EDAP TMS SA
Form 20-F
April 12, 2019

As filed with the Securities and Exchange Commission on April 12, 2019

UNITED STATES 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

ý Annual Report Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

For the Fiscal Year Ended December 31, 2018

Or

Transition Report Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

For the transition period from _____ to _____

Or

Shell Company Report Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

Date of the event requiring this shell company report_____

000-29374

(Commission file number)

EDAP TMS S.A.

(Exact name of registrant as specified in its charter)

France

(Jurisdiction of incorporation or organization)

Parc d'Activites la Poudrette-Lamartine

4/6, rue du Dauphiné

69120 Vaulx-en-Velin, France

(Address of principal executive offices)

Mrs. Blandine Confort -Tel. +33 4 72 15 31 50, E-mail: bconfort@edap-tms.com

Parc d'Activites la Poudrette-Lamartine, 4/6, rue du Dauphiné, 69120 Vaulx-en-Velin, France

(Name, Telephone, E-mail and Address of Company Contact Person)

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
American Depositary Shares, each representing One Ordinary Share	NASDAQ Global Market
Ordinary Shares, nominal value €0.13 per share	NASDAQ Global Market

Securities registered or to be registered pursuant to Section 12(g) of the Act: **None**

Securities for which there is a reporting obligation pursuant to Section 15(d) of the Act: **None**

Outstanding shares of each of the issuer's classes of capital or common stock as of December 31, 2018: 28,997,866 Ordinary Shares

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act.

Yes ___ No _X_

If this report is an annual or transition report, indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934. Yes ___ No _X_

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

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes _X_ No ___

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or an emerging growth company. See definition of "large accelerated filer", "accelerated filer" and "emerging growth company" in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer ___ Accelerated filer _X_ Non-accelerated filer ___ Emerging growth company ___

If an emerging growth company that prepares its financial statements in accordance with U.S. GAAP, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards† provided pursuant to Section 13(a) of the Exchange Act. ___

† The term “new or revised financial accounting standard” refers to any update issued by the Financial Accounting Standards Board to its Accounting Standards Codification after April 5, 2012.

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

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

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

Item 17 ___ Item 18 ___

If this is an annual report, indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ___ No _X_

1

TABLE OF CONTENTS

Page

PART III

[THIS PAGE INTENTIONALLY LEFT BLANK]

3

PRESENTATION OF FINANCIAL AND OTHER INFORMATION

Unless the context otherwise requires, references herein to “we,” “us,” “our” or “group” are to EDAP TMS S.A. and its consolidated subsidiaries and references herein to the “Company,” “EDAP” or “EDAP TMS” are to EDAP TMS S.A.

We prepare our consolidated financial statements in conformity with United States generally accepted accounting principles (‘‘U.S. GAAP’’). In this annual report, references to ‘‘euro’’ or ‘‘€’’ are to the legal currency of the countries of the European Monetary Union, including the Republic of France, and references to ‘‘dollars,’’ ‘‘U.S. dollars’’ or ‘‘$’’ are to the legal currency of the United States of America. Solely for the convenience of the reader, this annual report contains translations of certain euro amounts into dollars at specified rates. These translations should not be construed as representations that the euro amounts actually represent such dollar amounts or could be converted into dollars at those rates. See Item 11, ‘‘Quantitative and Qualitative Disclosures about Market Risk’’ for a discussion of the effects of fluctuations in currency exchange rates on the Company.

The following are registered trademarks of the Company in the United States: EDAP TMS® & associated logo, EDAP®, Ablatherm®, Ablasonic®, Ablapak®, Sonolith i-sys®, Sonolith i-move®, Focal.One®. This annual report also makes references to trade names and trademarks of companies other than the Company.

CAUTIONARY STATEMENT ON FORWARD-LOOKING INFORMATION

This annual report includes certain forward-looking statements within the meaning of Section 27A of the U.S. Securities Act of 1933 (the “Securities Act”) or Section 21E of the U.S. Securities Exchange Act of 1934 (the “Exchange Act”), which may be identified by words such as ‘‘believe,’’ ‘‘plan,’’ ‘‘intend,’’ “should,” ‘‘estimate,’’ ‘‘expect’’ and ‘‘anticip expressions, which reflect our views about future events and financial performance. Forward-looking statements involve inherent known and unknown risks and uncertainties including matters not yet known to us or not currently considered material by us. Actual events or results may differ materially from those expressed or implied in such forward-looking statements as a result of various factors that may be beyond our control. Factors that could affect future results or cause actual events or results to differ materially from those expressed or implied in forward-looking statements include, but are not limited to:

- the success of our High Intensity Focused Ultrasound (“HIFU”) technology;
- the clinical and regulatory status of our HIFU devices in various geographical territories;
- the uncertainty of market acceptance for our HIFU devices;
-

- the uncertainty in the U.S. FDA review and approval process for any of our devices and changes in FDA recommendations and guidance;
- effects of intense competition in the markets in which we operate;
- the uncertainty of reimbursement status of procedures performed with our products;
- the market potential for our lithotripters' range and our HIFU devices;
- the impact of government regulation, particularly relating to public healthcare systems and the commercial distribution of medical devices;
- dependence on our strategic suppliers and distribution partners;
- any event or other occurrence that would interrupt operations at our primary production facility;
- reliance on patents, licenses and key proprietary technologies;
- cybersecurity risks and incidents,
- product liability risk;
- risk of exchange rate fluctuations, particularly between the euro and the U.S. dollar and between the euro and the Japanese yen;
- fluctuations in results of operations due to the cyclical nature of demand for medical devices;
- risks associated with the current uncertain worldwide economic, political and financial environment;
- risks relating to ownership of our securities; and
- risks relating to securities litigations involving class actions.

You should also consider the information contained in Item 3, ''Key Information—Risk Factors'' and Item 5, ''Operating and Financial Review and Prospects,'' or further discussion of the risks and uncertainties that may cause such differences to occur. Forward-looking statements speak only as of the date they are made. Other than required by law, we do not undertake any obligation to update them in light of new information or future developments.

PART I

Item 1. Identity of Directors, Senior Management and Advisors

Not applicable.

Item 2. Offer Statistics and Expected Timetable

Not applicable.

Item 3. Key Information

Selected Financial Data

The following table sets forth selected consolidated financial data for the periods indicated. This information is qualified by and should be read in conjunction with the consolidated financial statements and the Notes thereto included in Part III of this annual report, as well as Item 5, ‘‘Operating and Financial Review and Prospects.’’ The selected balance sheet data as of December 31, 2018 and 2017 and the selected income statement data for the years ended December 31, 2018, 2017 and 2016 set forth below have been derived from our consolidated financial statements included in this annual report. Our consolidated financial statements have been prepared in accordance with U.S. GAAP. To date, we have not been required, and presently are not required under French law, to prepare consolidated financial statements under French GAAP or IFRS, nor have we done so.

Year Ended and at December 31,

In thousands of euro, except per share data in euro	2018	2017	2016	2015	2014
INCOME STATEMENT DATA					
Total revenues	39,183	35,746	35,611	32,253	26,785
Totalsales	39,163	35,686	35,579	32,218	26,252
Gross profit	16,917	14,808	16,411	13,785	11,201

Operating expenses	(18,232)	(16,835)	(16,019)	(13,298)	(12,937)
Income (loss) from operations	(1,315)	(2,027)	392	488	(1,736)
Basic Income (loss) from operations per common share	(0.05)	(0.07)	0.01	0.02	(0.07)
Diluted Income (loss) from operations per common share	(0.05)	(0.07)	0.01	0.02	(0.07)
Income (loss) before income taxes	20	(294)	4,444	(907)	(396)
Income tax (expense) benefit	(358)	(388)	(602)	(759)	(116)
Net income (loss)	(338)	(681)	3,842	(1,667)	(512)
Basic earnings (loss) per share	(0.01)	(0.02)	0.14	(0.07)	(0.02)
Diluted earnings (loss) per share	(0.01)	(0.02)	0.13	(0.07)	(0.02)
Dividends per share[(1)]	—	—	—	—	—
Basic weighted average shares outstanding	28,997,866	28,961,928	27,823,313	25,021,966	23,601,428
Diluted weighted average shares outstanding	28,997,866	28,961,928	29,365,583	25,021,966	23,601,428
BALANCE SHEET DATA					
Total current assets	40,376	39,574	40,502	32,992	26,575
Property and equipment, net	4,208	3,682	2,770	2,123	2,122
Total assets	48,740	46,897	46,591	38,581	32,154
Total current liabilities	16,812	16,134	15,010	16,271	12,158
Capital lease obligations, less current portion	852	528	313	294	355
Long-term debt, less current portion	1,339	834	3,665	4,798	2,434
Common stock, €0.13 par value; 29,368,394 shares issued and 28,997,866 shares outstanding; at December 31, 2018 and 2017 respectively	3,818	3,818	3,783	3,348	3,282
Total shareholders' equity	24,964	25,158	24,451	14,430	15,141

(1) No dividends were paid with respect to fiscal years 2014 through 2017 and subject to approval of the annual shareholders' meeting to be held in 2018 the Company does not anticipate paying any dividend with respect to fiscal year 2018. See Item 8, ''Financial Information — Dividends and Dividend Policy.''

RISK FACTORS

In addition to the other information contained in this annual report, the following risk factors should be carefully considered in evaluating us and our business. These statements are intended to highlight the material risk factors that may cause actual financial, business, research or operating results to differ materially from expectations disclosed in this annual report. See also factors disclosed under "Cautionary statement on forward-looking information".

Risks Relating to Our Business

We have a history of operating losses and it is uncertain whether we can reach profitability in the future.

Although we achieved operational profitability in 2015 and 2016, we have incurred operating losses in 2018 and 2017 and in each previous fiscal year prior to 2015, since 1998. We expect that our marketing, selling and research and development expenses will increase as we attempt to develop and commercialize our lithotripsy and particularly our HIFU devices. We may not, however, generate a sufficient level of revenue to offset these expenses and may not be able to adjust spending in a timely manner to respond to any unanticipated decline in revenue. We cannot guarantee that we will realize sufficient revenue to reach profitability in the future. See Item 5, ''Operating and Financial Review and Prospects.''

Our future revenue growth and income depend, among other things, on the success of our HIFU technology.

Our Extracorporeal Shockwave Lithotripsy ("ESWL") line of products competes in a mature market that has experienced overall declining unit sales prices in recent years. We depend on the success of our HIFU technology for future revenue growth and net income. In particular, we are dependent on the successful development and commercialization of other product lines, such as medical devices based on HIFU, particularly but not limited to the Ablatherm and the Focal One, to generate significant additional revenues and achieve and sustain profitability in the future.

Although we are particularly dependent on the success of our HIFU technology to grow our business, other revenues, generated by our Urology Devices and Services ("UDS") division and directly linked to the distribution of other complementary products on behalf of medical companies, continue to increase significantly and contribute to our revenue growth. While we believe that our UDS division can successfully pursue the marketing of its worldwide distribution platform, any termination of distribution commitments from such medical third parties could have a material adverse effect on our business, financial condition or results of operations. See "—Item 4, "Information on the Company—UDS Division— UDS Division Services and Distribution."

We utilize distributors for our sales abroad, which subjects us to a number of risks that could harm our business.

We have developed strategic relationships with a number of distributors for sales and service of our devices in certain foreign countries where we are not directly represented by a subsidiary. If these relationships are terminated and not replaced, our revenues and/or ability to market or service our devices in the related territories could be adversely affected. Our distributors' actions may affect our ability to effectively market our devices in certain foreign countries if, for example, a distributor holds the regulatory authorizations in such countries and causes, by action or inaction, the suspension of such regulatory authorizations or sanctions for non-compliance. It may be difficult, expensive, and time consuming for us to re-establish market access or regulatory compliance in such case. Moreover, our distributors must be in compliance with anti-corruption laws, such as the U.S. Foreign Corrupt Practices Act, and other local laws prohibiting corrupt payments to governmental officials or to customers and we may not be able to trace or be kept informed of such corruption. In addition, we may be named as a defendant in lawsuits against our distributors related to sales or service of our devices performed by these distributors. See our risk factor below "*We face a significant risk of exposure to product liability claims in the event that the use of our products results in personal injury or death.*"

We operate in a highly regulated industry and our future success depends on obtaining and maintaining government regulatory approval of our products, which we may not receive or be able to maintain or which may be delayed for a significant period of time.

Government regulation significantly impacts the development and marketing of our products, particularly in the United States, EU and Japan. We are regulated in each of our major markets with respect to preclinical and clinical testing, manufacturing, labeling, distribution, sale, marketing, advertising and promotion of our products. To market and sell products, we are required to obtain approval or clearance from the relevant regulatory agencies, including the FDA with respect to the United States. In that respect, the FDA may not act favorably or quickly in its review of our submissions, or we may encounter significant difficulties in our efforts to obtain FDA clearance or approval, all of which could delay or preclude the sale of new products in the U.S. In the European Union, the regulation of medical devices is being updated -the European Medical Device Regulation ("MDR") and will be effective as of 2020 imposing stricter requirements on the conformity assessment and the commercialization of our products. An MDR gap analysis is currently being performed in preparation of MDR transition within the expected timelines. During transition period, regulatory actions are being implemented to ensure our devices continue to be distributed on European and international markets after May 2020.

The process of applying for regulatory approval is often lengthy and requires the expenditure of substantial resources. Further, there can be no assurance that we will receive the required approvals for our products from the required regulatory authorities or, if we do receive the required approvals, that we will receive them on a timely basis, on the conditions and for the indications we seek, or that we will otherwise be able to satisfy the conditions of such approval, if any.

Even if regulatory approval to market a product is granted, it may include limitations on the indicated uses for which the product may be marketed. Failure to comply with regulatory requirements can result in fines, suspension or withdrawal of regulatory approvals, product recalls, seizure of products, operating restrictions and criminal prosecutions. Regulatory policy may change and additional government regulations may be established that could prevent or delay regulatory approval of our products. Any delay, failure to receive regulatory approval or the loss of previously received approvals could have a material adverse effect on our business, financial condition and results of operations. For more information on the regulation of our business, see Item 4, ‘‘Information on the Company—Government Regulation’’ and “Information on the Company—HIFU Division—HIFU Division Clinical and Regulatory Status.”

Moreover, we may also be required to abandon previous strategies for regulatory approval, despite having made significant financial and time investments, or refocus our efforts on alternative regulatory strategies, resulting in increased costs and efforts of management, without any guarantee of success, which could materially adversely affect our business, financial condition and results of operations.

Furthermore, we are also subject to healthcare laws and regulations pertaining to physician payment transparency, privacy and regulations. These regulations include, but are not limited to (i) the U.S. federal Health Insurance Portability and Accountability Act (“HIPAA”) of 1996, as amended by the Health Information Technology for Economic and Clinical Health Act, which governs the conduct of certain electronic healthcare transactions and protects the security and privacy of protected health information; (ii) the U.S. federal Physician Payment Sunshine Act (the “Sunshine Act”), which requires manufacturers of medical devices for which payment is available under Medicare, Medicaid, to report annually to the Centers for Medicare & Medicaid Services (“CMS”) information related to payments or other “transfers of value” made to physicians, (iii) two main sets of laws enacted in France about transparency requirements: “The French Anti-Gift Law” which regulates the provision of gifts, discounts and other incentives to physicians and the “Loi Bertrand” which imposes disclosure obligations on companies relating to benefits and remunerations granted to, and agreements concluded with, physicians. Any failure to comply with these regulations may have a material adverse effect on our business, financial condition and results of operations.

Finally, changes to regulatory policy or the adoption of additional statutes or regulations that affect our business could impose substantial additional costs or otherwise have a material adverse effect on our business, financial condition and results of operations.

Our clinical trials related to products using HIFU technology may not be successful and we may not be able to obtain regulatory approvals necessary for commercialization of all of our HIFU products.

Before obtaining regulatory approvals for the commercial sale of any of our devices under development, we must demonstrate through preclinical testing and clinical trials that the device is safe and effective for use in each indication. Product development, including pre-clinical studies and clinical trials is a long, expensive and uncertain process, and is subject to delays and failures at any stage. We or the relevant regulatory authorities may suspend or terminate clinical trials at any time and regulating agencies may even refuse to grant exemptions to pursue clinical trials. The results from preclinical testing and early clinical trials may not predict the results that will be obtained in large scale clinical trials. Companies can suffer significant setbacks in advanced clinical trials, even after promising results in earlier trials. Furthermore, data obtained from a trial can be insufficient to demonstrate that our products are safe, effective, and marketable. The commencement, continuation or completion of any of our clinical trials may be delayed or halted, or inadequate to support approval of an application to regulatory authorities for numerous reasons including, but not limited to:

· that regulatory authorities do not approve a clinical trial protocol or a clinical trial, or place a clinical trial on hold,

· discussions with regulatory authorities to improve our clinical protocols may prove difficult and lengthy; See Item 4, ‘‘Information on the Company—HIFU Division Clinical and Regulatory Status.’’

· slower than expected rates of patient recruitment and enrolment;

- inability to adequately monitor patient during or after treatment;
- failure of patients to complete the clinical trial;
- prevalence and severity of adverse events and other unforeseen safety issues;
- third-party organizations not performing data collection and analysis in a timely and accurate manner;
- governmental and regulatory delays or changes in regulatory requirements, policies or guidelines;
- the interim or final results of a clinical trial are inconclusive or unfavorable as to safety or efficacy; and
- that regulatory authorities conclude that our trial design is inadequate to demonstrate safety and efficacy.

The data we collect from our current clinical trials, our pre-clinical studies and other clinical trials may not be sufficient to support requested regulatory approval. Additionally, certain regulatory authorities may disagree with our interpretation of the data from our pre-clinical studies and clinical trials, or may find the clinical trial design, conduct or results inadequate to prove safety or efficacy, and may require us to pursue additional pre-clinical studies or clinical trials, which would increase costs and could further delay the approval of our products. If we are unable to demonstrate the safety and efficacy of our products in our clinical trials, we will be unable to obtain regulatory approval to market our products.

Our HIFU devices that have not received regulatory approval may not prove to be effective or safe in clinical trials or may not be approved by the appropriate regulatory authorities. If our HIFU devices do not prove to be effective and safe in clinical trials to the satisfaction of the relevant regulatory authorities, our business, financial condition and results of operations could be materially adversely affected.

The commercial success of our products depends on whether procedures performed by those products are eligible for reimbursement approved by national health authorities and third-party payers.

Our success depends, among other things, on the extent to which reimbursement can be obtained from healthcare payers for procedures performed with our products. In the United States, we are dependent upon favorable decisions by CMS for Medicare reimbursement, individual managed care organizations, private insurers and other payers. These decisions may be revised from time to time, which could negatively affect reimbursement for procedures performed using our devices. In May 2017, CMS granted a C-code for the use of HIFU for prostate tissue ablation, effective July 1st, 2017. This C-code covers hospital practical fees. We are currently in discussion with private insurers to advance

on the reimbursement of HIFU procedures for prostate tissue ablation. Outside the United States, and in particular in the European Union and Japan, third-party reimbursement is generally conditioned upon decisions by national health authorities. In the European Union, there is no harmonized procedure for obtaining reimbursement and, consequently, we must seek regulatory approval in each Member State. Procedures performed with our HIFU devices are not reimbursed in the European Union with the exception of Italy, Germany, in the United Kingdom (where procedures are partially reimbursed by either public healthcare systems or private insurers and in France under certain conditions). On April 18, 2014, the French healthcare government authorities announced the reimbursement of prostate cancer treatment procedures using HIFU as part of a specific process ("Forfait Innovation") to further validate breakthrough therapies and to accelerate their related reimbursement process based on clinical trials and data registries. HIFU patients are still being treated and entered into the dedicated registry. Under this specific process, French healthcare government authorities will review the clinical data gathered following this decision in view of granting definitive reimbursement for HIFU. However, we cannot guarantee that a definitive reimbursement code will finally be granted.

Lithotripsy procedures currently are reimbursed by public healthcare systems in the European Union, in Japan and in the United States. However, a decision in any of those countries to modify reimbursement policies for these procedures could have a material adverse effect on our business, financial conditions and results of operations. For example, in April 2016, the Japanese authorities decided to stop reimbursing lithotripters' disposables (electrodes) necessary to perform a lithotripsy procedure. This decision had and will have a material effect on our current and future sales of lithotripsy disposables in Japan.

We cannot assure investors that additional reimbursement approvals will be obtained in the near future. If reimbursement for our products is unavailable, limited in scope or amount, or if pricing is set at unsatisfactory levels, and if we fail to establish or maintain a certain level of reimbursement or full reimbursement from healthcare payers or governments and private healthcare payers' policies change, it could have a material adverse effect on our business, financial condition and results of operations.

HIFU technology may not be adopted by the medical community and may never become a standard of care.

Our HIFU devices represent new therapies for the conditions that they are designed to treat. Notwithstanding any positive clinical results that our HIFU devices may have achieved or may achieve in the future in terms of safety and efficacy and any marketing approvals that we have obtained or may obtain in the future, there can be no assurance that such products will gain adoption by the medical community. Physician adoption depends, among other things, on evidence of the cost effectiveness of a therapy as compared to existing therapies and on adequate reimbursement from healthcare payers. Furthermore, acceptance by patients depends in part on physician recommendations, as well as other factors, including the degree of invasiveness, the rate and severity of complications and other side effects associated with the therapy as compared to other therapies.

If our HIFU devices do not achieve an adequate level of acceptance by physicians, patients, health care payers and the medical community and never become a standard of care, we may not generate or maintain positive cash flows and we may not become profitable or be able to sustain profitability. If we do achieve market acceptance of our products, we may not be able to sustain it or otherwise achieve it to a degree, which would support the ongoing viability of our operations.

Our cash flow is highly dependent on demand for our products.

Our cash flow has historically been subject to significant fluctuations over the course of any given financial year due to cyclical demand for medical devices, and the resulting annual and quarterly fluctuations in trade and other receivables and inventories. This has in the past resulted in significant variations in working capital requirements and operating cash flows. Although in 2015 and 2016, our operating cash flow was positive, in 2018 our operating cash flow was negative due to the operating loss and working capital cash requirements, to expand our worldwide activities. Since we anticipate relying on cash flow from operating activities to meet our liquidity requirements, a decrease in the demand for our products, or the inability of our customers to meet their financial obligations to us, would reduce the funds available to us. In the future, our liquidity may be constrained and our cash flows may be uncertain, negative or significantly different from period to period. Our future cash flow will be affected by increased expenses in clinical trials, sales efforts as well as marketing campaigns and promotional tools, particularly to implement our expanded U.S. and global strategy following the FDA clearance of Ablatherm, and Focal One, while there is no assurance that this will result in the increase in the demand for our products and services.

Competition in the markets in which we operate is intense and is expected to increase in the future.

Competition in the markets in which we operate is intense and is expected to increase in the future. In each of our main businesses, we face competition both directly from other manufacturers of medical devices that apply the same technologies that we use, as well as indirectly from existing or emerging therapies for the treatment of urological

disorders.

We believe that because ESWL has long been the standard treatment for urinary tract calculus disease, competition in that market comes principally from current manufacturers of lithotripters, including Wolf, Storz and Dornier. In the markets that we target for our HIFU products, competition comes from new market entrants and alternative therapies, as well as from current manufacturers of medical devices. In the HIFU market, our devices, in particular the Ablatherm and the Focal One, compete with all current treatments for localized tumors, including surgery, external beam radiotherapy, brachytherapy and cryotherapy. Other energies addressing prostate cancer ablation are also currently being developed such as electroporation and microwave. Other companies working with HIFU technology for the minimally invasive treatment of tumors include SonaCare Medical, a U.S. company that markets a device called the Sonablate for the ablation of prostatic tissue. Sonablate was approved by the FDA for commercialization in the U.S. in October 2015. Profound Medical, a Canadian company, is developing transurethral ultrasound therapy for prostate cancer. Profound Medical acquired Philips Healthcare's HIFU activity, integrating the development of HIFU devices addressing uterine fibroids, breast tumors and drug delivery activated by HIFU. Insightec, an Israeli company owned mainly by General Electric and Elbit Medical Imaging, has developed a device using HIFU technology to treat uterine fibroids, painful bone tumors and brain disorders. Theraclion, a French company licensed by EDAP to use of some of our HIFU patents, is currently marketing the Echopulse HIFU device to treat thyroid tumors and benign breast tumors. Haifu, a Chinese company, is developing HIFU products addressing various types of cancers. See Item 4, ''Information on the Company—HIFU Division— HIFU Competition'' and Item 4, ''Information on the Company—UDS Division.''

Many of our competitors have significantly greater financial, technical, research, marketing, sales, distribution and other resources than we have and may have more experience in developing, manufacturing, marketing and supporting new medical devices. In addition, our future success will depend in large part on our ability to maintain a leading position in technological innovation, and we cannot assure investors that we will be able to develop new products or enhance our current ones to compete successfully with new or existing technologies. Rapid technological development by competitors may result in our products becoming obsolete before we recover a significant portion of the research, development and commercialization expenses incurred with respect to those products.

We also face competition for our maintenance and service contracts. Larger hospitals often utilize their in-house maintenance departments instead of contracting with equipment manufacturers like us to maintain and repair their medical equipment. In addition, third-party medical equipment maintenance companies increasingly compete with equipment manufacturers by offering broad repair and maintenance service contracts to hospitals and clinics. This increased competition for medical devices and maintenance and service contracts could have a material adverse effect on our business, financial condition and results of operations.

Our manufacturing operations are highly regulated and failure to comply with those regulations would harm our business.

Our manufacturing operations must comply with regulations established by regulatory agencies in the United States, the European Union and other countries, and in particular with the Current Good Manufacturing Practices (‘‘CGMP’’) mandated by the FDA and European Union standards for quality assurance and manufacturing process control. Since such standards may change, we may not, at all times, comply with all applicable standards and, as a result would be unable to manufacture our products for commercial sale. Our manufacturing facilities are subject to inspection by regulatory authorities at any time. If any inspection by the regulatory authorities reveals deficiencies in manufacturing, we could be required to take immediate remedial actions, suspend production or close the current and future production facilities, which would disrupt our manufacturing processes. Accordingly, failure to comply with these regulations could have a material adverse effect on our business, financial condition and results of operations.

We depend on a single site to manufacture our products, and any interruption of operations could have a material adverse effect on our business.

Most of our manufacturing currently takes place in a single facility located in Vaulx-en-Velin, on the outskirts of Lyon, France. In the event of a significant interruption in the operations of our sole facility for any reason, such as fire, flood or other natural disaster or a failure to obtain or maintain required regulatory approvals, we would have no other means of manufacturing our products until we were able to restore the manufacturing capabilities at our facility or develop alternative facilities, which could take considerable time and resources and have a material adverse effect on our business, financial condition and results of operations. If we are unable to manufacture a sufficient or consistent supply of our products or products we are developing, or if we cannot do so efficiently, our revenue, business and financial prospects would be adversely affected.

For certain components or services, we depend on a single supplier who, due to events beyond our control may fail to deliver sufficient supplies to us or increase the cost of items supplied, which would interrupt our production processes or negatively impact our results of operations.

We purchase the majority of the components used in our products from a number of suppliers, but rely on a single supplier for some key components. In addition, we rely on single suppliers for certain services. If the supply of these components or services were interrupted for any reason, our manufacturing and marketing of the affected products would be delayed. These delays could be extensive, especially in situations where a component substitution would require regulatory approval. In addition, such suppliers could decide unilaterally to increase the price of supplied items and therefore cause additional charges for the Company. We expect to continue to depend upon our suppliers for the foreseeable future. Failure to obtain adequate supplies of components or services in a timely manner and at the agreed price could have a material adverse effect on our business, financial condition and results of operations.

Intellectual property rights are essential to protect our medical devices, and any dispute with respect to these rights could be costly and have an uncertain outcome.

Our success depends in large part on our ability to develop proprietary products and technologies and to establish and protect the related intellectual property rights, without infringing the intellectual property rights of third parties. The validity and scope of claims covered in medical technology patents involve complex legal and factual questions and, therefore, the outcome of such claims may be highly uncertain. The medical device industry has been characterized by extensive patents and other intellectual property rights litigation. From time to time we may receive letters from third parties drawing our attention to their patent rights. Our products, including our HIFU devices, may be subject to litigation involving claims of patent infringement or violation of other intellectual property rights of third parties. The defense and prosecution of intellectual property suits, patent opposition proceedings and related legal and administrative proceedings are both costly and time consuming and may result in a significant diversion of effort and resources by our technical and management personnel. An adverse determination in any such litigation or proceeding to which we become a party could subject us to significant liability to third parties, require us to seek licenses from third parties and pay ongoing royalties, require us to redesign certain products or subject us to injunctions preventing the manufacture, use or sale of the affected products. In addition to being costly, drawn-out litigation to defend or prosecute intellectual property rights could cause our customers or potential customers to defer or limit their purchase or use of our products until the litigation is resolved. See Item 4, ‘‘Information on the Company—HIFU Division—HIFU Division Patents and Intellectual Property’’ and Item 4, ‘‘Information on the Company—UDS Division—UDS Division Patents and Intellectual Property.’’

We own patents covering several of our technologies and have additional patent applications pending in the United States, the European Union, Japan and elsewhere. The process of seeking patent protection can be long and expensive and there can be no assurance that our patent applications will result in the issuance of patents. We also cannot assure investors that our current or future patents are or will be sufficient to provide meaningful protection or commercial advantage to us. Our patents or patent applications could be challenged, invalidated or circumvented in the future. Failure to maintain or obtain necessary patents, licenses or other intellectual property rights from third parties on acceptable terms or the invalidation or cancellation of material patents could have a material adverse effect on our business, financial condition or results of operations. Litigation may be necessary to enforce patents issued to us or to determine the enforceability, scope and validity of the proprietary rights of others. Our competitors, many of which have substantial resources and have made substantial investments in competing technologies, may apply for and obtain patents that will interfere with our ability to make, use or sell certain products, including our HIFU devices, either in the United States or in foreign markets.

We also rely on trade secrets and proprietary know-how, which we seek to protect through non-disclosure agreements with employees, consultants and other parties. It is possible, however, that those non-disclosure agreements will be breached, that we will not have adequate remedies for any such breach, or that our trade secrets will become known to, or independently developed by, competitors. Litigation may be necessary to protect trade secrets or know-how owned by us. In addition, effective copyright and trade secret protection may be unavailable or limited in certain countries.

The occurrence of any of the foregoing could have a material adverse effect on our business, financial condition and result of operations.

We face a significant risk of exposure to product liability claims in the event that the use of our products results in personal injury or death.

Our products are designed to be used in the treatment of severe affections and conditions. Despite the use of our products, patients may suffer personal injury or death, and we may, as a result, face significant product liability claims. We maintain separate product liability insurance policies for the United States and Canada and for the other markets in which we sell our products. Product liability insurance is expensive and there can be no assurance that it will continue to be available on commercially reasonable terms or at all. In addition, our insurance may not cover certain product liability claims or our liability for any claims may exceed our coverage limits. A product liability claim or series of claims brought against us with respect to uninsured liabilities or in excess of our insurance coverage, or any claim or product recall that results in significant cost to or adverse publicity against us could have a material adverse effect on our business, financial condition and results of operations. Also, if any of our products prove to be defective, we may be required to recall or redesign the product which could result in costly corrective actions and harm to our business reputation, which could materially affect our business, financial condition and results of operations.

