and Intellectual Property" and "—Product Liability and Insurance."

The Company was involved in a dispute with the French tax authorities regarding the tax treatment by the Company of a ε 0.6 million royalty payment made to the Company. In 1999, the Administrative Court of Appeals reversed the decision of the administrative tribunal, which in the first instance had entered judgment against the Company, and ordered the repayment to the Company of the ε 0.7 million (representing the full amount of the claim plus interest to the date of payment) which the Company had paid in court following the decision in the first instance.

Item 4. ***Control of Registrant***

To the Company's knowledge, it is not directly or indirectly owned or controlled by another corporation or by any foreign government. At December 31, 1999, to the Company's knowledge, the following persons had beneficial ownership of more than 10% of the Shares: Heartland Advisors, Inc., which owned 1,364,100 ADSs, representing 15.7% of the total share capital of the Company and 17.5% of voting rights, Siemens S.A., which owned 1,003,250 Shares, representing 11.6% of the total share capital of the Company and 12.8% of voting rights, and Benson Associates LLC, which owned 990,100 ADSs, representing 11.4% of the total share capital of the Company and 12.7% of voting rights.

At December 31, 1999, the number of Shares owned by all directors and officers of the Company as a group was 377,875, representing 4.5% of the total share capital of the Company (excluding 83,965 treasury Shares which may be purchased upon exercise of options exercisable within 60 days by all directors and officers as a group, but as to which they disclaim beneficial ownership).

Item 5. ***Nature of Trading Market***

The Shares are traded solely in the form of ADSs, each ADS representing one Share. Each ADSs 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 were quoted initially under the symbol "EDAPY." The principal non-United States trading market for the ADSs is the European Association of Securities Dealers Automated Quotation System ("EASDAQ"), on which the ADSs are quoted under the symbol "EDAP."

On December 22, 1999, the Company announced its intention to proceed with the restatement of its consolidated financial statements for the year 1998, the three-month periods ended March 31, June 30 and September 30, 1999, the six-month period ended June 30, 1999 and the nine-month period ended September 30, 1999. See Item 9A, "Management's Discussion and Analysis of Financial Condition and Results of Operations—Restatement of the Company's Financial Statements." Following that announcement, Nasdaq notified the Company that it no longer met the requirements for the continued listing of the ADSs on Nasdaq due to non-compliance with Rule 4320(e)(12) of the Marketplace Rules of the National Association of Securities Dealers, Inc. (the "NASD") and that the ADSs would be delisted from Nasdaq unless it filed an amended report on Form 20-F/A for the year 1998 with the Commission by January 3, 2000. Rule 4320(e)(12) requires foreign issuers of securities listed on Nasdaq to file with the NASD copies of the documents and reports filed with the Commission. Effective on January 4, 2000, Nasdaq also changed the symbol under which the ADSs are quoted from "EDAPY" to "EDAYE" to reflect the Company's non-compliance with Nasdaq's continued listing requirements. On December 31, 1999, the Company requested a hearing to review Nasdaq's determination to delist the ADSs. The request for a hearing suspended the delisting of the ADSs. A hearing was held on February 11, 2000. On March 29, 2000, Nasdaq notified the Company that it had determined to continue the listing of the ADSs on the condition that the Company files publicly an amended report on Form 20-F/A including an unqualified audit opinion by March 31, 2000 and that the Company files publicly unaudited restated consolidated financial statements for the three months ended March 31, June 30 and September 30, 1999, for the six months ended June 30, 1999 and for the nine months ended September 30, 1999 by April 14, 2000. Nasdaq also required that the Company provide a detailed status update on its investigation of the original recording of revenue by April 14, 2000. Nasdaq stated that the Company must be able to demonstrate compliance with all requirements for continued listing on The Nasdaq Stock Market. Nasdaq stated that it would review the amended annual report on Form 20-F/A and the other requested materials and expressly reserved the right to reverse or modify its determination to continue the listing of the ADSs. An amended report on Form 20-F/A was filed with the Commission and Nasdaq on March 31, 2000. On April 12, 2000, the Company also filed unaudited restated financial statements for the three months ended March 31, June 30 and September 30 1999, for the six months ended June 30 1999 and for the nine months ended September 30, 1999 with the Commission and Nasdaq. The Company also provided Nasdaq with a detailed update on its investigations as required by April 14, 2000. While to date the Company has filed in a timely manner all the materials required to be filed by Nasdaq as a condition to the continued listing of the ADSs on Nasdaq, and such listing has been provisionally continued, Nasdaq is currently reviewing these materials and as of the date of this Annual Report has not notified the Company of its final decision in this matter. In the event that Nasdaq delists the ADSs, there would likely be a material adverse effect on the marketability and price of the ADSs. The Company is not aware of any effort by EASDAQ to delist the ADSs.

The following tables set forth, for the periods indicated, the reported high and low sales prices of the ADSs on Nasdaq and EASDAQ:

	Nasdaq	
	High	**Low**
	(in dollars)	
1998		
First Quarter	7.25	5.13
Second Quarter	7.00	4.50
Third Quarter	5.00	2.00
Fourth Quarter	2.88	1.31
1999		
First Quarter	2.66	0.88
Second Quarter	2.03	1.13
Third Quarter	2.31	1.63
Fourth Quarter	1.94	0.63
2000		
First Quarter (through April 20, 2000)	3.13	1.13

	EASDAQ	
	High	Low
	(in dollars)	
1998		
First Quarter	7.25	5.63
Second Quarter	7.00	4.94
Third Quarter	4.75	2.31
Fourth Quarter	2.13	1.44
1999		
First Quarter	2.38	1.30
Second Quarter	1.83	1.32
Third Quarter	2.13	1.63
Fourth Quarter	1.90	1.05
2000		
First Quarter (through April 20, 2000)	3.03	1.10

At April 20, 2000, 8,315,400 Shares were issued, including 7,784,850 outstanding shares and 530,550 treasury shares. At the same date, there were outstanding 6,439,598 ADSs, each representing one Share, all of which were held of record by 15 holders in the United States (including The Depositary Trust Company).

Since certain of the ADSs are held by brokers or other nominees (including The Depository Trust Company), the number of direct record holders in the United States may not be fully indicative of the number of direct beneficial owners in the United States or of where the direct beneficial owners of such shares are resident.

Item 6. ***Exchange Controls and Other Limitations Affecting Security Holders***

Foreign 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.

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).

Form and Holding of Shares

The Company's *statuts* provide that Shares can be held only in registered form. 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 each Shares are registered. Such confirmations do not constitute documents of title and are not negotiable instruments.

Item 7. ***Taxation***

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 French tax laws or in any applicable double taxation conventions or treaties with France occurring after such date.

This discussion is intended only as a descriptive summary and does not purport to be a complete analysis or listing of all potential tax effects of the purchase or the ownership of the Shares or ADSs.

There are currently no procedures available for holders of ADSs or nominee-registered Shares that are not U.S. residents to claim or receive from the French tax authorities any tax treaty benefits in respect of dividends (including payment of the *avoir fiscal* and availability of a reduced withholding tax rate, see "— Taxation of Dividends" below) that a holder may be entitled to receive pursuant to a treaty between France and the Holder's country of residence. Potential purchasers of ADSs, including those who are not U.S. residents, are urged to consult their own tax advisors concerning the consequences of ownership and disposition of ADSs.

Taxation on Sale or Disposition of Shares or ADSs

Subject to more favorable provisions of any relevant double tax treaty, persons who are not French residents for the purposes of French taxation (including, generally, foreign states, international organizations and certain foreign public bodies) and who have held not more than 25% of the dividend rights (*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 any sale or disposition of Shares or ADSs.

The share transfer of a non-listed company is subject to a 1% registration duty assessed on the higher of the purchase price or the market value of the shares (subject to a maximum assessment of ε 3,049 per transfer), no matter whether such transfer is evidenced by a written agreement. If a share transfer of a listed company is evidenced by a written agreement, such share transfer agreement is, in principle, subject to registration formalities and therefore to a 1% registration duty (subject to a maximum assessment of ε 3,049 per transfer). Generally, no such duty is due if the written share transfer agreement is executed outside France. If a share transfer of a listed company is not evidenced by a written agreement, no such duty is due. Although 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. Prospective investors in ADSs should consult their own advisors concerning the applicability of French transfer tax law to the transfer of their ADSs.

Taxation of Dividends on Shares

In France, dividends are paid out of after-tax income. French residents are entitled to a tax credit, known as the *avoir fiscal*. Since January 1, 2000, the rate of the *avoir fiscal* available in respect of dividends paid to companies is generally equal to 40% of the dividend paid and the *avoir fiscal* available in respect to dividends paid to individuals is equal to 50% of the dividend paid. Dividends paid to non-residents normally are subject to a 25% French withholding tax and, under French domestic law, non-residents are not eligible for the benefit of the *avoir fiscal*. 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 taxation, and may be entitled to receive a refund of the *avoir fiscal*, as described below.

France has entered into treaties with the following countries, Territories and *Territoires d'Outre-Mer* under which qualifying residents are entitled to obtain from the French tax authorities a reduction (generally to 15%) of all or part of such withholding tax and a refund of the *avoir fiscal* (net of applicable withholding tax) or, in the case of German tax residents, a tax credit in an amount equal to the amount of the applicable *avoir fiscal* and the amount of

the applicable withholding tax. Treaties with some of the countries or territories listed below contain specific limitations applicable to corporate entities' eligibility to benefit from a refund of the *avoir fiscal*, or limit the rights to such a refund strictly to individual residents (as opposed to corporate entities).

Countries

Australia	Italy	Senegal
Austria	Ivory Coast	Singapore
Belgium	Japan	South Korea
Bolivia	Luxembourg	Spain
Brazil	Malaysia	Sweden
Burkina Faso	Mali	Switzerland
Cameroon	Malta	Togo
Canada	Mauritius	Turkey
Finland	Mexico	Ukraine
Gabon	Namibia	United Kingdom
Ghana	Netherlands	United States of America
Germany	New Zealand	Venezuela
Iceland	Niger	
India	Norway	
Israel	Pakistan	

Territoires d'Outre-Mer and Other

Mayotte
New Caledonia
Saint-Pierre et Miquelon

Dividends paid to non residents of France benefiting from a refund of the *avoir fiscal* in accordance with a tax treaty (other than German residents) will be subject at the time of payment to the withholding tax at the reduced rate provided for by such treaty (subject to certain filing formalities) rather than to the French withholding tax at the rate of 25% to be later reduced to the treaty rate, provided however that they establish their entitlement to such reduced rate before the payment.

Amounts distributed as dividends by French companies out of profits which have not been taxed at the ordinary corporate rate, or which have been earned and taxed more than five (5) years before the distribution, are subject to a payment by such companies of an equalization tax called the *précompte*. The *précompte* is generally equal to one-half of the net dividends before withholding tax. Since January 1, 2000, shareholders entitled to the *avoir fiscal* at a rate of 40% may obtain from the French tax authorities an additional tax credit equal to 20% of the *précompte* actually paid in cash by the French company distributing the dividends. When a tax treaty in force does not provide for a refund of the *avoir fiscal* or when the non-resident investor is not entitled to such refund but otherwise entitled to the benefits of a tax treaty, such investor may obtain from the French tax authorities a refund of the *précompte* actually paid in cash by the company, if any (net of applicable withholding tax).

Estate and Gift Tax

France imposes estate and gift tax on shares of a French company acquired by inheritance or gift from a non-resident of France. 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. Prospective investors in ADSs should consult their own advisors concerning the applicability of French estate and gift tax to their shareholding in the Company and the availability of, and the conditions for claiming exemption under such a treaty.

Wealth Tax

In the absence of a more favorable tax treaty, the French wealth tax (*impôt de solidarité sur la fortune*) does not apply to non-French resident individual investors owning directly or indirectly less than 10% of the Company's share capital.

Taxation of U.S. Investors

The following summary of certain U.S. federal and French tax matters contains a description of the principal U.S. federal and French tax consequences of the purchase, ownership and disposition of Shares or ADSs by Eligible U.S. Holders (as defined below). The summary does not purport to be a comprehensive description of all of the tax considerations that may be relevant to a decision to purchase Shares or ADSs. In particular, the summary deals only with Eligible U.S. Holders that hold Shares or ADSs as capital assets, and does not address the tax considerations relevant to investors that are subject to special tax rules, such as banks, insurance companies, securities dealers, persons that will hold ADRs or Shares as part of an integrated investment (including a "straddle") comprised of a share or ADS and one or more other positions for tax purposes and persons that have a functional currency other than the U.S. Dollar. The 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. For a discussion of French tax matters relating to the holding of Shares or ADSs generally, see "—French Taxation."

The summary is based on the tax laws and practice of the United States and France in effect on the date of this Annual Report, which are subject to change. Prospective investors in Shares or ADSs should consult their own advisers as to the tax consequences of the purchase, ownership and disposition of Shares or ADSs in light of their particular circumstances, including the effect of any state or local tax laws.

The summary uses the term "Eligible U.S. Holders" to refer to beneficial owners of Shares or ADSs who hold directly or indirectly less than 10% of the share capital of the Company and whose ownership of such Shares or ADSs is not effectively connected with a permanent establishment or a fixed base in France, and that are considered residents of the United States for purposes of the income tax convention between the United States and France dated August 31, 1994 (the "Treaty") and are fully entitled to benefits under the Treaty. Owners that are individual citizens or residents of the United States for federal income tax purposes, corporations organized under U.S. law, and partnerships, estates or trusts (to the extent their income is subject to U.S. tax as the income of a U.S. resident either directly or in the hands of partners, beneficiaries or grantors) generally will be considered residents of the United States for purposes of the Treaty. Eligible U.S. Holders also include regulated investment companies (if more than 80% of the shares of such a company are owned by persons who are citizens or residents of the United States). The Treaty provides specific rules with respect to holders not subject to U.S. federal income tax such as certain U.S. pension funds. Special rules apply under the Treaty for purposes of determining the residence of individuals who otherwise would be resident in both jurisdictions.

For purposes of the Treaty and the U.S. Internal Revenue Code of 1986, owners of ADSs will be treated as the owners of the Shares represented by such ADSs.

