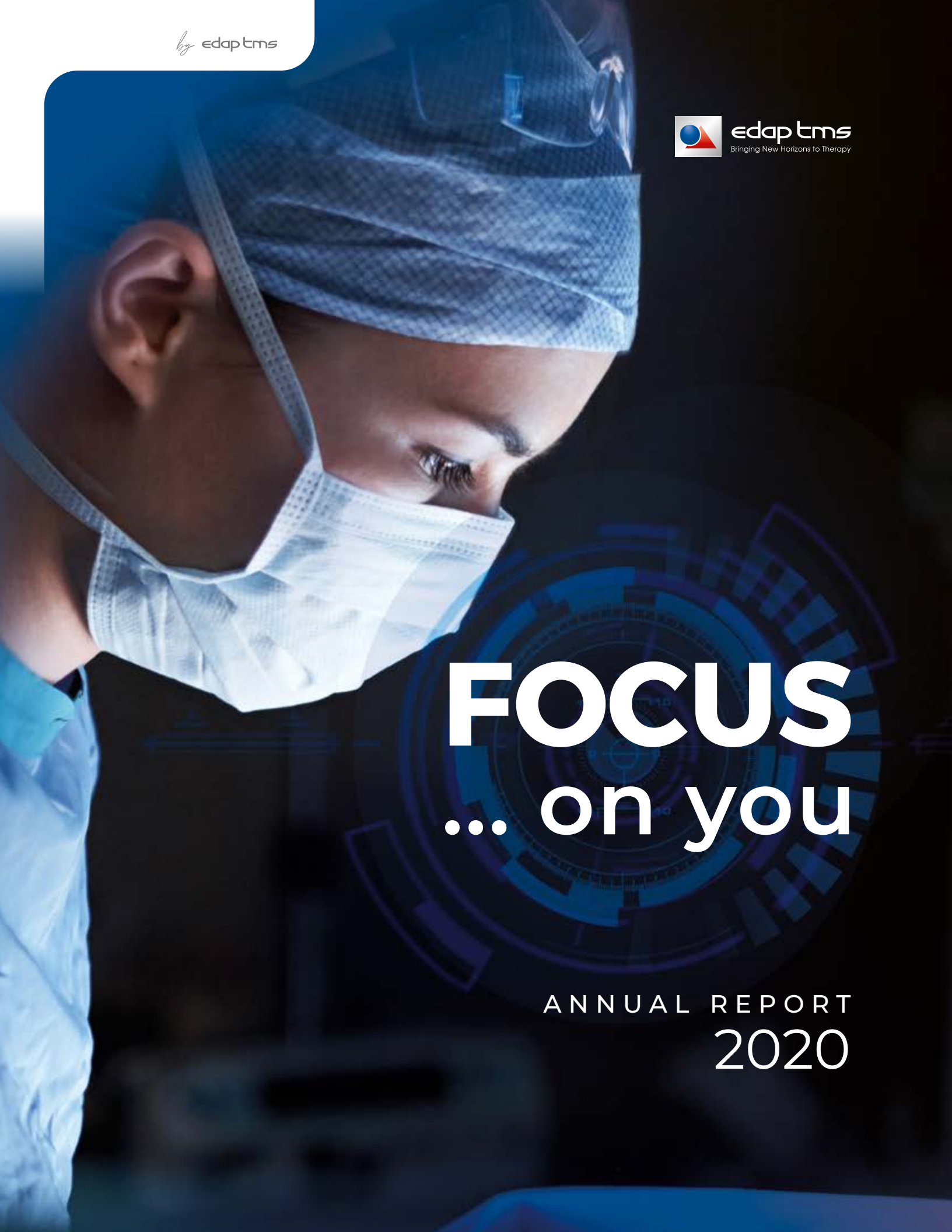
by edap tms

edap tms
Bringing New Horizons to Therapy



FOCUS
... on you

ANNUAL REPORT
2020

June 3, 2021

To my fellow Shareholders,

With the challenges of 2020 largely behind us, we remain focused on the future, and the great opportunities that exist for our suite of novel Focal One high intensity focused ultrasound (HIFU) and related technologies. In particular, we are still in the very early stages of expanding into the U.S., our most important market. Of course, the successful commercialization of any new technology, particularly into complex healthcare reimbursement systems, must be supported by prudent and timely investments. To that end, in April 2021, we had the opportunity to raise substantial capital that will enable us to fully support our ongoing U.S. Focal One commercialization and market access efforts.