We are exposed to risks related to cybersecurity threats and incidents.

In the conduct of our business, we collect, use, transmit and store data on information technology systems. This data includes confidential information belonging to us, our customers and other business partners, as well as personally identifiable information of individuals. We also store data related to our clinical trials on our information technology systems. We also rely in part on the reliability of certain tested third parties' cybersecurity measures, including firewalls, virus solutions and backup solutions. Cybersecurity incidents, such as breaches of data security, disruptions of information technology systems and cyber threats, may result in business disruption, the misappropriation, corruption or loss of confidential information and critical data (ours or that of third parties), reputational damage, litigation with third parties, diminution in the value of our investment in research and development, data privacy issues and increased cybersecurity protection and remediation costs. Like many companies, we may experience certain of these incidents given that the external cyber-attack threat continues to grow. Moreover, we devote significant resources to network security, data encryption and other measures to protect our systems and data from unauthorized access or misuse, including meeting certain information security standards that may be required by our customers, all of which increases cybersecurity protection costs. We have not experienced any significant or material cybersecurity threats or incidents through the date of this annual report. As these threats, and government and regulatory oversight of associated risks, continue to grow, we may be required to expend additional resources to enhance or expand upon the security measures we currently maintain.

There can be no assurance that our efforts or those of our third-party service providers to implement adequate security and control measures would be sufficient to protect against breakdowns, service disruption, data deterioration or loss in the event of a system malfunction, or prevent data from being stolen or corrupted in the event of a cyber-attack, security breach, industrial espionage attacks or insider threat attacks which could result in financial, legal, business or reputational harm. Future cybersecurity breaches or incidents or further increases in cybersecurity protection costs may have a material adverse effect on our business, financial condition or results of operations.

The expansion of social media platforms and new technologies present risks and challenges for our business and reputation.

We increasingly rely on social media and new technologies to communicate about our products and technologies. The use of these media requires specific attention. Unauthorized communications, such as press releases or posts on social media, purported to be issued by the Company, may contain information that is false or otherwise damaging and could have an adverse impact on our stock price. Negative or inaccurate posts or comments about the Company, our business, directors or officers on any social networking website could seriously damage our reputation. In addition, our employees and partners may use social media and mobile technologies inappropriately, which may give rise to liability for the Company, or which could lead to breaches of data security, loss of trade secrets or other intellectual property or public disclosure of sensitive information, including information about our employees, clinical trials or customers. Such uses of social media, mobile technologies, or information technology more generally could have a material adverse effect on our reputation, business, financial condition and results of operations.

Our French and international operations expose us to additional costs and legal and regulatory risks, which could have a material adverse effect on our business, results of operations and financial condition.

We have significant French and international operations. We have direct distribution channels in over fifty countries outside of France, our country of incorporation, and through our foreign subsidiaries. Compliance with complex foreign and French laws and regulations that apply to our international operations increases our cost of doing business. These regulations include, among others, U.S. laws such as the U.S. Foreign Corrupt Practices Act (FCPA) and other U.S. federal laws and regulations established by the Office of Foreign Asset Control, laws such as the UK Bribery Act 2010 or other local laws, which prohibit corrupt payments to governmental officials or certain payments or remunerations to customers. We have adopted a Code of Ethics that requires employees to comply with applicable laws and regulations and particularly with Article 8 of law n°2016-1691 (known as Sapin II law). In accordance with Sapin II law, we have implemented a whistle-blowing policy. These numerous and sometimes conflicting laws and regulations include, among others, data privacy requirements (particularly with respect to the recent invalidation of the U.S.-European Union safe harbor by the European Court of Justice), labor relations laws, tax laws, anti-competition regulations, “Know Your Customer” requirements, import and trade restrictions, export requirements.

Given the high level of complexity of these laws, there is a risk that we may inadvertently breach some provisions, for example, through fraudulent or negligent behavior of individual employees, our failure to comply with certain formal documentation requirements, or otherwise. Our success depends, in part, on our ability to anticipate these risks and manage these challenges. We have a dispersed international sales organization, and this structure makes it more difficult for us to ensure that our international selling operations comply with our global policies and procedures.

Violations of these laws and regulations could result in fines, criminal sanctions against us, our officers or our employees, requirements to obtain export licenses, cessation of business activities in sanctioned countries and prohibitions on the conduct of our business. Violations of laws and regulations also could result in prohibitions on our ability to offer our products in one or more countries and could materially damage our reputation, our brand, our international expansion efforts, our ability to attract and retain employees, or our business, results of operations and

financial condition.

In May 2018, the new EU data protection framework, the General Data Protection Regulation ("GDPR") took effect. The GDPR significantly increases the level of data protection and imposes a greater compliance burden on companies. In particular, it now treats also clinical data as personal data, requiring us to implement more extensive procedures in the collection and processing of clinical trial data. Furthermore, the GDPR significantly increases the level of sanctions for non-compliance. The European Union data protection authorities have the power to impose administrative fines of up to a maximum of €20 million or 4% of the Company's consolidated revenues for the preceding financial year, whichever is higher. We believe that the regulation should not have a material impact on our business or the way our technologies operate. However, due to the small size of the Company, we may not be able to adequately document all data collection, to obtain related consents in due time, to adequately protect private collected data or nor to react in due time to address an individual request linked to GDPR application.

We sell our products in many parts of the world and, as a result, our business is affected by fluctuations in currency exchange rates.

We are exposed to foreign currency exchange rate risk because the mix of currencies in which our costs are denominated is different from the mix of currencies in which we earn our revenue. In 2018, approximately 74% of our total costs of sales and operating expenses were denominated in euro, while approximately 41% of our sales were denominated in currencies other than euro (primarily the U.S. dollar and the Japanese yen). Our operating profitability could be materially adversely affected by large fluctuations in the rate of exchange between the euro and other currencies. For instance, a decrease in the value of the U.S. dollar or the Japanese yen against the euro would have a negative effect on our revenues, which may not be offset by an equal reduction in operating expenses and would therefore negatively impact operating profitability. From time to time we enter into foreign exchange forward sale contracts to hedge against fluctuations in the exchange rates of the principal foreign currencies in which our receivables are denominated (in particular, the U.S. dollar and the Japanese yen), but there can be no assurance that such hedging activities will limit the effect of movements in exchange rates on our results of operations. As of December 31, 2018, we had no outstanding hedging instruments. In addition, since any dividends that we may declare will be denominated in euro, exchange rate fluctuations will affect the U.S. dollar equivalent of any dividends received by holders of ADSs. For more information concerning our exchange rate exposure, see Item 11. “Quantitative and Qualitative Disclosures about Market Risk.”

Our results of operations have fluctuated significantly from quarter to quarter in the past and may continue to do so in the future, as we experience long and variable product sales cycles which are long and seasonal

Our results of operations have fluctuated in the past and are expected to continue to fluctuate significantly from quarter to quarter depending upon numerous factors, including, but not limited to, the timing and results of clinical trials, changes in healthcare reimbursement policies, cyclicality of demand for our products, changes in pricing policies by us or our competitors, new product announcements by us or our competitors, customer order deferrals in anticipation of new or enhanced products offered by us or our competitors, product quality problems and exchange rate fluctuations. Furthermore, because our main products have relatively high unit prices, the amount and timing of individual orders can have a substantial effect on our results of operations in any given quarter.

The sales cycle of our products is lengthy as our products are high value capital items for our customers which purchase generally requires the approval of management or Boards of hospitals, purchasing groups and government authorities if applicable. In addition, some sales are subject to public tender offer processes and approvals which could happen to be lengthy and as a result, hospitals may delay their purchase orders according to their timelines and budget allocation. It is difficult to predict the exact timing for closing product sales directly linked to the length of capital expenditure cycles. Historically, our sales of products have tended to be stronger during the fourth quarter of each fiscal year.

Our results of operations and financial condition could be adversely affected by the adverse economic, geo-political and financial developments.

The current geo-political, economic and financial environment has affected the level of public and private spending in the healthcare sector generally. A cautious or negative outlook may cause our customers to further delay or cancel investment in medical equipment, which would adversely affect our revenues.

In addition, we rely on the credit market to secure dedicated lease financings to fund the development of our Revenue-Per-Procedure ("RPP") business model related to the sale of treatments' procedures. Due to the limited availability of lending, we may be unable to access sufficient lease financing. Without lease financing, we may be unable to continue the development of our RPP model or we may need to fund such activity out of our existing working capital. Similarly, some of our clients rely on lease financing to finance their purchases of equipment. Limited availability of lease financing facilities may also affect their purchasing decisions and may adversely impact our equipment sales.

The United Kingdom (the "UK") held a referendum in 2016 in which voters approved an exit from the European Union (the "EU"), commonly referred to as "Brexit." On March 29, 2017, the UK formally notified the EU of its intention to withdraw pursuant to Article 50 of the Lisbon Treaty. The EU and UK have negotiated a draft withdrawal agreement, which however has not yet been ratified by the UK. If the agreement is ratified by the UK, there will be a transition period with negotiations between UK and EU to determine future relationship between the UK and EU countries. If the agreement is not ratified, there will be no transition period. In either case, it is possible that there will be greater restrictions on imports and exports between the UK and EU countries, increased regulatory complexities, and economic and political uncertainty in the region. However, on March 15, 2019, the British Parliament voted for an extension of Article 50 process. A further vote will be needed to decide of the conditions and timing of an effective withdrawal. We sell devices and spare parts in the UK and need to regularly maintain and service our installed base of equipment. Such restrictions on imports and exports may have a significant impact on our business in the UK.

New device developments and introductions may adversely impact our financial results.

From time to time, we develop and introduce new devices with enhanced features and extended capabilities, targeting new clinical applications or improving existing approaches. The success of new device introductions depends on a number of factors including, but not limited to, timely and successful research and development, regulatory clearances or approvals, pricing, competition, market and consumer acceptance, the manufacturing and supply costs, and the risk that new devices may have quality or other defects in the early stages of introduction.

We invest in various research and development projects to expand our product offerings. Our research and development efforts are critical to our success, and our research and development projects may not be successful. We may be unable to develop and market new products successfully, and the products we invest in and develop may not be well-received by customers or meet our expectations. Our research and development investments may not generate significant operating income or contribute to our future operating results for several years, and such contributions may not meet our expectations or even cover the costs of such investments.

If we fail to effectively develop new products, obtain regulatory clearances or approval and manage new product introductions in the future, our business, financial condition, results of operations, or cash flows could be materially adversely impacted.

We have been and we may in the future be the target of securities class action or other litigation, which could be costly and time consuming to defend.

In the past, securities class action litigation has often been brought against companies following a decline in the market price of its securities. This risk is especially relevant for us because innovative life sciences and medical device companies have experienced significant stock price volatility in recent years.

Any litigation, if instituted, could cause us to incur substantial costs and our management resources may be diverted to defending such litigation, which could adversely affect our financial condition or results of operations.

We have identified a material weakness in our internal controls over financial reporting and, if we fail to remediate adequately this material weakness and achieve an effective system of internal controls, we may not be able to report our financial results accurately. In addition, the trading price of our securities may be adversely affected by a related negative market reaction.

As a publicly traded company, we are subject to the reporting requirements of the Exchange Act and the Sarbanes-Oxley Act of 2002. We have incurred, and expect to continue to incur, significant continuing costs, including accounting fees and staffing costs, to maintain compliance with the internal control requirements of the Sarbanes-Oxley Act of 2002. As described in Item 15, we have identified a material weakness in our internal control over financial reporting with respect to the implementation of a new integrated information management system (SAP version 4HANA) which we launched in production on July 1, 2018, and that includes our accounting, as well as our production and inventory processes. This material weakness results from several significant deficiencies in the development and change program which, considered in aggregation, gave rise to a material weakness and to the conclusion that our internal control over financial reporting was not effective as of December 31, 2018. We also in the past identified a material weakness in our internal control over financial reporting with respect to the insufficient segregation of duties within the consolidation process directly linked to the limited size of our finance team. Our

management concluded that, as a result, our internal control over financial reporting was not effective as of December 31, 2017. This material weakness was remediated as of December 31, 2018. Nevertheless, we concluded that neither material weakness resulted in a material misstatement of the consolidated financial statements for the year ended December 31, 2018 or restatement of any prior period previously reported by the Company.

Although we initiated remediation actions to address these material weaknesses, we may not be able to produce adequate additional documentation or correct settings to address deficiencies linked to implementation of above SAP system and, as a small company, we may have insufficient personnel to allow us to segregate duties, and consistently execute the Company's internal controls.

Furthermore, the ongoing requirements of the Sarbanes-Oxley Act may place a strain on our systems and resources. Our management is required to evaluate the effectiveness of our internal control over financial reporting as of each year-end, and we are required to disclose management's assessment of the effectiveness of our internal control over financial reporting, including any material weakness in our internal control over financial reporting.

Our internal control over financial reporting has been designed to provide our management and Board of Directors with reasonable assurance regarding the preparation and fair presentation of our consolidated financial statements. On an on-going basis, we are reviewing, documenting and testing our internal control procedures. In order to maintain and improve the effectiveness of our disclosure controls and procedures and internal control over financial reporting, and as our business develops, additional resources and management oversight may be required.

In an effort to remediate the identified material weaknesses and to enhance our overall control environment, we already have produced additional documentation, reviewed segregation of duty around access to production and changed certain configuration settings. As of the date of this filing, two of these significant deficiencies were already remediated and remediation for the remainder is underway. Additional controls were performed to demonstrate no inappropriate use of our IT system between July 1, 2018 and December 31, 2018. In view of addressing the 2017 material weakness linked to the insufficient segregation of duties, we also hired a person responsible for the consolidation process, so that our Chief Financial Officer can be the primary person responsible for performing the review control.

Any failure to complete our assessment of our internal control over financial reporting, to remediate any material weaknesses that we have identified or may identify in the future, any failure to implement new or improved controls, or difficulties encountered in their implementation, could harm our operating results, cause us to fail to meet our reporting obligations or result in material misstatements in our financial statements. Any failure to maintain adequate internal controls over financial reporting and provide accurate financial statements may subject us to litigation, render future financings more difficult or expensive, and could cause the trading price of our common stock to decrease substantially. Inferior controls and procedures could cause investors to lose confidence in our reported financial information, which may give rise to a class action and have a negative effect on the trading price of our common stock. Any such failure could also adversely affect the results of the periodic management evaluations of our internal controls and, in the case of a failure to remediate any material weaknesses that we have identified or may identify in the future, would adversely affect the annual auditor attestation reports regarding the effectiveness of our internal control over financial reporting that are required under Section 404 of the Sarbanes-Oxley Act.

Risks Relating to Ownership of Securities

Our securities may be affected by volume fluctuations, and may fluctuate significantly in price, causing you to lose some or all of your investment.

Our ADSs are currently traded on the NASDAQ Global Market. The average daily trading volume of our ADSs in 2018 was 204,760, the high and low bid price of our ADSs for the last two financial years ended on December 31, 2018 and December 31, 2017, was $4.25 and $1.35, and $3.85 and $2.25, respectively. Our ADSs have experienced, and are likely to experience in the future, significant price and volume fluctuations, which could adversely affect the market price of our ADSs without regard to our operating performance. For example, average daily trading volume of our ADSs in December 2017 was 61,031 as opposed to 204,760 for the same period of 2018. The price of our securities and our ADSs in particular, may fluctuate as a result of a variety of factors, including changes in our business, operations and prospects, and factors beyond our control, including regulatory considerations, results of clinical trials of our products or those of our competitors, developments in patents and other proprietary rights, and general market and economic conditions. Any downward pressure on the price of ADSs caused by the sale of ADS could also encourage short sales by third parties. In a short sale, a prospective seller borrows shares from a shareholder or broker and sells the borrowed shares. The prospective seller hopes that the share price will decline, at which time the seller can purchase shares at a lower price for delivery back to the lender. The seller profits when the share price declines because it is purchasing shares at a price lower than the sale price of the borrowed shares. Such

sales could place downward pressure on the price of our ADSs by increasing the number of ADSs being sold, which could further contribute to any decline in the market price of our ADSs.

These broad market and industry factors may adversely affect the market price of our ADSs, regardless of our operating performance. If you invest in our ADSs, you could lose some or all of your investment.

In addition, following periods of volatility in the market price of a company's securities, securities class action litigation has often been instituted. Any additional litigation, if instituted, causes and could cause us to incur substantial costs and our management resources are and could be diverted to defending such litigation, which could adversely affect our financial condition or results of operations.

We may issue additional securities that may be dilutive to our existing shareholders.

On February 18, 2016, our shareholders adopted a resolution allowing the Board of Directors to issue 1 million new shares under the form of subscription options to motivate and reward teams dedicated to successfully implement our U.S. and worldwide expansion plans. As of December 31, 2018, all options authorized under this Plan have been allocated.

The issuance of additional ordinary shares, including any additional ordinary shares issuable pursuant to the exercise of preferential subscription rights that may not be available to all of our shareholders, would reduce the proportionate ownership and voting power of the then-existing shareholders.

We are subject to different corporate disclosure standards that may limit the information available to holders of our ADSs.

As a foreign private issuer, we are not required to comply with the notice and disclosure requirements under the Exchange Act relating to the solicitation of proxies for shareholder meetings. Although we are subject to the periodic reporting requirements of the Exchange Act, the periodic disclosure required of foreign private issuers under the Exchange Act is more limited than the periodic disclosure required of U.S. issuers. Therefore, there may be less publicly available information about us than is regularly published by or about other public companies in the United States.

We currently do not intend to pay dividends, and cannot assure shareholders that we will make dividend payments in the future.

We have never paid any dividend on our shares and do not anticipate paying any dividends for the foreseeable future. Thereafter, declaration of dividends on our shares will depend upon, among other things, future earnings, if any, the operating and financial condition of our business, our capital requirements, general business conditions and such other factors as our Board of Directors deems relevant. See Item 8, “Financial Information—Dividends and Dividend Policy.”

Judgments of U.S. courts, including those predicated on the civil liability provisions of the federal securities laws of the United States, may not be enforceable in French courts.

An investor in the United States may find it difficult to:

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

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

Holders of ADSs do not have the same rights as shareholders and accordingly, cannot exercise rights of shareholders against us. The Bank of New York Mellon, as Depositary (the “Depositary”), is the registered shareholder of the

deposited shares underlying the ADSs, and therefore holders of ADSs will generally have to exercise the rights attached to those shares through the Depositary. We have used and will continue to use reasonable efforts to request that the Depositary notify the holders of ADSs of upcoming votes and ask for voting instructions from them. If a holder fails to return a voting instruction card to the Depositary by the date established by it for receipt of such voting instructions, or if the Depositary receives an improperly completed or blank voting instruction card, or if the voting instructions included in the voting instruction card are illegible or unclear, then such holder will be deemed to have instructed the Depositary to vote its shares and the Depositary shall vote such shares in favor of any resolution proposed or approved by our Board of Directors and against any resolution not so proposed or approved.

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

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

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

Holders of our ADSs may be exposed to increased transaction costs as a result of proposed European financial transaction taxes.

On February 14, 2013, the EU Commission adopted a proposal for a Council Directive (the "Draft Directive") on a common financial transaction tax (the "FTT"). According to the Draft Directive, the FTT should have been implemented and should have entered into effect in 10 EU Member States (Austria, Belgium, Estonia, France, Germany, Greece, Italy, Portugal, Spain, Slovakia, and Slovenia, each a “Participating Member State”). In March of 2016, Estonia indicated its withdrawal from enhanced cooperation.

Pursuant to the Draft Directive, the FTT was to be payable on financial transactions provided at least one party to the financial transaction was established or deemed established in a Participating Member State and there was a financial institution established or deemed established in a Participating Member State which was a party to the financial transaction, or was acting in the name of a party to the transaction. Under the Draft Directive, the FTT should not have applied, however, to (inter alia) primary market transactions referred to in Article 5(c) of Regulation (EC) No 1287/2006, including the activity of underwriting and subsequent allocation of financial instruments in the framework of their issue. The rates of the FTT were to be fixed by each Participating Member State but for transactions involving financial instruments other than derivatives would have amounted to at least 0.1 per cent of the taxable amount. The taxable amount for such transactions would have been generally determined by reference to the consideration paid or owed in return for the transfer. The FTT would have been payable by each financial institution established or deemed established in a Participating Member State which was either a party to the financial transaction, or acting in the name of a party to the transaction or where the transaction had been carried out on its account. Where the FTT due had not been paid within the applicable time limits, each party to a financial transaction, including persons other than financial institutions, would have become jointly and severally liable for the payment of the FTT due.

The Draft Directive has not been adopted. The FTT proposal is still subject to negotiation between the Participating Member States and therefore may be changed at any time. Moreover, once a final agreement on such FTT proposal will be reached (the "FTT Directive"), it will need to be implemented into the respective domestic laws of the Participating Member States and the domestic provisions implementing the FTT Directive might deviate from the FTT Directive itself. See Item 10, "Certain Income Tax Considerations."

Prospective holders should therefore note, in particular, that any sale, purchase, or exchange of the Shares or ADSs could become subject to the FTT at a minimum rate of 0.1 per cent. The holder may be liable to itself pay this charge or reimburse a financial institution for the charge, and / or may affect the value of the Shares or ADSs.

In any case, prospective holders should consult their own advisers in relation to the consequences of the FTT associated with subscribing for, purchasing, holding and disposing of ADSs.

Item 4. Information on the Company

We develop and market robotic HIFU devices, advanced choices for the treatment of localized prostate cancer. HIFU treatment is shown to be a minimally invasive and effective treatment option for localized prostate cancer (T1-T2) with a low occurrence of side effects. Our HIFU devices are also used for patients who failed a radiotherapy treatment. In addition, we are developing a HIFU platform for the treatment of various types of tumors including rectal endometriosis, liver and pancreatic cancer, but also breast and gynecological tumors. We also produce and commercialize medical equipment for the treatment of urinary tract stones using ESWL and distribute other types of urology devices in certain countries.

History and Development of the Company

Our legal name is EDAP TMS S.A. and our commercial name is EDAP TMS. EDAP TMS S.A. was incorporated on December 3, 1979 as a *société anonyme* organized under the laws of the Republic of France for a duration of 60 years from the date of incorporation. Our principal executive offices are located at Parc d'Activités la Poudrette- Lamartine, 4/6, rue du Dauphiné, 69120 Vaulx-en-Velin, France and our telephone number is +33 (0) 4 72 15 31 50. Corporation Service Company, 251 Little Falls Drive, Wilmington, DE19808-1674, United States, is our agent for service of process in the United States. The SEC maintains an Internet site that contains reports, proxy and information statements, and other information regarding the Company's electronic filings with the SEC. Such electronics filings can be found by visiting the SEC web site at http://www.sec.gov or the Company's web site at http://www.edap-tms.com.

On April 14, 2016, we issued 3,283,284 ordinary shares in the form of ADSs to certain institutional investors in a registered direct placement (the "April 2016 Placement"), at a price of $3.50 per share, raising $11,491,494 mainly in view of acceleration of HIFU marketing expansion in the US following FDA clearance of our Ablatherm device.

On September 11, 2017, we submitted a (510K) application for our Focal One HIFU device in accordance with FDA guidance.

On October 4, 2017, we obtained FDA clearance for our Ablatherm Fusion device which incorporates our proprietary fusion software and merges MRI and ultrasound images, providing increased accuracy during planning and prostate treatment for physicians.

On June 7, 2018, we obtained FDA clearance for our Focal One device dedicated to the focal ablation of prostate cancer. It incorporates our proprietary fusion software, which merges MRI and ultrasound images, providing increased

accuracy during planning and prostate treatment for physicians. Focal approach in the treatment of localized prostate cancer reduces side effects and improves patients' quality of life.

Business Overview & Strategy

EDAP TMS S.A. is a holding company and is responsible for providing common services to its subsidiaries, including preparation and consolidation of the financial statements for the group, complying with the requirements of various regulatory agencies and maintaining the listing of its publicly held securities and, in conjunction with its Board of Directors, directing the overall strategy of our group.

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

Our HIFU and UDS divisions operate in Europe, the Americas, Asia and the rest of the world. Total net sales for the HIFU division (in net contributions to total consolidated sales) were €11.0 million, €9.5 million and €13.8 million for 2018, 2017 and 2016, respectively. Those sales are generated in Europe, the United States and the rest of the world, excluding certain countries in Asia (including Japan) where our HIFU devices are not approved yet. Total net sales for the UDS division were €28.1 million (including €13.9 million in Asia and €14.2 million in Europe and the rest of the world), €26.2 million (including €13.4 million in Asia and €12.8 million in Europe and the rest of the world), and €21.8 million (including €10.3 million in Asia and €11.5 million in Europe and the rest of the world), each for 2018, 2017 and 2016, respectively.

See Note 28 to our consolidated financial statements for a breakdown of total sales and revenue during the past three fiscal years by operating division and Item 5, "Operating and Financial Review and Prospects."

HIFU Division

The HIFU division is engaged in the development, manufacturing and marketing of medical devices based on HIFU technology for the minimally invasive treatment of urological and other clinical indications. Our HIFU business is cyclical and generally linked to lengthy hospital decision and investment processes. Hence, our quarterly revenues are often impacted and fluctuate according to these parameters, generally resulting in a higher purchasing activity in the last quarter of the year. The HIFU division contributed €11.0 million to our consolidated net sales during the fiscal year ended December 31, 2018.

HIFU Division Business Overview

The HIFU division currently develops, manufactures and markets devices for the minimally invasive ablation of certain types of localized tumors using HIFU technology. HIFU technology uses a high-intensity convergent ultrasound beam generated by high power transducers to produce heat. HIFU technology is intended to allow the surgeon to destroy a well-defined area of diseased tissue without damaging surrounding tissue and organs, thereby eliminating the need for incisions, transfusions and general anesthesia and associated complications. The HIFU division markets three HIFU devices: the Ablatherm, the Ablatherm Fusion and the Focal One. The Ablatherm and Ablatherm Fusion are dedicated to the treatment of organ-confined prostate cancer, referred to as T1-T2 stage. The Focal One high-end device is a HIFU fully robotic device dedicated to the focal therapy of localized prostate cancer of T1-T2 stage, thereby destroying targeted cancer cells only. The robotic features of our HIFU devices make the treatment procedure much safer for the patient and less operator dependent. All three devices can be used for patients who are not candidates for surgery or who have failed a radiotherapy treatment.

In addition to selling HIFU devices, the HIFU division also records revenues driven from HIFU treatments performance (“HIFU Treatment Driven Revenues”) which include net sales of (i) disposables, (ii) leases (iii) revenue-per-procedure (“RPP”) and (iv) treatment related services. The HIFU mobile treatment option provides access to our HIFU devices without requiring hospitals and clinics to make an up-front investment in the equipment. Instead, hospitals and clinics perform treatments using these devices and remunerate us on a RPP basis (i.e., on the basis of the number of individual treatments provided). With this model, once the treatment is established in the medical community, a permanent installation may become more attractive, leading to the sale of the device in some of the larger locations.

In addition, the HIFU division also generates revenues from net sales of maintenance services associated to our HIFU devices installed base. As of December 31, 2018, the HIFU division had an installed base of 109 Ablatherm machines, 33 Focal One machines and 519 certified trained clinical sites worldwide had access to this technology.

HIFU Division Business Strategy

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

- *Provide Minimally Invasive Solutions to Treat Localized Prostate Cancer using HIFU*. Building upon our established position in the ESWL market, our HIFU division is striving to become the leading provider of our minimally invasive HIFU treatment option for prostate cancer. We believe that there is a large market opportunity with an increase in incidence linked to the aging male population, an increase in screening and recent campaigns to increase awareness. We also believe that HIFU could represent a credible alternative to surgery, external beam radiotherapy, brachytherapy and cryotherapy for the treatment of organ-confined prostate cancer without the cost, in-patient hospitalization and adverse side effects associated with those therapies. With the growing demand for more focused treatments destroying the tumor only (focal therapy) while continuously controlling the disease, HIFU and its focused approach, is well positioned to address this new clinical approach. The HIFU division intends to achieve this through a direct sales network in key European countries and the United States and through selected distributors in other European countries and in Asia. The HIFU division has built a strong clinical credibility based on clinical articles published in peer-reviewed journals. We ensure effective patient and physician education through a focused communication program.

- *Achieve Long-Term Growth by Expanding HIFU Applications Beyond Prostate Cancer*. The HIFU division's long-term growth strategy is to apply our HIFU technology toward the treatment of other medical conditions beyond prostate cancer. We believe that HIFU could represent an alternative to surgery and radiotherapy for the treatment of many tumors without the cost, in-patient hospitalization and adverse side effects associated with those therapies. The HIFU division is working on various other applications such as rectal endometriosis, liver, pancreatic cancers, breast and gynecological tumors where HIFU could provide an alternative to current therapies. In 2018, the HIFU division maintained expenses at levels similar to 2017 on research and development ("R&D") projects to develop HIFU applications beyond prostate cancer. The division is considering increasing levels of R&D spending in 2019 and future years to strengthen its technological leadership in HIFU and expand its application beyond urology.

HIFU Products

Currently, we commercialize three products utilizing the HIFU technology. Cell destruction by HIFU is accomplished by a combination of thermal and cavitation effects caused by focused application of piezoelectric-generated high-intensity ultrasound; HIFU procedures are performed under general or spinal anesthesia.

- The Ablatherm is an ultrasound guided robotic HIFU device for the treatment of organ-confined prostate cancer. It consists of a treatment module, including a HIFU endorectal probe, a control table with a computer and a computer screen, and a diagnostic ultrasound device connected to the treatment module. After insertion of an endorectal probe, the physician visualizes the prostate using ultrasound imaging and defines the area to be treated. The computer automatically calculates the optimum treatment distribution of lesions. During the treatment, the probe automatically moves and fires HIFU beams at each predefined lesion until the entire targeted area has been treated. At the same time, the physician is able to control and visualize the treatment in real time due to the integrated imaging system.

- Ablatherm Fusion is an evolution of Ablatherm, and incorporates the Company's proprietary fusion software which merges MRI and ultrasound images providing physicians with increased accuracy during planning and treatment.

- The Focal One is a HIFU fully robotic device dedicated to the focal therapy of prostate cancer. Focal One combines the three essential components to efficiently perform a focal treatment of localized prostate cancer: (i) high-quality imaging to localize tumors with the use of magnetic resonance imaging (MRI) combined with real-time ultrasound, (ii) high precision of HIFU treatment focused on identified targeted cancer areas and (iii) immediate feedback on treatment efficacy utilizing Contrast-Enhanced Ultrasound Imaging. Focal One provides an effective and accurate ablative treatment of localized tumors with the capacities of being flexible and repeatable, while preserving patient quality of life.