Taxation of Dividends

French Tax Considerations

Dividends paid to nonresidents of France generally are subject to French withholding tax at a 25% rate and are not eligible for the benefit of the *avoir fiscal*, which is a tax credit to which French resident holders are generally entitled. The *avoir fiscal* generally is equal to 40% of the dividend paid, unless an individual is entitled to use it in which case such *avoir fiscal* is equal to 50% of the dividend paid. Under the Treaty, Eligible U.S. Holders can claim the benefit of a reduced withholding rate of 15%. Eligible U.S. Holders are also entitled to a payment equal to the *avoir fiscal* (*i.e.*, 40% or 50% of the dividend paid, depending on whether the holder is an individual or not), less a 15% withholding tax. Dividends paid to an Eligible U.S. Holder will be subject to the reduced rate of withholding of 15% at the time of payment, provided that the holder establishes 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 the Shares represented by ADSs (including, but not limited to, dividend rights). An Eligible U.S. Holder generally will be entitled to receive a payment of the *avoir fiscal* only if such 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.

Thus, for example, if the Company pays a dividend of 100 to an Eligible U.S. Holder who is an individual and who is subject to U.S. tax (entitled to a refund of the *avoir fiscal* at the rate of 50%), such Eligible U.S. Holder will initially 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 7.5). However, the additional payment will not be made available until after the close of the calendar year in which the dividend was paid.

If the Company pays a dividend of 100 to an Eligible U.S. Holder entitled to a refund of the *avoir fiscal* at the rate of 40%, such Eligible U.S. Holder will be entitled to an additional payment of 34, consisting of the *avoir fiscal* of 40, less a 15% withholding tax on that amount (equal to 6). In the event the distribution by the Company triggers the payment of the *précompte*, the Eligible U.S. Holder may obtain from the French tax authorities an additional tax credit equal to 20% of the *précompte* actually paid in cash by the Company, less a 15% withholding tax. However, these additional payments will not be made available after the close of the calendar year in which the dividend was paid.

Certain U.S. tax-exempt pension funds, entities and arrangements are entitled to a reduced withholding tax rate of 15%, and to a partial refund of the *avoir fiscal* equal to 30/85 of the gross *avoir fiscal*, less 15% withholding tax. For example, if the Company pays a dividend of 100, a U.S. pension fund that complies with the required certification procedures generally would receive an initial payment of 85 and an additional payment in respect of the *avoir fiscal* of 12.

Currently, to claim the reduced rate of French withholding tax, full or partial refund of the *avoir fiscal* and payment of the additional tax credit equal to 20% of the *précompte* actually paid in cash by the Company, an Eligible U.S. Holder must complete and file a French Treasury Form (RF 1A EU-No. 5052 entitled "Application for Refund") (the "Form") before the date of payment of the relevant dividend together with, if such Eligible U.S. Holder is not an individual, an affidavit attesting that it is the owner of all the rights attached to the full ownership of such Shares or ADSs (including but not limited to dividend rights) or, if such holder is not the owner of all such rights, certain information concerning the holder of the rights other than the dividend rights. If such completion of the Form and the attached affidavit is not possible prior to the payment of dividends, the Eligible U.S. Holder may, however, be eligible for the 15% reduced rate of withholding tax, at the time the dividends are paid, for refund of the *avoir fiscal* and for payment of the additional tax credit equal to 20% of the *précompte* actually paid in cash by the Company if he duly and timely completes and provides the French tax authorities prior to the payment of dividends a simplified certificate (the "Certificate"), stating that (i) the Eligible U.S. Holder is a U.S. resident within the meaning of the Treaty; (ii) the Eligible U.S. Holder has no permanent establishment or fixed base in France with which the holding giving rise to the dividend is effectively connected; (iii) the Eligible U.S. Holder owns all the rights attached to the full ownership of the securities or shares, including but not limited to dividend rights; and (iv) the Eligible U.S. Holder meets all the requirements of the Treaty for obtaining the benefit of the reduced rate of withholding tax and the refund of the French *avoir fiscal*. Finally, tax-exempt pension funds with a right to obtain a refund or a partial refund of avoir *fiscal* must also establish that they qualify as pension funds under the U.S. Internal Revenue Code of 1986.

Under the Deposit Agreement (the "Deposit Agreement") dated July 31, 1997 by and among the Company, the Bank of New York, as Depositary (the "Depositary") and the Owners and Beneficial Owners of American Depositary Receipts, the Form, together with instructions, will be provided by the Depositary to any ADR Holder 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 Forms or Certificates completed by Eligible U.S. Holders and returned to the Depositary in time for prompt filing with the French tax authorities. If the Form is not timely filed, such holders may claim a refund of the excess withholding tax and may claim the *avoir fiscal* by filing the Form before December 31 of the year following the year in which the related dividend is paid.

Amounts distributed as dividends by French companies out of profits which have not been taxed at the ordinary corporate income tax rate or which have been earned and taxed more than five years before the distribution are subject to a *précompte* or prepayment by such companies equal to one-half of the net amount distributed. Providing that they meet the filing formalities described above, Eligible U.S. Holders entitled to a refund of the *avoir fiscal* at a rate of 40% may obtain from the French tax authorities an additional tax credit equal to 20% of the *précompte* actually paid in cash by the Company, less a 15% withholding tax. The French tax authorities have not indicated whether holders entitled to a partial refund of the *avoir fiscal* could benefit from this additional tax credit and under which conditions.

Holders not entitled to a refund of the *avoir fiscal* generally may obtain from the French tax authorities a refund of the précompte paid in cash by the Company in respect of the dividends, less a 15% French withholding tax. Holders who are entitled to a partial refund of the avoir *fiscal* (30/85) may obtain from the French tax authorities a refund of the *précompte* paid in cash by the Company in respect of the dividends less the partial refund of the *avoir fiscal*, net of French withholding tax. U.S. holders entitled to the refund of the *précompte* must apply for such refund by filing a French Treasury Form RF 1 B EU-No.5053 before the end of the year following the year in which the dividend was paid. The form, together with instructions, are available from United States Internal Revenue Service or at the *Centre des Impôts des Non-Résidents* (9, rue d'Uzès, 75094 Paris Cedex 2).

U.S. Tax Considerations

The gross amount (that is, before reduction for French withholding tax) of dividends received by an Eligible U.S. Holder generally will be subject to U.S. federal income taxation as foreign source dividend income. *Avoir fiscal* and *précompte* payments will be considered dividends to the same extent. Such dividends will not be eligible for the dividends received deduction allowed to domestic corporations. Dividends paid in French francs will be included in the income of such a holder in a U.S. dollar amount calculated by reference to the exchange rate in effect on the day the dividends are received by the U.S. Holder, in the case of Shares, or by the Custodian, in the case of ADSs. If the dividends paid in French francs are converted into U.S. dollars on the day of receipt, Eligible U.S. Holders generally will not realize foreign currency gain or loss in respect of the amounts so converted. If the dividends paid in French francs are not converted into U.S. dollars on the date of receipt, an Eligible U.S. Holder may realize foreign currency gain or loss on a subsequent conversion or other disposition of the French francs. Eligible U.S. Holders may be required to recognize foreign currency gain or loss upon the receipt of a refund of the excess withholding tax initially withheld from a dividend payment if the refund is converted into U.S. dollars at an exchange rate different than the rate used to translate the holder's dividend income.

French withholding taxes at the 15% Treaty rate will be treated as foreign income taxes that, subject to generally applicable limitations, may be claimed as credits against a holder's U.S. federal income tax liability. Dividends generally will constitute "passive income" or, in the case of certain U.S. holders, "financial services income" for U.S. foreign tax credit purposes. Foreign tax credits generally 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 an Eligible U.S. Holder's expected economic profit, after non-U.S. taxes, is insubstantial. Eligible U.S. Holders should consult their own advisers concerning the implications of these rules in light of their particular circumstances. Alternatively, an Eligible U.S. Holder may elect to deduct all foreign taxes in computing its taxable income, in lieu of taking credits for such taxes.

Distributions of additional Shares to owners with respect to their Shares or ADSs that are made as part of a pro rata distribution to all shareholders of the Company generally will not be subject to U.S. federal income tax.

Taxation of Capital Gains

French Tax Considerations

In general, an Eligible U.S. Holder will not be subject to French tax on any capital 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.

U.S. Tax Considerations

Gain or loss realized by an Eligible U.S. Holder on the sale or other disposition of Shares or ADSs will be subject to U.S. federal income taxation as capital gain or loss in an amount equal to the difference between such Holder's basis in the Shares or the ADSs and the amount realized on the disposition (or its U.S. dollar equivalent, determined at the spot rate on the date of disposition, if the amount realized is denominated in a foreign currency). Such gain or loss realized by an Eligible U.S. Holder generally will be long-term capital gain or loss if, at the time of the disposition, the shares of common stock have been held for more than one year. Long-term capital gain realized by an individual Eligible U.S. Holder generally is subject to a maximum rate of 20 percent in respect of property held for more than one year. 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

Special 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 passive income; 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 derive sufficient active revenues and to hold sufficient active assets, so that in the long term it will not be classified as a PFIC. However, the Company's plan to obtain additional financing may in the current year result in the Company being classified as a PFIC.

In the event that the Company is classified as a PFIC in any year, U.S. Holders can avoid the unfavorable rules described below 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 basis in those Shares or ADSs. In addition, any gain recognized upon the sale of Shares or ADSs will be taxed as ordinary income in the year of sale.

If the Company is determined to be a PFIC, a U.S. Holder who does not make a mark-to-market election will be subject to a special tax at ordinary income tax rates on "excess distributions," including certain distributions by the Company and gain recognized on the sale of Shares and ADSs. The amount of income tax on excess distributions will be increased by an interest charge to compensate for tax deferral, calculated as if excess distributions were earned ratably over the holding period of the Shares or ADSs. Classification as a PFIC may also have other adverse tax consequences, including, in the case of individuals, the denial of a step-up in the basis of Shares and ADSs at death.

The Company does not intend to furnish holders with the information necessary to make a qualified electing fund ("QEF") election to include the Company's income on a current basis.

U.S. Holders should consult their own tax advisors regarding the U.S. federal income tax considerations discussed above and the desirability of making 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 an Eligible U.S. Holder entitled to benefits under that convention will not be subject to French gift or inheritance tax, unless the donor or the decedent was domiciled in France at the time of making the gift, or of his or her death, or the Shares or ADSs were used or held for use in the conduct of a business or profession through a permanent establishment or fixed base in France.

French Wealth Tax

The French Wealth Tax (*impôt de solidarité sur la fortune*) does not apply to an Eligible U.S. Holder.

Information Reporting and Backup Withholding

Dividends on Shares or ADSs, and payments of the proceeds of a sale of Shares or ADSs, paid within the United States or through certain U.S.-related financial intermediaries are subject to information reporting and may be subject to backup withholding at a 31% rate 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. The amount of any backup withholding from a payment to an Eligible U.S. Holder will be allowed as a credit against such holder's U.S. federal income tax liability. 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 to establish its non-U.S. status in connection with payments received within the United States or through certain U.S.-related financial intermediaries.

Item 8. *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 9, "Management's Discussion and Analysis of Financial Condition and Results of Operations." The balance sheet data as of December 31, 1998 and 1999 and the income statement data for the years ended December 31, 1997, 1998 and 1999 set forth below have been derived from the Consolidated Financial Statements. The income statement data for the years ended December 31, 1995 and 1996 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,					
	1995(2)	1996(2)	1997(2)	1998(2)	1999	1999(1)
INCOME STATEMENT DATA						
Total revenues	€ 17,256	€ 26,515	€ 33,086	€ 20,668	€ 19,881	U.S.$ 18,640
Net sales	17,147	24,223	31,677	19,263	19,107	17,915
Gross profit	9,466	14,861	16,707	9,210	9,211	8,636
Operating expenses(3)	(11,444)	(13,500)	17,438	(18,721)	(16,869)	(15,816)
Income (loss) from operations	(1,978)	1,361	(731)	(9,511)	(7,658)	(7,180)
Income (loss) before income taxes	(2,318)	1,834	189	(9,636)	(6,487)	(6,082)
Income taxes(4)	782	(222)	125	(181)	256	240
Net income (loss)	(1,537)	1,638	191	(9,817)	(6,231)	(5,842)
Net income (loss) per Share	(0.28)	0.29	0.03	(1.19)	(0.80)	(0.75)
Dividends per Share(5)	—	—	—	—	—	—
BALANCE SHEET DATA						
Total current assets	20,900	31,233	40,828	32,856	23,897	22,405
Property, plant and equipment, net	3,075	2,945	2,881	1,719	3,089	2,896
Total current liabilities	7,485	17,106	13,463	14,559	13,953	13,082
Total assets	24,832	39,781	51,424	44,923	36,355	34,085
Long-term debt, less current portion(6)	1,174	1,637	1,518	7,053	6,344	5,948
Total shareholders' equity	13,392	18,958	34,182	22,363	15,424	14,461

(1) Translated for convenience of the reader at the Noon Buying Rate on April 20, 2000 of $ 1 = € 1.0666. See "Presentation of Financial and Other Information" on page 3 of this Annual Report.

(2) Amounts have been restated from French francs in euros using the exchange rate set by the Council of the European Union for use as of January 1, 1999 of ε 1 = FF 6.55957.

(3) The Company incurred restructuring costs of ε 0.8 million in 1995 and recorded a charge for impairment of long-lived assets of ε 0.8 million in 1998. See Item 9, "Management's Discussion and Analysis of Financial Condition and Results of Operations."

(4) In the years 1995 and 1996, the Company benefited from a special corporate income tax regime. See Item 9, "Management's Discussion and Analysis of Financial Condition and Results of Operations."

(5) No dividends were paid with respect to fiscal years 1995, through 1998 and subject to approval of the annual shareholders' meeting to be held in June 2000, the Company does not anticipate paying any dividend with respect to fiscal year 1999. See "Dividends and Dividend Policy."

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

Dividends and Dividend Policy

The Company currently intends to use all of its distributable earnings, if any, to finance its product research and development and its current operations and does not expect to pay any cash dividends in the foreseeable future. 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 shareholders' ordinary general meeting. Dividends, if any, would be paid in French francs 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 residents 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 7, "Taxation—Taxation of U.S. Investors—Taxation of Dividends." Prospective purchasers of ADSs should consult their own advisers with respect to the tax consequences of an investment of ADSs.

No dividends were paid with respect to fiscal years 1995 through 1998, and subject to approval of the annual shareholders' meeting to be held in June 2000, the Company does not anticipate paying any dividends with respect to fiscal year 1999.

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 in euros on the Shares in the form of ADSs. Moreover, such fluctuations may affect the dollar price of the ADSs on Nasdaq and on EASDAQ.