This capital raise was strategically important for several reasons. First and foremost, our strengthened balance sheet now provides us the additional resources to fully engage multiple channels across the U.S. healthcare market. In addition to investing further in market access and reimbursement, these additional funds will allow us to attract top-tier talent with vast expertise in driving adoption of innovative technologies such as Focal One. In addition, we are building out our U.S. clinical, marketing and sales organizations so that we are well positioned as pandemic related restrictions continue to ease. With HIFU gaining broader acceptance as an effective and less invasive paradigm for the management of prostate cancer relative to surgical options, we will firmly establish ourselves as the leader in this field. We will continue to invest in our U.S. infrastructure, complemented by the many top-tier hospitals that have already adopted Focal One that are serving as important reference accounts for our company.

Launching a new medical technology in the U.S. healthcare market brings several challenges, not least of which is navigating a complex reimbursement, third-party payor landscape. Securing attractive reimbursement levels and achieving the broadest possible patient coverage for Focal One remain top priorities for our company, and our recent strategic partnerships with MTP and Argenta Advisors, coupled with the previously announced establishment of a Category 1 CPT code and reimbursement to physicians performing ablation of malignant prostate tissue with HIFU in the U.S, will help us drive further adoption and growth across the U.S.

In closing, I am proud of the way the EDAP team responded to the pandemic and quickly adapted so that we can pursue our mission without interruption. We continue to build a foundation from which to drive future growth. I am very optimistic about this year and beyond.

We would like to thank you, our shareholders, for your continued support, commitment and confidence. We look forward to sharing in our continued success.

Sincerely,

/s/ Marc Oczachowski
Chairman of the Board
& Chief Executive Officer
EDAP TMS S.A.

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

☒ ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(D) OF THE SECURITIES EXCHANGE ACT OF 1934
For the Fiscal Year Ended December 31, 2020

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)
Ms. 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	Trading Symbol	Name of each exchange on which registered
American Depositary Shares, each representing one Ordinary Share (Ordinary Shares, nominal value €0.13 per share)	**EDAP**	**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, 2020: 29,165,316 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 __
This filing includes an auditor attestation to our management's assessment of the effectiveness of our internal control over financial reporting 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

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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®, Ablatherm®, Ablasonic®, Ablapak®, 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 ''anticipate'' or similar 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:

- risks associated with the current uncertain worldwide economic, political and financial environment, in particular with respect to the COVID-19 pandemic and its related impact on our business operations;
- the success of our High Intensity Focused Ultrasound ("HIFU") technology;
- the uncertainty of market acceptance for our HIFU devices;
- the clinical and regulatory status of our devices in various geographical territories;
- the uncertainty in the regulatory agencies review and approval process for any of our devices and changes in their recommendations and guidance;
- the impact of government regulation, particularly relating to public healthcare systems and the commercial distribution of medical devices;
- effects of intense competition in the markets in which we operate;
- the uncertainty of reimbursement status of procedures performed with our products and their level of reimbursement;
- the market potential for our HIFU devices;
- dependence on our strategic suppliers and distribution partners;
- difficulties to attract and recruit high-level experts in software, design, and development of high technology devices such as our HIFU products
- 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 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. Following recent SEC rule changes on the presentation of selected financial data, we have chosen to present the information below to facilitate assessment of our financial condition and results of operations. 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, 2020 and 2019 and the selected statement of income (loss) data for the years ended December 31, 2020, 2019 and 2018 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. As the Company has exceeded certain levels of revenues and balance sheet set under French law, the appointment of a joint-auditor, as well as the production of consolidated accounts under International Financial Reporting Standards, is required for the fiscal year 2020. On June 30, 2020, the shareholders appointed the audit firm of Agili(3F) as our independent joint-auditors starting with the 2020 fiscal year for the audit of the statutory consolidated financial statements prepared in accordance with International Financial Reporting Standards.

In thousands of euro, except per share data in euro	2020	2019	2018
INCOME STATEMENT DATA			
Total revenues	41,662	44,912	39,183
Total net sales	41,649	44,859	39,163
Gross profit	18,379	21,002	16,917
Operating expenses	(18,110)	(18,802)	(18,232)
Income (loss) from operations	269	2,201	(1,315)
Basic Income (loss) from operations per common share	0.01	0.08	(0.05)
Diluted Income (loss) from operations per common share	0.01	0.07	(0.05)
Income (loss) before income taxes	(1,188)	2,191	20
Income tax (expense) benefit	(516)	(679)	(358)
Net income (loss)	(1,704)	1,512	(338)
Basic earnings (loss) per share	(0.06)	0.05	(0.01)
Diluted earnings (loss) per share	(0.06)	0.05	(0.01)
Dividends per share[1]	—	—	—
Basic weighted average shares outstanding	29,148,108	29,016,118	28,997,866
Diluted weighted average shares outstanding	29,148,108	29,615,466	28,997,866
BALANCE SHEET DATA			
Total current assets	45,393	42,097	40,376
Property and equipment, net	3,704	4,069	4,208
Total assets	55,193	53,068	48,740
Total current liabilities	21,504	17,493	16,812
Financing lease obligations, less current portion[2]	555	653	852
Long-term debt, less current portion	1,143	957	1,339
Common stock, €0.13 par value; 29,457,744 and 29,433,994 shares issued and 29,165,316 and 29,141,566 shares outstanding; at December 31, 2020 and 2019 respectively	3,830	3,826	3,818
Total shareholders' equity	26,248	27,359	24,964