HIFU Division Patents and Intellectual Property

As of December 31, 2018, the HIFU division's patent portfolio contained 37 patents consisting of 10 granted patents in the United States, 20 patents in the European Union and Japan and six patents in both Israel and the rest of the world. They belong to 17 groups of patents covering key technologies related to therapeutic ultrasound principles, systems and associated software.

During 2018, one patent, covering our dynamic focusing technology embedded in the Focal One device, has been delivered in the United States, in Europe, in Japan and in China. One patent related to liver treatment was granted in China and Japan. Two European patents, not exploited, expired in 2018.

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

In August 2004, we licensed our HIFU technology for the specific treatment of the ''cervicofacial'' lesions, including the thyroid, to Theraclion, a French company created by our former director of research and development. On January 11, 2011, we extended the above license by granting Theraclion exclusivity for the treatment of benign breast tumors and by granting a non-exclusive license for the treatment of malignant breast tumors. This license agreement provides for the payment of certain royalties calculated on the basis of Theraclion's sales of devices. We determined that we could not invest in these specific applications at that time and this license agreement therefore allows Theraclion to pursue the development of HIFU for these applications. We own no interest in Theraclion..

Although we believe that our HIFU patents are valid and should be enforceable against third parties and that our patent applications should, if successfully pursued, result in the issuance of additional enforceable patents, there can be no assurance that any or all of these patents or patent applications will provide effective protection for the HIFU division's proprietary rights in such technology. HIFU devices, as they are currently or may in the future be designed, may also be subject to claims of infringement of patents owned by third parties, which could result in an adverse effect on our ability to market HIFU systems. See Item 3, "Risk Factors – Risks relating to Intellectual Property Rights."

HIFU Division Clinical and Regulatory Status

Clinical and Regulatory Status in Europe

Based on clinical results obtained from an extensive European Multicentric study which assessed safety and effectiveness of our Ablatherm system, we obtained a CE Marking in May 1999 allowing us to market the Ablatherm for prostate primary care in the European Union and in other territories in the world where CE Marking is required. CE Marking was further extended to address radiation failures. As of today, Ablatherm CE Marked devices previously placed on the market are maintained for use according to applicable regulation and any new placement of HIFU devices, in Europe or in territory covered by CE Marking, is being addressed with a Focal One new generation device.

In June 2011, a new clinical trial was initiated to evaluate the new technical improvements in HIFU technology: the Dynamic Focusing technology. This technology gives the ability to target a more precise area within the prostate making the dynamic focusing technology the perfect tool for focal therapy. It also allows for the treatment of bigger prostates and for a more precise contouring of the gland providing a better control over sensitive areas responsible for continence and sexual functions. As a result, the Dynamic Focusing technology has been incorporated into the new Focal One HIFU device. Based on the above study clinical results, we obtained a CE Marking in June 2013 that allowed us to market the Focal One in the European Union and in worldwide territories where CE Marking is required.

Clinical and Regulatory Status in the United States

In 2005, EDAP started an Investigational Device Exemption ("IDE") study (G050103) to assess the safety and effectiveness of Ablatherm HIFU in the U.S. for the treatment of low risk, localized prostate cancer. This study was designed as a pivotal study to support PMA approval. This study was planned as a multicentric, prospective, non-randomized, concurrently controlled clinical trial comparing Ablatherm HIFU to cryotherapy in patients with low risk, localized prostate cancer. Due to accrual difficulties, particularly in the cryosurgery arm, this planned study was not completed. Of the planned 205 patients per arm, 136 and five patients were recruited to the Ablatherm HIFU and cryosurgery arms, respectively. We completed the treatment of 134 patients in June 2010, the required two years' follow-up phase was completed in June 2012. Clinical outcomes from these patients combined with our strong

European long-term database formed the foundation of our PMA submission to the FDA on January 31, 2013.

On March 9, 2015, we announced that based on our collaborative discussions with the FDA, we planned to seek clearance of Ablatherm HIFU by way of a direct de novo 510(k) application as opposed to the PMA application amendment we had been considering. The FDA indicated that while PMA approval would be required for specific claims regarding treatment of prostate cancer, a prostate tissue ablation claim could be cleared via a direct de novo 510(k) application.

In November 2015, we received 510(k) clearance from the FDA to market Ablatherm® Integrated Imaging HIFU in the U.S. for the ablation of prostate tissue and in October 2017, we were granted a 510(k) clearance for our Ablatherm Fusion device in 2017.

On June 7, 2018, we obtained FDA 510(k) clearance for our Focal One device.

Clinical and Regulatory Status in Japan

We have initiated discussions with the Japanese authorities (“PMDA”) on the best process to apply to obtain Japanese approval for our Focal One device and we are currently reviewing all options to obtain PMDA clearance. We might need to conduct a clinical trial in Japan to obtain clearance for our HIFU Focal One device. The process of requesting approval to market the Focal One in Japan may be long and may never result in the approval to market the Focal One in Japan. See Item 3, ‘‘Key Information—Risk Factors—Our future revenue growth and income depend, among other things, on the success of our HIFU technology.’’

Clinical and Regulatory Status in China

We entered into an exclusive distribution agreement with Shaw Han Biomedical Co. Ltd in 2010 to distribute Ablatherm throughout China, once approved by Chinese authorities. We did not obtained marketing clearance of our Ablatherm by Chinese authorities due to lengthy and complex processes. We are currently reviewing our strategy with a new partner to go through the approval process of our Focal One in China.

Clinical and Regulatory Status in the rest of the world

The Ablatherm is cleared for distribution in Canada, Costa Rica, Peru, Russia and Taiwan.

The Focal One device is cleared for distribution in Saudi Arabia, Argentina, Brazil, Canada, South Korea, Costa Rica, United Arab Emirates, Malaysia, Mexico, Peru, Russia, Serbia, and Venezuela.

See Item 3, “Risk Factors” – “We operate in a highly regulated industry and our future success depends on government regulatory approval of our products, which we may not receive or which may be delayed for a significant period of time.”

HIFU Clinical Data

To date, clinical results related to our HIFU devices have been published in more than 85 renowned peer-reviewed journals. In 2010, the results of a major multicentric study on 803 patients were published showing a local control of the disease in 77.9% of the patients. In 2013, three long-term studies presenting results obtained over a period of more than 14 years on 538 patients, 704 patients and 1,002 patients were published, showing excellent cancer-specific and metastasis-free survival in primary patients (Ganzer et al. BJU 2013, Thuroff et al. Journal of Urology 2013 and Crouzet et al. European Urology 2013).

In 2014, the first clinical results of focal treatments with Ablatherm were published by Baco et al. in the British Journal of Urology International (“BJUInt”) and Van Velthoven et al. in *Prostate Cancer* magazine. Baco et al. published promising results of hemi-salvage HIFU (treatment of one lobe of the prostate) after External Beam Radiation Therapy (“EBRT”) and brachytherapy recurrences. In this fragile population of patients, the treatment of the infected lobe isreported to provide better functional outcomes and preserves quality of life. A similar approach of HIFU prostate Hemi-ablation was presented by Van Velthoven et al. for primary care patients. With a maximum

follow-up of 61 months the study showed a rate of 100% full continence and 75% erectile function preservation combined with only 11% of salvage treatment (re-HIFU in the contralateral lobe). Authors concluded primary zonal HIFU is a valid focal therapy strategy, which is safe and feasible in a day-to-day practice showing good promising results. This study was updated and published in 2016 in *Prostate Cancer and Prostatic Diseases* journal with 50 patients treated with Hemi-HIFU strategy and provided 100% five-year cancer specific survival rate. The functional results included 94% pad free patients and 80% erectile function preservation at the end of follow-ups.

We have set up an extensive worldwide patient database called "@-registry." This on-line database wasdesigned to compile treatment information and follow-up data for patients who have undergone HIFU for prostate cancer. The goal of the @-registry was to further demonstrate the safety, effectiveness and durability of Ablatherm. Information from the registry are submitted to medical conferences for presentation and to peer-reviewed medical journals for publication. Based on more than 10,000 patients included into our @-registry database, we presented at the European Association of Urology (EAU) held in Paris in February 2012, an abstract presentation covering 5,662 primary patients, and an abstract covering 929 patients treated with Ablatherm after radio-recurrence with seven years follow-up. Thüroff et al presented a poster at the American Urology Association (AUA) 2014 on the long term HIFU retreatment rate, evaluating 2,632 patients. Thüroff et al concluded that technical development and adjuvant transurethral radical prostatectomy (“TURP”) before HIFU resulted in higher local efficacy and lower HIFU retreatment rates.

In October 2016, clinical results were published in the *European Urology* journal (Rischmann et al.). They were relating to the validation of a new strategy of minimally invasive HIFU treatment of prostate cancer localized in a single lobe of the prostate. The goal of Hemi-ablation is to reduce the complications associated with standard treatments, notably the risks of incontinence and impotence. At 1-year follow-up, HIFU-Hemi-ablation was efficient with 95% absence of clinically significant cancer associated with low morbidity and preservation of quality of life (urinary continence was preserved in 97% of patients and sexual function was preserved in 78%). Radical treatment-free survival rate was 89% at 2 years.

In January 2014, a new clinical trial on multifocal HIFU treatments with the Focal One device began in France in six investigational centers. The aim of this study is to evaluate the efficacy and safety results of different focal HIFU treatment strategies. Thanks to Focal One technical capacities (Dynamic Focusing technology, elastic fusion of MRI and ultrasound images and Contrast Enhanced Ultrasound treatment validation) various HIFU focal treatments approaches are now possible allowing for treatment that is individually tailored to the patient's disease. In January 2015, the last patient was included in the above study, clinical results analysis is currently ongoing and may be published in the coming months.

In February 2015, the reimbursement evaluation study of HIFU was initiated under the "Forfait Innovation". This process, piloted by French Association of Urology (AFU), compares primary whole-gland or sub-total HIFU and salvage whole-gland and focal HIFU results with those of radical prostatectomy in 42 French urological centers. The primary outcome is the salvage treatment free rate at two years. In October 2018, 1,375 patients have been treated in primary setting and 431 patients for the salvage indication. Inclusion period will be terminated in October 2019.

In December 2016, Professor Roland van Velthoven from Institut Bordet Oncology Center, Brussels, Belgium published a matched pair analysis of HIFU Hemi-ablation vs robotic assisted laparoscopic prostatectomy. In this study, 55 patients with unilateral localized prostate cancer were treated using Ablatherm-HIFU and their outcomes were compared 1:1 with patients having similar clinical criteria but underwent robotic assisted laparoscopic prostatectomy. The matched pair analysis concluded that HIFU was comparable to robotic-assisted radical prostatectomy in the management of prostate cancer and showed HIFU to have significantly better functional outcomes.

In 2017, Crouzet et al. reported the oncological outcome of salvage high-intensity focused ultrasound (S-HIFU) for locally recurrent prostate cancer after external beam radiotherapy (EBRT) from the @-registry multicenter database in *British Journal of Urology* (BJU) International journal. This retrospective study comprises patients from nine centers with local recurrent disease after EBRT treated with S-HIFU from 1995 to 2009. The publication is the largest series of salvage treatment, confirming very positive oncological outcomes for this population (7 years metastasis free rate of 81%). It also insists on the importance of treating recurrence of prostate cancer early after failure, as it largely improves outcomes.

More recently, Ganzer & al., EDAP's users in Germany, evaluated focal HIFU Hemi-ablation in a prospective trial. Their data were published in *Journal of Urology* in April 2018. In their conclusion, they reported that Focal therapy Hemi-ablation is safe with little alteration of functional outcome and concluded that the oncologic outcome was acceptable on short-term follow-up.

In early 2018, a new database, called the Focal Robotic Ultrasound Ablation Registry ("FoR-UsA"), has been established to collect high quality clinical data of U.S. patients treated with Ablatherm Robotic HIFU. The FoR-UsA Registry is the first in the U.S. that specifically collects data on patients who have had HIFU focal therapy for prostate tissue ablation, giving urologists around the U.S. greater access to short and long term HIFU outcomes. The registry

also holds the potential for the FDA, which cleared HIFU for prostate tissue ablation in 2015, to re-evaluate the technology in the future for a prostate cancer indication. Likewise, health insurance reimbursements on a wider scale are also possible with a registry documenting HIFU data from patients in the U.S.

HIFU Division Market Potential

Prostate cancer is currently the first or second most common form of cancer among men in many populations. In the United States, the American Cancer Society estimates the number of new prostate cancers diagnosed every year to be approximately 174,650, of which approximately 70% are diagnosed with localized stage prostate cancer. Additionally, the HIFU division believes, based on figures provided by the World Health Organization that the worldwide incidence of localized prostate cancer is approximately twice this U.S. figure. A more effective diagnostic method for prostate cancer, the PSA test, has increased public awareness of the disease in developed countries since its introduction. 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.

The HIFU division believes that HIFU therapy could be expanded to other medical conditions, such as certain localized thyroid, breast, gynecological, bladder, kidney, liver, brain, pancreatic and retroperitoneal tumors. We decided to focus on developing HIFU for certain types of pathologies. For example, in late 2016, we initiated a clinical Phase I study to address certain types of deep endometriosis situated in the low rectum, using Focal One HIFU. Nineteen patients have been treated successfully. A multi-centric study is to be initiated in 2019. As per the European Society of Human Reproduction and Embryology, endometriosis is estimated to affect approximately one in 10 women of reproductive age. In June 2015, we entered into a multi-partner liver cancer development project organized by the HECAM (“HEpatocellular CArcinoma Multi-technological”) consortium. This project aims at developing innovative diagnostic, imaging and therapeutic technologies to address liver cancer. EDAP’s focus within the HECAM consortium is on developing a novel HIFU treatment for liver cancer in cooperation with its long-term academic partner INSERM and leading cancer centers. To fund this development program, EDAP will receive a maximum of €2.4 million in non-dilutive financing from Bpifrance over the five-year project period of which we received the first instalment of €0.7 million in June 2015 and a second installment of €0.8 million in June 2017 (i.e. a total of €1.5 million including €1.0 million as a conditional subsidy and €0.5 million as a grant). The HECAM project is ongoing and a multicentric study will be initiated mid-2019 based on a first mono-centric study implemented with Lyon’s Centre Leon Bérard cancer center. We also anticipate to develop HIFU technology to address pancreatic, breast and gynecological tumors. However, the expansion of the use of HIFU to other areas of treatment will require a significant investment in research and development, an investment we will undertake gradually while focusing on the acceptance of HIFU as a treatment for localized prostate cancer.

HIFU Competition

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

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

We also believe that Focal One will be well positioned to address the growing demand for a "focal" approach of localized prostate cancer which cannot be answered by surgery or radiation therapy. "Focal" treatment (also known as "partial" or "zonal" treatment, as opposed to "radical" treatment) provides an effective and accurate ablative treatment of localized tumors with the capacities of being flexible and repeatable, while preserving patient quality of life.

Other companies are working with HIFU for the minimally invasive treatment of tumors. See Item 3, "Risk Factors – Risks Relating to Competition."

Certain existing and potential competitors of our HIFU division may have substantially greater financial, research and development, sales and marketing and personnel resources than us and may have more experience in developing, manufacturing, marketing and supporting new products. We believe that an important factor in the potential future market for HIFU treatments will be the ability to make the substantial investments in research and development required to advance the technology beyond the treatment of prostate cancer. These future investments are wholly dependent on the successful acceptance of the device for the treatment of prostate cancer.

HIFU Division Sales and Distribution of Products

The HIFU division markets and sells its products through our own direct marketing and sales organization as well as through selected third-party distributors and agents in several countries. Using our direct subsidiaries or representative offices network, the HIFU division maintains direct marketing and sales forces in France, United States, Germany,

Russia and Italy, which currently represent its largest HIFU markets. Additionally, the HIFU division markets and sells its products through our distribution platform in the Middle East, South Korea and South East Asia.

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

The HIFU division's marketing efforts currently include the organization of information and training programs for urologists, mainly in key European countries and in the United States where HIFU awareness is growing, comprehensive media and web programs to educate patients on the availability of HIFU technology to treat localized prostate cancer and strong participation in focused dedicated urological events. Our dedicated web site www.hifu-prostate.com for patients and physicians is visited regularly. The information contained on that website is not incorporated by reference herein.

The HIFU division is also committed to exclusively distribute HIFU products on behalf of Theraclion, in France, including the Echopulse device dedicated to the treatment of benign breast tumors and thyroid tumors.

UDS Division

The UDS division is engaged in the development, marketing, manufacturing and servicing of medical devices for the minimally invasive diagnosis or treatment of urological disorders, mainly urinary stones, and other clinical indications. The UDS division contributed €28.1 million to our consolidated net sales during the fiscal year ended December 31, 2018.

Our UDS business is quite cyclical and generally linked to lengthy hospital decision and investment processes and their activities. Hence our quarterly revenues are often impacted and fluctuate according to these parameters, generally resulting in a higher selling activity in the last quarter of the year.

UDS Division Business Overview

The UDS division's primary business is producing and marketing devices, known as lithotripters, for the treatment of urinary tract stones by means of ESWL technology. ESWL uses extracorporeal shockwaves, which can be focused at urinary stones within the human body to fragment the stones, thereby permitting their natural elimination and preventing the need for incisions, transfusions, general anesthesia, and the resulting complications. The UDS division currently manufactures two models of lithotripters: the Sonolith i-move and the Sonolith i-sys. As of December 31, 2018, the UDS division has sold 933 ESWL lithotripters worldwide to this date and actively maintained or otherwise serviced 725 installed lithotripters.

In addition to its manufacturing and selling of lithotripters, the UDS division also generates revenues from the leasing of lithotripters, as well as from the sale of disposables, spare parts and maintenance services. It also derives revenues from the distribution of urodynamics products and urology lasers.

UDS Division Business Strategy

The business strategy for the UDS division is to capitalize on its expertise in ESWL and its position in urology to achieve long-term growth as a leader in the development, production, marketing and distribution of minimally invasive medical devices for urological and other clinical indications. The UDS division manufactures its own products as part of EDAP TMS France SAS ("EDAP TMS France"), our wholly owned subsidiary. The key elements of the UDS division's strategy are:

- *Capitalize on the Current ESWL Installed Base*. The UDS division's long-term growth strategy relies on its ability to capitalize on its extensive installed base of ESWL lithotripters to recognize ongoing revenue from sales of disposables, accessories, services and replacement machines. We believe that offering highly innovative units that are easily adaptable to various treatment environments, as well as a commitment to quality and service will allow the UDS division to achieve this goal. See ''Information on the Company—UDS Division Products''.

- *Capitalize on an Established Distribution Platform in Urology by Expanding Distribution Possibilities*. We believe that we can achieve additional long-term growth by offering our established distribution platform in urology to other developers of medical technologies and acting as a distributor for their devices. Our distribution platform in urology consists of a series of well-established subsidiaries in Europe, United States, Middle East and Asia as well as a network of third-party distributors worldwide.

- *Provide Manufacturing Solutions to Other Developers of Medical Technologies*. Building upon its established position in the high-tech medical devices market, we believe that the UDS division can become a provider of manufacturing alternatives to other developers of medical technologies that do not have or do not wish to invest in their own manufacturing facilities. We believe that our FDA-inspected and ISO 13485: 2016 certified facilities allow us to offer manufacturing services to a wide range of potential medical equipment developers.

UDS Division Products

The UDS division offers the Sonolith i-move to small and mid-size hospitals, while the Sonolith i-sys is offered to large hospitals that can afford a fully dedicated and integrated lithotripter. The UDS division also sells disposable parts for lithotripters, including the piezoelectric elements of the LT02, (a machine we discontinued manufacturing in 2002) and the electrodes of the Sonolith line, which need to be replaced approximately every ten treatments. These parts incorporate key proprietary technologies, and the UDS division has retained sole marketing rights for these parts.

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

The UDS division's ESWL customers are located worldwide and have historically been principally large hospitals, urology clinics and research institutions. To increase its penetration of the market segment of smaller hospitals and outpatient clinics, the UDS division developed the Sonolith i-move, an electroconductive lithotripter designed for smaller clinics. It is more compact than the Sonolith i-sys, which is more fully integrated and dedicated to larger hospitals and can be used as a urological workstation to perform endourological procedures. The Sonolith i-move, launched in 2010, brings a novel approach to the market by offering a wide range of configurations to suit various budgets and various local market needs. The Sonolith range has also been very successful thanks to its innovative *Visio-Track* ultrasound stone localization: a unique three-dimensional virtual system that uses infrared stereovision proprietary technology to guide the treatment robotically.

UDS Division Patents and Intellectual Property

As of December 31, 2018, the UDS division's patent portfolio contained 11 granted patents consisting of one patent in the United States, eight patents in the European Union and Japan and two patents in both Israel and the rest of the world. They belong to five groups of patents covering key technologies relating to ESWL systems and associated software capabilities. The UDS division's patents cover both piezoelectric and electroconductive technologies associated to ESWL generator, localization systems and device design. The UDS division's ongoing R&D objectives in ESWL are to further increase the clinical efficacy, the cost-effectiveness and the ease of use of its products to make them accessible to wider patient and user populations.

As with the development of our HIFU technology, we cooperate with INSERM to develop our ESWL technology. This cooperation gave rise to co-owned patents in some cases. We have entered in the past into various license agreements with INSERM whereby we committed to pay a fixed amount of royalties to INSERM based on the net revenues generated from the sales of ESWL devices using co-owned patents. Under these agreements, we had the exclusive right to the commercial use of the co-owned patents, including the right to out-license such commercial rights. These license agreements expired in 2016, allowing EDAP to freely use the related patents.

UDS Division Regulatory Status

The Sonolith i-move is available for commercial distribution in the European Union, South Korea, Malaysia, Thailand, Taiwan, Singapore, Russia, Serbia, Peru, Colombia, Costa Rica, Argentina, Japan, United States, Saudi Arabia, Argentina, Mexico and Brazil.

The Sonolith i-sys is available in the European Union, South Korea, Canada, United States, Peru, Colombia, Mexico, Costa Rica, Chile, Russia, Serbia, Japan, Australia, Malaysia, Singapore, Vietnam, Saudi Arabia, China and Taiwan.

The UDS division continues to provide disposables, replacement parts and services for the current installed base of Sonolith Praktis, even though we discontinued the manufacture of these machines.

UDS Division Market Potential

We estimate that roughly 5% of the world population suffers from kidney or ureteric stones during their lifetime and that 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 more than 35 years ago, ESWL has become the standard treatment for urinary calculi. ESWL consists of fragmenting calculi within the body using extracorporeal shockwaves without any surgery. We believe that the market for lithotripters includes both buyers looking for a sophisticated, higher-priced machine (generally hospitals and larger urology clinics) but also buyers looking for simpler and less expensive machines (typically smaller clinics). We also believe that after a period of fast growth in the mid-1980s and early 1990s, the market for lithotripters is now mature and has become primarily a replacement and service and maintenance market in most of the world. Several geographical opportunities remain in under-equipped countries or in some countries where the national health system strategy is being reviewed for hospitals and clinics equipment. ESWL is today in competition with less costly stone laser devices. Consequently, in order to remain competitive, EDAP integrated stone laser products into its ESWL product range.

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

UDS Division Competition

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

UDS Division Sales and Distribution of Products

The UDS division markets, sells and services its products through our direct sales and service platform in France, Italy, Germany, United States, Japan, South Korea, Malaysia and, most recently, in the United Arab Emirates through our representative office in Dubai. The UDS division also markets its products through agents and third-party distributors in several other countries.

The UDS division’s customers are located worldwide and have historically been mainly public and private hospitals and urology clinics. We believe that the division’s customer base provides it with excellent access to the urological community and enables it to introduce new products and conduct trials under satisfactory conditions.

No single customer of the UDS division represents a significant portion of the division’s installed base. The UDS division’s marketing efforts include the organization of training programs for urologists worldwide.

The UDS division is also pursuing various distribution options that use its strong network of worldwide subsidiaries and agents. In Japan, the UDS division distributes urodynamics products on behalf of Laborie Company, including MMS (Medical Measurement Systems) products, and Andromeda Company, and also distributes x-ray imaging systems for the diagnosis and treatment of diseases on behalf of French company EOS Imaging. In France, the UDS division distributes laser urology solutions from Lumenis and from Quanta System in Asia and the Middle East. We believe that the laser use in endo-urology will increase in the coming years, for both the treatment of urinary stones and for other urological procedures such as HoLEP (Holmium Laser Enucleation of Prostate). We believe that the UDS division can successfully market its worldwide distribution platform to a wide range of medical equipment development companies, thus allowing for quick, easy and economically sound entry for these companies into markets covering most of the world.

Manufacturing

Our current manufacturing operations consist of manufacturing medical products in our facility, which is FDA-approved and certified under international ISO 13485: 2016 standards. We believe that this facility could possibly extend its outsourced services to provide device and disposable development and manufacturing services to a range of medical equipment development companies. Each division manufactures its own products through EDAP TMS France.

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

Quality and Design Control

The manufacturing operations of EDAP TMS France must comply with all regulations of countries where we market our products, including the GMP regulations enacted by the FDA, which establish requirements for assuring quality by controlling components, processes and document traceability and retention, among other things. EDAP TMS France's facilities are also subject to inspections performed by the FDA. EDAP TMS France is ISO 13485: 2016 certified which indicate compliance by EDAP TMS France's manufacturing facilities with international standards for quality assurance, design and manufacturing process control. EDAP TMS France also complies with the applicable requirements that will allow it to affix the CE Marking to certain of its products. Our manufacturing site also complies with Taiwanese, Japanese and Canadian regulations, as well as with the U.S. Quality System Regulation. See ''Information on the Company—Government Regulation—Healthcare Regulation in the United States'' and ''—Government Regulation—Healthcare Regulation in the European Union.''

Organizational Structure

The following table sets forth the fully consolidated subsidiaries of the Company as of the date of this annual report:

Name of the Company	Jurisdiction of Establishment	Percentage Owned[(1)]
EDAP TMS France SAS	France	100%
EDAP Technomed Inc.	United States	100%
EDAP Technomed Co. Ltd	Japan	100%
EDAP Technomed Sdn Bhd	Malaysia	100%
EDAP Technomed Srl	Italy	100%
EDAP TMS GmbH	Germany	100%

(1) Percentage of equity capital owned by EDAP TMS S.A. directly or indirectly through subsidiaries (percentage of capital owned and voting rights are the same).

Property and Equipment

We have one principal facility, which is located in Vaulx-en-Velin, on the outskirts of Lyon, France. The premises comprise 4,150 square meters and are leased to us under a renewable ten-year commercial lease agreement signed on July 1, 2015. We use this facility to manufacture our device portofolio. We believe the terms of the lease reflect commercial practice and market rates.. We are not aware of any environmental issues that could affect utilization of the facility.

In addition, we lease office and/or warehouse facilities in Kuala Lumpur (Malaysia), Rome (Italy), Flensburg (Germany), Austin (U.S.), Moscow (Russia), Seoul (South Korea), Fukuoka, Osaka, Sapporo and Tokyo (Japan), Dubai (United Arab Emirates).

Government Regulation

Government regulation in our major markets, in particular the United States, the European Union and Japan, is a significant factor in the development and marketing of our products and in our ongoing research and development activities. See Item 3, “Risk Factors –Risks Related to Government Regulations.”

Regulation in the United States

We and our products are regulated in the United States by the FDA under a number of statutes including the Federal Food, Drug and Cosmetic Act (‘‘FDC Act’’). Pursuant to the FDC Act, the FDA regulates the preclinical and clinical testing, manufacturing, labeling, distribution, sale, marketing, advertising and promotion of medical devices in the United States. Medical devices are classified in the United States into one of three classes - Class I, II or III - on the basis of the controls reasonably necessary to ensure their safety and effectiveness. Class I devices are those whose safety and effectiveness can be ensured through general controls, such as establishment and registration, medical device listing, FDA-mandated CGMP, labeling. Most Class I devices are exempt from premarket notification (510(k)). Class II devices are those whose safety and effectiveness can reasonably be ensured through the use of general controls and ‘‘special controls,’’ such as special labeling requirements, mandatory performance standards, and post-market surveillance. Class II medical devices require 510(k) submission and clearance. The FDA may also require the submission of clinical data as part of the 510(k) for Class II devices. The FDA introduced the de novo 510(k) process for novel devices that present low to moderate risk where there is no suitable predicate device to support a standard 510(k) submission. Class III devices are those that require submission of a PMA by the FDA to ensure their safety and effectiveness. The PMA process is expensive and often lengthy, typically requiring several years, and may not necessarily result in approval. The manufacturer or the distributor of the device must obtain an IDE approval from the FDA before commencing human clinical trials in the United States in support of the PMA. Some newer PMA devices must also go before a clinical review panel before FDA approval. Our lithotripsy range of products are now classified by the FDA as Class II devices. As far as our Ablatherm or Focal One HIFU devices are concerned, they also have been classified as Class II. Advertising and promotional activities in the United States are subject to regulation by the FDA and, in certain instances, by the U.S. Federal Trade Commission. The FDC Act also regulates quality and manufacturing procedures by requiring us to demonstrate and maintain compliance with current Quality System Regulations (QSR). Our manufacturing facilities are in compliance with the requirements of the QSR.

Regulation in the European Union

In the European Union, we annually perform ISO 13485: 2016 certification audits, showing that we comply with standards for quality assurance, manufacturing and design control. In the European Union, our products are still subject to legislation implementing the European Union Council Directive 93/42/EEC concerning medical devices (the ‘‘Medical Device Directive’’). The Medical Device Directive provides that medical devices that meet certain safety standards must bear a certification of conformity, the European Community approval ‘‘CE Marking.’’ Except in limited circumstances, member states of the European Union may not prohibit or restrict the sale, free movement or use for its intended purpose of a medical device bearing the CE Marking. Medical devices marketed throughout the European Union must comply with the requirement of the Medical Device Directive to bear a CE Marking (subject to certain exceptions).

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

On May 25, 2017, Europe’s new Medical Device Regulation (“MDR”) was enacted and came into force. Manufacturers with currently approved medical devices in their portfolio will have a transition time of three years, i.e. until May 26, 2020 to meet new MDR requirements. MDR addresses substantial changes to the way medical device manufacturers bring their devices to the European market and how they maintain compliance throughout the product's life cycle. MDR will replace the EU’s current Medical Device Directive (93/42/EEC). We are updating our organization and quality system to be able to handle the transition within the expected timelines for our existing devices ranges and the devices under development. During the transition period, regulatory actions are being implemented to ensure our devices continue to be marketed on European and international market after May 2020.