As of January 1, 1999, the conversion rate between the euro and the French franc was fixed irrevocably at ε 1 = FF 6.55957. See "Presentation of Financial Information" and Item 9, "Management's Discussion and Analysis of Results of Operations and Financial Condition—Introduction of the Euro."

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 1995 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 ε 1 = FF 6.55957 and expressed in euros per $ 1.00.

Year ended December 31,	High	Low	Average[1]	End of Period
	ε	ε	ε	ε
2000 (through April 30, 2000).....	1.10	0.97	1.05	1.10
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
1996.....	0.81	0.75	0.78	0.79
1995.....	0.82	0.73	0.76	0.75

(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 3 of this Annual Report.

Item 9. *Management's Discussion and Analysis of Financial Condition and Results of Operations*

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, 1997, 1998 and 1999 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 3 of this Annual Report.

Significant Financial and Accounting Developments

Restatement of the Company's Financial Statements

Following the departure of the former President of the Company's U.S. subsidiary in October 1999, the Company discovered side letters from the Company's U.S. subsidiary setting forth conditions to certain Prostatron orders and guaranteeing end-user payments to a third-party lessor of medical equipment, in violation of the Company's revenue recognition policies. These side letters related to sales transactions entered into by the U.S. subsidiary in 1998 and the first six months of 1999. These side letters were not disclosed to the Company's management, and the Company therefore was not aware of them at the time the revenue from these transactions was recognized. No such problems were found in orders from Company customers outside the United States.

The Company has an agreement with a third-party lessor of medical equipment, DVI Financial Services, Inc. ("DVI"). Under this Agreement, DVI purchases Prostatron units and leases them to end-users such as urology clinics or urologists' offices. The Company collects the lease payments and remits them to DVI. However, in accordance with Company policy, the Company normally does not guarantee the performance by the end-users of their obligations under the lease, and DVI performs its own analysis of the creditworthiness of the end-users. The Company's liability is limited to remitting to DVI the lease payments received from end-users. In connection with these transactions, it is therefore appropriate for the Company to recognize revenue upon the sale of the unit because the risk of ownership has transferred to the third-party lessor. In 1998, the Company's U.S. subsidiary sold 10 Prostatron units for an aggregate amount of U.S.$ 2.0 million to DVI (the "DVI Transaction"). The Company originally recorded the revenue from these sales in 1998. However, pursuant to a side agreement of which the Company was not made aware at the time revenue was recognized, the 10 Prostatron units were leased by DVI to Northwest Prostate Treatment Center, Inc. ("Northwest"), a provider of urological devices, and in turn by Northwest to the end-users, and the U.S. subsidiary guaranteed to Northwest the performance by the end-users of their obligations under the lease.

In 1998 and in the first six months of 1999, the U.S. subsidiary also issued side letters granting customers rights of return or setting forth other conditions to the order, such as payment terms tied to acceptance or customer use of the machine, in connection with the sale of 8 other Prostatron units in the United States.

Following a detailed review of these transactions, management concluded that there should be a restatement of the Company's audited consolidated financial statements for the year ended December 31, 1998 and of the Company's unaudited consolidated quarterly financial statements for the three months ended March 31, June 30 and September 30, 1999, the six months ended June 30, 1999 and the nine months ended September 30, 1999.

On March 31, 2000, the Company filed an amendment to its annual report on Form 20-F for the year 1998, including restated audited consolidated financial statements for the year 1998, with the Commission and Nasdaq. The Company also filed on April 12, 2000 restated unaudited consolidated financial statements for the three months ended March 31, June 30 and September 30, 1999, for the six months ended June 30, 1999 and for the nine months ended September 30, 1999 with the Commission and Nasdaq under cover of Form 6-K.

As a result of these adjustments, previously reported consolidated total revenue for 1998 was reduced from ε 23.2 million to ε 20.7 million, while previously reported gross profit was revised from ε 11.6 million to ε 9.2 million, and previously reported net loss increased from ε 7.1 million to ε 9.8 million. Restated earnings per share are a negative ε 1.19 instead of a negative ε 0.87 as reported initially. For the first quarter of 1999, previously reported revenue of ε 5.7 million was reduced to ε 4.1 million, with net loss increasing from ε 0.2 to ε 1.8 million. Second quarter revenue of ε 4.8 million was reduced to ε 4.5 million, with net loss for the quarter increasing from ε 0.6 million to ε 0.9 million. Third quarter revenue of ε 4.8 million remained stable and net loss for the quarter increased from ε 2.2 million to ε 2.3 million.

For additional information about these adjustments, please see Note 26 of the Notes to the Consolidated Financial Statements, Item 9, "Management's Discussion and Analysis of Financial Condition and Results of Operations" in the Company's amended annual report on Form 20-F for the year 1998 and the Company's restated unaudited consolidated financial statements for the three months ended March 31, June 30 and September 30, 1999, for the six months ended June 30, 1999 and for the nine months ended September 30, 1999.

Liquidity and Capital Resources Requirements

As discussed under "—Liquidity and Capital Resources," the Company does not have sufficient resources to meet its anticipated operating requirements through the year 2000 without obtaining additional financing or reducing operating expenses. See "—Liquidity and Capital Resources" for a discussion of management's plans in this respect.

Results of Operations

Summary

Total revenues includes sales of the Company's medical devices and sales of 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 and ESWL lithotripters.

The sale price of the Company's medical devices is subject to variation based on a number of factors, including warranties, payment terms and guarantees. 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 includes revenues arising from maintenance services furnished by the Company for the installed base of Prostatrons and ESWL lithotripters and from sales of disposable parts for Prostatrons and ESWL lithotripters, both net of commissions, as well as from operating leases of the

Company's medical devices. The proportion of net sales derived from net sales of spare parts, supplies and services has increased from 42.3% in 1997 to 63.6% in 1998 and to 70.6% in 1999, principally due to increases in maintenance services in Japan, in sales of Prostatron disposable parts and in revenues from operating leases as well as a decrease in net sales of medical devices over that period. The Company derives a significant portion of its net sales of spare parts, supplies and services from its operations in Japan (representing approximately 36% of such sales in 1999), principally because approximately 27% of the installed base of the Company's ESWL lithotripters is located in Japan. Such sales are effected through EDAP Technomed Co. Ltd., the Company's wholly owned Japanese subsidiary. In 1999, the Company's Japanese operations realized an operating profit of ε 0.6 million, while the Company realized an operating loss of ε 7.7 million. See Note 21 of the Notes to the Consolidated Financial Statements.

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 13 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 and certain quarterly payments which EDAP Technomed, Inc., the Company's U.S. subsidiary ("EDAP USA"), agreed to make to former shareholders of Technomed International, Inc., a U.S. company acquired by EDAP TMS, as consideration for the sale of their shares in October 1994. Such payments are based on a percentage of sales of the Prostatron and its disposable parts in the United States for a period of seven years beginning with the approval of the Prostatron by the FDA in May 1996.

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. Approximately 40% of the total provision for slow-moving inventory at December 31, 1999 related to used devices, which were purchased in 1994 from customers of Technomed International S.A., a company acquired by EDAP TMS out of liquidation, for commercial reasons. The Company no longer engages in such repurchases.

Operating expenses includes 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 includes 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 ε 0.3 million as of December 31, 1999. Total research and development expenses have amounted to an average of approximately 13% of total revenues over the past three fiscal years. Management expects the budget for research and development expenses for the foreseeable future to range from 10% to 20% of the anticipated total revenues in each fiscal year.

Non-recurring operating expenses includes charges recorded to account for certain non-recurring events. The Company recorded non-recurring operating expenses of ε 0.3 million in 1999 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. See "—Significant Financial and Accounting Developments" above and Note 26 of the Notes to the Consolidated Financial Statements. The Company recorded non-recurring operating expenses of ε 0.8 million in 1998 for impairment of long-lived assets reflecting the adjustment to fair value less cost to sell of the Company's Croissy-Beaubourg facility, following the Company's unsuccessful efforts to sell this facility. See Note 15 of the Notes to the Consolidated Financial Statements.

The Company benefited in 1998 and 1997 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 ε 0.2 million in 1998 and ε 0.4 million in 1997. See Note 18 of the Notes to the Consolidated Financial Statements.

In the years 1997 through 1999, *Agence Nationale de Valorisation de la Recherche* ("ANVAR"), a French government agency that provides interest-free financing to French companies involved in research and development projects, granted an interest-free loan to the Company to finance the development of certain aspects of its HIFU technology. Based on an assumed interest rate of 6% per annum (which reflects the terms and conditions upon which the Company believes it would have obtained from a commercial bank in France for a loan similar to the ANVAR loan as to principal amount and repayment schedule), the amount of interest that the Company would have paid in 1997 and 1998 if the ANVAR loan had been bearing interest is ε60,000 per year. The ANVAR loan was terminated in 1998 following the Company's decision to discontinue the Pyrotech program. ANVAR waived repayment of ε 0.5 million of the ε 0.9 million outstanding amount of the loan in 1998 and of the remaining amount in 1999. See "—Liquidity and Capital Resources" and Note 10 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 ε 3.2 million of goodwill, a ε 0.12 million step-up in the historical carrying value of certain tangible assets of TMS and a ε 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. The yearly impact of the amortization of the goodwill resulting from this transaction is ε 0.14 million, while the yearly amount of the additional depreciation and amortization due to the step-up in the historical carrying value of tangible and identifiable intangible assets (net of deferred taxes) is ε 15,000 and ε 46,000, 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 ε 60,000. Although the Company reported a net loss of ε 9.8 million in 1998 and in 1999, the Company believes that undiscounted estimated future cash flows are sufficient to recover the recorded amount of the goodwill, and accordingly that it is appropriate for the Company to continue to amortize the goodwill over the periods described in this paragraph.

In the years 1997 through 1999, the Company experienced declining sale prices in the market for ESWL lithotripters. The Company believes that the market for ESWL lithotripters in developed countries is now mature and has become primarily a replacement and maintenance market, with high equipment penetration rates driving down demand and increasing price competition. While the market for ESWL lithotripters in developing countries still offers growth potential, any growth in these markets is subject to significant risk and uncertainties. In addition, in the ESWL market too, 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.

In the second half of 1998, the Company implemented a cost reduction program in response to difficult market conditions in developing countries at that time and severe price competition in developed countries. This program included a reduction in headcount from 184 in September 1998, to 168 at December 31, 1998 and to 165 in March 1999, the postponement of certain non-strategic research and development projects and the rationalization of the Company's sales efforts worldwide (including the closure of its Moscow office). All expenses resulting from the cost reduction program were recorded in the year 1998. The Company estimates that as a result of this program operating expenses and cost of sales decreased by approximately ε 2.5 million in the aggregate in 1999.

The Company believes that its results of operations in the near future may be adversely affected by the Company's implementation of a new marketing strategy focusing on expanding the leasing of the Prostatron in the United States and increased expenses in connection with the marketing of the Prostatron and the development and commercial launch of HIFU applications, if any. See "—Liquidity and Capital Resources." Such increased expenses may be offset only partially by revenues arising from increased sales of the Prostatron or from sales of HIFU devices.

The Company's future results of operations will also depend to a large extent on its ability to gain significant additional market acceptance for the Prostatron and to promote increased usage of the Prostatron installed base.

Fiscal Year Ended December 31, 1999 Compared to Fiscal Year Ended December 31, 1998

Total revenues. The Company's total revenues decreased 3.8% from ε 20.7 million in 1998 to ε 19.9 million in 1999, principally due to a decrease in net sales of medical devices.

The Company's net sales of medical devices decreased 18.8% from ε 6.9 million in 1998 to ε 5.6 million in 1999, primarily due to a decrease in the number of EWSL lithotripters sold in 1999 compared to 1998, as well as a 7.5% decrease in the average unit sale price of ESWL lithotripters in 1999 compared with 1998. The decrease in the number of lithotripters sold in 1999 resulted principally from the delay in the launch in Japan of the Company's new Sonolith Praktis, a compact lithotripter launched in the EU in October 1998, until June 1999, while the decrease in average unit sale price in 1999 reflected increased price competition. The Company also experienced slightly lower sales of Prostatrons in 1999 in the EU, with the average unit sale price of the Prostatrons sold in 1999 being stable compared with 1998.

Net sales of spare parts, supplies and services increased 9.8% from ε 12.4 million in 1998 to ε 13.5 million in 1999, due to a 29.8% increase in sales of Prostatron disposable parts and a 24.7% 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 following the creation in October 1996 of EDAP Technomed Co. Ltd. See "—Results of Operations—Summary."

Other revenues decreased from ε 1.4 million in 1998 to ε 0.8 million in 1999. This decrease reflected principally non-recurring license revenues arising from the sale of a license relating to Prostatron technology in Japan in 1998.

Cost of sales. Cost of sales decreased 7.0% from ε 11.5 million in 1998 to ε 10.7 million in 1999, and as a percentage of net sales decreased from 59.5% in 1998 to 55.8% in 1999, due to increased sales of Prostatron disposable parts and changes in product mix, with a higher proportion of compact Prostatron Praktis and Sonolith Praktis units sold in 1999 compared with 1998. These compact models have lower manufacturing costs compared to previous generation devices. The decrease in cost of sales in 1999 compared with 1998 also reflected the impact on a full fiscal year of the cost reduction program initiated in the second half of 1998. See "—Results of Operations—Summary."

Operating expenses. Operating expenses decreased from ε 18.7 million in 1998 to ε 16.9 million in 1999, principally due to decreased selling and general and administrative expenses as well as lower non-recurring operating expenses.

Research and development expenses decreased 4.6% from ε 3.3 million in 1998 to ε 3.1 million in 1999. This decrease reflected principally the postponement of certain non-strategic research and development projects as part of the Company's cost reduction program initiated in the second half of 1998. See "—Results of Operations—Summary."

Selling expenses decreased 8.7% from ε 6.9 million in 1998 to ε 6.3 million in 1999, primarily due to the impact on a full fiscal year of the rationalization of the Company's sales efforts worldwide (including the closure of its Moscow office) as part of the Company's cost reduction program initiated in the second half of 1998.

General and administrative expenses decreased 16.1% from ε 6.2 million in 1998 to ε 5.2 million in 1999, primarily due to the reduction in the number of general and administrative employees as part of the Company's cost reduction program initiated in the second half of 1998.

Non-recurring operating expenses in 1999 consisted of a charge of ε 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. See "—Significant Financial and Accounting Developments" above.

Income from operations. As a result of the factors discussed above, the Company realized an operating loss of ε 7.7 million in 1999, as compared to an operating loss of ε 9.5 million in 1998.