(1) No dividends were paid with respect to fiscal years 2016 through 2019 and subject to approval of the annual shareholders' meeting to be held in 2021 the Company does not anticipate paying any dividend with respect to fiscal year 2020. See Item 8, ''*Financial Information — Dividends and Dividend Policy.*''

(2) Financing lease obligations for 2020 and capital lease obligations for previous years

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

Worldwide contagious, epidemic diseases may impact our international activities and could have a material adverse effect on our business, results of operations and financial condition.

Epidemic, contagious and even pandemic diseases, such as the current COVID-19 virus, is expected to impact the development of our business worldwide. Since the occurrence in 2020 of the COVID-19 virus which represented a new challenge to us, we have taken steps to require the majority of our employees to work remotely, maintain minimum supply chain and development activity and curtail most business travels. These measures are still in place as of the date of filing. During 2020, we also (i) implemented partial unemployment, (ii) temporarily closed certain sites and (iii) used certain mechanisms to limit the impact on cash flow (such as deferral of social security or tax payments, deferral of lease payments). The pandemic has resulted in further postponement and/or cancelation of the sale and installation of new devices and disposables in hospitals or clinics as investment decisions are put on hold or their resources are refocused on COVID-19. These occurrences could also prevent us from servicing our installed base of devices and we have experienced cancellations of treatments in certain circumstances, which had some impact on our recurring business. We may continue to experience further postponements, cancellation of sales or significant reduction in the demand for our products, as hospitals and clinics are diverting their priorities towards handling the COVID-19 crisis. In addition, the pandemic could also result in the postponement of clinical trials using our devices and may continue to impact the performance of clinical trials and recruitment of patients. Such outbreak of a contagious disease has also negatively affected hospital admission rates and disrupted our global business, and it may continue to negatively impact our activities, including our ability to manufacture and distribute our devices, for example due to potential quarantine measures. Although we are constantly monitoring the impact across our businesses of the coronavirus pandemic which already caused disruption of our activities in 2020, the severity of the operational and financial impact will depend on how long and widespread the disruption lasts. Furthermore, worldwide economies and capital markets have been negatively impacted by the COVID-19 pandemic, and the impact may cause an extended local and/or global economic recession. Such economic disruption could have a material adverse effect on our business as clinics and hospitals curtail and reduce capital and overall expenditures. Finally, we cannot predict the impact that COVID-19 will have on our customers, suppliers and other business partners, and the financial conditions of these actors; however, any material effect on these parties could adversely impact us. The impact of COVID-19 may also exacerbate other risks discussed in this section, any of which could have a material effect on us. As of the date of filing of this report, the global economy remains heavily impacted by the outbreak of the coronavirus and the extent to which the COVID-19 pandemic may materially adversely affect the Company's financial condition, liquidity, or results of operations is uncertain. We believe that the recently emerged variants of the COVID-19 are not likely to modify the risks as described above.

We have a history of operating losses and although we achieved profitability in 2019, it is uncertain whether we can maintain profitability in the future.

Although we achieved operational profitability in 2019, we have incurred operating losses in 2020, 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 further develop and commercialize 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 sustain 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.

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 but not limited to the Focal One, to generate significant additional revenues, achieve, and sustain profitability in the future.

Although we are particularly dependent on the success of our HIFU technology to grow our business through our HIFU ("HIFU") division, other revenues, generated by our Extracorporeal ShockWave Lithotripsy ("ESWL") division and our Distribution ("Distribution") division directly linked to the distribution of other complementary products on behalf of third party medical companies, continue to increase significantly and contribute to our revenue growth. While we believe that our Distribution 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—Distribution Division—Distribution Division Sales and Distribution of Products.*"

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 reputation, 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.*"

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, receipt of regulatory clearances or approvals, pricing, competition, market and consumer acceptance, manufacturing and supply costs, and the risk that new devices may have quality or other defects.

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 and adversely impacted.

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. The process of applying for regulatory approval or clearance is often lengthy and requires the expenditure of substantial resources. Further, there can be no assurance that we will receive the required approvals or clearance 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.

The regulatory agencies may not act favorably or quickly in their review of our submissions, or we may encounter significant difficulties in our efforts to obtain their clearance or approval, or to maintain our existing approvals, all of which could delay or preclude the sale of new or existing products in the related territories. In the European Union, the regulation of medical devices is being updated by the European Medical Device Regulation ("MDR") effective as of May 26, 2021, following the expiration of the four-year transition period, imposing stricter requirements on the conformity assessment and the commercialization of our products. An MDR compliance action plan is currently being performed in preparation of MDR enforcement within the expected timelines. We are implementing regulatory actions to ensure our devices may be distributed on the European and international market after May 2021.