Regulation in Japan

The import and sales of medical devices in Japan is regulated by the Japanese Ministry of Health, Labor and Welfare (‘the “MHLW’’) under the license “Marketing Authorization Holder” Our Japanese subsidiary has obtained a general license as well as specific approvals to import our products that have been approved in Japan. Our Japanese subsidiary is also operating under the statute of Designated Marketing Authorization Holder (“DMAH”) on behalf of some companies to act as their representative on the Japanese Territory, before Japanese regulatory authorities. The MHLW also administers various national health insurance programs to which each Japanese citizen is required to subscribe. These programs cover, among other things, the cost of medical devices used in operations. The MHLW establishes a

price list of reimbursable prices applicable to certain medical devices under the national health insurance programs and until a new device is included in this list its costs are not covered by the programs. The LT02, the Sonolith Praktis, the Sonolith Vision, the Sonolith i-sys and the Sonolith i-move are all included on the MHLW's list for reimbursement.

Item 4A. Unresolved Staff Comments

None.

Item 5. Operating and Financial Review and Prospects

The following discussion of our results of operations and liquidity and capital resources for the fiscal years ended December 31, 2018, 2017 and 2016 is based on, and should be read in conjunction with, our consolidated financial statements and the notes thereto included in Item 18 of this annual report. The consolidated financial statements have been prepared in accordance with U.S. GAAP and refer to the new topic-based FASB Accounting Standards Codification.

The following discussion contains certain forward-looking statements that involve risks and uncertainties. Actual results may differ materially from those contained in such forward-looking statements. See ''Cautionary Statement on Forward-Looking Information'' at the beginning of this annual report.

Critical Accounting Policies

The discussion and analysis of our financial condition and results of operations are based upon the consolidated financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States. The preparation of these financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, revenues and expenses, and related disclosure of contingent assets and liabilities. On an on-going basis, we evaluate our estimates, including those related to revenue recognition, accounts receivable, bad debts, inventories, warranty obligations, employee stock-option plans, goodwill impairment, provisions for retirement indemnities, litigation and deferred tax assets. We base our estimates on historical experience and on various other assumptions that are believed to be reasonable under the circumstances. These estimates and assumptions form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

We believe our more significant judgments and estimates used in the preparation of our consolidated financial statements are made in connection with the following critical accounting policies.

Revenue Recognition

The Company adopted ASC Topic 606, *Revenue from Contracts with Customers*, on January 1, 2018.

The Company’s revenue consists of:

- Sales of goods (devices and consumables), where invoicing takes place upon delivery.

- Revenue-per-Procedures (“RPP”) and leases: they comprise (i) revenues on a per treatment basis which are invoiced after each treatment, or in advance, or on a periodic basis, (ii) leases of devices, which are generally invoiced on a monthly or quarterly basis, and (iii) lease components arising from multiple-element arrangements, where specific sales terms are negotiated in accordance with each customer’s individual requirements and which are generally invoiced based on contract terms,

- Sales of spare parts and services (maintenance, upgrades, mobility and others). Spare parts are invoiced when delivered. Regarding services, invoicing is performed either on a subscription basis (in advance or at the end of the

period) or when performed.

The Company invoices its customers based on the billing schedules in its sales arrangements. Payments are generally due between one to three months from date of invoice.

The Company accounts for a contract with a customer when there is a legally enforceable contract between the Company and its customer, the rights of the goods or services and their payment terms can be identified, the contract has commercial substance, collectability of the contract consideration is probable, it is approved and the parties are committed to their obligations.

Our sale arrangements may contain multiple elements, including device(s), consumables and services. For these multiple-element arrangements, the Company accounts for individual goods and services as separate performance obligations: (i) if they are a distinct good or service that is separately identifiable from other items in the multiple-element arrangement; and (ii) if a customer can benefit from the good or service on its own or with other resources that are readily available to the customer. The Company's sale arrangements may include a combination of the following performance obligations: device(s), consumables, leases and services (such as, but not limited to, warranty extension).

For multiple-element arrangements, revenue is allocated to each performance obligation based on its relative standalone selling price. Standalone selling prices are based on observable prices at which the Company separately sells the goods or services. If a standalone selling price is not directly observable, then the Company estimates the standalone selling price considering market conditions and entity-specific factors including, but not limited to, features and functionality of the goods and services, geographies, and type of customer. The Company regularly reviews standalone selling prices and updates these estimates as necessary.

The Company recognizes revenue when the performance obligations are satisfied by transferring control over the good or service to a customer.

The Company's revenue consists of the following:

Sales of goods:

Sales of goods are and have historically been comprised of net sales of medical devices (ESWL lithotripters and HIFU devices) and net sales of disposables (mostly Ablapaks and Focalpaks in the HIFU division and electrodes in the UDS division). Sales of goods also includes products such as urology laser and urodynamics devices distributed through our agents and third-party distributors.

For devices and disposables, revenue is recognized when the Company transfers control to the customer (i.e. when the customer has the ability to direct the use of, and obtain substantially all of the remaining benefit from, the device or disposables), which is generally at the point of delivery or installation, depending on the terms of the arrangement (i.e. when the customer can use the good to provide services or sell or exchange the good), and based on contractual incoterms.

The Company's sales arrangements do not provide a right of return. The goods are generally covered by a period of one to two years standard warranty upon installation. The Company also provides training associated with the sales of goods; such training-related costs are immaterial in the context of the contract with the customer and do not constitute a distinct performance obligation.

Sales of RPPs and leases:

Sales of RPP and leases include the revenues from the sale of treatment procedures and from the leasing of machines. We provide machines to clinics and hospitals for free for a limited period, rather than selling the devices. These hospitals and clinics perform treatments using the devices and usually pay us based on the number of individual treatments provided.

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

Regarding multiple-element arrangements with a lease component, a portion of the contract is allocated to the lease component on the basis of observable market prices applied by the Company for similar devices under operating leases. The lease component is recognized on a straight line basis over the contractual period. Other components under the contract are recognized in accordance with their nature.

Sales of spare parts and services:

Revenues related to spare parts are recognized when spare parts are delivered to distributors who perform their own maintenance services. Spare parts used in the performance of EDAP's own maintenance and repair services are generally not recognized separately, unless specified in the contract.

Revenues related to Services mainly consist of maintenance contracts which rarely exceed one year and are recognized on a straight line basis over the term of the service period as the customer benefits from the service throughout the service contract period. For services rendered when no maintenance contract is in place or for services not included in the scope of a maintenance contract, revenues are recorded when services are performed.

The Company recognizes revenue for extended warranties included in the multiple-element arrangements as a separate performance obligation in Sales of services on a straight-line basis over the extended warranty period. In the majority of countries in which the Company operates, the statutory warranty period is one to two years and the extended warranty covers periods beyond this statutory period. Standard warranties do not constitute a separate performance obligation. The Company accrues for the warranty costs at the time of sale of the device through the multiple-element arrangement.

Agents and distributors:

As part of its sale process in countries other than continental France, when the Company does not have a local subsidiary, sales of goods to end-customers are performed through agent and distributors. Such agent and distributors are primarily responsible for the sales' process, bear the inventory risk, and are free to determine the sale prices. Sales of goods to agents and distributors are recognized at the time of the sale to the related agent or distributor, based on contractual incoterms.

Deferred revenue:

Deferred revenue for the periods presented primarily relates to service contracts where the service fees are billed up-front, generally quarterly or annually, prior to those services having been performed, and consists primarily of billing or cash receipts in advance of services due under maintenance contracts or extended warranty contracts. The associated deferred revenue is generally recognized ratably over the service period.

Disaggregation of revenue:

Disaggregation by primary geographical market, and timing of revenue recognition is reported in Note 17.

Contract Balances:

Details on contract liabilities are reported on Note 10.

The Company applies the practical expedient in paragraph 606-10-50-14 and does not disclose information about remaining performance obligations that have original expected durations of one year or less. This relates mainly to maintenance services.

Warrants

On May 28, 2013, pursuant to a securities purchase agreement dated May 20, 2013, as amended, the Company issued new ordinary shares in the form of ADSs to selected institutional investors in a registered direct placement (the "May 2013 Placement") with warrants attached (the "May 2013 Investor Warrants"). The Company also issued warrants to the placement agent, H.C. Wainwright & Co., LLC (the "May 2013 Placement Agent Warrants" and together with the May 2013 Investor Warrants, the "May 2013 Warrants"). As the May 2013 Warrants included an exercise price determined in U.S. dollars while the functional currency of the Company is the euro, the Company determined that the May 2013 Warrants should be accounted for as a liability.

The Company used the Black-Scholes pricing model to value the May 2013 Warrants at inception, with changes in fair value recorded as a financial expense or income.

On April 14, 2016, pursuant to a securities purchase agreement dated April 7, 2016, the Company issued new ordinary shares in the form of ADSs to selected institutional investors in a registered direct placement (the "April 2016 Placement") with warrants attached (the "April 2016 Investor Warrants"). As the April 2016 Warrants comprised the same structure and provisions than the May 2013 Warrants, including an exercise price determined in U.S. dollars while the functional currency of the Company is the Euro, the Company determined that the April 2016 Warrants should be accounted for as a liability.

The Company used the Black-Scholes pricing model to value the April 2016 Warrants at inception, with changes in fair value recorded as a financial expense or income.

As of December 31, 2018, all warrants had expired.

Allowance for Doubtful Accounts

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

Operating Results

Overview

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

Sales of goods have historically been comprised of net sales of medical devices (ESWL lithotripters and HIFU devices) and net sales of disposables (mostly Ablapaks and Focalpaks in the HIFU division and electrodes in the UDS division). Sales of goods also included products such as urology laser and urodynamics devices distributed through our agents and third-party distributors. The sale price of our medical devices is subject to variation based on a number of factors, including market competition, warranties and payment terms. Consequently, a particular sale of a medical device may, depending on its terms, result in significant fluctuations in the average unit sale price of the product for a given period, which may not be indicative of a market trend.

Sales of RPP and leases include the revenues from the sale of Ablatherm and Focal One treatment procedures and from the leasing of Ablatherm and Focal One devices. We provide Ablatherm and Focal One devices to clinics and hospitals for free for a limited period, rather than selling the devices. These hospitals and clinics perform treatments using the devices and usually pay us based on the number of individual treatments provided. With this business model, the hospital or clinic does not make an initial investment until the increase in patient demand justifies the purchase of a HIFU device. Consequently, we are able to make Ablatherm or Focal One treatments available to a larger number of hospitals and clinics, which we believe should serve to create more long-term interest in the product. Compared to the sale of devices, this business model initially generates a smaller, although more predictable stream of revenue and, if successful, should lead to more purchases of Ablatherm and Focal One devices by hospitals and clinics in the long term.

In 2018, 2017 and 2016, our UDS sales activity benefited from the success of our Sonolith i-sys device and our Sonolith i-move device, together with a sustained commercial effort in distributing additional urology devices which allowed us to capture market share worldwide. We believe that the market for ESWL lithotripters is now mature and has become primarily a replacement and maintenance market, with intense competition. As a result, we expect total market volumes for our UDS Division to remain stable in the foreseeable future.

Sales of spare parts and services include revenues arising from maintenance services furnished by us for the installed base of ESWL lithotripters and HIFU devices.

We derive a significant portion of both net sales of medical devices and disposables and net sales of spare parts and services from our operations in Asia, through our wholly-owned subsidiaries or representative offices in Japan (Edap Technomed Co. Ltd), Malaysia (Edap Technomed Sdh Bhd) and South Korea (Edap Technomed Korea). Net sales derived from our operations in Asia represented approximately 36% of our total consolidated net sales in 2018. Net sales of goods in Asia represented approximately_42% of such sales in 2018 and consisted mainly of sales of urology devices and disposables. Net sales of spare parts, supplies and services in Asia represented approximately 38% of such sales in 2018 and related primarily to ESWL lithotripters, reflecting the fact that approximately 45% of the installed base of our ESWL lithotripters that we actively maintain or otherwise serve is located in Asia. See Note 28 of our consolidated financial statements. We sell our products in many parts of the world and, as a result, our business is affected by fluctuations in currency exchange rates. We are exposed to foreign currency exchange rate risk because the mix of currencies in which our costs are denominated is different from the mix of currencies in which we earn revenues. In 2018, approximately 74% of our costs of sales and research and development, selling, marketing and general and administrative expenses were denominated in euro, while approximately 41% of our sales were denominated in currencies other than euro (primarily the U.S. Dollar and Japanese yen). Our operating profitability could be materially affected by large fluctuations in the rate of exchange between the euro and such other currencies. To minimize our exposure to exchange rate risks, we sometimes use certain financial instruments for hedging purposes. See Item 3, ‘‘Key Information—Risk Factors—We sell our products in many parts of the world and, as a result, our business is affected by fluctuations in currency exchange rates’’ and Item 11, ‘‘Quantitative and Qualitative Disclosures About Market Risk’’ for a description of the impact of foreign currency fluctuations on our business and results of operations.

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

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

Consolidated research and development expenses, as described above, amounted to €4.1 million, €3.9 million, and €3.9 million in 2018, 2017 and 2016, respectively, representing approximately 10.4%, 10.9%, and 10.9% of total revenues in 2018, 2017 and 2016, respectively. Research and development government grants and tax credits are deducted from our consolidated research and development expenses for amounts of €0.8 million, €0.7 million and €0.7 million in 2018, 2017 and 2016, respectively. Beginning in 2019, management expects the budget for research and development expenses in Europe to increase at approximately 10.7% of total revenues, which we expect will allow us to maintain our strategy to launch new clinical studies (thus strengthening our clinical credibility), to continue to focus our efforts on obtaining regulatory approvals in Japan in particular, and reimbursement in key countries, to continue to develop our HIFU and ESWL product range and to fund projects to expand the use of HIFU beyond the treatment of prostate cancer.

Consolidated selling and marketing expenses amounted to €10.6 million in 2018, €9.5 million in 2017 and €8.9 million in 2016. Selling and marketing expenses included net impact of allowances for doubtful accounts of €0.4 million in 2018, €0.1 million in 2017 and €(0.02) million in 2016. The €1.0 million or 10.8% increase in selling and marketing expenses from 2017 to 2018 was primarily a result of the increase in global sales and marketing activity. Management expects marketing and sales efforts to stay at significant levels in the future to consolidate the Ablatherm and Focal One HIFU technology's status as a standard of care for prostate pathologies, and to sustain the Company's worldwide market position in urology. Beginning in 2019, management expects selling and marketing expenses to continue to increase in view of the Company's expansion.

We believe that our results of operations in the near future will be affected by our ability to grow our sales volumes both in the prostate cancer and the lithotripsy markets, along with our ability to control expenses in connection with the development, marketing and commercial expansion of HIFU for prostate cancer and other applications worldwide, . See ''—Liquidity and Capital Resources.''

Fiscal Year Ended December 31, 2018 Compared to Fiscal Year Ended December 31, 2017

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

(in millions of euros)	2018	2017
Total revenues	39.2	35.7
Total net sales	39.2	35.7
Of which HIFU	11.0	9.5
Of which UDS	28.1	26.2
Total cost of sales	(22.3)	(20.9)
Gross profit	16.9	14.8
Gross profit as a percentage of total net sales	43.2 %	41.5 %
Total operating expenses	(18.2)	(16.8)
Income (loss) from operations	(1.3)	(2.0)
Net income (loss)	(0.3)	(0.7)

Total revenues

Our total revenues increased 9.6% from €35.6 million in 2017 to €39.2 million in 2018.

HIFU division. The HIFU division's total revenues increased by 16.1% from €9.5 million in 2017 to €11.0 million.

The HIFU division's net sales of medical devices increased 58.0% to €3.6 million in 2018, with one Ablatherm unit and six Focal One units sold, as compared to €2.3 million, with two Ablatherm and three Focal One units sold in 2017.

Treatment-driven revenue, which includes net sales of RPP & leases, net sales of disposables and treatments related services, slightly decreased by 1% to €6.1 million in 2018.

Net sales of HIFU maintenance services increased from €1.1 million in 2017 to €1.3 million in 2018, reflecting the development of the installed base.

Other HIFU-related revenues decreased to €19 thousand in 2018 from €36 thousand in 2017 and were comprised of license-based revenues from Theraclion.

UDS division. The UDS division's total revenues increased 7.3 % from €26.2 million in 2017 to €28.1 million in 2018, mostly due to the increase in consumables and maintenance revenues.

The UDS division's net sales of medical devices increased 1.6% from €15.1 million in 2017 to €15.3 million in 2018 with 33 ESWL devices sold in 2018 compared to 40 ESWL units sold in 2017. The increase was driven by a 33% growth in the sales of distribution machines.

Net sales of UDS-related consumables, spare parts, supplies, RPP, leasing and services increased 15.2% from €11.1 million in 2017 to €12.8 million in 2018, as a result of the larger installed base of UDS machines and the development of the distribution products revenues.

Cost of sales.

Cost of sales increased 6.3% from €20.9 million in 2017 to €22.3 million in 2018, and represented 56.9% as a percentage of net sales in 2018, down from 58.7% as a percentage of net sales in 2017, due primarily to the effect of the increase of net sales on the fixed costs.

Operating expenses.

Operating expenses increased 8.3%, or €1.4 million, from €16.8 million in 2017 to €18.2 million in 2018.

Marketing and sales expenses increased €1.0 million, or 10.8% at €10.6 million, reflecting the sales and marketing efforts on expanding the business.

Research and development expenses increased 5.3% at €4.1 million in 2018 from €3.9 million in 2017, mainly driven by development projects and strengthening of regulatory requirements and are net of R&D grants and tax credits of €0.8 million in 2018 and €0.7 million 2017.

General and administrative expenses increased 4.8% to €3.6 million in 2018, mainly due to the higher level of activity, the implementation of SAP program and the impact of the remediation plan following the 2017 identified material weakness.

Operating profit (loss).

As a result of the factors discussed above, we recorded a consolidated operating loss of €1.3 million in 2018, as compared to a consolidated operating loss of €2.0 million in 2017.

We realized an operating loss in the HIFU division of €2.3 million in 2018, as compared with an operating loss of €2.7 million in 2017, and an operating profit in the UDS division of €2.3 million in 2018, as compared to an operating profit of €2.1 million in 2017.

Financial (expense) income, net.

Net financial income was €0.8 million in 2018, including a €0.9 million income for fair value adjustments on the outstanding warrants, compared with a net financial income of €2.6 million in 2017, including a €2.7 million income due to fair value adjustments.

In 2018, we recorded a net foreign currency exchange income of €0.5 million, mainly due to the variation of the Euro against the U.S. Dollar and the Japanese Yen, compared to a loss of €0.9 million in 2017.

Income taxes.

Income tax was an expense of €0.4 million in 2018 and 2017.

Net income / (loss)

As a result of the above, we realized a consolidated net loss of €0.3 million in 2018 compared with a consolidated net loss of €0.7 million in 2017.

Fiscal Year Ended December 31, 2017 Compared to Fiscal Year Ended December 31, 2016

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

(in millions of euros)	2017	2016
Total revenues	35.7	35.6

Total net sales	35.7	35.6
Of which HIFU	9.5	13.8
Of which UDS	26.2	21.8
Total cost of sales	(20.9)	(19.2)
Gross profit	14.8	16.4
Gross profit as a percentage of total net sales	41.5 %	46.1 %
Total operating expenses	(16.8)	(16.0)
Income (loss) from operations	(2.0)	0.4
Net income (loss)	(0.7)	3.8

35

Total revenues

Our total revenues increased 0.3% from €35.6 million in 2016 to €35.7 million in 2017.

HIFU division. The HIFU division's total revenues decreased by 31.2% to €9.5 million in 2017 as compared to €13.8 million in 2016.

The HIFU division's net sales of medical devices decreased 70.7% to €2.3 million in 2017, with two Ablatherm units and three Focal One units sold, as compared to €7.8 million, with six Ablatherm and eight Focal One units sold in 2016.

Treatment-driven revenue, which includes net sales of RPP & leases, net sales of disposables and treatments related services, increased 12.9% to €6.1 million in 2017.

Net sales of HIFU maintenance services increased from €0.6 million in 2016 to €1.1 million in 2017.

Other HIFU-related revenues increased to €36 thousand in 2017 from €28 thousand in 2016 and were comprised of license-based revenues from Theraclion.

UDS division. The UDS division's total revenues increased 20.4 % from €21.8 million in 2016 to €26.2 million in 2017, mostly due to the increase in machine sales and maintenance revenues.

The UDS division's net sales of medical devices increased 23.6% from €12.2 million in 2016 to €15.1 million in 2017 with 40 ESWL devices sold in 2017 compared to 36 ESWL units sold in 2016.

Net sales of UDS-related spare parts, supplies, RPP, leasing and services increased 16.1% from €9.6 million in 2016 to €11.1 million in 2017, as a result of the larger installed base of UDS machines and the development of the distribution products revenues.

Cost of sales.

Cost of sales increased 9.1% from €19.2 million in 2016 to €20.9 million in 2017, and represented 58.7% as a percentage of net sales in 2017, up from 54.0% as a percentage of net sales in 2016, due primarily to the decrease in HIFU revenues and the adverse mix between HIFU and UDS division, as HIFU margins are higher than UDS margins.

Operating expenses.

Operating expenses increased 5.1%, or €0.8 million, from €16.0 million in 2016 to €16.8 million in 2017.

Marketing and sales expenses increased €0.7 million, or 7.6% at €9.5 million, reflecting the sales and marketing efforts on expanding the business.

Research and development expenses increased 0.4% at €3.9 million in 2017 from €3.9 million in 2016, mainly driven by HIFU development projects and comprised R&D grants and tax credits of €0.7 million in 2017 and 2016.

General and administrative expenses increased 4.0% to €3.4 million in 2017, mainly due to implementation of SAP program.

Operating profit (loss).

As a result of the factors discussed above, we recorded a consolidated operating loss of €2.0 million in 2017, as compared to a consolidated operating profit of €0.4 million in 2016.

We realized an operating loss in the HIFU division of €2.7 million in 2017, as compared with an operating profit of €1.0 million in 2016, and an operating profit in the UDS division of €2.1 million in 2017, as compared to an operating profit of €0.7 million in 2016.

Financial (expense) income, net.

Net financial income was €2.6 million in 2017, including a €2.7 million income for fair value adjustments on the outstanding warrants, compared with a net financial income of €3.9 million in 2016, including a €3.8 million income due to fair value adjustments.

In 2017, we recorded a net foreign currency exchange loss of €0.9 million, mainly due to the variation of the Euro against the U.S. Dollar and the Japanese Yen, compared to an income of €0.1 million in 2016.

Income taxes.

Income tax was an expense of €0.4 million in 2017 and €0.6 million in 2016.

Net income / (loss)

As a result of the above, we realized a consolidated net loss of €0.7 million in 2017 compared with a consolidated net income of €3.8 million in 2016.

Effect of Inflation

Management believes that the impact of inflation was not material to our net sales or loss from operations in the three years ended December 31, 2018.

Liquidity and Capital Resources

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

We anticipate that cash flow in future periods will be derived mainly from ongoing operations. As of the date of this annual report we do not employ any off-balance sheet financing. Because we anticipate relying principally on cash and cash equivalent balances to meet our liquidity requirements, a decrease in the demand for our products, or the inability of our customers to meet their financial obligations to us due to operating difficulties or adverse market

conditions, would reduce the availability of funds to us.

(in thousands of euros)	2018	2017	2016
Net cash generated by/(used in) in operating activities	175	(3,059)	1,209
Net cash generated by/(used in) in investing activities	(1,569)	(2,032)	(384)
Net cash generated by/(used in) in financing activities	1,178	2,871	7,604
Net effect of exchange rate changes	(323)	235	(19)
Net increase/(decrease) in cash and cash equivalents	(539)	(1,985)	8,410
Cash and cash equivalents at the beginning of the year	20,004	21,989	13,578
Cash and cash equivalents at the end of the year	19,465	20,004	21,989

Our cash position as of December 31, 2018, 2017 and 2016, was €19.5 million (with no short-term treasury investments), €20.0 million (with no short-term treasury investments) and €22.0 million (with no short-term treasury investments), respectively. We experienced negative cash flows of €0.5 million in 2018, negative cash flows of €2.0 million in 2017 and positive cash flows of €8.4 million in 2016.

In 2018, our negative net cash flow was primarily due to the high level of cash used in investing activities partly offset by net cash generated by financing activities which included the new Long Term debt (€1.0 million) granted during the year. In 2017, our negative net cash flow was primarily due to the negative cash flow from operations and the high level of cash used in investing activities. In 2016, our positive net cash flow was due to the April 2016 Placement and our positive cash flow from operations.

In 2018, net cash generated by operating activities was €0.2 million compared with net cash used in operating activities of €3.1 million in 2017 and compared with net cash generated by operating activities of €1.2 million in 2016.

In 2018, net cash generated by operating activities reflected principally

- a net loss of €0.3million;
- elimination of €1.8 million of net loss without effects on cash, including a gain of €0.9 million due to fair value variations of financial instruments, €1.6 million of depreciation and amortization, and €0.3 million of non-cash compensation linked to stock-options plans.
- an increase in working capital of €1.3 million reflecting the higher level of activity and the high level of net sales recorded in December 2018 which will be collected in 2019.

In 2017, net cash used in operating activities reflected principally:

- a net loss of €0.7 million;
- elimination of €0.7 million of net gain without effects on cash, including a gain of €2.7 million due to fair value variations of financial instruments, €1.6 million of depreciation and amortization, and €0.4 million of non-cash compensation linked to stock-options plans.
- an increase in trade accounts and other receivables of €1.7 million;
- a decrease in inventories of €0.7 million;
- an increase in payables of €0.4 million;
- a decrease in accrued expenses and other current liabilities of €1.0 million.

In 2016, net cash generated in operating activities reflected principally:

- a net income of €3.8 million;

- elimination of €2.4 million of net gain without effects on cash, including a gain of €4.0 million due to fair value variations of financial instruments, €1.0 million of depreciation and amortization, and €0.4 million of non-cash compensation linked to stock-options plans.

- a decrease in trade accounts and other receivables of €1.8 million;

- an increase in inventories of €2.0 million;

- a decrease in payables of €0.2 million;

- a increase in accrued expenses and other current liabilities of €0.1 million.

In 2018, net cash used in investing activities was €1.6 million compared with net cash used in investing activities of €2.0 million in 2017 and compared with net cash used of €0.4 million in investing activities in 2016.

Net cash used in investing activities of €1.6 million in 2018 reflected investments of €0.8 million in capitalized assets produced by the Company (devices), mostly for RPP activity (€0.3 million) and R&D program (€0.5 million) and investment of €1.1 million in property, equipment (including €0.3 million of equipment for mobile activity) and software (including new Enterprise Resource Planning "ERP" implementation for €0.4 million), and net proceeds from sales of leased-back assets of €0.4 million.

Net cash used in investing activities of €2.0 million in 2017 reflected investments of €1.0 million in capitalized assets produced by the Company (devices), mostly for RPP activity (€0.5 million) and R&D program (€0.3 million) and investment of €1.0 million in property, equipment and software (including new Enterprise Resource Planning "ERP" implementation for €0.5 million), and net proceeds from sales of leased-back assets of €0.1 million.

Net cash used in investing activities of €0.4 million in 2016 reflected investments of €0.9 million in capitalized assets produced by the Company, mostly for commercial demonstrations, training and RPP activity and investment of €0.5 million in property, equipment and software, and net proceeds from sales of short term investments of €1,0 million.

In 2018, net cash generated in financing activities was €1.1 million compared with a net cash generated in financing activities of €2.9 million in 2017 and net cash generated in financing activities of €7.6 million in 2016.

Net cash generated in financing activities of €1.1 million in 2018 reflected principally the new long term borrowings of €1.0 million in Germany and Japan, repayment of long-term borrowings and lease financing for €0.8 million and an increase of short-term borrowings of €0.9 million.

Net cash generated in financing activities of €2.9 million in 2017 reflected principally the net proceeds of €0.7 million from the exercise of stock options and warrants, but also new long term borrowings of €0.8 million related to new investments financing, €0.8 million of conditional advances to finance research HECAM project, repayment of long-term borrowings and lease financing for €0.5 million and an increase of short-term borrowings of €1.1 million.

Net cash generated in financing activities of €7.6 million in 2016 reflected principally the €9.2 million net proceeds from the April 2016 Placement and the net proceeds of €0.1 million from the exercise of warrants, repayment of short-term and long-term borrowings and lease financing for €1.8 million.

Our policy is that our treasury department should maintain liquidity with the use of short-term borrowings and the minimal use of long-term borrowings. The treasury department currently adheres to this objective by using fixed-rate debt, which normally consists of long-term borrowing and with certain long-term borrowings consisting of sale and leaseback equipment financing. Currently the short-term debt consists of account receivables factored and for which the Company is supporting the collection risk. We maintain bank accounts for each of our subsidiaries in the local currencies of each subsidiary. The primary currencies in which we maintain balances are the euro, the U.S. dollar and the Japanese yen. To minimize our exposure to exchange rate risks, we may use certain financial instruments for hedging purposes from time to time. As of December 31, 2018, there were no outstanding hedging instruments. See Notes 13 and 14 to the consolidated financial statements for further information on our borrowings.

Contractual Obligations and Commercial Commitments as of December 31, 2018 (in thousands of euro)

	Payments Due by Period				
	Total	Less than 1 year	1-3 years	4-5 years	More than 5 years
Short-Term Debt	3,683	3,683			
Long-Term Debt	1,830	491	841	324	174
Capital Lease Obligations	1,235	383	596	246	10
Operating Leases	2,933	638	1,080	722	493
Interest	96	31	45	15	4

Recent Accounting Pronouncements

See “NOTE 1—SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES -- *1.25 New Accounting Pronouncements*” of the Notes to Consolidated Financial Statements for a description of recent accounting pronouncements including the respective expected dates of adoption and estimated effects, if any, on our Consolidated Financial Statements.

Research and Development, Patents and Licenses

See “—Operating Results—Overview” and Item 4, ‘‘Information on the Company—HIFU Division—HIFU Division Patents a Intellectual Property’’ and ‘‘Information on the Company—UDS Division—UDS Division Patents and Intellectual Property.’’

The French government provides tax credits to companies for innovative research and development. This tax credit is calculated based on a percentage of eligible research and development costs and it can be refundable in cash.

Off-Balance Sheet Arrangements

At December 31, 2018, we had no off-balance sheet arrangements other than those specified in Note 14-1 of our consolidated financial statements.

Item 6. Directors, Senior Management and Employees

Senior Executive Officers

The following table sets forth the name, age and position of each of our Senior Executive Officers as of April 12, 2019. The Chief Executive Officer and the Chief Financial Officer listed below have entered into employment contracts with us or our subsidiaries (which permit the employee to resign subject to varying notice periods). In addition, in case of a change of control of the Company, or of a termination of their employment contract by the Company without cause, the Senior Executive Officers are entitled to receive severance packages totaling approximately €0.6 million.

Name	Position
Marc Oczachowski Age: 49	Chief Executive Officer of EDAP TMS S.A. and Member of the Board of Directors President of EDAP TMS France SAS and EDAP Technomed, Inc.