Other income. Other income increased from ε 46,000 in 1998 to ε 54,000 in 1999. In 1999, the increase in the value of the U.S. dollar and the Japanese yen against the euro resulted in currency gains totaling ε 1.4 million with respect sales transactions denominated in U.S. dollars and Japanese yen, which were partially offset by a ε 0.2 million increase in interest expense resulting from the increase in the aggregate amount of the Company's long term debt in 1999. See Note 17 of the Notes to the Consolidated Financial Statements.

Income taxes. The Company recorded a corporate income tax credit of ε 55,000 in 1999, principally reflecting income tax credits with respect to the results of subsidiaries.

Net income. The Company realized a consolidated net loss (after minority interests) of ε 6.2 million in 1999 compared with a consolidated net loss of ε 9.8 million in 1998, as a result of the factors mentioned above.

Fiscal Year Ended December 31, 1998 Compared to Fiscal Year Ended December 31, 1997

Total revenues. The Company's total revenues decreased 37.5% from ε 33.1 million in 1997 to ε 20.7 million in 1998, principally due to a decrease in sales of medical devices.

The Company's net sales of medical devices decreased 62.3% from ε 18.3 million in 1997 to ε 6.9 million in 1998, due to a sharp decrease in sales of Prostatrons in 1998 compared with 1997. Of the Prostatrons sold in 1998, over 80% were sold in the United States and Japan. The decrease in net sales of Prostatrons in 1998 resulted principally from adverse market conditions in Asia (including Japan) and Eastern Europe (including Russia) in 1998, as well as from a change in the product mix as sales of Prostatrons Praktis, with lower unit prices, represented a greater proportion of total Prostatron sales in 1998 compared with 1997. In addition, the Company also experienced lower sales of Prostatrons in the United States due to uncertainties relating to third-party reimbursement and an increase in the number of units placed at no charge on a cost-per-procedure basis by competitors in the United States, as discussed under "—Results of Operations—Summary" above.

Net sales of ESWL lithotripters in 1998 decreased by three units, to 17. The delay in the launch of the SONOLITH Praktis, which was initially anticipated to take place in June 1998 but occurred only in October 1998, combined with the impact of adverse market conditions in Asia and Eastern Europe, contributed to this decrease. The average unit sale price of lithotripters in 1998 decreased 23.5% as compared to 1997. See "—Results of Operations—Summary."

Net sales of spare parts, supplies and services decreased 7.7% from ε 13.4 million in 1997 to ε 12.4 million in 1998, due principally to the renewal of certain maintenance contracts on less favorable terms as well as the decrease in the value of the Japanese yen relative to the French franc; a substantial portion of the Company's maintenance services are derived from the Company's Japanese operations following the creation in October 1996 of EDAP Technomed Co. Ltd. See "—Results of Operations—Summary." As a percentage of total revenues, net sales of spare parts, supplies and services increased from 40.5% in 1997 to 59.8% in 1998.

Other revenues remained stable at ε 1.4 million in 1998. In 1998, an increase in subsidies received from French governmental agencies, reflecting the waiver of ε 0.5 million of a ε 0.9 million loan owing to ANVAR by the Company, was partially offset by a decrease in license fees. In 1998, other revenues included a one-time payment of ε 0.3 million in connection with the grant of a non-exclusive license relating to one of the Company's patents.

Cost of sales. Cost of sales decreased 30.0% from ε 16.4 million in 1997 to ε 11.5 million in 1998, and as a percentage of net sales increased from 51.7% in 1997 to 59.5% in 1998, due to changes in the mix of sales of medical devices and sales of spare parts, supplies and services, with increased sales of services, lower unit

production volumes, and the decline in the average unit sale price of both the Prostatrons and ESWL lithotripters sold in 1998.

Operating expenses. Operating expenses increased 7.3% from ε 17.4 million in 1997 to ε 18.7 million in 1998, principally due to increased selling expenses and general and administrative expenses. As a percentage of total revenues, operating expenses increased from 52.7% in 1997 to 90.6% in 1998, due to sharply lower net sales in 1998 compared with 1997.

Research and development expenses decreased 4.0% from ε 3.4 million in 1997 to ε 3.3 million in 1998, but increased as a percentage of total revenues from 10.3% in 1997 to 15.9% in 1998. The continued decrease in research and development expenses in absolute terms reflected the fact that most of the research and development expenses in connection with the approval of the Prostatron in the United States and Japan were incurred in 1995 and prior years, and the increase in research and development expenses as a percentage of total revenues reflected lower net sales. See "—Results of Operations—Summary."

Selling expenses increased 2.0% from ε 6.8 million in 1997 to ε 6.9 million in 1998, due to costs incurred by the Company in connection with the continued build-up in the marketing efforts relating to the Prostatron in the United States.

General and administrative expenses increased 6.9% from ε 5.8 million in 1997 to ε 6.2 million in 1998, primarily due to expenses related to the initiation of the Company's cost reduction program, including severance payments. As a percentage of total revenues general administrative expenses increased from 17.5% in 1997 to 29.9% in 1998, primarily reflecting the decrease in total revenues in 1998 compared with 1997. No compensation costs were recognized in connection with the options granted or amended in 1998.

The Company recorded non-recurring operating expenses of ε 0.8 million for impairment of long-lived assets relating to the Company's Croissy-Beaubourg facility. See Note 15 of the Notes to the Consolidated Financial Statements and "—Results of Operations—Summary."

Income from operations. As a result of the factors discussed above, the Company realized an operating loss of ε 9.5 million in 1998, as compared to an operating loss of ε 0.7 million in 1997.

Other income. Other income decreased slightly from ε 85,000 in 1997 to ε 46,000 in 1998. No significant net capital gain on fixed assets or other non-recurring transaction generating other income was recorded in 1998.

Income taxes. The Company recorded a corporate income tax liability of ε 0.3 million for 1998, which was partially offset by an increase in tax credit receivables of ε 0.1 million. See Note 18 of the Notes to the Consolidated Financial Statements. In accordance with French tax law, the Company elected to credit the tax loss incurred by TMS in 1998 against corporate income taxes paid in the previous three fiscal years. Thus, the Company recorded in 1998 a tax credit receivable of ε 0.1 million, to be credited against taxes payable before the fiscal year ended December 31, 2001 or paid in cash after that date. In addition, the Company benefited in 1998 from tax credits for certain research and development expenditures. Total research tax credits for the year 1998 amounted to ε 0.2 million. See Note 18 of the Notes to the Consolidated Financial Statements.

Net income. The Company realized consolidated net loss (after minority interests) of ε 9.8 million in 1998 compared with consolidated net income of ε 0.2 million in 1997, 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, 1999.

Liquidity and Capital Resources

The Consolidated Financial Statements have been prepared on a going concern basis, which contemplates the realization of assets and the satisfaction of liabilities in the normal course of business. As shown in the Consolidated Financial Statements, the Company reported net losses of ε 6.2 million in 1999 and ε 9.8 million in 1998. In addition, for the years ended December 31, 1999 and 1998, net cash used in operating activities totaled ε 2.5 million and ε 8.3 million, respectively. As a result, as of the date of this Annual Report, the Company does not have sufficient resources to meet its anticipated operating requirements through the year 2000 without obtaining additional financing. The Company is actively pursuing additional financing through discussions with potential investors. This financing plan would include the split of the Company's business into two separate businesses, consisting of the ESWL and HIFU businesses on the one hand, and the TUMT business on the other hand, followed by a sale of an interest in, or certain assets of, either or both of these businesses to institutional or strategic investors. Alternatively, the Company may pursue additional equity financing.

If the Company is unable to obtain financing in a timely manner and on acceptable terms, management is developing and intends to implement a plan that would allow the Company to continue to operate through the year 2000. This plan would include sales of assets and/or a significant reduction in operating expenses through the termination of certain research and development activities, a reduction in workforce and a decrease in marketing and other discretionary expenditures. The Consolidated Financial Statements do not include any adjustments that might result from the Company's inability to obtain additional equity financing, sell assets or reduce operating expenses in 2000.

The Company's cash flow has historically been subject to significant fluctuations over the course of any given financial year due to the cyclicality of demand for medical devices. The cyclicality of 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.

In 1999, net use of cash in operating activities of ε 2.5 million reflected principally the net loss of ε 6.2 million in that year. In 1999, changes in net working capital items included a decrease of ε 3.2 million in trade accounts and notes and other receivables, partially offset by a decrease in trade accounts and notes payable of ε 0.5 million, in each case due to lower equipment sales volume. The Company also recorded an increase of ε 0.5 million in allowances for doubtful accounts and slow moving inventories.

In 1998, net use of cash in operating activities of ε 8.3 million reflected principally a net loss of ε 9.8 million in that year. In 1998, changes in net working capital items resulted principally from a decrease in trade accounts and notes and other receivables of ε 2.6 million offset by an increase in inventories of ε 1.2 million and a decrease in accrued expenses and other current liabilities of ε 0.7 million, in each case due to lower sale volumes.

In 1999, net cash used in investing activities was ε 1.8 million and reflected principally acquisitions of fixed assets for ε 2.1 million, including ε 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 ε 0.3 million.

Net cash used in investing activities was ε 0.3 million in 1998, as compared to ε 6.5 million in 1997. The Company's investing activities in 1998 included principally sales of short-term investments of ε 3.4 million, offset by an increase in restricted cash equivalents of ε 3.4 million. The increase in restricted cash equivalents in 1998 resulted from the reclassification of certain cash equivalents pledged to secure new long-term borrowings of the Company.

Net cash used in financing activities was ε 1.8 million in 1999, reflecting principally scheduled long-term debt repayments totaling ε 1.6 million and repayment of short-term borrowings of ε 0.2 million.

In 1998, net cash provided by financing activities was ε 5.4 million, reflecting principally a new 5-year secured loan of $6 million obtained by EDAP USA from a credit institution, as well as new long-term debt of 150 million Japanese yen obtained by EDAP Technomed Co. Ltd. The $6 million term loan bears interest at a fixed rate of 6.31% per annum and is secured by cash equivalents representing approximately 60% of the outstanding principal amount of the loan. The Japanese-yen denominated debt bears interest at a fixed rate of 2.48% per annum. In addition, as described under "—Significant Financial and Accounting Developments" above and Note 26 of the Notes to the Consolidated Financial Statements, as part of the restatement of its 1998 consolidated financial statements, the Company recorded a long term debt of U.S.$ 2.0 million as at December 31, 1998 with respect to the DVI Transaction. The Company will repay this amount in sixty monthly installments beginning February 1, 1999. In 1998, the Company's financing activities also included the repurchase of 691,100 Shares in open market transactions pursuant to the Company's corporate stock repurchase program at an average price per share of ε 3.4 ($3.7, based on historical exchange rates) or ε 2.3 million in the aggregate.

The Company paid no dividends with respect to fiscal years 1997 and 1998 and subject to the approval of the general shareholders' meeting in June 2000, will not pay dividends with respect to fiscal year 1999. The Company does not anticipate paying any dividends in the foreseeable future.

In 1994 and 1996, the Company obtained a loan commitment from ANVAR in order to fund research and development relating to the Pyrotech. The total amount of the commitment was ε 1.8 million. As of December 31, 1997, the Company had received an aggregate amount of ε 0.9 million from ANVAR. In December 1998, the Company announced the discontinuation and technical failure of the Pyrotech program and as a result in 1998 and 1999 ANVAR waived the remaining amount owed to it. See Note 10 of the Notes to the Financial Statements.

The Company's future cash flow may be affected to the extent the Company decides to continue to expand the leasing of its products. In an effort to increase sales of its equipment to individual urologists and smaller urology clinics, the Company implemented in 1999 a new marketing strategy which includes expanding the leasing of its medical devices, either by selling devices to a third-party financial institution specializing in leasing capital goods equipment, which in turn leases the devices to end-users on a cost-per-procedure basis (a "financing lease"), or by leasing devices directly to end-users on a cost-per-procedure basis (an "operating lease"). Under a financing lease, the lessee has the option to purchase the leased equipment from the financial institution at a nominal price at the end of the lease term, but the Company is under no obligation vis-à-vis that institution or the lessee to repurchase the equipment. As a result, financing leases do not have a material adverse impact on the Company's results of operations, liquidity or capital resources, except that the increased complexity of the sale documentation for these transactions may from time to time result in an extension of the time period from the date of the purchase order to the completion of the sale. By contrast, operating leases generate a smaller immediate contribution to total revenues than sales. The Company currently leases 3 ESWL lithotripters and 24 Prostatrons under operating leases.

To the extent the Company obtains additional financing as discussed above, the Company expects to make substantial expenditures over the next several years, particularly in connection with clinical trials for HIFU devices and marketing expenses relating to the Prostatron. In addition, to the extent that cash and cash equivalents balances are in excess of the Company's anticipated capital expenditure requirements, the Company may decide from time to time, subject to applicable French and U.S. laws and regulations, to continue repurchasing ADSs representing Ordinary Shares of the Company under its corporate share repurchase program, in open market transactions on the Nasdaq National Market or EASDAQ or in any other manner.

Year 2000 Issues

Many computer systems and software products accept only two-digit entries in the date code field. These date code fields will need to accept four-digit entries to distinguish 21st century dates from 20th century dates. As a result, computer systems and software used by many companies will need to be upgraded to comply with this "Year 2000" requirement. Systems that do not properly recognize such information could generate erroneous data or fail. Significant uncertainty exists in the software industry concerning the potential effects associated with non-compliance.

The Company's internal software and hardware systems and installed electronics, as well as its products, have not suffered any significant disruption to date as a result of the Year 2000 problem. Although there can still be no assurance that the Company and third parties have taken all the necessary steps to ensure Year 2000 compliance in relation to the advent of the year 2000 or critical dates beyond January 1, 2000, the Company believes that as of the date hereof there has been no material change from the disclosure contained under Item 9, "Management's Discussion and Analysis of Financial Condition and Results of Operations – Year 2000 Issues" in its annual report on Form 20-F for the year 1998.

Introduction of the Euro

As part of the European Economic and Monetary Union (EMU), a single currency (the "euro") will replace the national currencies of most of the European countries in which the Company conducts business. The conversion rates between the euro and the participating nations' currencies was fixed irrevocably as of January 1, 1999, with the participating national currencies being removed from circulation between January 1, 2002 and June 30, 2002 and replaced by euro notes and coins. The conversion rate between the euro and the French franc was fixed at 1 ε = FF 6.55957. During the "transition period" from January 1, 1999 through December 31, 2001, public and private entities as well as individuals may pay for goods and services using checks, drafts or wire transfers denominated in euros or the participating country's national currency. Under the regulations governing the transition to a single currency, there is a "no compulsion, no prohibition" rule which states that no one is obliged to use the euro until the notes and coins have been introduced on January 1, 2002. According to French law, companies may keep their accounts in either francs or euros during the transition period, but once they convert to euros, they may not go back to francs. In the EU, the Company currently lists its prices and invoices its customers in both local currencies and in euros. The Company expects to complete full conversion of all operations to the euro by the time national currencies are removed from circulation. The Company's software systems are already euro compliant. Beginning with the financial statements for the year 1999, the Company is reporting its financial results into euros. See "Presentation of Financial and Other Information" on page 3 of this Annual Report.

The Company does not expect conversion to the euro to have a significant impact on its competitive strategies in the affected countries.

Item 9A. *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 is exposed to foreign currency exchange rate risk because a significant portion of its costs are denominated in a currency (the euro) other than those in which it earns revenues. In 1999, approximately 65% of the Company's general and administrative expenses and approximately 80% of the Company's research and development expenses were denominated in euros, while approximately 72% of the Company's sales were denominated in currencies other than euros (primarily the U.S. dollar and the Japanese yen). Similarly, 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. 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, 1999. 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

The Company has material exchange rate exposures with respect to the U.S. dollar and the Japanese yen. Approximately ε 7.1 million and ε 1.2 million of the indebtedness of the Company at December 31, 1999 were denominated in U.S. dollars and in Japanese yen, respectively. In addition, at December 31, 1999, the Company had approximately ε 0.4 million and ε 0.7 million of financial assets denominated in U.S. dollars and in Japanese yen, respectively, representing principally the cash balances of its U.S. and Japanese subsidiaries at such date. The

potential immediate loss to the Company that would result from a hypothetical 10% change in the exchange rate of the U.S. dollar against the euro would be approximately ε 0.7 million. The potential immediate loss to the Company that would result from a hypothetical 10% change in the exchange rate of the Japanese yen against the euro would be approximately ε 50,000. In addition, if such changes were to be sustained, the Company's cost of financing would increase by an estimated ε 73,000 per year (based on principal amounts outstanding as of December 31, 1999). This sensitivity analysis assumes an unfavorable 10% fluctuation in the exchange rates affecting the foreign currencies in which the financial assets and liabilities are denominated from such rates as of December 31, 1999, 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

At December 31, 1999, the Company had approximately ε 8.3 million in loans and financing outstanding, all of which bore interest at fixed rates. The Company invests its excess liquidity (ε 3.3 million at December 31, 1999) 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, 1999, resulting from a hypothetical, instantaneous and unfavorable change of 100 basis points in the interest rate applicable to such financial instruments would be approximately ε 111,000. A hypothetical and instantaneous change of 100 basis points in interest rates applicable to floating-rate financial assets and liabilities held at December 31, 1999 would result in a loss of future earnings over one year of approximately ε 39,000. The above sensitivity analyses are based on the assumption of an unfavorable 100 basis point movement of the interest rates applicable to each homogeneous category of financial assets and liabilities from such rates as at December 31, 1999. 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.

Item 10. *Directors and Officers of Registrant*

Executive Board and Executive Officers

The Company's affairs are managed by an Executive Board *(Directoire)* and by the President of the Executive Board, who has full executive authority to manage the affairs of the Company. The Executive Board is placed under the control and supervision of a Supervisory Board *(Conseil de Surveillance)*. According to the By-laws *(statuts)* of the Company, the Executive Board must be composed of up to five members. The Executive Board is presently 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 following table sets forth the name, age and position of each of the members of the Executive Board and the 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). The Supervisory Board on February 18, 2000 appointed the current members of the Executive Board for another period of three years ending on February 18, 2003.

Name	Age	Position
Eric Simon	39	President of the Executive Board and Chief Executive Officer and acting Chief Financial Officer
Hugo Verpeet	49	Member of the Executive Board and President and General Manager of TMS
François Lacoste	49	Member of the Executive Board and Vice President, Research and Development
Antoine Tétard	35	President, United States Operations and Japanese Operations
Jacques Berthet	56	Vice President, Manufacturing

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 Chief Executive Officer of EDAP TMS in March 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.

Hugo Verpeet

Hugo Verpeet joined the Company in May 1998 as President and General Manager of TMS and member of the Executive Board of EDAP TMS. Prior to this position, Mr. Verpeet was President and General Manager for Celsis International plc (Cambridge UK), a microbiology company, from 1996 to 1998. Previously, he worked for Becton Dickinson Group for 20 years occupying various positions with responsibilities from Sales, Regulatory, to Vice-President and General Manager, and was based in Belgium, then California and finally France. Mr. Verpeet holds a BA in Medical Technology & Clinical Biology from Hoger Rijks Institute, Brussels.

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.

Antoine Tétard

Antoine Tétard joined the Company in 1990 as area sales manager and became Vice President in charge of Japanese operations in 1996 and President of U.S. and Japanese operations in January 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 EU and North America. Mr. Tétard holds an MBA from Institut Supérieur de Gestion, Paris.

Jacques Berthet	Jacques Berthet joined the Company in 1996 as Vice President in charge of manufacturing. Prior to joining the Company, Mr. Berthet was the parapharmaceutical production manager of four factories for Roussel-Uclaf, a subsidiary of the German chemical and pharmaceutical company Hoechst. From 1988 to 1996, Mr. Berthet was also vice president in charge of industrial activity for COLETICA, a medical device manufacturer. Mr. Berthet holds an MS in food industry from Ecole Supérieure des Industries Alimentaires, Paris.

Supervisory Board

The Supervisory Board reviews and monitors the actions of the Executive Board. Pursuant to the Company's *statuts*, the Supervisory Board must be composed of a minimum of three and a maximum of twelve members. The Supervisory Board is presently composed of five members. Members of the Supervisory Board are elected by the voting shareholders at a general meeting to serve terms not exceeding six years and may be re-appointed for consecutive terms. They may resign at any time and may be removed at any time by the voting shareholders at a general meeting. In order to perform its duties, the Supervisory Board may at any time make such investigations and obtain communication of such documents as it deems necessary. The Supervisory Board also reviews quarterly reports on the Company's affairs prepared by the Executive Board and verifies and controls the Company's annual accounts. The Supervisory Board appoints the members of the Executive Board and its President. Under French law, a member of the Supervisory Board may be an individual or a legal entity. A legal entity which serves as a member of the Supervisory Board must appoint an individual as a "permanent representative" to represent such legal entity on the Board. 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.

On April 27, 2000, the Supervisory Board has decided to appoint two members of the Supervisory Board 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.

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	Philippe Chauveau was appointed as a member of the Company's Supervisory Board in January 1997 and became President of the Board in April 1997. Mr. Chauveau is Senior Principal of the TIME practice at Arthur D. Little International. 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 Frank Anton	Siemens France S.A. was appointed as a member of the Company's Supervisory Board in January 1997.

Christian Baillet	Christian Baillet was appointed as a member of the Company's Supervisory Board in October 1993. 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	Bernard Péjouan was appointed as a member of the Company's Supervisory Board in April 1997. 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	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 and lives in London.

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, Scott Department of Urology, Baylor College of Medicine (Houston, Texas). 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.
Alain Leduc	Chief of the Urology Department, Hospital St. Louis (Paris, France). Dr. Leduc is a member of the French Urological Association, the American Urology Association, the Academy of European Urology and the Academy of Surgery. Dr. Leduc received his M.D. and his Ph.D from Paris University Hospital in surgery and urology.

Item 11. *Compensation of Directors and Officers*

Aggregate compensation paid by the Company and its subsidiaries to its directors and executive officers as a group paid or accrued for services in all capacities for the fiscal year 1999 was approximately ε 0.8 million. No amount was set aside or accrued by the Company to provide pension, retirement or similar benefits for its executive officers and members of the Executive Board as a group in respect of the year 1999.

Item 12. *Options to Purchase Securities from Registrant or Subsidiaries*

In December 1996, the shareholders of the Company authorized the Executive Board to grant up to 177,750 options to buy treasury Shares and 156,625 options to subscribe to newly issued Shares, in both cases at a price of ε 6.97 per share. On February 7, 1997, the Executive Board issued 117,125 options to buy treasury Shares to four officers of the Company. Twenty-five percent of those options are exercisable as from the date on which they were granted and the right to exercise the remaining 75% of the options vests at the rate of 25% on January 1 of each year starting on January 1, 1998. According to their original terms. the options expire on the fifth anniversary of the date of the grant. On March 3, 1997, the remaining 60,625 options to purchase treasury Shares, and 134,750 options to subscribe to newly issued Shares, were granted to an additional seven employees of the Company and of EDAP USA, with the same terms and conditions as the 117,125 options previously issued. See Note 24-1 of the Notes to the Consolidated Financial Statements.

In May 1998, the shareholders of the Company authorized the Executive Board to grant to directors and officers of the Company and its principal subsidiaries up to 713,425 options to buy Shares from the Company at a price and on terms to be determined by the Executive Board, provided that the exercise price of the options may not be less than the average stock market price of the ADSs over the 20 business days preceding the grant of the options. Up to 279,000 of these options were reserved for the amendment of the terms of outstanding stock options. The shareholders also authorized the Executive Board to cause the Company to repurchase up to 535,675 Shares to cover

the options granted under the new plan. The authorization to grant share purchase options expires within one year of the completion of the share repurchase program by the Company. See Note 24-1 of the Notes to the Consolidated Financial Statements.

On October 29, 1998, the Executive Board attributed 327,000 new options to French employees meeting certain tenure criteria. The options were granted at or above the minimum exercise price specified in the shareholders' resolution, may not be exercised prior to two years from grant, vest over four years, and expire either ten years from the date they were granted or when the grantee ceases to be an employee of the Company, whichever occurs earlier. Shares acquired pursuant to the options cannot be sold prior to three years from their purchase or five years from the grant of the option, whichever occurs first. Also on October 29, 1998, pursuant to the authorization of the shareholders granted in December 1996, the Executive Board amended the terms of 124,125 of the options previously granted to directors and officers of the Company, to conform those terms to the terms of the new options issued on that date. See Note 24-1 of the Notes to the Consolidated Financial Statements.

Pursuant to the decision of the general shareholders' meeting in 1998, on January 4, 1999, the Board of Directors granted 24,000 options to French employees meeting certain tenure criteria at an exercise price of ε 3.81 per share for 11,000 options and ε 1.33 per share for 13,000 options. The options begin vesting two years after the date of grant and fully vest 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 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 at an exercise price of ε 3.81 per share for 40,000 options and ε 2.74 per share for 20,000 options. Of the options granted on that date, 50,000 begin vesting two years after the date of grant and fully vest as of June 1, 2002. 40,000 of these options expire on March 31, 2009 and 10,000 options expire on December 31, 2009, or in each case when employment with the Group ceases, whichever occurs earlier. Fifty percent of the remaining 10,000 options granted on March 15, 1999 are exercisable as of the date of grant, with the remaining fifty percent vesting at the rate of 25% each January 1 following the date of grant. These options expire on December 31, 2003.

Shares acquired pursuant to the options granted in 1999 to date cannot be sold prior to five years from the date of grant. Exercise prices corresponding to the options granted in 1999 to date were not less than the average stock market price of the shares over the 20 business days preceding the date of grant.

In accordance with the decision of the general shareholders' meeting in 1998, on March 15, 1999, the Board of Directors also amended the terms of 122,250 of certain options to subscribe to new shares which have been originally granted in 1997. On March 15, 1999, these options contracts were modified into options to purchase shares at an exercise price of ε 3.81 (compared with an original exercise price of ε 6.97), without modifying the exercise and vesting conditions. The Board also amended the terms of 20,125 share purchase options granted in 1997 modifying the exercise price to ε 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 ε 1.83 per share. The options begin vesting two years after the date of grant and fully vest as of January 1, 2003. The options expire on December 31, 2009, or when employment with the Group ceases, whichever occurs earlier. See Note 24-1 of the Notes to the Consolidated Financial Statements.

Shares acquired pursuant to the options granted in 1999 to date cannot be sold prior to five years from the date of grant. Exercise prices corresponding to the options granted in 1999 to date were not less than the average stock market price of the shares over the 20 business days preceding the date of grant.

Item 13. *Interest of Management in Certain 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 President 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 a fee of ε 54,882 for its services during the year 1999. In

accordance with French company law, the continuation of the agreement during the fiscal year 1999 will be submitted for ratification to the Company's shareholders at the annual shareholders' meeting in June 2000.

PART II

Item 14. *Description of Securities to be Registered*

Not applicable.

PART III

Item 15. *Defaults upon Senior Securities*

None.

Item 16. *Changes in Securities and Changes in Security for Registered Securities and Use of Proceeds*

None reportable in respect of (a) through (d).

Use of Proceeds

Pursuant to a registration statement on Form F-1 (File No. 333-7200) filed by EDAP TMS (the "Form F-1 Registration Statement") which was declared effective by the Securities and Exchange Commission on July 31, 1997, EDAP TMS registered for sale pursuant to the Securities Act of 1933, as amended, an aggregate of 4,000,000 Shares in the form of ADSs (the "Firm ADSs"), of which 2,000,000 ADSs were offered by the Company and 2,000,000 ADSs were offered by certain shareholders of the Company (collectively, the "Selling Shareholders").

The aggregate net proceeds to EDAP TMS from the offering of the 2,000,000 Firm ADSs, after deduction of underwriting discounts and commission and expenses of the offering, were approximately $16.7 million. At December 31, 1999 (the end of the reporting period to which this report relates), the Company had used all of the proceeds from the offering. The Company used approximately ε 8 million for research and development, in particular the development of HIFU products, approximately ε 6 million for marketing expenses relating to the Prostatron, and approximately ε 1 million for capital expenditures. Such uses of the net proceeds of the offering does not represent a material change from the use of proceeds as described in the prospectus that was part of the Form F-1 Registration Statement.

PART IV

Item 17. *Financial Statements*

Not applicable.

Item 18. *Financial Statements*

Reference is made to Item 19(a) for a list of all financial statements filed as part of this Annual Report.