Marc Oczachowski joined the Company in May 1997 as Area Sales Manager, based in Lyon, France. From March 2001 to January 2004, he held management positions as General Manager of EDAP Technomed Malaysia. He was appointed Chief Operating Officer of EDAP TMS in November 2004 and became Chief Executive Officer of the Company on March 31, 2007. From July 2012 to July 2017, he relocated to Austin, Texas to manage EDAP’s U.S. operations. Previously he worked for Sodem Systems, which manufactures orthopedic power tools, as Area Sales Manager. He is a graduate of Institut Commercial de Lyon, France.

François Dietsch Age: 43	Chief Financial Officer of EDAP TMS S.A. François Dietsch joined EDAP in 2005 as Internal Audit and Consolidation Manager, leading the implementation of internal controls for Sarbanes-Oxley Compliance, consolidation of financial statements from the Company's subsidiaries and preparation of financial statements in accordance with U.S. GAAP, including EDAP's annual report on Form 20-F. In 2012, he was promoted to Group Financial Control Manager and Finance Manager of EDAP's French subsidiary where, in addition to his previous responsibilities, he managed accounting firm relationships at the subsidiary level and was the primary liaison between the Company and its external auditors. He also managed the Finance department at EDAP France. He was appointed Chief Financial Officer of the Company on July 14, 2015. Prior to joining EDAP he held finance positions at Valeo, a leading global supplier of components and systems to the automotive industry. He holds Master's Degrees in Management and Corporate Finance from University of Paris Dauphine.

Board of Directors

The following table sets forth the names and backgrounds of the members of the Board of Directors. None of the directors has service contracts with the Company or any of its subsidiaries providing for benefits upon termination of employment. All of the Board members are independent within the meaning of NASDAQ Marketplace Rule 5605(2). Four Board of Directors mandates terminate in June 2020 at the General Meeting of Shareholders approving the 2019 accounts.

Philippe Chauveau Age: 83 Mandate: 6 years Appointment: April. 8, 1997 (renewed in 2014) Expiration: 2019	Philippe Chauveau was named chairman of EDAP TMS S.A.'s Supervisory Board in 1997. In 2002, the Company’s two-tiered board structure was replaced by a single Board of Directors with Philippe Chauveau serving as Chairman and CEO until 2004 when he was succeeded as CEO. From 2000 to 2007, Philippe Chauveau served as founding Chairman of the Board of Scynexis Inc., funded by private equity, which is an innovative drug discovery company based in the United States. He was Vice-President of research and development at AT&T Bell Labs and has also served as Chairman of Apple Computer Europe, preceded by increasing marketing roles in ITT and in Procter & Gamble. He has an Honours Degree from Trinity College Dublin with a B.A. and a Bsc.

Pierre Beysson Age: 77	
Mandate: 6 years Appointment: September 27, 2002 (renewed in 2014) Expiration: 2019	Pierre Beysson was appointed as a member of the Board of Directors in September 2002. Pierre Beysson was then the Chief Financial Officer of Compagnie des Wagons-Lits ("CWL"), the on-board train service division of Accor, a French multinational Hotel and Business Services Group. In this capacity, he sat on a number of boards of companies related to the Accor Group. Before his assignment at CWL, Pierre Beysson held a number of senior financial positions with Nixdorf Computers, Trane (Air Conditioning), AM International (Office Equipment) and FMC (Petroleum Equipment). Pierre Beysson was trained as a CPA, has auditing experience and holds an MBA from Harvard Business School.
Argil Wheelock Age: 71	
Mandate: 6 years Appointment: June 25, 2009 (renewed in 2014) Expiration: 2019	Dr. Argil Wheelock was elected as a member of the Company's Board of Directors in June 2009. Dr. Wheelock, a U.S. board certified urologist, is currently Senior Physician at the University of Tennessee Department of Urology at Erlanger Medical Center, a tertiary care and teaching hospital in Chattanooga, Tennessee. He is Chief Medical Advisor to HealthTronics Inc., a privately held company. HealthTronics is a leading U.S. provider of urological services and products. From 1996 to 2005, Dr. Wheelock served as Chairman and CEO of HealthTronics, a publicly traded NASDAQ company where he was a founder. He has built a successful track record introducing new medical devices to the U.S. and navigating the FDA approval process. He is widely known among the U.S. urological community for bringing clinical benefits to patients and economic value to urology practices. Dr. Wheelock graduated from the University of Tennessee College of Medicine and completed urological training at Mount Sinai Hospital in New York City.
Rob Michiels	Rob Michiels was elected as a member of the Company's Board of Directors in July 2009. He is a 30-year U.S. veteran of the medical device industry. He most recently serves as Chief Executive

Age: 69

Mandate: 6 years

Appointment: July 16, 2009

(renewed in 2014)

Expiration: 2019

Officer (CEO) of CardiAQ Valve Technologies, a venture funded start-up developing Transcatheter Mitral Valve Implantation which was acquired by Edwards Lifesciences during the second half of 2015. He previously served as Chief Operating Officer (COO) of CoreValve (acquired by Medtronic); and as President and COO of InterVentional Technologies (acquired by Boston Scientific). He helped drive both companies from cardiovascular start-ups to established market leaders, using new and innovative technologies which have strong synergies to the HIFU story. Rob Michiels is a director of Aegis Surgical Ltd, Atrius Ltd, and FEops NV, all privately held companies developing cutting edge cardio-vascular less-invasive Technologies. Rob Michiels is a founding partner of CONSILIUM, a medical device market research company active in identifying, funding and greenhousing start-up technologies. Fluent in English, French and Dutch languages, he holds a bachelor's degree in economics from Antwerp University in Belgium and a Master's in business administration (MBA) from Indiana University.

Marc Oczachowski

Age: 49

See Marc Oczachowski's background above (Senior Executive Officers).

Mandate: 6 years

Appointment: July 1, 2017

Expiration: 2022

Compensation

Aggregate compensation paid or accrued for services in all capacities by the Company and its subsidiaries to Senior Executive Officers and to the Board of Directors as a group for the fiscal year 2018 was approximately €514 thousand including performance bonuses of €81 thousand and benefits in kind of €9 thousand (benefits in kind comprise car allowances for senior management). No amount was set aside or accrued by us to provide pension, retirement or similar benefits for Senior Executive Officers and to the Board of Directors as a group in respect of the year 2018. For information regarding compensation paid in the form of stock options, see "Directors, Senior Management and Employees-Share Ownership" and "Directors, Senior Management and Employees-Options to Purchase or Subscribe for Securities."

41

Compensation Committee

The Compensation Committee is comprised of the following independent members: Mr. Philippe Chauveau, Mr. Pierre Beysson, Dr. Argil Wheelock and Mr. Rob Michiels. The Committee gathers once a year to review the compensation of our Chief Executive Officer, as per the approved charter of the Compensation Committee, and to propose to the Board of Directors any changes to the Chief Executive Officer's compensation. The Chief Executive Officer is not present when the Compensation Committee reviews his compensation. In August 2014, the Compensation Committee updated its charter which was subsequently approved by the Board of Directors.

Audit Committee

The Board of Directors' Audit Committee comprises four independent members of the Board: Mr. Pierre Beysson, acting as Head of the Audit Committee and financial expert, Mr. Philippe Chauveau, Dr. Argil Wheelock and Mr. Rob Michiels. The purpose of the Audit Committee, in accordance with its annually approved charter, is as stated below, but not limited to:

- Provide assistance to the Board of Directors in fulfilling their oversight responsibility to the shareholders, potential shareholders, the investment community and others relating to: the integrity of our financial statements, our compliance with legal and regulatory requirements, our accounting practices and financial reporting processes, the effectiveness of our disclosure controls and procedures and internal control over financial reporting,

- Review the independent auditor's qualifications, compensation and independence, and the performance of our internal audit function and independent auditors,

- Recommend the appointment of the independent auditors for consideration and approval by the Company's shareholders in accordance with French law.

- Review and discuss annual financial statements with Management and independent auditors and prepare the Audit Committee report, prior to SEC filings, as well as review related press releases.

- Request any officer or employee of the Company or our outside counsel or independent auditor to attend a meeting of the Audit Committee or to meet with any members of, or consultants to, the Audit Committee.

For more information on the missions of our Audit Committee, please refer to our web site www.edap-tms.com, under Investor Relations Section, where our Audit Committee Charter is available.

Nomination Committee

The Company's Board of Directors recommends for the Board's selection director nominees to submit to the vote of the Company's shareholders. In addition, under specified circumstances and in accordance with French law, shareholders may also submit resolutions to the general meeting to appoint directors.

The Company's nominations practice is formalized in a Board resolution and at its Board meeting in February 2015, the Board resolved that in the event that one or more directors is or are no longer independent, the Board will create a Nominations Committee (composed exclusively of independent Directors). A Nominations Committee Charter was approved accordingly, the terms of which apply to the Board of Directors when considering director nominees. As per this Charter, upon the appointment of Mr. Marc Oczachowski to the Board as a non-independent Director, on June 30, 2017, the Board of Directors, was convened on July 10, 2017, and decided to create a Nominations Committee composed exclusively of independent Directors.

Employees

As of December 31, 2018, we employed 215 individuals on a full-time basis, as follows:

	Sales & Marketing	Manufac-turing	Service	Research & Dvpt	Regula-tory	Clinical Affairs	Adminis-trative	Total
France	25	32	20	18	6	9	16	126
Italy	3	0	0	0	0	0	2	5
Germany	4	0	3	0	0	0	2	9
Japan	21	0	16	0	3	0	6	46
Malaysia	2	0	3	0	0	0	2	7
South Korea	2	0	3	0	0	0	1	6
USA	7	0	2	0	1	2	4	16
Total	64	32	47	18	10	11	33	215

As of December 31, 2017, we employed 200 individuals on a full-time basis, as follows:

	Sales & Marketing	Manufac-turing	Service	Research & Dvpt	Regula-tory	Clinical Affairs	Adminis-trative	Total
France	21	32	21	17	4	9	14	118
Italy	4	0	0	0	0	0	2	6
Germany	4	0	3	0	0	0	2	9
Japan	18	0	15	0	2	0	4	39
Malaysia	2	0	3	0	0	0	2	7
South Korea	2	0	3	0	0	0	1	6
USA	7	0	3	0	0	1	4	15
Total	58	32	48	17	6	10	29	200

As of December 31, 2016, we employed 197 individuals on a full-time basis, as follows:

	Sales & Marketing	Manufac-turing	Service	Research & Dvpt	Regula-tory	Clinical Affairs	Adminis-trative	Total
France	23	34	23	18	2	8	13	121
Italy	4	0	0	0	0	0	2	6
Germany	4	0	3	0	0	0	2	9
Japan	17	0	14	0	2	0	4	37
Malaysia	2	0	3	0	0	0	2	7
South Korea	1	0	0	0	0	0	1	2
USA	7	0	3	0	0	1	4	15

Total	58	34	46	18	4	9	28	197

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

Share Ownership

As of April 12, 2019, the total number of shares issued was 29,368,394 with 370,528 shares held as treasury shares, thus bringing the total number of shares outstanding to 28,997,866.

As of April 12, 2019, the Board of Directors and the Senior Executive Officers of the Company held a total of 68,923 Shares**.** The Board of Directors and Senior Executive Officers beneficially own, in the aggregate less than 1% of the Company's shares.

As of April 12, 2019, Senior Executive Officers held a total of 20,001 Shares and an aggregate of 570,000 options to purchase or to subscribe a total of 570,000 ordinary shares, with a weighted average exercise price of €2.73 per share. Of these options, 30,000 expire on June 25, 2020, 200,000 expire on January 18, 2023, 220,000 expire on April 26, 2026, 55,000 expire on April 25, 2027, 25,000 expire on August 29, 2028 and 40,000 expire on April 4, 2029.

Options to Purchase or Subscribe for Securities

On May 22, 2007, the shareholders authorized the Board of Directors to grant up to 600,000 options to subscribe to 600,000 new shares at a fixed price to be set by the Board of Directors.

On June 24, 2010, the shareholders authorized the Board of Directors to grant up to 229,100 options to purchase pre-existing shares at a fixed price to be set by the Board of Directors. All of the shares that may be purchased through the exercise of stock options are currently held as treasury stock.

On December 19, 2012, the shareholders authorized the Board of Directors to grant up to 500,000 options to subscribe to 500,000 new shares at a fixed price to be set by the Board of Directors.

On February 18, 2016, the shareholders authorized the Board of Directors to grant up to 1,000,000 options to subscribe to 1,000,000 new shares at a fixed price to be set by the Board of Directors.

As of April 12 2019, we had sponsored four stock purchase and subscription option plans open to employees of EDAP TMS group.

On December 31, 2018, the expiration of our stock option contracts was as follows:

Date of expiration	Number of Options
June 25, 2020	170,100
January 18, 2023	297,500
April 26, 2026	505,000
April 25, 2027	210,000
August 25, 2028	165,000

44

As of December 31, 2018, a summary of stock option activity to purchase or to subscribe to shares under these plans is as follows:

	2018		2017		2016	
	Options	Weighted average exercise price (€)	Options	Weighted average exercise price (€)	Options	Weighted average exercise price (€)
Outstanding on January 1,	1,207,600	2.61	1,427,438	2.94	917,188	2.79
Granted	165,000	2.65	260,000	2.39	575,000	3.22
Exercised	-	-	(60,000)	1.91	-	-
Forfeited	(25,000)	3.05	(134,750)	3.09	(64,750)	3.30
Expired	-	-	(285,088)	3.99	-	-
Outstanding on December 31,	1,347,600	2.61	1,207,600	2.61	1,427,438	2.94
Exercisable on December 31,	772,600	2.44	598,850	2.29	774,938	2.87
Share purchase options available for grant on December 31	250,428		250,428		243,428	

The following table summarizes information about options to purchase existing shares held by the Company, or to subscribe to new Shares, at December 31, 2018:

	Outstanding options				**Fully vested options** [1]		
Exercise price (€)	Options	Weighted average remaining contractual life	Weighted average exercise price (€)	Aggregate Intrinsic Value (2)	Options	Weighted average exercise price (€)	Aggregate Intrinsic Value (2)
3.22	505,000	7.3	3.22	-	252,500	3.22	-
2.65	165,000	9.7	2.65	-	-	-	-
2.39	210,000	8.3	2.39	-	52,500	2.39	-
2.38	120,100	1.5	2.38	-	120,100	2.38	-
1.91	297,500	4.0	1.91	-	297,500	1.91	-
1.88	50,000	1.5	1.88	-	50,000	1.88	-
1.88 to 3.22	1,347,600	5.4	2.61	-	772,600	2.44	-

(1) Fully vested options are all exercisable options

(2) The aggregate intrinsic value represents the total pre-tax intrinsic value, based on the Company's closing stock price of $1.85 at December 31, 2018, which would have been received by the option holders had all in-the-money option holders exercised their options as of that date.

Item 7. Major Shareholders and Related Party Transactions

Major Shareholders

To our knowledge, we are not directly or indirectly owned or controlled by another corporation, by any foreign government, or by any other natural or legal person or persons acting severally or jointly.

To the best of our knowledge and on the basis of the notifications received or filed with the SEC, there are no shareholders who are beneficial owners of more than 5% of our shares as of December 31, 2018.

There are no arrangements known to us, the operation of which may at a later date result in a change of control of the Company. All shares issued by the Company have the same voting rights, except the treasury shares held by the Company, which have no voting rights.

As of April 12, 2019, 29,368,394 shares were issued, including 28,997,866 outstanding and 370,528 treasury shares. At March 15, 2019, there were 29,342,294 ADSs, each representing one Share, all of which were held of record by 16 registered holders in the United States (including The Depository Trust Company).

Related Party Transactions

The General Manager of the Company's Korean branch "EDAP-TMS Korea", who resigned from his position with EDAP on October 11, 2017, was also the Chairman of a Korean company named Dae You. A new independent General Manager was immediately appointed as Head of EDAP-TMS Korea with no relation with the company Dae You, therefore, since that date, transactions with this company are no longer considered related party transactions. EDAP-TMS Korea subcontracted until October 11, 2017, the service contract maintenance of our medical devices installed in Korea to Dae You. The amounts invoiced by Dae You under this contract were €41 thousand and €62 thousand, for 2017 and 2016 respectively. As of December 31, 2018 and 2017, the Company recorded no payables to Dae You.

Dae You has purchased medical devices from us, which it operates in partnership with hospitals or clinics. These purchases (‘Sales of goods’) amounted to €161 thousand and €483 thousand, in 2017 and 2016, respectively. As of December 31, 2018 and 2017, the Company recorded no receivables.

In 2018, EDAP Technomed Co. Ltd. (Japan) contracted a loan amounting 80,000,000 JPY. As a current practice in Japan, this loan required a personal warranty from the representative director, president and CEO of the subsidiary Mr. Jean-François Bachelard. EDAP TMS S.A., as the mother company, counter-warranted this personal loan and agreed to indemnify Mr. Bachelard, in an indemnification letter dated November 27, 2018.

In 2018, EDAP Technomed Sdn Bdh (Malaysia) contracted a loan amounting 90,000 MYR. As a current practice in Malaysia, this loan required a personal warranty from the representative director, president and CEO of the subsidiary Mr. Hervé de Soultrait. EDAP TMS S.A., as the mother company, counter-warranted this personal loan and agreed to indemnify Mr. de Soultrait, in an indemnification letter dated January 29, 2019.

Interests of Experts and Counsel

Not applicable.

Item 8. Financial Information

Consolidated Financial Statements

See Item 18, ‘‘Financial Statements.’’

Export Sales

As of December 31, 2018, total consolidated export net sales, which we define as sales made outside of mainland France, were €27.6 million, which represented 70% of total net sales.

As part of our business, we are engaged in sales and marketing activities with hospitals, clinics, distributors or agents in countries on a worldwide basis where we can provide our minimally invasive therapeutic solutions to patients with prostate cancer or urinary stones. The following information complies with the sub-section “Disclosure of Certain Activities Relating to Iran” of the Section 13 of the U.S. Securities Exchange Act of 1934 as amended: in 2015 we honored warranty contracts on previous sales of lithotripsy devices to three Iranian public hospitals in order to provide the hospitals with the necessary disposables and services to treat patients with kidney stones using our devices. As part of these warranty commitments, in 2016, 2017 and 2018 we did not invoice any medical equipment to the hospitals.

Legal Proceedings

From time to time, we may become involved in legal proceedings or be subject to claims arising in the ordinary course of our business. Regardless of the outcome, litigation can have an adverse impact on us because of defense and settlement costs, diversion of management resources and other factors.

Dividends and Dividend Policy

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

No dividends were paid with respect to fiscal years 2014 through 2017, and we do not anticipate paying any dividends for the foreseeable future. Thereafter, any declaration of dividends on our shares as well as the amount and payment will be determined by majority vote of the holders of our shares at an ordinary general meeting, following the recommendation of our Board of Directors. Such declaration will depend upon, among other things, future earnings, if any, the operating and financial condition of our business, our capital requirements, general business conditions and such other factors as our Board of Directors deems relevant in its recommendation to shareholders.

Significant Changes as of April 12, 2019

None.

Item 9. The Offer and Listing

Description of Securities

The shares are traded solely in the form of ADSs, each ADS representing one ordinary share. Each ADS may be evidenced by an American Depositary Receipt issued by The Bank of New York, our Depositary. The principal United States trading market for the ADSs, which is also the principal trading market for the ADSs overall, is the NASDAQ Global Market of the NASDAQ Stock Market, Inc. (''NASDAQ"), on which the ADSs are quoted under the symbol ''EDAP.''

Item 10. Additional Information

Memorandum and Articles of Association

Set forth below is a brief summary of significant provisions of our by-laws (or *statuts*) and applicable French laws. This is not a complete description and is qualified in its entirety by reference to our by-laws, a translation of which is provided in Exhibit 1.1 to this annual report. Each time they are modified, which can only occur with the approval of a two third majority of the shareholders present or represented at a shareholders' meeting, we file copies of our *statuts* with, and such by-laws are publicly available from, the Registry of Commerce and Companies in Lyon, France, under number 316 488 204.

Our corporate affairs are governed by our by-laws and by Book II of the French Commercial Code, as amended.

Our by-laws were last updated in January 2018 to reflect the latest increases in share capital related to the issuance of additional shares following the exercise of warrants and options. No shares were issued in the course of 2018.

Corporate Purposes

Pursuant to Article 2 of the by-laws, the corporate purpose of the Company is:

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

Board of Directors

The Board of Directors is currently composed of five members, four of which were appointed by the shareholders for a period of six years expiring on the date of the annual general shareholders' meeting approving the accounts for fiscal year 2019. Mr. Marc Oczachowski, Chief Executive Officer, was appointed director of the Company by the shareholders on June 30, 2017, effective July 1, 2017, for a period of six years expiring on the date of the annual general shareholders' meeting approving the accounts for the fiscal year 2022. See Item 6, ''Directors, Senior Management and Employees.'' A director's term ends at the end of the ordinary general shareholders" meeting convened to vote on the accounts of the then-preceding fiscal year and held in the year during which the term of such director comes to an end. Directors may be re-elected; a director may also be dismissed at any time at the shareholders' meeting.

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

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

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

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

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

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

The number of directors that have employment contracts with the Company may not exceed one third of the directors then in office and in any case, a maximum of five members.

Pursuant to our by-laws, a director may not be over eighty-five years old. If a director reaches this age limit during his/her term, such director is automatically considered to have resigned at the next general shareholders meeting.

A director cannot borrow money from the Company.

The Board of Directors determines the direction of our business and supervises its implementation. Within the limits set out by the corporate purposes and the powers expressly granted by law to the general shareholders' meeting, the Board of Directors may deliberate upon our operations and make any decisions in accordance with our business. A director must abstain from voting on matters in which the director has an interest. The resolutions passed in a meeting of the Board of Directors are valid only if a quorum of half of the Directors is reached.

French law provides that the functions of Chairman of the Board and Chief Executive Officer in a French *société anonyme* may be distinct and held by two separate individuals.

The Chairman of the Board

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

The Chairman represents the Board of Directors and organizes its work. The Chairman reports on the Board's behalf to the general shareholders' meeting. The Chairman is responsible for ensuring the proper functioning of our governing bodies and that the Board members have the means to perform their duties.

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

48

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

The Chief Executive Officer

We are managed by the Chairman of the Board of Directors or by an individual elected by the Board of Directors bearing the title of Chief Executive Officer. The choice between these two methods of management belongs to the Board of Directors and must be made pursuant to our by-laws. On March 31, 2007, the Board of Directors appointed Mr. Marc Oczachowski as Chief Executive Officer.

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

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

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

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

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

Dividend and Liquidation Rights (French Law)

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

Under French law, we are required to allocate at least 5% of our unconsolidated net profits in each fiscal year to a legal reserve fund before dividends may be paid with respect to that year. Such allocation is compulsory until the amount in such reserve fund is equal to 10% of the nominal amount of the registered capital. The legal reserve is distributable only upon the liquidation of the Company.

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

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

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

Under French law, dividends are distributed to shareholders pro rata according to their respective shareholdings. Dividends are payable to holders of shares outstanding on the date of the annual shareholders' meeting deciding the distribution of dividends, or in the case of interim dividends, on the date of the Board of Directors meeting approving the distribution of interim dividends. However, holders of newly issued shares may have their rights to dividends limited with respect to certain fiscal years. The actual dividend payment date is decided by the shareholders in an ordinary general meeting or by the Board of Directors in the absence of such a decision by the shareholders. The payment of the dividends must occur within nine months from the end of our fiscal year. Under French law, dividends not claimed within five years of the date of payment revert to the French State.

If the Company is liquidated, our assets remaining after payment of our debts, liquidation expenses and all of our remaining obligations will be distributed first to repay in full the nominal value of the shares, then the surplus, if any, will be distributed pro rata among the shareholders based on the nominal value of their shareholdings and subject to any special rights granted to holders of priority shares, if any. Shareholders are liable for corporate liabilities only up to the par value of the shares they hold and are not liable to further capital calls of the Company.

Changes in Share Capital (French Law)

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

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

Repurchase of Shares (French Law)

Pursuant to French law, the Company may not acquire its own shares except (a) to reduce its share capital under certain circumstances with the approval of the shareholders at an extraordinary general meeting or (b) to provide shares for distribution to employees under a profit sharing or a stock option plan. However, the Company may not hold more than 10% of its shares then-issued. A subsidiary of the Company is prohibited by French law from holding shares of the Company and, in the event it becomes a shareholder of the Company, such shareholder must transfer all the shares of the Company that it holds.

Attendance and Voting at Shareholders' Meetings (French Law)

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

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

The Board of Directors is required to convene an annual ordinary general shareholders' meeting, which must be held within six months of the end of our fiscal year, for approval of the annual accounts. Other ordinary or extraordinary meetings may be convened at any time during the year. Shareholders' meetings may be convened by the Board of Directors or, if the Board of Directors fails to call such a meeting, by our statutory auditors or by a court-appointed agent. The court may be requested to appoint an agent either by one or more shareholders holding at least 5% of the our registered capital or by an interested party under certain circumstances, or, in case of an urgent matter, by the Work Council (*Comité d'entreprise*) representing the employees. The notice calling a meeting must state the agenda for such meeting.

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

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

All shareholders who have properly registered their shares have the right to participate in general shareholders' meetings, either in person, by proxy, or by mail, and to vote according to the number of shares they hold. Each share confers on the shareholder the right to one vote. Under French law, an entity we control directly or indirectly is prohibited from holding shares in the Company and, in the event it becomes a shareholder, shares held by such entity would be deprived of voting rights. A proxy may be granted by a shareholder whose name is registered on our share registry to his or her spouse, to another shareholder or to a legal representative, in the case of a legal entity, or by sending a proxy in blank to the Company without nominating any representatives. In the latter case, the Chairman of the shareholders' meeting will vote such blank proxy in favor of all resolutions proposed by the Board of Directors and against all others.

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

At an ordinary general meeting or an extraordinary general meeting deciding upon any capital increase by capitalization of reserves, a simple majority of the votes of the shareholders present or represented by proxy is required to approve a resolution. At any other extraordinary general meeting, two-thirds of the votes cast is required.

However, a unanimous vote is required to increase liabilities of shareholders. Abstention from voting by those present or represented by proxy is viewed as a vote against the resolution submitted to a vote.

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

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

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

Preferential Subscription Rights (French Law)

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

Form and Holding of Shares (French Law)

Form of Shares

Our by-laws provide that shares can only be held in registered form.

Holding of Shares

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

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

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

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

Also, certain foreign investments in companies incorporated under French laws are subject to the prior authorization from the French Minister of the Economy, where all or part of the target's business and activity relate to a strategic sector, such as energy, transportation, public health, telecommunications, etc.

Certain Exemptions (French Law)

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

Enforceability of Civil Liabilities (French Law)

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

of July 16, 1980, which may preclude or restrict obtaining evidence in France or from French persons in connection with such actions.

Material Contracts

None.

Exchange Controls

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

Certain Income Tax Considerations

The following generally summarizes the material French and U.S. tax consequences of purchasing, owning and disposing of shares or ADS (the “Securities”). The statements set forth below are based on the applicable laws, treaties and administrative interpretations of France and the United States as of the date hereof, all of which are subject to change.

This discussion is intended only as a descriptive summary and does not purport to be a complete analysis or listing of all potential tax effects of the purchase, ownership or disposition of Securities. It does not constitute legal or tax advice.

Investors should consult their own tax advisors regarding the tax consequences of the purchase, ownership and disposition of Securities in light of their particular circumstances, including especially the laws of all jurisdictions in which they are resident for tax purposes.

French Taxation

The following summary of the French tax consequences of purchasing and disposing of Securities does not address the treatment of Securities that are held by a resident of France (except for purposes of describing related tax consequences for other holders) or in connection with a permanent establishment or fixed base through which a holder

carries on business or performs personal services in France, or by a person that owns, directly or indirectly, 5% or more of the stock of the Company. Moreover, the following discussion of the tax treatment of dividends only deals with distributions made on or after January 1, 2019.

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

French law provides for specific rules relating to trusts, in particular specific tax and filing requirements as well as modifications to wealth, estate and gift taxes as they apply to trusts. Given the complex nature of these rules and the fact that their application varies depending on the status of the trust, the grantor, the beneficiary and the assets held in the trust, the following summary does not address the tax treatment of Securities held in a trust. *If Securities are held in trust, the grantor, trustee and beneficiary are urged to consult their own tax adviser regarding the specific tax consequences of acquiring, owning and disposing of Securities.*

Taxation of Dividends on Securities - Withholding Tax

Dividends paid by a French corporation, such as EDAP, to non-residents normally are subject to a 30% French withholding tax (reduced to 12.8% when non-residents are individuals and 15% for distributions made to not-for-profit organizations with a head office in a Member State of the European Economic Area which would be subject to the tax regime set forth under article 206-5 of the French Tax Code, or FTC, if their head office was located in France and which meet the criteria set forth in the administrative guidelines BOI-RPPM-RCM-30-30-10-70-20171004, n°130).

Dividends paid by a French corporation transferred to non-cooperative States or territories (*Etat ou territoire non coopératif*), within the meaning of Article 238-0 A of the FTC (a "Non-Cooperative State"), will be subject to French withholding tax at a rate of 75% irrespective of the tax residence of the beneficiary of the dividends, if the dividends are received in such States or territories (subject to certain exceptions and the more favorable provisions of an applicable double tax treaty, provided that the double tax treaty is found to apply and the relevant conditions are fulfilled). The list of Non-Cooperative States is published by ministerial executive order, which is updated from time to time. However, non-resident holders that are entitled to and comply with the procedures for claiming benefits under an applicable tax treaty may be subject to a reduced rate (generally 15%) of French withholding tax. If a non-resident holder establishes its entitlement to treaty benefits prior to the payment of a dividend, then French tax generally will be withheld at the reduced rate provided under the treaty.

Taxation on Sale or Disposition of Securities

Generally, holders who are not residents of France for tax purposes, will not be subject to any French income tax or capital gains tax upon the sale or the disposal of Securities provided such holders have not held more than 25% of EDAP dividend rights, known as ("*droits aux bénéfices sociaux*"), at any time during the preceding five years, either directly or indirectly, and, as relates to individuals, alone or with relatives (as an exception holders who are established or incorporated in a Non-Cooperative State are subject to a 75% withholding tax in France on any such capital gain, regardless of the fraction of the dividend rights they hold).

If the holders are resident in a State with which France has signed a double tax treaty that contains more favorable provisions, the holders may be exempt from any French income or capital gains tax when they sell or dispose of any Securities even if one of the above statements applies to them.

Pursuant to Article 235 ter ZD of the FTC, purchases of certain securities issued by a French company, including ordinary shares and ADSs, which are listed on a regulated market of the EU or an exchange market formally acknowledged by the AMF (in each case within the meaning of the French Monetary and Financial Code, or the FMFC) are subject in France to a 0.3% tax on financial transactions, or the TFT, provided *inter alia* that the issuer's market capitalization exceeds €1.0 billion as of December 1 of the year preceding the taxation year.