Item 19. *Financial Statements and Exhibits*

(a) Index to Financial Statements

(b) Index to Exhibits

1.1 List of Subsidiaries of EDAP TMS S.A. as of May 2000.

2.1 Agreement for Sales Leads Generation Services dated October 29, 1999 entered into with Bard Urological Division, C.R. Bard, Inc.*

* Confidential treatment has been requested with respect to certain portions of this exhibit. Omitted portions have been filed separately with the Securities and Exchange Commission.

EDAP TMS S.A. and Subsidiaries

Consolidated Financial Statements

For the Years Ended December 31, 1999 and 1998

CONTENTS

Report of Independent Accountants

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. and subsidiaries as of December 31, 1999 and 1998, and the related consolidated statements of income, comprehensive income, shareholders' equity, and cash flows for the year then ended. 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, 1999 and 1998, and the consolidated results of their operations and their cash flows for the years then ended in conformity with accounting principles generally accepted in the United States.

The accompanying financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 1 to the financial statements, the Company has suffered recurring losses from operations and an operating cash deficiency that raise substantial doubt about its ability to continue as a going concern. Management’s plans in regard to these matters are also described in Note 1. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

ERNST & YOUNG Audit

Represented by
Jean-Luc Desplat

April 14, 2000
Lyons, France

EDAP TMS S.A. AND SUBSIDIARIES
CONSOLIDATED BALANCE SHEETS
December 31, 1999 and 1998
(in thousands of euros unless otherwise noted, except per share data)

ASSETS

	Notes	1999	1998
Current assets			
Cash and cash equivalents		3,261	8,795
Trade accounts and notes receivable, net of allowance of ε 1,664 in 1999 and ε 1,389 in 1998	2	8,967	12,201
Other receivables	3	2,461	2,662
Inventories	4	8,503	8,803
Deferred income taxes	18	313	106
Prepaid expenses		392	289
Total current assets		23,897	32,856
Property, plant and equipment, net	5	3,089	1,719
Intangible assets	6	890	1,418
Goodwill, net of accumulated amortization of ε 587 in 1999 and ε 172 in 1998		4,184	4,291
Net assets held for sale	15	245	245
Restricted cash equivalents	10	3,398	3,398
Deposits and other non-current assets		652	996
Total assets		36,355	44,923

LIABILITIES AND SHAREHOLDERS' EQUITY

Current liabilities			
Short-term borrowings		13	272
Trade accounts and notes payable	7	4,882	5,344
Accrued expenses and other current liabilities	8	6,628	7,038
Current portion of obligations under capital leases	9	91	86
Current portion of long-term debt	10	2,339	1,819
Total current liabilities		13,953	14,559
Obligations under capital leases	9	427	518
Long-term debt	10	5,917	6,535
Other provisions and long-term liabilities	11	634	945
Minority interests in consolidated subsidiaries		0	3
Total liabilities		20,931	22,560
Commitments and contingent liabilities	19		
Shareholders' equity			
Common stock, ε 0.12 par value, 9,318,875 shares authorized; 8,688,500 shares issued; 7,784,850 and 7,819,650 shares outstanding at December 31, 1999 and 1998, respectively	12	1,060	1,060
Additional paid-in capital		19,811	19,811
Retained earnings	12	(1,619)	4,612
Deferred compensation		0	(22)
Cumulative other comprehensive income		(730)	(49)
Treasury stock, at cost; 903,650 and 868,850 shares at December 31, 1999 and 1998, respectively	12	(3,098)	(3,049)
Total shareholders' equity		15,424	22,363
Total liabilities and shareholders' equity		36,355	44,923

Balances have been restated from French Francs into euros using the official fixed conversion rate of ε 1=FF 6.55957. 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, 1999, 1998 and 1997
(in thousands of euros unless otherwise noted, except per share data)

	Notes	1999	1998	1997
Net sales of medical devices		5,613	6,896	18,271
Net sales of spare parts, supplies and services		13,494	12,367	13,406
Net sales		19,107	19,263	31,677
Other revenues	13	774	1,405	1,409
Total revenues		19,881	20,668	33,086
Cost of sales (exclusive of items shown separately below)		(10,670)	(11,458)	(16,379)
Gross profit		9,211	9,210	16,707
Research and development expenses		(3,133)	(3,285)	(3,421)
Selling expenses		(6,314)	(6,914)	(6,784)
General and administrative expenses		(5,220)	(6,183)	(5,792)
Depreciation and amortization		(1,864)	(1,542)	(1,441)
Non recurring operating expenses	15	(338)	(797)	0
Operating loss		(7,658)	(9,511)	(731)
Interest (expense) income, net		(240)	259	301
Currency exchange gains (losses), net		1,357	(430)	534
Other income, net	16	54	46	85
(Loss) Income before taxes and minority interests		(6,487)	(9,636)	189
Income tax (expense) credit	18	256	(181)	125
(Loss) Income before minority interests		(6,231)	(9,817)	314
Minority interests in consolidated subsidiaries		0	0	(123)
Net (loss) income		(6,231)	(9,817)	191
Basic earnings per share	1-15	(0.80)	(1.19)	0.03
Weighted average shares outstanding used in basic calculation	1-15	7,815,272	8,247,669	7,321,709
Diluted earnings per share	1-15	(0.80)	(1.19)	0.03
Weighted average shares outstanding used in diluted calculation	1-15	7,815,272	8,247,669	7,329,383

Balances have been restated from French Francs into euros using the official fixed conversion rate of ε 1=FF 6.55957.

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, 1999, 1998 and 1997
(in thousands of euros unless otherwise noted, except per share data)

	1999	1998	1997
Net (loss) income	(6,231)	(9,817)	191
Other comprehensive income:			
Foreign currency translation adjustments	(681)	285	(235)
Comprehensive income, net of tax	(6,912)	(9,532)	(44)

Balances have been restated from French Francs into euros using the official fixed conversion rate of ε 1=FF 6.55957.

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, 1999, 1998 and 1997
(in thousands of euros unless otherwise noted, except per share data)

	Number of shares	Common stock	Additional paid-in capital	Retained earnings	Deferred Compensation	Cumulative Other Comprehensive Income	Treasury stock	Total
Balance as of December 31, 1996	6,510,750	816	4,710	14,238	0	(99)	(707)	18,958
Issuance of shares	2,000,000	244	14,846					15,090
Deferred compensation arising from issuance of options			255		(255)			0
Amortization of deferred Compensation.....					178			178
Net income.....				191				191
Change in foreign translation Adjustment.....						(235)		(235)
Balance as of December 31, 1997	8,510,750	1,060	19,811	14,429	(77)	(334)	(707)	34,182
Amortization of deferred Compensation.....					55			55
Net income.....				(9,817)				(9,817)
Translation adjustment.....						285		285
Acquisition of treasury shares.....	(691,100)						(2,342)	(2,342)
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)	0	(730)	(3,098)	15,424

Balances have been restated from French Francs into euros using the official fixed conversion rate of ε 1=FF 6.55957.

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, 1999, 1998 and 1997
(in thousands of euros unless otherwise noted, except per share data)

	1999	1998	1997
Cash flows from operating activities			
Net (loss) income	(6,231)	(9,817)	191
Elimination of expenses and benefits without effect on cash:			
Depreciation and amortization	1,791	1,542	1,441
Non cash charge for impairment of long-lived assets	0	797	0
Change in allowances for doubtful accounts & slow-moving inventories	550	(361)	326
Change in long-term provisions	(311)	(782)	47
Cancellation of government grants	(366)	(549)	0
Net capital loss on disposals of assets	17	17	14
Deferred tax charge / (benefit)	(207)	151	(102)
Minority interests in consolidated subsidiaries	(3)	0	123
Stock compensation expense	22	86	178
	1,493	901	2,027
Increase / Decrease in operating assets and liabilities:			
Decrease / (Increase) in trade accounts and notes and other receivables	3,160	2,560	612
Decrease / (Increase) in inventories	25	(1,210)	795
(Decrease) / Increase in prepaid expenses	(103)	(145)	34
(Decrease) / Increase in trade accounts and notes payable	(462)	193	(3,743)
(Decrease) / Increase in accrued expenses, other current liabilities and minority interests	(410)	(741)	(295)
	2,210	657	(2,597)
Net cash used in operating activities	(2,528)	(8,259)	(379)
Cash flows from investing activities			
Acquisitions of property, plant and equipment	(497)	(674)	(495)
Acquisitions of intangible assets	(15)	(44)	(1,990)
Capitalized assets produced by the Company	(1,581)	0	0
Proceeds from sales of assets		15	3
Acquisitions of short-term investments	0	0	(3,354)
Proceeds from sale of short-term investments	0	3,354	0
Disbursement for loans granted	0	0	(603)
Reimbursement of loans granted	0	294	0
Increase in deposits and guarantees	(10)	(96)	(46)
Change in restricted cash equivalents	0	(3,398)	0
Reimbursement of deposits and guarantees	336	279	0
Net cash used in investing activities	(1,767)	(270)	(6,485)
Cash flow from financing activities			
Acquisition of treasury shares	(49)	(2,342)	15,090
Proceeds from new long-term borrowings	0	7,988	0
Repayment of long term borrowings	(1,594)	0	0
Repayment of obligations under capital leases	(85)	(119)	(150)
(Decrease) / Increase in bank overdrafts and short-term borrowings	(22)	(148)	383
Repayment of advance from Nippon Eurotec	0	0	(571)
Net cash (used in) / provided by financing activities	(1,750)	5,379	14,752
Net effect of exchange rate changes on cash	511	58	32
Net (decrease) / increase in cash and cash equivalents	(5,534)	(3,092)	7,920
Cash and cash equivalents at beginning of year	8,795	11,887	3,967
Cash and cash equivalents at end of year	3,261	8,795	11,887

Balances have been restated from French Francs into euros using the official fixed conversion rate of ε 1=FF 6.55957.

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

EDAP TMS S.A. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

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

1—SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

1-1 Nature of operations

EDAP TMS S.A. and its subsidiaries ("the 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 operations.

1-2 Reporting currency

Until December 31, 1998 EDAP TMS S.A. prepared and reported its consolidated financial statements in French Francs (FRF). With the introduction of the euro ("euro" or "ε") on January 1, 1999 EDAP TMS S.A. has begun to report financial information in euro. Thus, solely for the convenience of the reader, the accompanying consolidated financial statements as of and for the three year period ended December 31, 1998, have been restated in euro using the official conversion rate of ε 1=FF 6.55957, and depict the same trends as would have been presented if it had continued to present its consolidated financial statements in FF. The Group's consolidated financial statements will, however, not be comparable to the euro financial statements of other companies that previously reported their financial information in a currency other than French Francs.

1-3 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.

1-4 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 and EDAP Technomed Co. Ltd. (formerly Nippon Euro Edap Technomed KK). Edap Technomed Sdn Bhd was incorporated in early 1997. Edap Technomed Co. Ltd. was created in late 1996. EDAP S.R.L., an Italian subsidiary consolidated in prior years, is no longer consolidated since 1996 as all activity of this subsidiary has been transferred to the Group's other Italian subsidiary, Edap Technomed Italia S.R.L., and EDAP S.R.L. is in liquidation. Innelect S.A.R.L., a subsidiary dedicated to R&D, which was consolidated in prior years, was merged into TMS S.A. in early 1997. All significant intercompany transactions and balances are eliminated in consolidation.

1-5 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.

1-6 Ability of the Company to continue as a going concern

The Consolidated Financial Statements have been prepared on a going concern basis, which contemplates the realization of assets and the satisfaction of liabilities in the normal course of business. As shown in the Consolidated Financial Statements, the Company reported net losses of ε 6.2 million in 1999 and ε 9.8 million in 1998. In addition, for the years ended December 31, 1999 and 1998, net cash used in operating activities totaled ε 2.5 million and ε 8.3 million, respectively. As a result, as of the date of this Annual Report, the Company does not have sufficient resources to meet its anticipated operating requirements through the year 2000 without obtaining additional financing. The Company is actively pursuing additional financing through discussion with potential investors. This financing plan would include the split of the Company's business into two separate businesses, consisting of the ESWL and HIFU businesses on the one hand, and the TUMT business on the other hand, followed by a sale of an interest in, or certain assets of, either or both of these businesses to institutional or strategic investors. Alternatively, the Company may pursue additional equity financing. If the Company is unable to obtain financing in a timely manner and on acceptable terms, management is developing and intends to implement a plan that would allow the Company to continue to operate through the year 2000. This plan would include sales of assets and/or a significant reduction in operating expenses through the termination of certain research and development activities, a reduction in workforce and a decrease in marketing and other discretionary expenditures. The Consolidated Financial Statements do not include any adjustments that might result from the Company's inability to obtain additional equity financing, sell assets or reduce operating expenses in 2000.

1-7 Cash equivalents

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

1-8 Inventories

Inventories are valued at the lower of manufacturing cost, which is principally comprised of components and labor costs, or market (net realizable value). Cost is determined on a first-in, first-out basis for components and spare parts and by specific identification for finished goods (medical devices). Appropriate consideration is given to deterioration, obsolescence and other factors in evaluating net realizable value.

1-9 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.

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

1-10 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.

1-11 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.

1-12 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.

1-13 Research and development costs

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

1-14 Advertising costs

Advertising costs are recorded as an expense in the period in which they are incurred. Advertising costs for the years ended December 31, 1999, 1998 and 1997 were not material to the consolidated financial statements.

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

1-15 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;
- 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.

1-16 Earnings per share

Basic earnings per share is computed by dividing income available to common shareholders by the weighted average number of shares of common stock outstanding for the period. Diluted earnings per share reflects potential dilution that could occur if securities or other contracts to issue common stock were exercised or converted into common stock or resulted in the issuance of common stock that then shared in the earnings of the 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.

A reconciliation of the numerators and denominators of the basic and diluted EPS calculations for the years ended December 31, 1999 and 1998 is as follows:

	For the year ended Dec. 31, 1999			For the year ended Dec. 31, 1998		
	Loss in Euros (Numerator)	Shares (Denominator)	Per-Share Amount	Loss in Euros (Numerator)	Shares (Denominator)	Per-Share Amount
Basic EPS						
Income available to common Shareholders	(6,231,000)	7,815,272	(0.80)	(9,817,000)	8,247,669	1.19
Diluted EPS						
Income available to common shareholders + assumed conversions	(6,231,000)	7,815,272	(0.80)	(9,817,000)	8,247,669	1.19

For the years ended December 31 1998 and December 31, 1999, the numerators and denominators used for the diluted EPS calculation were identical to those used for the basic EPS calculation as there were no dilutive securities outstanding in those years.

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

1-17 New accounting standards

In June 1998, the Financial Accounting Standards Board ("FASB") issued SFAS No. 133, "Accounting for Derivative Instruments and Hedging Activities," which establishes accounting and reporting standards for derivative instruments, including forward foreign exchange contracts, and for hedging activities. In June 1999, the FASB issued SFAS No. 137, "Accounting for Derivative Instruments and Hedging Activities – Deferral of the Effective Date of FASB Statement No. 133". SFAS No. 133 is now effective for fiscal years beginning after June 15, 2000 and, therefore, the Company will adopt this accounting standard effective January 1, 2001. Adoption of this standard is not expected to have a material effect on the Group's financial position, results of operations or cash flows.

2—TRADE ACCOUNTS AND NOTES RECEIVABLE, NET

	December 31,	
	1999	**1998**
Trade accounts and notes receivable	10,632	13,590
Less: allowance for doubtful accounts	(1,665)	(1,389)
Total	8,967	12,201

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

3—OTHER RECEIVABLES

	December 31,	
	1999	**1998**
Tax loss carryback receivable from the French State	1,464	1,485
Value-added taxes receivable from the French State	383	530
Research and development tax credit receivable from the French State	340	339
Refundable estimated tax payments made to the French State	(6)	69
Other receivables from the French State	180	61
Others	100	178
Total	2,461	2,662

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

The receivable for tax losses carried back to prior years, which was recorded in 1995, 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.

4—INVENTORIES

	December 31,	
	1999	**1987**
Components, spare parts and work-in-progress	7,129	6,983
Finished goods	3,626	3,797
Total gross inventories	10,755	10,780
Less: provision for slow-moving inventory	(2,252)	(1,977)
Total	8,503	8,803

5—PROPERTY, PLANT AND EQUIPMENT

	December 31,	
	1999	**1998**
Land and buildings	0	0
Equipment	4,461	2,366
Furniture, fixture, and fittings and other	2,418	2,345
Total gross value	6,879	4,711
Less: accumulated depreciation	(3,790)	(2,992)
Total	3,089	1,719

6—INTANGIBLE ASSETS

	December 31,	
	1999	**1998**
Licenses	1,655	1,432
Tradename and trademark	898	781
Patents	412	412
Organization costs	360	360
Total gross value	3,325	2,985
Less: accumulated amortization	(2,435)	(1,567)
Total	890	1,418

The net value of intangible assets at December 31, 1999 and 1998 consists principally of licenses, including a license purchased in 1996 by EDAP Technomed, Inc. from a company, and the "Technomed" tradename and trademark purchased in 1994 from Technomed International S.A. The license purchased in 1996 is a non-exclusive, non-transferable license covering all applicators for insertion into the urethra and the related microwave treatment systems. The net book value of this license amounts to ε 473 thousand and ε 707 thousand at December 31, 1999 and 1998, respectively.

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

7—TRADE ACCOUNTS AND NOTES PAYABLE

	December 31,	
	1999	1998
Trade accounts payable	4 ,461	3,732
Notes payable	421	1,612
Total	4,882	5,344

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

8—ACCRUED EXPENSES AND OTHER CURRENT LIABILITIES

	December 31,	
	1999	1998
Deferred revenue on product sales	0	681
Deferred royalty income	2,367	2,578
Deferred maintenance contract income	1,673	1,603
Social security and other payroll withholding taxes	531	703
Value-added taxes payable to the French State	287	384
Employee compensated absences	351	364
Income taxes payable	455	12
Others	964	713
Total	6,628	7,038

In July 1996, TMS S.A. sold a non-exclusive license to two companies for the use of technologies pertaining to the treatment of benign prostatic hyperplasia. Deferred royalty income represents a non-refundable advance on royalty payments which will be due by these companies to EDAP TMS S.A. in 2000 and future years based on sales in those future years of products incorporating the licensed technologies.

9—LEASE OBLIGATIONS

9-1 Capital leases

The following assets held under capital leases have been classified as assets held for sale at December 31, 1998 and 1999 (see Note 15):

	December 31,	
	1999	**1998**
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 ε 797.3 thousand impairment charge was recorded in the fourth quarter of 1998 (see Note 15).

Future minimum lease payments under capital leases in effect at December 31, 1999 are as follows (in thousands of euros):

	Future minimum lease payments	**Less interest portion**	**Net present value of future minimum lease payments**
2000	124	(33)	91
2001	124	(28)	96
2002	124	(22)	102
2003	124	(16)	108
Thereafter	132	(11)	121
Total	628	(110)	518
Less current portion	(124)	33	(91)
Total long-term portion	504	(77)	427

Interest paid for capital lease obligations was ε 39 thousand, ε 44 thousand and ε 48 thousand for the years ended December 31, 1999, 1998 and 1997, respectively.

Depreciation expense on assets held under capital leases is included in total depreciation expense for the years ended December 31, 1999, 1998 and 1997.

9-2 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 ε 267 thousand per year until 2003, or until otherwise canceled by the lessee.

Total rent expense under operating leases amounted to ε 1,200 thousand, ε 1,153 thousand and ε 702 thousand for the years ended December 31, 1999, 1998 and 1997, respectively.

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

10—LONG-TERM DEBT

Long-term debt consists of the following:

	December 31,	
	1999	1998
U.S. dollar term loan	4,779	5,140
Other U.S. dollar term loan	2,308	1,718
Japanese yen term loan	1,169	1,130
Agence Nationale de Valorisation de la Recherche ("ANVAR")	0	366
Total	8,256	8,354
Less current portion	(2,339)	(1,819)
Total long-term portion	5,917	6,535

The loan from ANVAR, a French government agency providing interest-free financing to French companies involved in research and development projects, was obtained by EDAP TMS S.A. to finance the Pyrotech research and development project (high-intensity focused ultrasound technology). The total loan authorization amounted to ε1,829 thousand of which only ε915 thousand had been received at December 31, 1998 and 1997. In 1998, the Group discontinued its Pyrotech program and pronounced its technical failure. Under the terms of the loan agreement with ANVAR, in case of failure of the technology financed by the loan, a portion of the loan is converted into a subsidy and need no longer be reimbursed to ANVAR. In accordance with those terms, ε549 thousand of the loan has been waived in 1998 and ε366 thousand in 1999. These amounts have been recorded in other revenues in 1998 and 1999 respectively.

The U.S. dollar five-year term loan had an initial principal of USD 6 million, bears interest at a fixed rate of 6.31%, calls for repayment of principal in ten semi-annual installments of USD 600 thousand beginning June 30, 1999 and ending December 31, 2003, and calls for quarterly payments of interest in arrears beginning March 31, 1999. Cash equivalents with a carrying value of ε3,398 thousand have been pledged as collateral for this loan. The amount of assets pledged as collateral will decrease in future years as the outstanding principal balance of the loan decreases.

As discussed in Note 26, the sale of 10 Prostatron units in the United States in 1998 was recharacterized as a financing lease of such units by the Company. The “Other U.S. dollar term loan” shown above was recorded to reflect the Company’s long term liability of USD 2,005 thousand as at December 31, 1999 pursuant to such lease. The Company has started to repay the amount due under the lease in sixty monthly installments of USD 53,643 beginning February 1, 1999.

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 installments of JPY 15 million beginning February 23, 1999 and one installment of JPY 30 million on February 24, 2003, and calls for semi-annual payments of interest in advance beginning February 23, 1998.

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

Long-term debt as at December 31, 1999 matures as follows:

2000	2,339
2001	1,864
2002	1,948
2003	2,052
2004	53
Total	8,256

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

11—OTHER PROVISIONS AND LONG-TERM LIABILITIES

	December 31,	
	1999	1998
Provision for warranty costs	359	496
Provision for income tax audits, interest and penalties	0	245
Provision for retirement indemnities	153	127
Other	122	77
Total	634	945

At December 31, 1998, the Group had provided ε 245 thousand for income taxes and related interest and penalties claimed as a result of an income tax audit notified in 1995. This amount was paid to the tax authorities in early 1999.

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, 1999 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.

12—SHAREHOLDERS' EQUITY

12-1 Common stock

As of December 31, 1999, EDAP TMS S.A.'s common stock consists of 9,318,875 authorized shares with a par value of ε0.12 each, of which 8,688,500 were issued and fully-paid and 7,784,850 were outstanding.

12-2 Retained earnings

Distributable statutory retained earnings amount to ε 21,925 thousand and ε 29,434 thousand at December 31, 1999 and 1998.

12-3 Treasury stock

Treasury stock consists of 177,750 shares acquired on December 2, 1996 for ε707 thousand, 691,100 shares acquired between June and December 1998 for ε2,342 thousand , and 34,800 shares acquired in November 1999 for ε 49 thousand. All 903,650 shares of treasury stock have been acquired to cover outstanding stock options (see Note 24). On February 14, 2000, the Company reduced its capital from ε1,059,643 to ε1,014,140 by cancelling 373,100 shares. These cancelled shares included 34,800 shares bought in November 1999 and 338,300 shares corresponding to shares purchase options initially allocated to employees of Group who left the Company, renouncing therefore to their stock purchase options. Following the reduction in capital, the Company now holds 530,550 of its issued shares.

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

13—OTHER REVENUE

	1999	1998	1997
Proceeds from sale of license	0	282	863
Royalties	298	291	311
Subsidies and others	476	832	235
Total	774	1,405	1,409

In July 1996, TMS S.A. sold a non-exclusive license to two companies for the use of technologies pertaining to the treatment of benign prostatic hyperplasia. An additional sum was received in 1997. Royalty income is due by these companies to TMS S.A. based on sales in future years of products incorporating the licensed technologies. Royalty revenue recognized is the greater of revenue due based on actual sales or revenue based on amortization of the license fee over the remaining license period. TMS S.A. also receives royalties on sales of lithotripters made by a German company. In June 1998, TMS S.A. sold a non-exclusive license to one additional company. No further royalties are due under that agreement.

TMS S.A. received ε 476 thousand ε 832 thousand and ε 235 thousand in subsidies in 1999, 1998 and 1997, respectively, from the French Ministry of Research and Development. Subsidies in 1998 and 1999 include the ε 549 thousand and ε 366 thousand respective waivers of a loan from the French Government agency ANVAR (see Note 10).

14—OPERATING EXPENSES

Operating expenses include bad debt expense of ε 592 thousand, ε 308 thousand, and ε 75 thousand for 1999, 1998, and 1997, respectively. These operating expenses also include allowance for slow moving inventory of ε 330 thousand, ε 437 thousand and ε 287 thousand for 1999, 1998, and 1997, respectively.

15—NON RECURRING OPERATING EXPENSES

Following the consolidation of the Group's operations in Lyons and the decision to sell its facility at Croissy-Beaubourg near Paris, in 1998 the Group reclassified these long-lived assets from Property, plant and equipment to Assets held for sale and recorded a non cash charge of ε797.3 thousand (ε797.3 thousand after-tax), as required by and in accordance with the provisions of SFAS No. 121, to write down the carrying value of the Croissy-Beaubourg facility to its estimated fair value less cost to sell of ε 245 thousand. Estimated fair value was determined based on the undiscounted estimated current market value of the facility.

The estimation process involved in determining if assets have been impaired and in the determination of fair value is inherently uncertain since it requires estimates of current market values as well as future events and conditions. The realization of the estimates applied by the Group is dependent upon future uncertain events and conditions and, accordingly, the actual amounts realized by the Group may be materially different from the estimated fair value as described herein.

Other non-recurring expenses of ε 338 thousand in 1999 reflect the cost related to the investigations and re-audit of the 1998 financial statements, following the departure of the former President of the Company’s US subsidiary in October 1999.

16—INTEREST (EXPENSE) INCOME, NET

	1999	1998	1997
Interest income	564	511	409
Interest expense	(804)	(252)	(108)
Total	(240)	259	301

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

17—OTHER INCOME , NET

	1999	1998	1997
Net capital loss on sale of fixed assets	4	(17)	(15)
Other, net	50	63	100
Total	54	46	85

18—INCOME TAXES

(Provision) / credit			
	1999	1998	1997
Current income tax provision	55	(288)	(744)
Research and development tax credit	1	149	445
Carryback of tax losses to prior years	0	109	526
Sub total current income tax	56	(30)	227
Deferred income tax (provision) credit	200	(151)	(102)
Total	256	(181)	125

18-1 Current income tax:

Refundable income taxes and a tax benefits of ε 109 thousand and ε 526 thousand have been recorded by EDAP TMS S.A. in 1998 and TMS S.A. in 1997, respectively, on the basis of tax losses amounting to ε 327 and ε 1,578 thousand, respectively.

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,	
	1999	1998
Elimination of intercompany profit in inventory	1,036	901
Bad debts not currently deductible for tax	0	385
Provision for impairment of long-lived assets	292	292
Inventory provisions not currently deductible for tax	0	287
Other items	218	568
Operating loss carryforwards	8,004	5,557
Total deferred tax assets	9,550	7,990

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

Capital leases treated as operating leases for tax	(190)	(161)
Other items	(240)	(279)
Total deferred tax liabilities	(430)	(440)
Net deferred tax assets	9,120	7,550
Valuation allowance for deferred tax assets	(8,807)	(7,444)
Deferred tax assets, net of allowance	313	106

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

Net operating loss carryforwards of ε 6,340 thousand, ε 1,379 thousand, ε 231 thousand and ε 54 thousand as of December 31, 1999 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 2000 through 2014. 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 increase in the valuation allowance for deferred tax assets for the years ended December 31, 1999 and 1998 was ε1,363 thousand and ε3,504 thousand, respectively, and related primarily to the valuation allowance established for additional net operating loss carryforwards recognized by the Company in those years.

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:

	1999	1998	1997
French statutory rate	41.7%	41.7%	41.7%
Research and development tax credit	0%	2.1%	(235.2)%
Income taxed at capital gains rate	0.8%	0.4%	(127.9%)
Carryback of tax losses to prior years	0%	(0.4%)	75.6%
Non deductible compensation expenses	(0.5)%	(0.5%)	53.9%
Non deductible amortization of goodwill and other intangibles	(1.9)%	(1.7)%	53.7%
Impact on deferred tax balances of change in French statutory tax rate			(34.6)%
Income of foreign subsidiaries taxed at different tax rates	(7.9)%	(2.8)%	33.6%
Effect of net operating loss carryforwards and valuation allowances	(34.2)%	(36.5)%	27.2%
Non deductible entertainment expenses	(0.4)%	(0.3)%	19.5%
Income exempt from taxation (tax holiday)			
Other	6.3%	(3.9%)	26.6%
Effective tax rate	3.9%	(1.9%)	(65.9%)

19—COMMITMENTS AND CONTINGENCIES

The Group has a number of commitments including operating and capital leases as described in Note 9. 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, 1999 and 1998.