A list of companies whose market capitalization exceeds €1.0 billion as of December 1 of the year preceding the taxation year within the meaning of Article 235 ter ZD of the FTC has been published by the French tax authorities in its official guidelines on December 17, 2018 (BOI-ANNX-000467-20181217). EDAP was not included in such list as its market capitalization did not exceed €1.0 billion as at December 1, 2018. Please note that such list may be updated from time to time, or may not be published anymore in the future. Furthermore, NASDAQ is not currently acknowledged by the French AMF, but this may change in the future. Therefore, purchases of the Securities are not subject to the TFT.

In the case where the TFT is not applicable, transfers of shares issued by a French company which are not listed on a regulated or organized market within the meaning of the FMFC are subject to uncapped registration duties at the rate of 0.1% notwithstanding the existence of a written statement (*acte*). Although the official guidelines published by the French tax authorities are silent on this point, ADSs should remain outside of the scope of the aforementioned 0.1% registration duties.

Estate and Gift Tax

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

Wealth Tax

The French Wealth tax ("*impôt de solidarité sur la fortune*") has been replaced with a French real estate wealth tax ("*impôt sur la fortune immobilière*") with effect from January 1, 2018. Individuals who are not residents of France for purposes of French taxation are not subject to a real estate wealth tax in France as a result of owning an interest in the share capital of a French corporation, provided that such individuals do not own directly or indirectly a shareholding exceeding 10% of the financial rights and voting rights of the corporation. Double taxation treaties may provide for a more favorable tax treatment.

Taxation of U.S. Holders

Shares

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

This summary does not deal with Securities that are not held as capital assets, and does not address the tax treatment of holders of ADSs that acquire them in "pre-release" transactions or holders that are subject to special rules, such as banks, insurance companies, dealers in securities or currencies, regulated investment companies, persons that elect mark-to-market treatment, persons holding Securities as a position in a synthetic security, straddle or conversion transaction, persons that own, directly or indirectly, 5% or more of our voting stock or 5% or more of our outstanding capital and persons whose functional currency is not the U.S. dollar.

This summary does not discuss the treatment of Securities 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. The summary is based on laws, treaties, regulatory interpretations and judicial decisions in effect on the date hereof, all of which are subject to change. Such changes could apply retroactively and could affect the consequences described below.

In particular, the United States and France signed a protocol on January 13, 2009, that entered into force on December 23, 2009 and make several significant changes to the Treaty, including changes to the "Limitation of Benefits" provision. U.S. holders are advised to consult their own tax advisors regarding the effect the protocol may have on their eligibility for Treaty benefits in light of their own particular circumstances.

A "U.S. holder" includes (1) a citizen or individual resident of the United States; (2) a corporation or other entity taxable as a corporation created or organized in the United States or under the laws of the United States, any state thereof or the District of Columbia; (3) an estate whose income is subject to U.S. federal income tax regardless of its source; and (4) a trust (i) whose administration is subject to the primary supervision of a U.S. court and which has one or more "U.S. persons" who have the authority to control all substantial decisions of the trust or (ii) which has made an election under applicable Treasury regulations to be treated as a U.S. person.

A U.S. holder generally will be entitled to Treaty benefits in respect of Securities if he is concurrently: (1) the beneficial owner of Securities (and the dividends paid with respect thereto); (2) an individual resident of the United States, a U.S. corporation, or a partnership, estate or trust to the extent its income is subject to taxation in the United States in its hands or in the hands of its partners or beneficiaries; (3) not also a resident of France for French tax purposes; and (4) not subject to an anti-treaty shopping article that applies in limited circumstances.

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

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

For U.S. federal income tax purposes, a U.S. holder’s ownership of our ADSs will be treated as ownership of our underlying ordinary shares.

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

Dividends and Paying Agents

Generally, dividend distributions to non-residents of France are subject to French withholding tax at a 30% rate (reduced to 12.8% when non-residents are individuals or to 75% if paid in a Non-Cooperative State, irrespective of the tax residence of the beneficiary of the dividends if the dividends are received in such Non-Cooperative State). Eligible U.S. holders providing evidence of the entitlement to Treaty benefits with respect to the dividend (article 30) under the ‘‘Limitation on Benefits’’ provision contained in the Treaty who are U.S. residents, as defined pursuant to the provisions of the Treaty, will not be subject to this 30% or 75% withholding tax rate, but may be subject to the withholding tax at a reduced rate (as described below).

Under the Treaty, the rate of French withholding tax on dividends paid to an eligible U.S. holder as defined pursuant to the provisions of the Treaty and whose ownership of Securities is not effectively connected with a permanent establishment or fixed base that such U.S. holder has in France is reduced to 15%, or to 5% if such U.S. holder is a corporation and owns directly or indirectly at least 10% of the share capital of the issuing company; such U.S. holder may claim a refund from the French tax authorities of the amount withheld in excess of the Treaty rates of 15% or 5%, if any. For U.S. holders that are not individuals, the requirements for eligibility for Treaty benefits, including the reduced 5% or 15% withholding tax rate, contained in the “Limitation on Benefits” provision of the Treaty are complicated, and certain technical changes were made to these requirements the protocol of January 13, 2009. U.S. holders are advised to consult their own tax advisers regarding their eligibility for Treaty benefits in light of their own particular circumstances.

French withholding tax will be withheld at the domestic rates mentioned above or the 5% or 15% Treaty rate if a U.S. holder has established before the date of payment that the holder is a resident of the United States under the Treaty by following the simplified procedure described below.

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

Subject to certain exceptions for short-term and hedged positions, the U.S. dollar amount of dividends received by an individual with respect to the Securities is currently subject to taxation at a maximum rate of 20% if the dividends are “qualified dividends.” Dividends paid on the Securities will be treated as qualified dividends if (i) the issuer is eligible for the benefits of a comprehensive income tax treaty with the United States that the IRS has approved for the

purposes of the qualified dividend rules and (ii) the Company was not, in the year prior to the year in which the dividend was paid, and is not, in the year in which the dividend is paid, a passive foreign investment company, or PFIC. The Treaty has been approved for the purposes of the qualified dividend rules. Based on our audited financial statements and relevant market and shareholder data, we do not believe we were a PFIC for U.S. federal income tax purposes with respect to our 2017 taxable year. In addition, we do not anticipate it becoming a PFIC for the 2018 taxable year (as described under "—Passive Foreign Investment Company Rules" below). Accordingly, dividends, if any, paid by us in 2017 to a U.S. holder would constitute "qualified dividends."

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

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

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

Capital Gains

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

For U.S. federal income tax purposes, gain or loss realized by a U.S. holder on the sale or other disposition of Securities will be capital gain or loss, and will be long-term capital gain or loss if the Securities were held for more than one year. The net amount of long-term capital gain recognized by an individual U.S. holder generally is currently subject to taxation at a maximum rate of 20%. U.S. holders' ability to offset capital losses against ordinary income is limited.

Additional Issues For U.S. Holders

Procedures for Claiming Treaty Benefits

Pursuant to the official guidelines published by the French tax authorities (BOI-INT-DG-20-20-20-20-20120912), U.S. holders can either claim Treaty benefits under a simplified procedure or under the normal procedure. The procedure to be followed depends on whether the application for Treaty benefits is filed before or after the dividend payment.

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

- the U.S. holder is beneficially entitled to the dividend;

- the U.S. holder is a U.S. resident within the meaning of the Treaty;

- the dividend is not derived from a permanent establishment or a fixed base that the U.S. holder has in France; and

- the dividend received is or will be reported to the tax authorities in the United States.

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

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

If Form 5000 is not filed prior to the dividend payment, a withholding tax will be levied at the 30% rate, and a holder would have to claim a refund for the excess under the normal procedure by filing both Form 5000 and Form 5001 no later than December 31 of the second calendar year following the year in which the dividend is paid.

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

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

Medicare Tax

Certain U.S. holders that are individuals, estates or trusts are required to pay an additional 3.8% tax on, among other things, dividends on and capital gains from the sale or other disposition of stock. U.S. holders that are individuals, estates or trusts should consult their tax advisors regarding the effect of this legislation on their ownership and disposition of the Securities.

Passive Foreign Investment Company Rules

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

As explained above, the Company believes that it was not a PFIC for U.S. tax purposes with respect to the year 2017, and also does not anticipate becoming a PFIC with respect to the year 2018. However, as discussed in Form 20-Fs filed by the Company with respect to certain prior years the Company believes that it was a PFIC in the past. Moreover, because the PFIC determination is made annually and is dependent upon a number of factors, some of which are beyond the Company's control (including whether the Company continues to earn substantial amounts of operating income as well as the market composition and value of the Company's assets), there can be no assurance that the Company will not become a PFIC in future years.

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

French Estate and Gift Tax

Under the estate and gift tax convention between the United States and France dated November 24, 1978 (as amended by the protocol signed on December 8, 2004), a transfer of Securities by gift or by reason of the death of a U.S. holder entitled to benefits under that convention generally will not be subject to French gift or inheritance tax, so long as the donor or transferor was not domiciled in France at the time of the transfer, and Securities were not used or held for use in the conduct of a business or profession through a permanent establishment or fixed base in France.

French Real Estate Wealth Tax

The French real estate wealth tax ("*impôt sur la fortune immobilière*"), which replaced the French wealth tax ("*impôt de solidarité sur la fortune*") with effect from January 1, 2018, does not generally apply to Securities of a U.S. holder if the holder is a resident of the United States for purposes of the Treaty and does not own directly or indirectly a shareholding exceeding 10% of the financial rights and voting rights of EDAP.

U.S. Information Reporting and Backup Withholding Rules

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

Information with Respect to Foreign Financial Assets

In addition, U.S. holders that are individuals (and, to the extent provided in future regulations, entities) are subject to reporting obligations with respect to the shares, securities, debt instruments and other obligations of a French corporation if the aggregate value of such assets and certain other "specified foreign financial assets" exceeds $50,000. Significant penalties can apply if a U.S. holder fails to disclose its specified foreign financial assets.

U.S. holders should also consider their possible obligation to file online a FinCEN Form 114 Foreign Bank and Financial Accounts Report as a result of holding the Securities. U.S. holders are urged to consult their tax advisors regarding these and any other reporting requirements that may apply with respect to their Securities.

The discussion above is a general summary. It does not cover all tax matters that may be important to you. You should consult your tax advisors regarding the application of the U.S. federal tax rules to your particular circumstances, as well as the state, local, non-U.S. and other tax consequences to you of the purchase, ownership and disposition of the Securities.

Statement by Experts

Not applicable.

Documents on Display

We file annual, periodic, and other reports and information with the SEC. These materials, including this annual report and the exhibits hereto, may be inspected and copied at the SEC's Public Reference Room at 100 F Street, N.E., Washington, D.C. 20549. The public may obtain information on the operation of the SEC's Public Reference Room by calling the SEC in the United States at +1 800 SEC 0330. Certain of our public filings are also available on the SEC's website at http://www.sec.gov (such documents are not incorporated by reference in this annual report).

Subsidiary Information

Not applicable.

Item 11. Quantitative and Qualitative Disclosures about Market Risk

We are exposed to market risk from changes in both foreign currency exchange rates and interest rates. We do not hold or issue derivative or other financial instruments. During 2018 and as of December 31, 2018, we had no outstanding foreign exchange sale or purchase contracts.

Exchange Rate Risk

Revenues and Expenses in Foreign Currencies

We are exposed to foreign currency exchange rate risk because a significant portion of our costs are denominated in currencies other than those in which we earn revenues. In 2018, approximately 74% of our total costs of sales and operating expenses were denominated in euro. During the same period, approximately 59% of our sales were denominated in euro, the rest being denominated primarily in U.S. dollars and Japanese yen.

A uniform 10% strengthening in the value of the euro as of December 31, 2018 relative to the U.S. dollar and the Japanese yen would have resulted in an increase in income before taxes of approximately € for the year ended December 31, 2018, compared to a decrease of approximately €93,000 for the year ended December 31, 2017. A uniform 10% decrease in the value of the euro as of December 31, 2018 relative to the U.S. dollar and the Japanese yen would have resulted in a decrease in income before taxes of approximately €66,511 for the year ended December 31, 2018 as compared to an increase of approximately €66,465 for the year ended December 31, 2017. This calculation assumes that the U.S. dollar and Japanese yen exchange rates would have changed in the same direction relative to the euro. In addition to the direct effect of changes in exchange rates quantified above, changes in exchange rates also affect the volume of sales.

We regularly assess the exposure of our receivables to fluctuations in the exchange rates of the principal foreign currencies in which our sales are denominated (in particular, the U.S. dollar and the Japanese yen) and, from time to time, hedge such exposure by entering into forward sale contracts for the amounts denominated in such currencies that we expect to receive from our local subsidiaries. As of December 31, 2018, we had no outstanding hedging instruments.

Financial Instruments and Indebtedness

Over the past three years, we also had exchange rate exposures with respect to indebtedness and assets denominated in Japanese yen and U.S. dollars. Approximately €0.6 million, €40 thousand and €0.1 million of our outstanding indebtedness at December 31, 2018, 2017 and 2016, respectively, were denominated in Japanese yen. Approximately €0 million, €0.8 million and €3.9 million of our outstanding indebtedness at December 31, 2017 and 2016, respectively, were denominated in U.S. dollars. In addition, we had approximately €1.3 million, €2.1 million and €2.8 million of cash denominated in U.S. dollars at December 31, 2018, 2017 and 2016, respectively, and €3.7 million, €3.9 million and €1.5 million of cash denominated in Japanese yen at December 31, 2018, 2017 and 2016, respectively.

Equity Price Risk

In connection with the funds we raised in 2013 and 2016, we issued a certain number of Investor and Placement Agent Warrants (see Item 5. “Operating and Financial Review and Prospects—Warrants”). These Warrants have all expired, the last series in October and November 2018. We recorded such Warrants as a liability at fair value and we adjusted the carrying value of the Warrants to their estimated fair value at each reporting date. The fair value increases (decreases) were recorded as a financial income (loss) in our consolidated Statement of Income. We used a Black-Scholes option pricing model to adjust the fair value of the Warrants. See Note 25 of our consolidated financial statements.

Item 12. Description of Securities Other than Equity Securities

American Depositary Shares

Fees Payable to ADS Holders

The Bank of New York Mellon, as the Company’s Depositary, currently collects its fees for the delivery and surrender of ADSs directly from investors depositing shares or surrendering ADSs for the purpose of withdrawal or from intermediaries acting for them.

The Depositary may collect fees for making distributions to investors by deducting those fees from the amounts distributed or by selling a portion of distributable property to pay the fees. The Depositary may collect its annual fee for Depositary services by deductions from cash distributions or by directly billing investors or by charging the book-entry system accounts of participants acting for them. The Depositary may generally refuse to provide

fee-attracting services until the fees for those services are paid.

Fees:	**For:**
$5.00 (or less) per 100 ADSs (or portion of 100 ADSs)	- Issuance of ADSs, including issuances resulting from a distribution of shares or rights or other property, - Cancellation of ADSs for the purpose of withdrawal, including if the deposit agreement terminates.
$0.2 (or less) per ADS	- Any cash distribution to ADS registered holders.
A fee equivalent to the fee that would be payable if securities distributed to you had been shares and the shares had been deposited to issuance of ADSs	- Distribution of securities distributed to holders of deposited securities which are distributed by the Depositary to ADS registered holders.

Registration or transfer fees	- Transfer and registration of shares on our share register to or from the name of the Depositary or its agent when you deposit or withdraw shares
Expenses of the Depositary	- Cable, telex and facsimile transmissions (when expressly provided in the deposit agreement) - Converting foreign currency to U.S. dollars
Taxes and other governmental charges the Depositary or the custodian have to pay on any ADS or share underlying an ADS, for example, stock transfer taxes, stamp duty or withholding taxes	- As necessary
Any charges incurred by the Depositary or its agents for servicing the deposited securities	- As necessary

Fees Payable to the Company by the Depositary

From January 1, 2018 to March 18, 2019, the following amounts were paid by the Depositary to the Company: $92,011.43 and $10,460.79 respectively for the administration of the ADR program and for expenses linked to the assistance in identifying shareholders of the Company.

61

PART II

Item 13. Defaults, Dividend Arrearages and Delinquencies

None**.**

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

Not applicable**.**

Item 15. Controls and Procedures

Disclosure Controls and Procedures

The Company's management, with the participation of the Chief Executive Officer and Chief Financial Officer, conducted an evaluation, pursuant to Rule 13a-15 promulgated under the Securities Act of 1934, as amended (the "Exchange Act"), of the effectiveness of our disclosure controls and procedures as of December 31, 2018. Based on this evaluation, the Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures were not effective because of the material weakness described below.

In response to the identification of the material weakness described below, the Company performed additional analysis and other post-closing procedures. Based upon the work performed, management believes that the Company’s consolidated financial statements included in this Annual Report on Form 20-F fairly present in all material respects the Company’s financial position, results of operations and cash flows, in conformity with U.S. generally accepted accounting principles.

Disclosure controls and procedures means controls and other procedures that are designed to ensure that information required to be disclosed by us in the reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the SEC’s rules and forms, and that such information required to be disclosed by us in the reports that we file or submit under the Exchange Act is accumulated and communicated to our management, including our principal executive and principal financial officers, or persons

performing similar functions, as appropriate to allow timely decisions regarding required disclosures. The Company's disclosure controls and procedures are designed to provide reasonable, not absolute, assurance that the objectives of its disclosure control system are met. Because of inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues, if any, within a company have been detected.

Management's Annual Report on Internal Control Over Financial Reporting

Management is responsible for establishing and maintaining adequate internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) and for the assessment of the effectiveness of our internal control over financial reporting. Internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles.

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

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

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

Management assessed the effectiveness of internal control over financial reporting as of December 31, 2018 based upon the framework as set forth by the Committee of Sponsoring Organizations of the Treadway Commission (2013 COSO) in Internal Control-Integrated Framework. Based on the management's assessment, management concluded that the Company's internal control over financial reporting was not effective as of December 31, 2018.

Based on this evaluation, management identified a material weakness in our internal control with respect to the implementation of a new integrated information management system (SAP version 4HANA) which we launched in production on July 1, 2018, and that includes our accounting, as well as our production and inventory processes. This material weakness results from several significant deficiencies in the development and change program which, considered in aggregation, gave rise to a material weakness and to the conclusion that our internal control over financial reporting was not effective as of December 31, 2018. Specifically, these significant deficiencies relate to (i) inappropriate documentation of program change request authorizations, (ii) inappropriate documentation of data migration testing, (iii) IT and user acceptance of program changes prior to migration to production is not systematically obtained or documented, (iv) inappropriate segregation of duties between development and production, and (v) inappropriate configuration of change request and change testing authorizations as changes and authorizations are not logged.

Remediation Activities

In an effort to remediate the material weakness that was identified as of December 31, 2018, the Company has produced additional documentation, reviewed segregation of duty around access to production and changed certain configuration settings. As of the date of this filing, some of these significant deficiencies were already remediated and remediation for the remainder is underway.

Additional controls were performed to demonstrate no inappropriate use of our IT system between July 1, 2018 and December 31, 2018, and this material weakness did not result in a material misstatement of the consolidated financial statements for the year ended December 31, 2018 or restatement of any prior period previously reported by the Company.

Change in Internal Control over Financial Reporting

In assessing the effectiveness of internal control over financial reporting as of December 31, 2017, we had identified a material weakness with respect to the insufficient segregation of duties linked to the small size of our Company, and in particular that we did not maintain sufficient segregation of duties within the consolidation process given the limited size of our finance team. Specifically, our Chief Financial Officer had the ability to prepare consolidated financial statements without sufficient evidence of independent review, and we had insufficient evidence of supporting documentation, calculations and assumptions used to prepare the consolidated financial statements. This

material weakness was satisfactorily remediated as of December 31, 2018 with the hiring of a person who is now responsible for the consolidation process, so that our Chief Financial Officer can be the primary person responsible for performing the controls over the consolidation process. We also reviewed the design of some of our review controls so that re-performance is to be used to demonstrate that the controls are operating effectively. In doing so, we also engaged an external consultant to assist us with the determination of certain complex accounting treatments, in particular certain assumptions used in estimates.

Except for the above remediation of the prior year material weakness and for the change related to the implementation of our new integrated information management system (SAP version 4HANA), there were no other changes in the Company's internal control over financial reporting as of the end of the period covered by this report that has materially affected, or is reasonably likely to materially affect the Company's internal control over financial reporting.

Attestation Report of Registered Public Accounting Firm

The effectiveness of the Company's internal control over financial reporting as of December 31, 2018, has been audited by KPMG S.A., an independent registered public accounting firm, as stated in its report on the Company's internal control over financial reporting included on page F-2 of this Annual Report.

Its report on the effectiveness of internal control over financial reporting as of December 31, 2018, expresses an opinion that the Company did not maintain effective internal control over financial reporting as of December 31, 2018 because of the effect of the material weakness described above.

Item 16. [Reserved]

Item 16A. Audit Committee Financial Expert

Our Board of Directors has determined that the chair of the Board's Audit Committee, Mr. Pierre Beysson, an independent director, qualifies as an audit committee financial expert.

Item 16B. Code of Ethics

We have adopted a code of ethics applicable to our Chief Executive Officer, Chief Financial Officer, principal accounting officers and to any persons performing similar functions. The code of ethics is reviewed every year by the Board of Directors, and an update of the code of ethics was approved by the Board of Directors on January 25, 2017. Our code of ethics is filed herewith as Exhibit 11.1 and we have made it available on our website at http://www.edap-tms.com. You may request a copy of our code of ethics free of charge upon request to Blandine Confort, Investor Relations Officer, at bconfort@edap-tms.com.

Item 16C. Principal Accountant Fees and Services

The following table summarizes the aggregate fees of our independent registered accounting firms, billed to us for the fiscal years ended December 31, 2018 and December 31, 2017 for audit and other services. KPMG S.A. ("KPMG") served as the Company's independent registered accounting firm for fiscal year 2018. PricewaterhouseCoopers Audit ("PwC") served as the Company's independent registered accounting firm for fiscal year 2017.

Nature of the Fees	Fees for 2018 (in €)	Fees for 2017 (in €)
Audit fees [(1)]	398,177	329,000
Audit-related fees	19,700	-
Tax fees	-	-
All other fees	-	-
Total	417,877	329,000

(1) *"Audit fees" for 2018 include 19,000 € paid to PwC in relation with their consent and audit report related to this Form 20-F.*

Audit Fees

The following services were billed under the category ''audit services'': audit of financial statements and services performed in relation to legal obligations, including the formulation of audit opinions, consents and reports, domestic and international legal audits and support in the preparation.

Audit-Related Fees

Audit-related services billed under this category only consists of attestation services related to financial reporting that are not required by statute or regulation.

Pre-approval policy

The ‘‘Audit and Non-Audit Services Pre-Approval Policy’’ was approved by our Audit Committee on December 22, 2003 (the “2003 Rules”) and reviewed on November 20, 2012. This requires all services which are to be performed by our external auditors to be pre-approved. Pre-approval may be in the form of a general pre-approval or as pre-approval on a case-by-case basis. All services to be performed by the external auditors were subjected to the above policy and approved in advance. The Audit Committee has been regularly informed of the services and the fees to be paid.

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

None.

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

In 2018, the Company recorded a purchase of 8,300 EDAP ADRs of the Company registered pursuant to Section 12 of the Exchange Act by the Company or by affiliated purchasers.

Item 16F. Change in Registrant's Certifying Accountant

The Audit Committee recommended the dismissal of PricewaterhouseCoopers Audit ("PwC") as its independent registered public accounting firm. The Board of Directors proposed this recommendation, which was approved at the General Meeting of shareholders held on June 29, 2018. PwC's reports on our consolidated financial statements for the years ended December 31 2017 and 2016 did not contain an adverse opinion or a disclaimer of opinion and were not qualified or modified as to uncertainty, audit scope or accounting principle.

For the years ended December 31, 2017 and 2016 and through June 29, 2018, there were (i) no disagreements within the meaning of Item 16F (a)(1)(iv) and the related instructions of Form 20-F between the Company and PwC on any matters of accounting principles or practices, financial statement disclosure or auditing scope or procedures which, if not resolved to PwC's satisfaction, would have caused PwC to make reference thereto in their reports, and (ii) no "reportable events" within the meaning of Item 16F(a)(1)(v) of Form 20-F, except as set forth in the following sentence. As previously disclosed in the Company's Annual Report on Form 20-F for the fiscal year ended December 31, 2017, the Company did not maintain, in all material respects, effective internal control over financial reporting as of December 31, 2017, based on criteria established in Internal Control - Integrated Framework (2013) issued by the COSO because a material weakness in internal control over financial reporting related to insufficient segregation of duties within the consolidation process given the limited size of the Company's finance team, existed as of that date.

The Company has provided PwC with a copy of the foregoing disclosure and has requested that they furnish the Company with a letter addressed to the SEC stating whether they agree with such disclosure and, if not, stating the respects in which they do not agree. A copy of PwC's letter, dated April 12, 2019, in which PwC states that they agree with such disclosure, is filed herewith as Exhibit 15.3.

The Audit Committee selected KPMG S.A. to serve as the Company independent registered public accounting firm for a period of six fiscal years. The Board of Directors proposed this recommendation, which was approved at the General Meeting of shareholders on June 29, 2018. KPMG S.A. will hold office until the 2024 Annual General Meeting of the Company approving the financial statements of the Company for the fiscal year ended December 31, 2023.

During the years ended December 31, 2017 and 2016, and in the subsequent interim period through June 29, 2018, neither the Company, nor anyone on its behalf, consulted KPMG S.A. regarding either: (1) the application of accounting principles to a specified transaction, either completed or proposed, or the type of audit opinion that might be rendered on Company's financial statements and neither a written report was provided to the Company or oral advice was provided that KPMG S.A. concluded was an important factor considered by the Company in reaching a decision as to the accounting, auditing or financial reporting issue, or (2) any matter that was either the subject of a disagreement or a reportable event.

Item 16G. Corporate Governance Requirements

Exemptions from Certain NASDAQ Corporate Governance Rules

EDAP is incorporated under the laws of France, with securities listed on the NASDAQ Global Market in the United States. As a foreign private issuer listed on the NASDAQ, under the NASDAQ corporate governance requirements, we may follow French law corporate governance practices in lieu of following certain NASDAQ corporate governance rules. We summarize below the main practices we follow in lieu of the NASDAQ corporate governance rules.

We are exempt from NASDAQ's quorum requirements applicable to meetings of shareholders. In keeping with French law and generally accepted business practices in France, the presence in person or by proxy of shareholders having not less than 20% (in the case of an ordinary general meeting or an extraordinary general meeting deciding upon any capital increase by capitalization of reserves) or 25% (in the case of an extraordinary general meeting) of the shares is necessary for a quorum. If a quorum is not present at any meeting, the meeting is adjourned. Upon recommencement of an adjourned meeting, there is no quorum requirement in the case of an ordinary general meeting or an extraordinary general meeting deciding upon any capital increase by capitalization of reserves. The presence in person or by proxy of shareholders having not less than 20% of the shares is necessary for a quorum in the case of any other type of extraordinary general meeting.

Under French law, the committees of our Board of Directors are advisory only, and where the NASDAQ requirements would vest certain decision-making powers with specific committees by delegation (e.g., nominating, compensation or audit committees), our Board of Directors is, pursuant to French law the only competent body to take such decisions, albeit taking into account the recommendation of the relevant committees. Additionally, under French corporate law, it is the shareholder meeting of the Company that is competent to appoint our auditors upon the proposal of our Board of Directors. On February 4, 2015, in order to conform with NASDAQ rules, the Board approved the creation of a Nominations Committee (composed exclusively of independent Directors), should one or more Directors become non-independent. A Nominations Committee Charter was approved accordingly. As per this Charter, upon the appointment of a non-independent Director to the Board on June 30, 2017, the Board of Directors, was convened on July 10, 2017 and decided to create a Nominations Committee composed exclusively of independent Directors.

Our Compensation Committee is composed of four members who meet the definition of independence contained in NASDAQ Listing Rule 5602(a) and is governed by a charter which sets forth its composition and defines its scope of authority. However, in accordance with French law, the Compensation Committee is not vested with the same scope of authority and responsibilities as set out in NASDAQ Listing Rules.

Item 16H. Mine Safety Disclosure

Not applicable.

PART III

Item 17. Financial Statements.

See Item 18, "Financial Statements."

Item 18. Financial Statements

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

Item 19. Exhibits

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

INDEX TO EXHIBITS

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

Number:	**Exhibit Description**
1.1	By-laws (*statuts*) of EDAP TMS S.A. as amended as of January 19, 2018[1]
4.1	French version of Commercial Lease dated July 1, 2015 between Maison Antoine Baud and EDAP TMS France[1]
4.2	English language summary of Commercial Lease dated July 1, 2015 between Maison Antoine Baud and EDAP TMS France[1]
4.3	Form of Amended and Restated Depositary Agreement between EDAP TMS SA and The Bank of New York Mellon, as depositary (incorporated herein by reference to Exhibit 1.2 to Form F-6 dated September 15, 2011, SEC File No. 333-176843). [1]
4.7	Form of Securities Purchase Agreement dated April 7, 2016 among EDAP TMS S.A. and each purchaser identified on the signature pages thereto (incorporated herein by reference to Exhibit 99.1 to Form 6-K dated April 14, 2016).[1]
4.8	Form of Ordinary Share Purchase Warrant (incorporated herein by reference to Exhibit 4.1 to Form 6-K dated April 14, 2016). [1]
8.1	List of subsidiaries of EDAP TMS S.A. as of April 12, 2019.

11.1	Code of Ethics as amended as of January 25, 2017. (1)
12.1	Certification of Chief Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
12.2	Certification of Chief Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
13.1	Certification of Chief Executive Officer and Chief Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
15.1	Consent of KPMG.
15.2	Consent of PricewaterhouseCoopers Audit for years ended 2017 and 2016
15.3	Letter to the SEC from PriceWaterhouseCoopers Audit re: disclosure in Item 16F
101	Interactive Data File

(1) *Previously filed.*

SIGNATURES

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

EDAP TMS S.A.

Dated: April 12, 2019

/s/ Marc Oczachowski

Marc Oczachowski

Chief Executive Officer

Dated: April 12, 2019

/s/ François Dietsch

François Dietsch

Chief Financial Officer

68

INDEX TO FINANCIAL STATEMENTS

Report of Independent Registered Public Accounting Firm on the Consolidated Financial Statements

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

Opinion on the Consolidated Financial Statements

We have audited the accompanying consolidated balance sheet of EDAP TMS S.A. and subsidiaries (the Company) as of December 31, 2018, the related consolidated statements of income (loss), comprehensive income (loss), shareholders' equity, and cash flows for the year then ended, and the related notes (collectively, the consolidated financial statements). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2018, and the results of its operations and its cash flows for the year then ended, in conformity with U.S. generally accepted accounting principles.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) (PCAOB), the Company's internal control over financial reporting as of December 31, 2018, based on criteria established in Internal Control – Integrated Framework (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission", and our report dated April 10, 2019 expressed an adverse opinion on the effectiveness of the Company's internal control over financial reporting.

Basis for Opinion

These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these consolidated financial statements based on our audit. We are a public accounting firm registered with the PCAOB and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audit in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement, whether due to error or fraud. Our audit included performing procedures to assess the risks of

material misstatement of the consolidated financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the consolidated financial statements. Our audit also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the consolidated financial statements. We believe that our audit provides a reasonable basis for our opinion.

Lyon, April 10, 2019

KPMG Audit

A division of KPMG S.A.

Sara Righenzi de Villers

Partner

We have served as the Company’s auditor since 2018.

Report of Independent Registered Public Accounting Firm on the Internal Control over Financial Reporting

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

Opinion on Internal Control Over Financial Reporting

We have audited EDAP TMS S.A.S and subsidiaries' (the Company) internal control over financial reporting as of December 31, 2018, based on criteria established in Internal Control – Integrated Framework (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission. In our opinion, because of the effect of the material weakness, described below, on the achievement of the objectives of the control criteria, the Company has not maintained effective internal control over financial reporting as of December 31, 2018, based on criteria established in Internal Control – Integrated Framework (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) (PCAOB), the consolidated balance sheet of the Company as of December 31, 2018, the related consolidated statements of income (loss), comprehensive income (loss), shareholders' equity, and cash flows for the year then ended, and the related notes (collectively, the consolidated financial statements), and our report dated April 10, 2019 expressed an unqualified opinion on those consolidated financial statements.

A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of the company's annual or interim financial statements will not be prevented or detected on a timely basis. A material weakness related to the implementation of a new integrated information management system has been identified and included in management's assessment. The material weakness was considered in determining the nature, timing, and extent of audit tests applied in our audit of the 2018 consolidated financial statements, and this report does not affect our report on those consolidated financial statements.

Basis for Opinion

The Company's management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting, included in the accompanying

Management's Annual Report on Internal Control Over Financial Reporting. Our responsibility is to express an opinion on the Company's internal control over financial reporting based on our audit. We are a public accounting firm registered with the PCAOB and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audit in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects. Our audit of internal control over financial reporting included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, and testing and evaluating the design and operating effectiveness of internal control based on the assessed risk. Our audit also included performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

Definition and Limitations of Internal Control Over Financial Reporting

A company's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company's internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

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

Lyon, April 10, 2019

KPMG Audit

A division of KPMG S.A.

Sara Righenzi de Villers

Partner

Report of Independent Registered Public Accounting Firm

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

Opinion on the Financial Statements

We have audited the consolidated balance sheet of EDAP TMS S.A. and its subsidiaries (the "Company") as of December 31, 2017, and the related consolidated statements of income (loss), the related consolidated comprehensive income (loss), shareholders' equity and cash flows for each of the two years in the period ended December 31, 2017, including the related notes (collectively referred to as the "consolidated financial statements"). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2017, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2017 in conformity with accounting principles generally accepted in the United States of America.

Basis for Opinion

These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's consolidated financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) (PCAOB) and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits of these consolidated financial statements in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement, whether due to error or fraud.

Our audits included performing procedures to assess the risks of material misstatement of the consolidated financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the consolidated financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the consolidated financial statements. We believe that our audits provide a reasonable basis for our opinion.

Lyon, France,

April 30, 2018

/s/ PricewaterhouseCoopers Audit

Represented by

/s/ Elisabeth L’hermite

We served as the Company's auditor from 2012 to 2017.

EDAP TMS S.A. AND SUBSIDIARIES

CONSOLIDATED BALANCE SHEETS

As of December 31, 2018 and 2017

(in thousands of euros unless otherwise noted)

ASSETS	**Notes**	2018	2017
Current assets			
Cash and cash equivalents	2	19,464	20,004
Current portion of net trade accounts and notes receivable	3	11,884	11,277
Other receivables	4	1,434	1,066
Inventories	5	7,212	6,739
Other assets, current portion	6	382	489
Total current assets		40,376	39,574
Non-current assets			
Property and equipment, net	7	4,208	3,682
Intangible assets, net	8	847	527
Goodwill	8	2,412	2,412
Deposits and other non-current assets		546	462
Deferred tax assets	22-3	324	165
Net Trade accounts and notes receivable, non-current	3	26	77
Total assets		48,740	46,897
LIABILITIES AND SHAREHOLDERS' EQUITY			
Current liabilities			
Trade accounts and notes payable	9	6,297	6,310
Deferred revenues, current portion	10	1,929	2,295
Social security and other payroll withholdings taxes		1,177	1,075
Employee absences compensation		612	575
Income taxes payable		118	147
Other accrued liabilities	11	2,122	1,536
Short-term borrowings	13	3,683	2,718
Current portion of capital lease obligations	12	383	255
Current portion of financial instruments carried at fair value	14-2	–	840
Current portion of long-term debt	14-1	491	383
Total current liabilities		16,812	16,134
Non-current liabilities			
Deferred revenues, non-current	10	973	562
Capital lease obligations, non-current	12	852	528
Financial instruments carried at fair value, non-current	14-2	–	–
Long-term debt, non-current	14-1	1,339	834
Other long-term liabilities	15	3,800	3,681

Total liabilities		23,776	21,739
Shareholders' equity			
Common stock, €0.13 par value; 29,368,394 shares issued and 28,997,866 shares outstanding at December 31, 2018 and 2017, respectively		3,818	3,818
Additional paid-in capital		65,983	65,694
Retained earnings		(39,947)	(39,608)
Cumulative other comprehensive loss		(3,748)	(3,604)
Treasury stock, at cost; 370,528 at December 31, 2018 and at December 31, 2017	16	(1,142)	(1,142)
Total shareholders' equity	16	24,964	25,158
Total liabilities and shareholders' equity		48,740	46,897

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

EDAP TMS S.A. AND SUBSIDIARIES

CONSOLIDATED STATEMENTS OF INCOME (LOSS)

For the years ended December 31, 2018, 2017 and 2016

(in thousands of euros except share and per share data)

	Notes	2018	2017	2016
Sales of goods		25,070	22,580	24,045
Sales of RPPs & leases		5,086	5,095	4,906
Sales of spare parts and services		9,007	8,011	6,628
Total sales	17	39,163	35,686	35,579
Other revenues	18	19	60	32
Total revenues		39,183	35,746	35,611
Cost of goods		(14,053)	(13,170)	(12,288)
Cost of RPPs & leases		(2,557)	(2,667)	(2,527)
Cost of spare parts and services		(5,655)	(5,101)	(4,385)
Total cost of sales	19	(22,266)	(20,938)	(19,200)
Gross profit		16,917	14,808	16,411
Research and development expenses	20	(4,088)	(3,881)	(3,868)
Selling and marketing expenses		(10,551)	(9,526)	(8,856)
General and administrative expenses		(3,593)	(3,428)	(3,296)
Income (loss) from operations		(1,315)	(2,027)	392
Financial (expense) income, net	21	797	2,643	3,949
Foreign currency exchange gain (loss), net		538	(909)	103
Income (loss) before taxes	22-1	20	(293)	4,444
Income tax (expense) benefit	22-2	(358)	(388)	(602)
Net income (loss)		(338)	(681)	3,842
Basic income (loss) per share	23	(0.01)	(0.02)	0.14
Diluted income (loss) per share	23	(0.01)	(0.02)	0.13
Basic Weighted average shares outstanding	23	28,997,866	28,961,928	27,823,313
Diluted Weighted average shares outstanding	23	28,997,866	28,961,928	29,365,583

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

F-7

EDAP TMS S.A. AND SUBSIDIARIES

CONSOLIDATED STATEMENTS OF COMPREHENSIVE INCOME (LOSS)

For the years ended December 31, 2018, 2017 and 2016

(in thousands of euros unless otherwise noted)

	Notes	2018	2017	2016
Net income (loss)		(338)	(681)	3,842
Other comprehensive income (loss):				
Foreign currency translation adjustments	16-6	(146)	288	(144)
Provision for retirement indemnities	16-6	–	57	(238)
Comprehensive income (loss), net of tax		(483)	(336)	3,460

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

F-8

EDAP TMS S.A. AND SUBSIDIARIES

CONSOLIDATED STATEMENTS OF SHAREHOLDERS' EQUITY

For the years ended December 31, 2018, 2017 and 2016

(in thousands of euros unless otherwise noted)

	Number of Shares	Common Stock	Additional paid-in Capital	Retained Earnings	Cumulative Other Comprehensive Income (loss)	Treasury Stock	Total
Balance as of December 31, 2015	25,383,461	3,348	58,560	(42,769)	(3,567)	(1,142)	14,430
Net (loss) / income	–	–	–	3,842	–	–	3,842
Translation adjustment	–	–	–	–	(144)	–	(144)
Warrants and stock options granted or exercised	–	–	360	–	–	–	360
Capital increase	3,344,155	435	5,765	–	–	–	6,200
Provision for retirement indemnities	–	–	–	–	(238)	–	(238)
Balance as of December 31, 2016	28,727,616	3,783	64,685	(38,927)	(3,949)	(1,142)	24,451
Net (loss) / income	–	–	–	(681)	–	–	(681)
Translation adjustment	–	–	–	–	288	–	288
Warrants and stock options granted or exercised	–	–	382	–	–	–	382
Capital increase	270,250	35	627	–	–	–	662
Provision for retirement indemnities	–	–	–	–	57	–	57
Balance as of December 31, 2017	28,997,866	3,818	65,694	(39,608)	(3,604)	(1,142)	25,158
Net (loss) / income	–	–	–	(338)	–	–	(338)
Translation adjustment	–	–	–	–	(146)	–	(146)
Warrants and stock options granted or exercised	–	–	289	–	–	–	289
Provision for retirement indemnities	–	–	–	–	–	–	–
Balance as of December 31, 2018	28,997,866	3,818	65,983	(39,947)	(3,748)	(1,142)	24,964

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

EDAP TMS S.A. AND SUBSIDIARIES

CONSOLIDATED STATEMENTS OF CASH FLOWS

For the years ended December 31, 2018, 2017 and 2016

(in thousands of euros unless otherwise noted)

	2018	2017	2016
Cash flows from operating activities			
Net income (loss)	(338)	(681)	3,842
Adjustments to reconcile net income (loss) to net cash generated by (used in) operating activities:			
Depreciation and amortization	1,610	1,573	1,025
Change in warrants fair value	(889)	(2,669)	(3,985)
Other Non-cash compensation	289	382	360
Change in allowances for doubtful accounts & slow-moving inventories	591	28	(75)
Change in long-term provisions	300	105	116
Net capital loss on disposals of assets	37	47	58
Deferred tax expense (benefit)	(153)	(153)	65
Operating cash flow	1,447	(1,368)	1,408
Increase/Decrease in operating assets and liabilities:			
Decrease (Increase) in trade accounts and notes and other receivables	(983)	(1,741)	1,752
Decrease (Increase) in inventories	(704)	669	(1,985)
Decrease (Increase) in other assets	115	(47)	46
(Decrease) Increase in trade accounts and notes payable	(70)	426	(153)
(Decrease) Increase in accrued expenses, other current liabilities	370	(998)	143
Net increase (decrease) in operating assets and liabilities	(1,272)	(1,691)	(197)
Net cash generated by (used in) operating activities	175	(3,059)	1,209
Cash flows from investing activities:			
Additions to capitalized assets produced by the Company	(827)	(988)	(853)
Net proceeds from sale of leased back assets	359	85	–
Acquisitions of property and equipment	(604)	(631)	(321)
Acquisitions of intangible assets	(438)	(453)	(151)
Proceeds from sale of short term investments	–	–	1,000
Increase in deposits and guarantees	(59)	(45)	(59)
Net cash generated by (used in) investing activities	(1,569)	(2,032)	(384)
Cash flow from financing activities:			
Proceeds from capital increase	–	548	6,200
Proceeds from stock-option exercise	–	115	–
Proceeds from long term borrowings, net of financing costs	1,032	1,638	3,168
Repayment of long term borrowings	(443)	(243)	(305)
Repayment of obligations under capital leases	(358)	(297)	(277)
Increase (decrease) in bank overdrafts and short-term borrowings	946	1,110	(1,182)
Net cash generated by (used in) financing activities	1,178	2,871	7,604

Net effect of exchange rate changes on cash and cash equivalents	(323)	235	(19)
Net increase (decrease) in cash and cash equivalents	(539)	(1,985)	8,410
Cash and cash equivalents at beginning of year	20,004	21,989	13,578
Cash and cash equivalents at end of year	19,464	20,004	21,989

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

EDAP TMS S.A. AND SUBSIDIARIES

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

1—SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

1-1 Nature of operations

EDAP TMS S.A. and its subsidiaries (‘‘the Company’’) are engaged in the development, production, marketing, distribution and maintenance of a portfolio of minimally-invasive medical devices for the treatment of urological diseases. The Company currently produces innovative robotic devices for treating stones of the urinary tract and localized prostate cancer. We also derive revenues from the distribution of urodynamics products and urology lasers. 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 Germany, Italy, the United States and Asia.

Moreover, the Company develops a novel HIFU treatment for liver cancer in cooperation with its long-term academic partner INSERM and leading cancer centers (the “HECAM” project).

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

1-2 Basis of preparation

These consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States (U.S. GAAP).

With the exception of the change in the Company’s Revenue Recognition Policy as a result of the adoption of ASC 606, there have been no changes to the accounting policies for the fiscal year ended December 31, 2018, that are of

significance, or potential significance, to the Company.

1-3 Management estimates

The preparation of financial statements in conformity with U.S. generally accepted accounting principles (‘‘U.S. GAAP’’) requires management to make estimates and assumptions, such as business plans, stock price volatility, duration of standard warranty per market, price of maintenance contract used to determine the amount of revenue to be deferred and life duration of our range of products. These estimates and assumptions 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 owned subsidiaries.

1-5 Revenue recognition

The Company adopted ASC Topic 606, *Revenue from Contracts with Customers*, on January 1, 2018.

The Company’s revenue consists of:

- Sales of goods (devices and consumables), where invoicing takes place upon delivery.

- Revenue-per-Procedures (“RPP”) and leases: they comprise (i) revenues on a per treatment basis which are invoiced after each treatment, or in advance, or on a periodic basis, (ii) leases of devices, which are generally invoiced on a monthly or quarterly basis, and (iii) lease components arising from multiple-element arrangements, where specific sales terms are negotiated in accordance with each customer’s individual requirements and which are generally invoiced based on contract terms,

F-11

EDAP TMS S.A. AND SUBSIDIARIES

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

- Sales of spare parts and services (maintenance, upgrades, mobility and others). Spare parts are invoiced when delivered. Regarding services, invoicing is performed either on a subscription basis (in advance or at the end of the period) or when performed.

The Company invoices its customers based on the billing schedules in its sales arrangements. Payments are generally due between one to three months from date of invoice.

The Company accounts for a contract with a customer when there is a legally enforceable contract between the Company and its customer, the rights of the goods or services and their payment terms can be identified, the contract has commercial substance, collectability of the contract consideration is probable, it is approved and the parties are committed to their obligations.

Our sale arrangements may contain multiple elements, including device(s), consumables and services. For these multiple-element arrangements, the Company accounts for individual goods and services as separate performance obligations: (i) if they are a distinct good or service that is separately identifiable from other items in the multiple-element arrangement; and (ii) if a customer can benefit from the good or service on its own or with other resources that are readily available to the customer. The Company’s sale arrangements may include a combination of the following performance obligations: device(s), consumables, leases and services (such as, but not limited to, warranty extension).

For multiple-element arrangements, revenue is allocated to each performance obligation based on its relative standalone selling price. Standalone selling prices are based on observable prices at which the Company separately sells the goods or services. If a standalone selling price is not directly observable, then the Company estimates the standalone selling price considering market conditions and entity-specific factors including, but not limited to, features and functionality of the goods and services, geographies, and type of customer. The Company regularly reviews standalone selling prices and updates these estimates as necessary.

The Company recognizes revenue when the performance obligations are satisfied by transferring control over the good or service to a customer.

The Company’s revenue consists of the following:

Sales of goods:

Sales of goods are and have historically been comprised of net sales of medical devices (ESWL lithotripters and HIFU devices) and net sales of disposables (mostly Ablapaks and Focalpaks in the HIFU division and electrodes in the UDS division). Sales of goods also includes products such as urology laser and urodynamics devices distributed through our agents and third-party distributors.

For devices and disposables, revenue is recognized when the Company transfers control to the customer (i.e. when the customer has the ability to direct the use of, and obtain substantially all of the remaining benefit from, the device or disposables), which is generally at the point of delivery or installation, depending on the terms of the arrangement (i.e. when the customer can use the good to provide services or sell or exchange the good), and based on contractual incoterms.

The Company’s sales arrangements do not provide a right of return. The goods are generally covered by a period of one to two years standard warranty upon installation. The Company also provides training associated with the sales of goods; such training-related costs are immaterial in the context of the contract with the customer and do not constitute a distinct performance obligation.

Sales of RPPs and leases:

Sales of RPP and leases include the revenues from the sale of treatment procedures and from the leasing of machines. We provide machines to clinics and hospitals for free for a limited period, rather than selling the devices. These hospitals and clinics perform treatments using the devices and usually pay us based on the number of individual treatments provided.

EDAP TMS S.A. AND SUBSIDIARIES

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

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

Regarding multiple-element arrangements with a lease component, a portion of the contract is allocated to the lease component on the basis of observable market prices applied by the Company for similar devices under operating leases. The lease component is recognized on a straight line basis over the contractual period. Other components under the contract are recognized in accordance with their nature.

Sales of spare parts and services:

Revenues related to spare parts are recognized when spare parts are delivered to distributors who perform their own maintenance services. Spare parts used in the performance of EDAP’s own maintenance and repair services are generally not recognized separately, unless specified in the contract.

Revenues related to Services mainly consist of maintenance contracts which rarely exceed one year and are recognized on a straight line basis over the term of the service period as the customer benefits from the service throughout the service contract period. For services rendered when no maintenance contract is in place or for services not included in the scope of a maintenance contract, revenues are recorded when services are performed.

The Company recognizes revenue for extended warranties included in the multiple-element arrangements as a separate performance obligation in Sales of services on a straight-line basis over the extended warranty period. In the majority of countries in which the Company operates, the statutory warranty period is one to two years and the extended warranty covers periods beyond this statutory period. Standard warranties do not constitute a separate performance obligation. The Company accrues for the warranty costs at the time of sale of the device through the multiple-element arrangement.

Agents and distributors:

As part of its sale process in countries other than continental France, when the Company does not have a local subsidiary, sales of goods to end-customers are performed through agent and distributors. Such agent and distributors are primarily responsible for the sales' process, bear the inventory risk, and are free to determine the sale prices. Sales of goods to agents and distributors are recognized at the time of the sale to the related agent or distributor, based on contractual incoterms.

Deferred revenue:

Deferred revenue for the periods presented primarily relates to service contracts where the service fees are billed up-front, generally quarterly or annually, prior to those services having been performed, and consists primarily of billing or cash receipts in advance of services due under maintenance contracts or extended warranty contracts. The associated deferred revenue is generally recognized ratably over the service period.

Disaggregation of revenue:

Disaggregation by primary geographical market, and timing of revenue recognition is reported in Note 17.

Contract Balances:

Details on contract liabilities are reported on Note 10.

The Company applies the practical expedient in paragraph 606-10-50-14 and does not disclose information about remaining performance obligations that have original expected durations of one year or less. This relates mainly to maintenance services.

EDAP TMS S.A. AND SUBSIDIARIES

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

1-6 Costs of sales

Costs of sales include all direct product costs, costs related to shipping, handling, duties and importation fees, as well as certain indirect costs such as service and supply chain departments expenses. Indirect costs are allocated by type of sales (goods, RPP and leases, spare parts and services) using an allocation method determined by management by type of costs and segment activities and reviewed on an annual basis.

1-7 Shipping and handling costs

Shipping and handling costs are not considered as performance obligations. Shipping and handling costs are recorded as a component of cost of sales.

1-8 Cash equivalents and short term investments

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

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

1-9 Accounts Receivables

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

1-10 Inventories

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

1-11 Property and equipment

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

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

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

1-12 Long-lived assets

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

Estimated future cash flows are based on assumptions and are subject to risk and uncertainty.

EDAP TMS S.A. AND SUBSIDIARIES

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

1-13 Goodwill and intangible assets

Goodwill represents the excess of purchase price over the fair value of identifiable net assets of businesses acquired. Goodwill is not amortized but instead tested annually for impairment or more frequently when events or change in circumstances indicate that the assets might be impaired by comparing the carrying value to the fair value of the reporting units to which it is assigned. Under ASC 350, “Goodwill and other intangible assets”, the impairment test is performed in two steps. The first step compares the fair value of the reporting unit with its carrying amount, including goodwill. If the fair value of the reporting unit is less than its carrying amount, a second step is performed to measure the amount of impairment loss. The second step allocates the fair value of the reporting unit to the Company’s tangible and intangible assets and liabilities. This derives an implied fair value for the reporting unit’s goodwill. If the carrying amount of the reporting units’ goodwill exceeds the implied fair value of that goodwill, an impairment loss is recognized equal to that excess. For the purpose of any impairment test, the Company relies upon projections of future undiscounted cash flows and takes into account assumptions regarding the evolution of the market and its ability to successfully develop and commercialize its products.

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

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

Patents (in years)	5
SAP Licenses (in years)	10
Other licenses (in years)	5
Trade name and trademark (in years)	7

1-14 Treasury Stocks

Treasury stock purchases are accounted for at cost. The sale of treasury stocks is accounted for using the first in first out method. Gains on the sale or retirement of treasury stocks are accounted for as additional paid-in capital whereas losses on the sale or retirement of treasury stock are recorded as additional paid-in capital to the extent that previous net gains from sale or retirement of treasury stocks are included therein; otherwise the losses shall be recorded to accumulated benefit (deficit) account. Gains or losses from the sale or retirement of treasury stock do not affect reported results of operations. Treasury stocks held by a Company cannot exceed 10% of the total number of shares issued.

1-15 Warranty expenses

The Company provides customers with a warranty for each product sold and accrues warranty expense at time of sale based upon historical claims experience. Standard warranty period may vary from 1 year to 2 years depending on the market. Actual warranty costs incurred are charged against the accrual when paid and are classified in cost of sales in the statement of income. Warranty expense amounted to €433 thousand, €316 thousand and €319 thousand for the years ended December 31, 2018, 2017 and 2016, respectively.

1-16 Income taxes

The Company accounts for income taxes in accordance with ASC 740, ‘‘Accounting for Income Taxes’’ Under ASC 740, deferred tax assets and liabilities are determined based on differences between the financial reporting and tax basis of assets and liabilities and are measured by applying enacted tax rates and laws to taxable years in which such differences are expected to reverse. A valuation allowance is established if, based on the weight of available evidence, it is more likely than not that some portion, or all of the deferred tax assets, will not be realized. In accordance with ASC740, no provision has been made for income or withholding taxes on undistributed earnings of foreign subsidiaries, such undistributed earnings being permanently reinvested.

EDAP TMS S.A. AND SUBSIDIARIES

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

Under ASC740, the measurement of a tax position that meets the more-likely-that-not recognition threshold must take into consideration the amounts and probabilities of the outcomes that could be realized upon ultimate settlement using the facts, circumstances and information available at the reporting date.

1-17 Research and development costs

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

The French government provides tax credits to companies for innovative research and development. This tax credit is calculated based on a percentage of eligible research and development costs and it can be refundable in cash and is not contingent on future taxable income. As such, the Company considers the research tax credits as a grant, offsetting research and development expenses.

1-18 Advertising costs

Advertising costs are recorded as an expense in the period in which they are incurred and are included in selling and administrative expenses in the accompanying consolidated statements of income (loss). Advertising costs amounted to €719 thousand, €672 thousand and €744 thousand for the years ended December 31, 2018, 2017 and 2016, respectively.

1-19 Foreign currency translation and transactions

Translation of the financial statements of consolidated companies

The reporting currency of EDAP TMS S.A. for all years presented is the euro (€). The functional currency of each subsidiary is its local currency. In accordance with ASC 830, all accounts in the financial statements are translated into euro from the functional currency at the following exchange rates:

- assets and liabilities are translated at year-end exchange rates;

- shareholders' equity is translated at historical exchange rates (as of the date of contribution);

- statement of income items are translated at average exchange rates for the year; and

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

Foreign currencies transactions

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

Presentation in the Statement of Income

Aggregate foreign currency transactions gains and losses are disclosed in a single caption in the Statement of Income under section "Foreign currency exchange gain (loss), net".

1-20 Earnings per share

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

F-16

EDAP TMS S.A. AND SUBSIDIARIES

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

1-21 Derivative instruments

ASC 815 requires the Company to recognize all of its derivative instruments as either assets or liabilities in the statement of financial position at fair value. The accounting for changes in the fair value (i.e., gains or losses) of a derivative instrument depends on whether it has been designated and qualifies as part of a hedging relationship and further, on the type of hedging relationship. For those derivative instruments that are designated and qualify as hedging instruments, the Company must classify the hedging instrument, based upon the exposure being hedged, as fair value hedge, cash flow hedge or a hedge of a net investment in a foreign operation.

Gains and losses from derivative instruments are recorded in the Statement of Income.

1-22 Employee stock option plans

At December 31, 2018, the Company had four stock-based employee compensation plans. ASC 718 requires the recognition of fair value of stock compensation as an expense in the calculation of net income (loss).

1-23 Warrants

The Company recorded outstanding warrants issued in March 2012, May 2013 and April 2016 as a liability. Pursuant to guidance of ASC 815-40-15-7(i), the Company determined that the said warrants could not be considered as being indexed to the Company’s own stock, on the basis that the exercise price of the warrants was determined in U.S. dollars while the functional currency of the Company is the Euro. As of December 31, 2018, there were no more warrants outstanding.

1-24 Leases and Sales and leaseback transactions

In accordance with ASC 840, Accounting for Leases, the Company classifies all leases at the inception date as either a capital lease or an operating lease. A lease is a capital lease if it meets any one of the following criteria; otherwise, it is an operating lease:

- Ownership is transferred to the lessee by the end of the lease term;

- The lease contains a bargain purchase option;

- The lease term is at least 75% of the property's estimated remaining economic life;

- The present value of the minimum lease payments at the beginning of the lease term is 90% or more of the fair value of the leased property to the lessor at the inception date.

For sales type leases, the following two additional criteria are applied:

- Collectability of the minimum lease payment is reasonably predictable;

- No important uncertainties surround the amount of un-reimbursable costs yet to be incurred by the lessor under the lease.

The Company enters into sale and leaseback transactions from time to time. In accordance with ASC 840, any profit or loss on the sale is deferred and amortized prospectively over the term of the lease, in proportion to the leased asset if a capital lease, or in proportion to the related gross rental charged to expense over the lease term, if an operating lease.

1-25 Recent accounting pronouncements

Recently Adopted Accounting Pronouncements

In July 2015, the FASB issued ASU 2015-14 Revenue from Contracts with Customers: Deferral of the Effective Date (ASU 2015-14) which deferred the effective date for ASU No. 2014-09, *Revenue from Contracts with Customers* (Topic 606), by one year. Topic 606supersedes the revenue recognition requirements in Revenue Recognition (Topic 605) and requires entities to recognize revenue in a way that depicts the transfer of control of promised goods or services to customers in an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services.

F-17

EDAP TMS S.A. AND SUBSIDIARIES

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

The Company adopted Topic 606 *Revenue from Contracts with Customers* with a date of initial application as of January 1, 2018. As a result, the Company has changed its accounting policy for revenue recognition as detailed below.

The Company applied Topic 606 using the cumulative effect method i.e. by recognizing the cumulative effect of initially applying Topic 606 as an adjustment to the opening balance of equity at January 1, 2018. Therefore, the comparative information has not been adjusted and continues to be reported under Topic 605. The details of the significant changes and quantitative impact of the changes are disclosed below.

In implementing Topic 606, the Company considered in particular that separate performance obligations and contract liabilities were already identified as such and dates of transfer of controls were similar under the previous accounting standards. Contract assets are non-material as of December 31, 2018 and 2017. The Company performed an analysis of its relationships with agents and distributors within the framework of topic 606, which did not result in a change of its conclusions that they are acting as principal.

The impact to the Company of adopting the new revenue standard primarily relates to additional and expanded disclosures, and in particular contract liabilities and disaggregated revenues. There is no impact on the opening balance of equity and on the 2018 revenue.

In November 2015, the FASB issued ASU No. 2015-17, *Balance Sheet Classification of Deferred Taxes* (ASU 2015-17), which requires that deferred tax liabilities and assets be classified as noncurrent in a classified statement of financial position. ASU 2015-17 is effective for the Company in its first quarter of fiscal 2017. The Company adopted the ASU 2015-17 retrospectively as of December 31, 2017.

In March 2016, the FASB issued ASU 2016-09, Improvements to Employee Share-Based Payment Accounting. ASU 2016-09 simplifies several aspects of the accounting for share-based payment transactions, including the income tax consequences, classification of awards as either equity or liabilities and classification on the statement of cash flows. For public business entities, the amendments in ASU 2016-09 are effective for annual periods beginning after 15 December 2016, and interim periods within those annual periods. No impact has been identified on Financial Statements upon adoption of ASU 2016-09.

Recent Accounting Pronouncements Not Yet Adopted

In February 2016, the FASB issued ASU No. 2016-02, Leases (ASU 2016-02), which supersedes ASC 840 “Leases” and creates a new topic, ASC 842 "Leases." This update requires lessees to recognize on their balance sheet a lease liability and a lease asset for all leases, including operating leases, with a term greater than 12 months. The update also expands the required quantitative and qualitative disclosures surrounding leases. This update is effective for fiscal years beginning after December 15, 2018 and interim periods within those fiscal years, with earlier application permitted. This update will be applied using a modified retrospective transition approach for leases existing at, or entered into after, the beginning of the earliest comparative period presented in the financial statements. The Company will adopt the new standard as of January 1, 2019. The Company performed an analysis of all contracts to identify lease components or rights of use. The Company determined that the new standard mostly applies to leases for facilities situated in France, Japan and in the U.S., for Company vehicles and printers. The last category has been determined as being below the threshold and not material. As of January 1, 2019, the estimated opening balance sheet impact is expected to amount to Euros 2.9 million on financial debt.

In January 2017, the FASB issued ASU 2017-04, “Intangibles - Goodwill and Other: Simplifying the Test for Goodwill Impairment.” This update eliminates step 2 from the goodwill impairment test, and requires the goodwill impairment test to be performed by comparing the fair value of a reporting unit with its carrying amount. An impairment charge should be recognized for the amount by which the carrying amount exceeds the reporting unit’s fair value; however, the loss recognized should not exceed the total amount of goodwill allocated to that reporting unit. This guidance is effective for the Company in the first quarter of 2020. Early adoption is permitted for interim or annual goodwill impairment tests performed on testing dates after January 1, 2017. The Company will assess the timing of adoption and impact of this guidance to future impairment considerations.