	December 31,			
	1999	1999	1998	1998
	Recorded Value	Estimated Fair Value	Recorded Value	Estimated Fair Value
Assets:				
Cash and cash equivalents	3,261	3,261	8,795	8,795
Trade accounts and notes receivable, net	8,967	8,967	12,201	12,201
Restricted cash equivalents	3,398	3,398	3,398	3,398
Liabilities:				
Short-term borrowings	13	13	272	272
Trade accounts payable	4,461	4,461	3,732	3,732
Notes payable	421	421	1,612	1,612
Long-term debt	5,917	4,743	6,535	5,005

The recorded amount of cash and cash equivalents, short-term investments, 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 ε 1,664 thousand and ε 1,389 thousand as of December 31, 1999 and 1998, respectively. Ultimate losses may vary from the current estimates, and any adjustments are reported in earnings in the periods in which they become known.

No customer accounted for more than 10% of net sales in 1999 or 1998.

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

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 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, 1999 and 1998, thus there are no such financial instruments outstanding at December 31, 1999 and 1998.

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:

	1999	1998	1997
Segment operating (loss) profit	(7,658)	(9,511)	(731)
Interest income (expense), net	(240)	259	301
Currency exchange (losses) gains, net	1,357	(430)	534
Other income, net	54	46	85
Income tax (expense) credit	256	(181)	125
Minority interests in consolidated subsidiaries	0	0	(123)
Consolidated income before taxes	(6,231)	(9,817)	191

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:

	1999	1998	1997
France	612	2,886	5,780
United States	1,213	946	7,640
Japan	2,875	2,231	4,576
Other geographical areas	913	833	275
External sales of medical devices	5,613	6,896	18,271
France	2,739	2,721	3,889
United States	3,330	2,820	1,861
Japan	4,874	4,516	5,549
Other geographical areas	2,551	2,310	2,107
External sales of spare parts, supplies and services	13,494	12,367	13,406
France	6,499	7,790	7,718
United States	3	0	164
Japan	59	50	0
Other geographical areas	6	0	276
Inter-segment revenues	6,567	7,840	8,158
France	(500)	(468)	(633)
United States	(373)	(354)	(305)
Japan	(122)	(153)	(67)
Other geographical areas	(66)	(62)	(58)
Depreciation and amortization	(1,061)	(1,037)	(1,063)
France	(3,175)	(5,061)	(1,469)
United States	(5,143)	(4,764)	(272)
Japan	626	225	872
Other geographical areas	34	89	138
Operating (loss) profit	(7,658)	(9,511)	(731)
France	19,491	28,931	36,009
United States	7,633	8,437	6,809
Japan	5,833	4,683	6,370
Other geographical areas	3,398	2,872	2,236
Segment assets	36,355	44,923	51,424
France	704	532	277
United States	1,204	70	85
Japan	16	58	53
Other geographical areas	153	14	80
Capital expenditure	2,077	674	495
France	1,868	2,043	2,890
United States	1,566	817	1,183
Japan	358	348	329
Other geographical areas	187	95	138
Long-lived assets	3,979	3,303	4,540

(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, 1996	1,317	2,084
Charges to costs and expenses	75	287
Deductions: write-off of bad debts provided in prior periods	(85)	(79)
Translation adjustment	135	(8)
Balance as of December 31, 1997	1,442	2,284
Charges to costs and expenses	308	437
Deductions: write-off of bad debts provided in prior periods	(352)	(365)
Translation adjustment	(9)	(379)
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

23—SUPPLEMENTAL DISCLOSURES OF CASH FLOW INFORMATION

Interest and income taxes paid:

	1999	1998	1997
Income taxes paid (refunds received)	324	397	989
Interest paid	744	114	86

24—STOCK OPTION PLANS

24-1 Parent company stock option plans

EDAP TMS S.A. currently sponsors two 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 ε 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 to newly issued shares to 10 employees. Twenty-five percent 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 to the terms of the 1998 option plan discussed below.

On May 14, 1998, the shareholders of EDAP TMS S.A. authorized the Board of Directors to grant up to 713,425 options to purchase pre-existing shares at a fixed exercise price to be set by the Board of Directors at the time of grant provided that the exercise price may not be less than the average stock market price of the shares over the 20 business days preceding the date of grant. The shareholders also authorized the Board of Directors to cause EDAP TMS S.A. to repurchase up to 535,675 of its own shares (treasury stock) to cover the options granted under the new plan. The authorization to grant the options expired one year after the completion of the share repurchase program, which was completed in December 1998. Up to 279,000 of the 713,425 options were reserved for 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 ε 3.81 per share for 152,000 options and ε 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 ε 3.81 per share for 11,000 options and ε 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 ε 3.81 and 20,000 options at an exercise price of ε 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 ε 3.81 instead of ε 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 ε 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 ε 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.

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

A summary of stock option activity under both plans is as follows in Euros:

	1999		1998		1997	
	Options	Weighted average exercise price	Options	Weighted average exercise price	Options	Weighted average exercise price
Outstanding on January 1	583,500	3.99	312,500	6.97	0	0
Granted	86,425	2.75	327,000	2.75	312,500	6.97
Exercised	0	0		0		
Forfeited	(168,375)	3.81	(56,000)	6.40		
Expired	0	0		0		
Outstanding on December 31	501,550	3.91	583,500	3.99	312,500	6.97
Exercisable on December 31	83,965	3.78	71,188	6.97	78,125	6.97
Shares available on December 31 for options that may be granted	903,650		868,850		177,750	

The following table summarizes information about stock options at December 31, 1999:

	Outstanding stock options			Exercisable stock options	
Exercise prices	Options	Weighted average remaining contractual life	Weighted average exercise price	Options	Weighted average exercise price
ε 3.81	291,125	7.88	3.81	81,425	3.81
ε 2.74	20,000	7.00	2.74	2,500	2.74
ε 1.83	190,425	9.01	1.83		0
ε 1.83 to ε 3.81	501,550	8.28	3.16	83,925	3.78

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

Compensation expense for the options granted in 1999, 1998 and 1997 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 ε 89 thousand, ε 269 thousand and ε 449 thousand, respectively. Had SFAS No. 123 been applied, compensation expense would have been increased and net results would have been decreased by ε 120 thousand (ε 0.014 per Basic and Diluted Share), ε 93 thousand (ε 0.011 per Basic and Diluted Share) and ε 141 thousand (ε 0.02 per Basic and Diluted Share) in 1998 and 1997, respectively, with no impact on income taxes.

Information used to calculate the fair value of options granted in 1999, 1998 and 1997 is as follows:

	1999	**1998**	**1997**
Weighted-average fair value per option	1.24	0.82	1.44
Valuation assumptions, using the Black-Scholes option pricing model:			
Weighted-average market value/fair value of share	1.56	1.58	7.79
Weighted-average exercise price	3.21	2.75	6.97
Expected option term (years)	5.0	5.0	2.5
Expected volatility	66.80%	72.73%	*(a)*
Expected dividend yield	0%	0%	0%
Risk-free interest rate	4.0%	3.67%	3.65%

(a) In accordance with SFAS 123, the calculation for 1997 does not take into account the expected volatility of the underlying shares as all options were granted prior to EDAP TMS's Initial Public Offering of shares.

24-2 Subsidiary stock buy-backs and stock option buy outs

On February 20, 1997, a former officer of the Group's U.S. subsidiary exercised options granted under a 1995 subsidiary stock option plan and purchased seven shares (6.4%) of the Group's U.S. subsidiary for 7,699.18. Shortly thereafter, the Group entered into a contract with the officer whereby the officer had an option to sell, and the Group had an option to buy his seven shares at a price per share equal to seven times the subsidiary's net earnings per share for 1997, with a minimum price of $15,000 per share. The options were exercisable at any time between March 1, and March 31, 1998. On March 6, 1998, the options were exercised by the Group at the minimum price of $15,000 per share. The payment to buy-back the shares, which amounted to $105,000, was compensatory; $80,000 was expensed in 1997 and $25,000 was expensed in 1998.

In March 1997, the Group entered into an agreement with a director and former officer of the Group's U.S. subsidiary to repurchase his three shares of the subsidiary which were purchased in 1995 by exercising options granted under the 1995 subsidiary stock option plan. The total payment for the three shares of $207,385 was recorded in 1997 as a purchase of a minority interest. The director also agreed to resign from the board of the subsidiary and to waive any claims that he might have against the Group.

In April 1997, the Group also entered into agreements with two other directors/officers of the Group's U.S. subsidiary to buy-out and cancel the remaining 26 options outstanding under the 1995 subsidiary stock option plan for $27,082 per share. The total payment of $704,132 to buy out the options was compensatory and was expensed in 1997.

As of December 31, 1998 and 1997, no options remain outstanding under the 1995 subsidiary stock option plan.

25—STOCK SPLIT

On April 8, 1997, the shareholders of EDAP TMS approved a 125 for 1 stock split, increasing the number of shares of common stock from 53,508 to 6,688,500 and reducing the par value from ε 15.2 to ε 0.12. All per share figures included in these consolidated financial statements have been adjusted to account for this stock split. On the same date, the shareholders increased the number of authorized shares of common stock from 6,845,125 to 9,318,875 and authorized, for a period of three years, the Board of Directors to issue the 2,473,750 newly authorized shares.

26—RESTATEMENT OF THE 1998 CONSOLIDATED FINANCIAL STATEMENTS

The Company has is restated its consolidated financial statements for the year ended December 31, 1998 to reflect certain sales contingencies identified as part of the Company's review of orders in the United States. Following the departure of the former President of the Company's U.S. subsidiary in October 1999, as further described in the following paragraph, the Company discovered side letters from the Company's U.S. subsidiary setting forth conditions to certain Prostatron orders and guaranteeing end-user payments to a third-party lessor of medical equipment, in violation of the Company's revenue recognition policies. These side letters were not disclosed to the Company's management, and the Company therefore was not aware of them at the time the revenue from these transactions was recognized. No such problems were found in orders from Company customers outside the United States.

The Company has an agreement with a third-party lessor of medical equipment, DVI Financial Services, Inc. ("DVI"). Under this Agreement, DVI purchases Prostatron units and leases them to end-users such as urology clinics or urologists' offices. The Company collects the lease payments and remits them to DVI. However, in accordance with Company policy, the Company normally does not guarantee the performance by the end-users of their obligations under the lease, and DVI performs its own analysis of the creditworthiness of the end-users. The Company's liability is limited to remitting to DVI the lease payments received from end-users. In connection with these transactions, it is therefore appropriate for the Company to recognize revenue upon the sale of the unit because

the risk of ownership has transferred to the third-party lessor. In 1998, the Company's U.S. subsidiary sold 10 Prostatron units to for an aggregate amount of U.S.$ 2.0 million to DVI (the "1998 DVI Transaction"). The Company originally recorded the revenue from these sales in 1998. However, pursuant to a side agreement of which the Company was not made aware at the time revenue was recognized, the 10 Prostatron units were leased by DVI to Northwest Prostate Treatment Center, Inc. ("Northwest"), a provider of urological devices, and in turn by Northwest to the end-users, and the U.S. subsidiary guaranteed to Northwest the performance by the end-users of their obligations under the lease. In 1998 the U.S. subsidiary also issued side letters granting customers rights of return or setting forth other conditions to the order, such as payment terms tied to acceptance or customer use of the machine, in connection with the sale of four other Prostatron units in the United States.

The Company has determined that as a result of the contingencies described in the preceding paragraph revenues from these sales were improperly included in the Company's total revenues for the year 1998. As a result, the 1998 audited consolidated financial statements were amended to reflect the following changes:

Income statement:

	Previously issued 1998 Financial Statements	**Restatement Adjustments**	**Restated 1998 Consolidated Financial statements**
		ε (thousand)	
Total revenues	23,187	(2,519)	20,668
Cost of sales	(11,637)	179	(11,458)
Gross profit	11,550	(2,340)	9,210
Operating expenses	(18,555)	(167)	(18,721)
Operating loss	(7,005)	(2,506)	(9,511)
Net loss	(7,141)	(2,677)	(9,817)
Net loss per share	(0.87)	(0.32)	(1.19)

The income statement adjustments described above reflected primarily a decrease in total revenues resulting from the exclusion from net sales of medical devices of revenues from the sales of 14 Prostatrons in the United States recorded in 1998.

Balance sheet:

	Previously issued 1998 Consolidated Financial Statements	**Restatement Adjustments**	**Restated 1998 Consolidated Financial Statements**
		ε (thousand)	
Accounts receivable, net	12,311	(110)	12,201
Inventories, net	8,641	162	8,803
Total current assets	33,346	(490)	32,856
Total assets	45,442	(519)	44,923
Total current liabilities	13,595	965	14,559
Long-term debt, less current portion	5,534	1,519	7,052
Shareholders' equity	24,926	(2,563)	22,363

The balance sheet adjustments described above reflected primarily an increase in inventories due to the return to inventories of the four units for which rights of return or conditional payment terms were granted to customers. In addition, in connection with the DVI Transaction, the Company recorded an increase in long term debt of U.S. $2.0 million as at December 31, 1998. The DVI transaction was recharacterized for purposes of the restatement as

involving a sale-and-leaseback of 10 Prostatron units from DVI to the Company, with the Company being directly liable for the repayment of the full amount of the lease to DVI.

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)

_____
Eric Simon
Chief Executive Officer

Dated: May , 2000

EXHIBIT INDEX

Exhibit Number	Description	Sequential Page Number
1.1	List of subsidiaries of EDAP TMS S.A. as of May 2000;	1
2.1	Agreement for Sales Leads Generation Services dated October 29, 1999 entered into with Bank Urological Division, C.R. Bard, Inc.	2

LIST OF EDAP TECHNOMED's SUBSIDIARIES
AS OF MAY 2000

TECHNOMED MEDICAL SYSTEMS, S.A., Vaulx-en-Velin. France

EDAP TECHNOMED Inc, Atlanta, USA

EDAP TECHNOMED Co Ltd, Tokyo, Japan

EDAP TECHNOMED Sdn Bhd, Kuala Lumpur, Malaysia

EDAP TECHNOMED Srl, Roma, Italia (subsidiary of Technomed Medical Systems)