EDAP TMS S.A. AND SUBSIDIARIES

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

2—CASH EQUIVALENTS

Cash and cash equivalents and short-term investments are comprised of the following:

	December 31,	
	2018	2017
Total cash and cash equivalents	19.464	20,004
Short term investments	–	–
Total cash and cash equivalents, and short term investments	19,464	20,004

3—TRADE ACCOUNTS AND NOTES RECEIVABLE, NET

Trade accounts and notes receivable consist of the following:

	December 31,	
	2018	2017
Trade accounts receivable	12,907	12,202
Notes receivable	408	181
Less: allowance for doubtful accounts	(1,405)	(1,029)
Total	11,910	11,354
Less current portion	(11,884)	(11,277)
Total long-term portion	26	77

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

Bad debt expenses amount to a cost of €362 thousand, a cost of €107 thousand and an income of €18 thousand, respectively for the years ended December 31, 2018, 2017 and 2016.

Long term portion consists of sales type leases of medical devices.

Future minimum payments to be received over the five coming years are as follows:

	Sales type leases
2019	42
2020	18
2021	8
2022	–
2022	–
Total minimum payments	70

EDAP TMS S.A. AND SUBSIDIARIES

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

4—OTHER RECEIVABLES

Other receivables consist of the following:

	December 31,	
	2018	2017
Research and development tax credit receivable from the French State	685	560
Value-added taxes receivable	390	216
Other receivables from Government and public authorities	233	238
Others	126	52
Total	1,434	1,066

5—INVENTORIES

Inventories consist of the following:

	December 31,	
	2018	2017
Components, spare parts	3,496	3,909
Work-in-progress	576	729
Finished goods – own manufactured products	2,672	1,167
Finished goods – distribution products	1,442	1,656
Total gross inventories	8,186	7,461
Less: allowance for slow-moving inventory and net realizable value	(974)	(722)
Total	7,212	6,739

The provision for slow moving inventory relates to components and spare parts. The allowance for slow moving inventory (excluding exchange rate impact), the changes in which are classified within cost of sales, amounted to a cost of €227 thousand for the year ended December 31, 2018, an income of €41 thousand for the year ended December 31, 2017, and a cost of €55 thousand for the year ended December 31, 2016, respectively.

6—OTHER ASSETS

Other assets consist of the following:

	December 31,	
	2018	2017
Prepaid expenses, current portion	382	489
Total	382	489

Prepaid expenses mainly consist of rental and future congresses expenses.

EDAP TMS S.A. AND SUBSIDIARIES

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

7—PROPERTY AND EQUIPMENT, NET

Property and equipment consist of the following:

	December 31,	
	2018	2017
Equipment	8,677	7,588
Furniture, fixture, and fittings and other	4,064	3,766
Total gross value	12,742	11,354
Less: accumulated depreciation and amortization	(8,534)	(7,672)
Total	4,208	3,682

Depreciation expense related to property and equipment amounted to €1,367 thousand, €1,153 thousand and €843 thousand for the years ended December 31, 2018, 2017 and 2016, respectively.

Assets under capital leases:

Capitalized costs on equipment held under capital leases of €2,704 thousand and €2,081 thousand are included in property and equipment at December 31, 2018 and 2017, respectively. Accumulated depreciation of these assets under capital leases was €2,291 thousand and €2,018 thousand, at December 31, 2018 and 2017, respectively.

Capitalized costs on vehicles and office and IT equipment held under capital leases of €1,423 thousand and €981 thousand are included in property and equipment at December 31, 2018 and 2017, respectively. Accumulated depreciation of these assets under capital leases was €619 thousand and €528 thousand, at December 31, 2018 and 2017, respectively.

Depreciation expense on assets held under capital leases is included in total depreciation expense and amounted to €386 thousand, €218 thousand and €164 thousand, for the years ended December 31, 2018, 2017 and 2016, respectively.

Assets leased to customers:

Capitalized costs on equipment leased to customers of €351 thousand and €474 thousand are included in property and equipment at December 31, 2018 and 2017, respectively. Accumulated amortization of these assets leased to third parties was €72 thousand and €27 thousand, at December 31, 2018 and 2017, respectively.

Depreciation expense on equipment leased to customer is included in total depreciation expense and amounted to €51 thousand, €24 thousand and €2 thousand, for the years ended December 31, 2018, 2017 and 2016, respectively.

8—GOODWILL AND INTANGIBLE ASSETS

As discussed in Note 1-13, ASC 350 requires that goodwill not be amortized but instead be tested at least annually for impairment, or more frequently when events or change in circumstances indicate that the asset might be impaired, by comparing the carrying value to the fair value of the reporting unit to which they are assigned. The Company considers its ASC 280 operating segment — High Intensity Focused Ultrasound (HIFU) and Urology Devices and Services (UDS) — to be its reporting units for purposes of testing for impairment. Goodwill amounts to €1,767 thousand for the UDS division and to €645 thousand for the HIFU division, at December 31, 2018.

The Company completed the required annual impairment test in the fourth quarter of 2018. To determine the fair value of the Company’s reporting units, the Company used the discounted cash flow approach for each of the two reportable units. In both cases, the fair value of the reporting unit was in excess of the reporting unit's book value, which resulted in no goodwill impairment.

EDAP TMS S.A. AND SUBSIDIARIES

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

Intangible assets consist of the following:

	December 31,	
	2018	2017
Licenses	1,431	993
Trade name and trademark	414	393
Patents	412	412
Organization costs	320	320
Total gross value	2,577	2,118
Accumulated amortization for licenses	(587)	(477)
Accumulated amortization for trade name and trademark	(411)	(383)
Accumulated amortization for patents	(412)	(411)
Accumulated amortization for organization costs	(320)	(320)
Less: Total accumulated amortization	(1,730)	(1,591)
Total	847	527

Licenses increase is mainly due to SAP program implementation. Amortization expenses related to intangible assets amounted to €110 thousand, €74 thousand and €42 thousand, for the years ended December 31, 2018, 2017 and 2016, respectively.

For the five coming years, the annual estimated amortization expense will consist of the following:

	December 31, 2018
2019	97
2020	89
2021	87
2022	85
2023	83
Total	441

9—TRADE ACCOUNTS AND NOTES PAYABLE

Trade accounts and notes payable consist of the following:

	December 31,	
	2018	2017
Trade accounts payable	6,286	6,220
Notes payable	11	90
Total	6,297	6,310

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

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

EDAP TMS S.A. AND SUBSIDIARIES

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

10—DEFERRED REVENUES

Deferred revenues consist of the following:

	December 31,	
	2018	2017
Deferred revenues on maintenance contracts	1,246	1,497
Deferred revenue on RPP	339	405
Deferred revenue on sale of devices	289	218
Deferred revenue on extension of warranty, included in sales contracts	855	676
Deferred research and development grants	173	61
Total	2,902	2,857
Less long term portion	(973)	(562)
Current portion	1,929	2,295

Deferred revenue on extension of warranty will be recognized over the following periods:

	December 31, 2018
2019	167
2020	264
2021	218
2022	162
2023	44
Total	855

The components of deferred revenue on extension of warranty for year ended December 31, 2018 are as follows:

	Total
Beginning balance	676

New extension of warranty	331
Recognition of revenue	(152)
Ending balance	855

EDAP TMS S.A. AND SUBSIDIARIES

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

11—OTHER ACCRUED LIABILITIES

Other accrued liabilities consist of the following:

	December 31,	
	2018	2017
Retirement indemnities	2,287	2,076
Provision for warranty costs	547	449
Accruals for payroll and associated taxes	680	611
Conditional government advances	1,039	1,039
Value added tax payable	327	125
Advances received from customers	115	108
Provision for Asset Retirement Obligation (Japan)	118	100
Provision for employee termination indemnities (Italy)	369	349
Provision for employee termination indemnities (Korea)	30	–
Others	411	360
Total	5,923	5,217
Less non-current portion	(3,800)	(3,681)
Current portion	2,122	1,536

We receive government conditional advances and grants for advanced research programs we conduct alone or in connection with other unrelated entities (mainly HECAM project) which are provided for and managed by French state-owned entities, and specifically “Banque Publique d’Investissement” (“Bpifrance”). We, alone or with other unrelated entities, enter into multi-year contractual arrangements for the financing of specific research programs. These arrangements consist of both grants and conditional advances which are paid in fixed instalments at predetermined contractual dates, subject generally to milestones based on progress of the research and documentation. Grants received are non-refundable. Conditional advances received are subject to a fixed 1.44% interest rate. If and when the research program is considered a commercial success, contractual repayment is required. In addition, if we decide to stop the research program, the conditional advance may be repayable. Grants that relate to expenses we incur for this research program are recognized in the line item “Research and Development Expenses” in the period in which the expenses subject to the grants have been incurred (see Note 20).

Conditional advances as of December 31, 2018, mature as follows, should the underlying Research Program advance as per contract:

2019	–
2020	–
2021	–
2022	203
2023 and thereafter	836
Total	1,039

EDAP TMS S.A. AND SUBSIDIARIES

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

Changes in the provision for warranty costs are as follows:

	December 31,	
	2018	2017
Beginning of year	449	548
Amount used during the year	(335)	(415)
New warranty expenses	433	316
End of year	547	449
Less current portion	(356)	(265)
Long term portion	191	184

12—LEASE OBLIGATIONS

12-1 Capital leases

The Company leases certain of its equipment under capital leases. At December 31, 2018, this equipment consists of medical devices for a liability amount of €432 thousand and vehicles and other IT equipment for a liability amount of €802 thousand. Future minimum lease payments under capital leases for the years ending December 31, 2018 are as follows:

	December 31,
2019	401
2020	361
2021	252
2022	170
2023 and thereafter	89
Total minimum lease payments	1273
Less: amount representing interest	(39)
Present value of minimum lease payments	1,234
Less: current portion	(383)

Long-term portion	852

Interest paid under capital lease obligations was €21 thousand, €13 thousand and €18 thousand for the years ended December 31, 2018, 2017 and 2016, respectively.

12-2 Operating leases

As of December 31, 2018, operating leases having initial or remaining non-cancelable lease terms greater than one year consist of one lease for the facilities of TMS S.A. in Vaulx-en-Velin, France, several leases for facilities in Japan and one lease for the facilities in the United States and Italy. The French lease contract signed on July 1, 2015 has a lease term of ten years expiring on June 30, 2025, including nine firm years.

Future minimum lease payments for these operating leases consist of the following amounts:

	France	Japan	USA	Italy
2019	329	227	45	37
2020	329	167	45	37
2021	329	132	4	37
2022	329	39	–	25
2023 and thereafter	822	–	–	–
Total	2,138	565	94	135

EDAP TMS S.A. AND SUBSIDIARIES

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

Total rent expenses under operating leases amounted to €1,002 thousand, €904 thousand and €841 thousand, for the years ended December 31, 2018, 2017 and 2016, respectively. These total rent expenses include the above-mentioned operating leases, but also lease expenses related to subsidiaries office rentals, office equipment and car rentals.

13—SHORT-TERM BORROWINGS

As of December 31, 2018, short-term borrowings consist mainly of €3,683 thousand of factored account receivables and for which the Company is bearing the collection risk As of December 31, 2017, short-term borrowings consist mainly of €2,718 thousand of factored account receivables factored and for which the Company is bearing the collection risk.

14—LONG TERM DEBT AND FINANCIAL INSTRUMENTS CARRIED AT FAIR VALUE

14-1 Long-term debt:

	December 31,	
	2018	2017
France term loan	526	700
Japanese term loan (YEN)	628	40
Germany term loan	632	399
Italy term loan	27	78
Malaysia term loan	17	–
Total long term debt	1,830	1,217
Less current portion	(491)	(383)
Total long-term portion	1,339	834

F-26

EDAP TMS S.A. AND SUBSIDIARIES

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

As of December 31, 2018, long-term debt in Japan consists of a new loan in Yen with the following conditions:

	Initial Amount	Maturity	Fixed Interest rate	Frequency of principal payments
EDAP Technomed Co. Ltd	80,000,000	November 30, 2025	1.98 %	Monthly instalment

As of December 31, 2017, long-term debt in Japan consists of two loans in Yen with the following conditions:

	Initial Amount	Maturity	Fixed Interest rate	Frequency of principal payments
EDAP Technomed Co. Ltd	55,000,000	June 30, 2018	1.80 %	Monthly instalment
	10,000,000	June 30, 2018	2.10 %	Monthly instalment

As of December 31, 2018 and 2017, long-term debt in Germany consists of two loans in euro with the following conditions:

	Initial Amount	Maturity	Fixed Interest rate	Frequency of principal payments
EDAP TMS GMBH	450,000	November 30, 2020	2.49 %	Monthly instalment

This loan is pledged by an HIFU equipment with a purchase value of €450 thousand.

	Initial Amount	Maturity	Fixed Interest rate	Frequency of principal payments
EDAP TMS GMBH	136,500	December 31, 2022	2.25 %	Monthly instalment

This loan is pledged by an UDS equipment with a purchase value of €136 thousand.

And a new loan as of December 31, 2018 with the following conditions:

	Initial Amount	Maturity	Fixed Interest rate	Frequency of principal payments
EDAP TMS GMBH	400,000	April 30, 2023	2.40 %	Monthly instalment

This loan is pledged by an HIFU equipment with a purchase value of €438 thousand.

As of December 31, 2018 and 2017, long-term debt in Italy consists of a loan in euro for an initial amount of €242 thousand with an interest rate of Euribor 1 month + 4.5% due to mature on June 6, 2019.

As of December 31, 2018 and 2017, long-term debt in France consists of one loan in Euro to finance the ERP project with the following conditions:

	Initial Amount	Maturity	Fixed Interest rate	Frequency of principal payments
EDAP TMS FRANCE	700,000	October 16, 2021	0.40 %	Quarterly instalment

EDAP TMS S.A. AND SUBSIDIARIES

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

As of December 31, 2018, long-term debt in Malaysia consists of a new loan in Ringgit with the following conditions:

	Initial Amount	Maturity	Fixed Interest rate	Frequency of principal payments
EDAP TECHNOMED SDN BHD	90,000	July 31, 2022	4.64 %	Monthly instalment

14-2 Financial instruments carried at fair value:

	December 31, 2018	2017
Investor Warrants	–	840
		–
Total	–	840
Less current portion	–	(840)
Total long-term portion	–	–

On March 28, 2012, pursuant to a securities purchase agreement dated March 22, 2012, as amended, the Company issued new ordinary shares in the form of ADSs to selected institutional investors in a registered direct placement (the "March 2012 Placement") with warrants attached (the "March 2012 Investor Warrants") allowing Investors to purchase up to 1,406,250 new ordinary shares of the Company. The Company also issued warrants to the placement agent, Rodman & Renshaw LLC (the "March 2012 Placement Agent Warrants" giving rights to the Placement Agent to purchase up to 168,750 new shares of the Company (together with the March 2012 Investor Warrants: the "March 2012 Warrants"). The Company determined that the March 2012 Warrants should be accounted for as a liability. The Company used the Black-Scholes pricing model to value the March 2012 Warrants at inception, with subsequent changes in fair value recorded as a financial expense or income.

On May 28, 2013, pursuant to a securities purchase agreement dated May 20, 2013, as amended, the Company issued 3,000,000 new ordinary shares in the form of ADSs to selected institutional investors in a registered direct placement (the "May 2013 Placement"), at a price of $4.00 per share, with warrants attached (the "May 2013 Investor Warrants"). The May 2013 Investor Warrants allowed investors to purchase up to 1,500,000 shares in the form of ADSs at an

exercise price of $4.25. The May 2013 Investor Warrants were exercisable as from November 29, 2013 and expired on November 29, 2018. The Company also issued warrants to the placement agent, H.C. Wainwright & Co., LLC with an exercise price of $5.00 per share (the “May 2013 Placement Agent Warrants” and together with the May 2013 Investor Warrants, the “May 2013 Warrants”), The May 2013 Placement Agent Warrants were exercisable from November 29, 2013 and expired on May 28, 2016. As the May 2013 Warrants comprised the same structure and provisions than the March 2012 Warrants, including an exercise price determined in U.S. dollars while the functional currency of the Company is the Euro, the Company determined that the May 2013 Warrants should be accounted for as a liability. Total gross proceeds for the May 2013 Placement amounted to $12 million (€ 9.270 million), out of which $3.817 million (€2.950 million) allocated to the Investor and Placement Agent Warrants based on their fair value and accounted for as liability, and the remaining $8.183 million (€6.320 million) allocated to the share capital increase (see note 16-1). The Company used the Black-Scholes pricing model to value the May 2013 Warrants at inception, with changes in fair value recorded as a financial expense or income.

On April 14, 2016, pursuant to a securities purchase agreement dated April 7, 2016, the Company issued 3,283,284 ordinary shares in the form of ADSs to selected institutional investors in a registered direct placement (the “April 2016 Placement”), at a price of $3.50 per share, with warrants attached (the “April 2016 Investor Warrants”). The April 2016 Investor Warrants allowed investors to purchase up to 3,283,284 shares in the form of ADSs at an exercise price of $4.50. The April 2016 Investor Warrants were exercisable from October 14, 2016 and expired on October 14, 2018. As the April 2016 Warrants comprised the same structure and provisions than the March 2012 and May 2013 Warrants, including an exercise price determined in U.S. dollars while the functional currency of the Company is the Euro, the Company determined that the April 2016 Warrants should be accounted for as a liability. Total gross proceeds for the placement amounted to $11.5 million (€ 10.2 million), out of which $3.578 million (€3.168 million) allocated to the Investor Warrants based on their fair value and accounted for as liability, and the remaining $7.913 million (€7.006 million) allocated to the share capital increase (see Note 16-1). The Company used the Black-Scholes pricing model to value the April 2016 Warrants at inception, with changes in fair value recorded as a financial expense or income.

EDAP TMS S.A. AND SUBSIDIARIES

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

Fair Value of the May 2013 Investor Warrants:

The valuation model of the Investor Warrants uses the following main assumptions and parameters based on a Black-Scholes model. Note that Warrant's maturity is assumed to be their legal duration as per Warrant contract.

	At inception date	December 31, 2018	December 31, 2017
Share price at closing date	$3.96	–	$2.87
Strike price of warrants	$4.25	–	$4.25
Risk free interest rate at 5.5 years	1.07%	–	0%
Share price volatility	71%	–	57.40%
Dividend rates	0%	–	0%
Unit fair value	$2.35	–	$0.26
Total fair value (in thousand $)	$3,525	–	$392
Total equivalent amount (in thousand €)	€2,725	–	€328

As of December 31, 2018, all of the May 2013 Investors Warrants were exercised or forfeited.

Fair Value of the April 2016 Investor Warrants:

The valuation model of the Investor Warrants uses the following main assumptions and parameters based on a Black-Scholes model. Note that Warrant's maturity is assumed to be their legal duration as per Warrant contract.

	At inception date	December 31, 2018	December 31, 2017
Share price at closing date	3.64	–	2.87
Strike price of warrants	$4.50	–	$4.50
Risk free interest rate at 2.5 years	0%	–	0%
Share price volatility	60.20%	–	57.40%

Dividend rates	0%	–	0%
Unit fair value	$1.09	–	$0.19
Total fair value (in thousand $)	$3,579	–	$614
Total equivalent amount (in thousands €)	€3,168	–	€512

As of December 31, 2018, all of the April 2016 Investors Warrants were exercised or forfeited.

Refer to Note 24 for more details on the fair value of Financial Instruments.

EDAP TMS S.A. AND SUBSIDIARIES

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

14-3 Long-term debt and financial instruments maturity:

Long-term debt and financial instruments carried at fair value at December 31, 2018 mature as follows:

2019	491
2020	460
2021	381
2022	205
2023 and thereafter	293
Total	1,830

15—OTHER LONG-TERM LIABILITIES

Other long-term liabilities consist of the following:

	December 31,	
	2018	2017
Provision for retirement indemnities (Japan & France), less current portion	2,222	2,008
Provision for employee termination indemnities (Italy) less current portion	170	349
Provision for employee termination indemnities (Korea) less current portion	30	–
Provision for Asset Retirement Obligation (Japan) less current portion	118	101
Provision for warranty costs, less current portion	191	184
Conditional government advances, less current portion	1,039	1,039
Accrued interest less current portion	30	–
Total	3,800	3,68 1

Provision for asset retirement obligation in Japan is related to subsidiary’s offices and warehouses.

Pension, post-retirement and post-employment benefits for most of the Company's employees are sponsored by European governments. In addition to government-sponsored plans, subsidiaries in Japan and France have defined benefit retirement indemnity plans in place. The provision for retirement indemnities at December 31, 2018 represents an accrual for lump-sum retirement indemnity payments to be paid at the time an employee retires if he or she is still present at the Company at the date of retirement. This provision has been calculated taking into account the estimated payment at retirement (discounted to the current date), turnover and salary increases.

The provision is management best estimate based on the following assumptions as of year-end:

	Pension Benefits - France	
	2018	2017
Discount rate	1.60%	1.60%
Salary increase	2.50%	2.50%
Retirement age	65	65
Average retirement remaining service period	24	24

	Pension Benefits - Japan	
	2018	2017
Discount rate	0.50%	0.50%
Salary increase	2.50%	2.50%
Retirement age	60	60
Average retirement remaining service period	14	14

EDAP TMS S.A. AND SUBSIDIARIES

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

The discount rate retained is determined by reference to the high quality rates for AA- rated corporate bonds for a duration equivalent to that of the obligations. It derives from a benchmark per monetary area of different market data at the closing date.

In 2018, provision presentation according to ASC 715 in thousands of euros:

	France	Japan
Non-current liabilities	966	1,255
Current liabilities	10	55
Accumulated other comprehensive income (loss)	(161)	(416)
Total	815	895

In 2017, provision presentation according to ASC 715 in thousands of euros:

	France	Japan
Non-current liabilities	867	1,141
Current liabilities	27	40
Accumulated other comprehensive income (loss)	(165)	(412)
Total	729	769

EDAP TMS S.A. AND SUBSIDIARIES

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

The Company does not have a funded benefit plan. Detailed reconciliation of pension cost components (in thousands of euros) during fiscal year for each of the three years ending December 31, 2018:

France	2018	2017	2016
Change in benefit obligations:			
Benefit obligations at beginning of year	895	842	694
Service cost	67	66	45
Interest cost	14	13	15
Actuarial (gain) / loss	–	–	88
Amortization of net prior service cost	1	1	–
Benefits paid	–	(27)	–
Benefit obligations at end of year [1]	976	895	842
Unrecognized actuarial (gain) loss [2]	141	144	147
Unrecognized prior service cost [2]	20	22	23
Accrued pension cost	815	729	672

(1) The accumulated benefit obligation was €692 thousand and €627 thousand at December 31, 2018 and 2017 respectively.

(2) The amount in accumulated other comprehensive income (loss) to be recognised as components of net periodic benefit costs in 2019 is €4 thousand.

Japan	2018	2017	2016
Change in benefit obligations:			
Benefit obligations at beginning of year	1,182	1,162	906
Service cost	131	118	81
Interest cost	6	6	10
Amortization of net loss	26	24	16
Actuarial (gain) / loss	–	(12)	147
Benefits paid	(94)	(17)	(38)
Exchange rate impact	(60)	(99)	40
Benefit obligations at end of year[1]	1,311	1,182	1,162
Unrecognized actuarial (gain) loss [2]	416	412	464
Unrecognized prior service cost [2]	–	–	–
Accrued pension cost	895	769	698

(1) The accumulated benefit obligation was €960 thousand and €872 thousand at December 31, 2018 and 2017, respectively.

(2) The amount in accumulated other comprehensive income (loss) to be recognised as components of net periodic benefit costs in 2019 is €26 thousand.

EDAP TMS S.A. AND SUBSIDIARIES

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

The benefits expected to be paid in each of the next five fiscal years, and in the aggregate for the five fiscal years thereafter, are detailed in the table below:

	France	Japan
2019	10	55
2020	–	6
2021	86	55
2022	–	75
2023	107	96
2024-2028	277	743

16—SHAREHOLDERS' EQUITY

16-1 Common stock

As of December 31, 2018, EDAP TMS S.A.'s common stock consisted of 29,368,394 issued shares fully paid and with a par value of €0.13 each. 28,997,866 of the shares were outstanding.

16-2 Pre-emptive subscription rights

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

16-3 Dividend rights

Dividends may be distributed from the statutory retained earnings, subject to the requirements of French law and the Company's by-laws. The Company has not distributed any dividends since its inception as the result of an accumulated statutory deficit of €15,011 thousand. Dividend distributions, if any, will be made in euros. The Company has no plans to distribute dividends in the foreseeable future.

16-4 Treasury stock

As of December 31, 2018, the 370,528 shares of treasury stock consisted of (i) 190,238 shares acquired between August and December 1998 for €649 thousand, and (ii) 180,290 shares acquired in June and July 2001 for €493 thousand. All 370,528 shares of treasury stock have been acquired to cover outstanding stock options (see Note 16-5).

16-5 Stock-option plans

As of December 31, 2018, the 370,528 ordinary shares held as treasury stock were dedicated to serve stock purchase option plans as follows: 120,100 shares which may be purchased at a price of €2.38 per share pursuant to the exercise of options that were granted on June 25, 2010.

As of December 31, 2018, EDAP TMS S.A. sponsored four stock purchase and subscription option plans:

On May 22, 2007, the shareholders of the Company authorized the Board of Directors to grant up to 600,000 options to subscribe to 600,000 new Shares.

Conforming to this stock option plan, on June 25, 2010, the Board of Directors granted the remaining 95,912 options to subscribe to new Shares to certain employees of EDAP TMS. The exercise price was fixed at €1.88 per share. Options were to begin vesting one year after the date of grant and were fully vested as of June 25, 2014 (i.e., four years after the date of grant). Shares acquired pursuant to the options cannot be sold prior to four years from the date of grant. The options expire on June 25, 2020 (i.e., ten years after the date of grant) or when employment with the Company ceases, whichever occurs earlier. There was no impact on 2016, 2017 and 2018 operating expenses, in accordance with ASC 718. Under this plan, 50,000 options are outstanding and exercisable at December 31, 2018.

EDAP TMS S.A. AND SUBSIDIARIES

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

On June 24, 2010, the shareholders authorized the Board of Directors to grant up to 229,100 options to purchase pre-existing Shares at a fixed price to be set by the Board of Directors. All of the Shares that may be purchased through the exercise of stock options are currently held as treasury stock. Conforming to this stock option plan, on June 25, 2010, the Board of Directors granted 229,100 options to purchase existing Shares to certain employees of EDAP TMS. The exercise price was fixed at €2.38 per share. Options were to begin vesting one year after the date of grant and were fully vested as of June 25, 2014 (i.e., four years after the date of grant). Shares acquired pursuant to the options cannot be sold prior to four years from the date of grant. The options expire on June 25, 2020 (i.e., ten years after the date of grant) or when employment with the Company ceases, whichever occurs earlier. There was no impact on 2016, 2017 and 2018 operating expenses, in accordance with ASC 718. Under this plan, 120,100 options are outstanding and exercisable at December 31, 2018.

On December 19, 2012, the shareholders authorized the Board of Directors to grant up to 500,000 options to subscribe to 500,000 new shares at a fixed price to be set by the Board of Directors. Conforming to this stock option plan, the Board of Directors granted 500,000 options to subscribe Shares to certain employees of EDAP TMS on January 18, 2013. The exercise price was fixed at €1.91 per share. Options were to begin vesting one year after the date of grant and all options were fully vested as of January 18, 2017 (i.e., four years after the date of grant). Shares acquired pursuant to the options cannot be sold prior to four years from the date of grant. The options expire on January 18, 2023 (i.e., ten years after the date of grant) or when employment with the Company ceases, whichever occurs earlier. At December 31, 2013 the total fair value of the options granted under this plan was €660 thousand. This non-cash financial charge has been recognized in the Company’s operating expenses over a period of 48 months (using the graded vesting method). The impact on operating income, in accordance with ASC 718, was €29 thousand, €2 thousand and €0 thousand, in 2016, 2017 and 2018, respectively. Under this plan, 297,500 options are outstanding and exercisable at December 31, 2018.

On February 18, 2016, the shareholders authorized the Board of Directors to grant up to 1,000,000 options to subscribe to 1,000,000 new shares at a fixed price to be set by the Board of Directors. Conforming to this stock option plan, the Board of Directors granted 575,000 options to subscribe Shares to certain employees of EDAP TMS on April 26, 2016. The exercise price was fixed at €3.22 per share. Options were to begin vesting one year after the date of grant and all options will be fully vested as of April 26, 2020 (i.e., four years after the date of grant). Shares acquired pursuant to the options cannot be sold prior to four years from the date of grant. The options expire on April 26, 2026 (i.e., ten years after the date of grant) or when employment with the Company ceases, whichever occurs earlier. At December 31, 2016 the total fair value of the options granted under this plan was €960 thousand. This non-cash financial charge will be recognized in the Company’s operating expenses over a period of 48 months (using the graded vesting method).

Conforming to this February 18, 2016 stock option plan, the Board of Directors granted 260,000 options to subscribe Shares to certain employees of EDAP TMS on April 25, 2017. The exercise price was fixed at €2.39 per share. Options were to begin vesting one year after the date of grant and all options will be fully vested as of April 25, 2021 (i.e., four years after the date of grant). Shares acquired pursuant to the options cannot be sold prior to four years from the date of grant. The options expire on April 25, 2027 (i.e., ten years after the date of grant) or when employment with the Company ceases, whichever occurs earlier. At December 31, 2017, the total fair value of the options granted on April 25, 2017 under this plan was €335 thousand. This non-cash financial charge will be recognized in the Company's operating expenses over a period of 48 months (using the graded vesting method).

Conforming to this February 18, 2016 stock option plan, the Board of Directors granted 165,000 options to subscribe Shares to certain employees of EDAP TMS on August 29, 2018. The exercise price was fixed at €2.65 per share. Options were to begin vesting one year after the date of grant and all options will be fully vested as of August 29, 2022 (i.e., four years after the date of grant). Shares acquired pursuant to the options cannot be sold prior to four years from the date of grant. The options expire on August 29, 2029 (i.e., ten years after the date of grant) or when employment with the Company ceases, whichever occurs earlier. At December 31, 2018, the total fair value of the options granted on August 29, 2018 under this plan was €219 thousand. This non-cash financial charge will be recognized in the Company's operating expenses over a period of 48 months (using the graded vesting method).

EDAP TMS S.A. AND SUBSIDIARIES

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

The impact on operating income, in accordance with ASC 718, was €331 thousand, €380 thousand and €289 thousand, in 2016, 2017 and 2018, respectively.

Under this 2016 plan, 880,000 options are outstanding and 305,000 options are exercisable at December 31, 2018.

Forfeited stock-options are recognized as they occur, in accordance with ASU 2016-09.

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

	Year Ended December 31,		
	2018	2017	2016
Weighted-average expected life (years)	6.25	6.25	6.25
Expected volatility rates[(1)]	52.6%	57.4%	60.60%
Expected dividend yield	0 %	0 %	0 %
Risk-free interest rate	0.18		