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 or clearance, 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.

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'') and other standards for quality assurance and manufacturing process control under applicable regulatory authorities. 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 or for clinical trial supply. 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.

Finally, changes to regulatory policies 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 or clearance 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 later-stage 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;
- 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 preclinical 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 preclinical 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 preclinical 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 robotic 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 coverage and benefit decisions by Centers for Medicare and Medicaid Services (CMS) for Medicare reimbursement, state Medicaid agencies, individual managed care organizations, private insurers and other payers. With the support of the American Urological Association, and the American Association of Clinical Urologists, the American Medical Association (AMA) established a new Category 1 CPT code for the ablation of malignant prostate tissue with HIFU technology, effective January 1, 2021. In late 2020, CMS published its final rules for ambulatory payment classification (APC) procedures and physician fee schedule established reimbursement rates that recognize both facility or hospital payment and physician professional service payments for HIFU procedures. For private insurers, policy coverage decisions supporting coverage and reimbursement related to HIFU procedures are limited given that HIFU is a new technology. To further support and raise awareness as to the use of HIFU as an alternative to more traditional treatments, we engaged Medical Technology Partners (MTP) and Argenta Advisors, two leading reimbursement consultancies, to assist in navigating reimbursement analysis and strategies, including technology feasibility and assessment needs, payor advisory panels, outcome studies and understanding manufacturer billing education resources. With expanded third party coverage decisions, our Focal One HIFU procedure will have broader market access in the United States. However, public or private payors may decide to limit coverage or reimbursement of HIFU technologies that are available to individuals, including potentially modifying existing guidance to further limit available coverage. Changes to coverage decisions, which may be revised from time to time, could negatively impact reimbursement for procedures performed using our devices and may result in a material adverse effect on our business, financial conditions and results of operations. 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 and we cannot guarantee that a definitive reimbursement will be granted. See Item 4, ‘‘*Information on the Company——HIFU Division—HIFU Reimbursement Status.*”

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 expanded coverage decisions or additional reimbursement approvals will be obtained in the near future. If payor coverage or reimbursement for procedures related to our products is unavailable, limited in scope or amount, or if certain levels of public or private payor reimbursement or coverage 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 robotic 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 coverage policies supporting 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 robotic 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 cyclical 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. 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 or distributors 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 and other market costs related to implementing our expanded U.S. and global strategy following the FDA clearance of Focal One and CMS CPT code which will require significant additional resources. However, there is no assurance that this will result in an increase in the demand for our products and services. Our future cash flow may also be affected by the decrease in revenues directly linked to delay and postponing of treatments and sales projects due to COVID-19 crisis and to the management by EDAP of the COVID-19 situation.

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.

In the markets that we target for our robotic HIFU products, competition comes from new market entrants and alternative therapies, as well as from current manufacturers of robotic 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. See Item 4, ''*Information on the Company—HIFU Division—HIFU Competition*'' and Item 4, ''*Information on the Company—ESWL 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.

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 pandemic diseases such the COVID-19 virus necessitating quarantine implementation 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. Since mid-March 2020, we have taken the previously announced steps of requiring the majority of our employees to work remotely, maintaining minimum supply chain activity and curtailing most business travel. 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, including COVID-19 pandemic and implied restrictions, 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.

We may have difficulties in attracting and recruiting highly qualified experts in software, design and development of high technology devices such as our HIFU and ESWL products

Our devices require highly qualified individuals as well as high-level of expertise and experience in design, software, mechanics and electronics. We are highly dependent on our ability to attract and retain qualified personnel and engineers to develop our devices. In addition, the learning curve required to master our systems is lengthy and, if we do not find qualified experts and engineers, we may not be able to meet our development schedule and obtain market approval in due time, which in time may delay market introduction of new products. Failure to recruit and attract experts in a timely manner may have a material adverse effect on our development, 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. We may receive letters from third parties drawing our attention to their patent rights, or patent grant contestations may be filed. Third parties also may challenge our patents before administrative bodies in the United States or abroad. Such mechanisms include re-examination, post-grant review, *inter partes* review, interference proceedings, derivation proceedings, and equivalent proceedings in foreign jurisdictions (e.g., opposition proceedings). Such proceedings could result in the revocation or cancellation of or amendment to our patents in such a way that they no longer cover our product candidates or provide any competitive advantage. For example, a patent granted to us by the European Patent Office ("EPO"), covering Visiotrack technology for lithotripsy products (patent EP 2340781), has been opposed by Storz Medical. The opposition was rejected by the EPO and Storz Medical has filed an appeal, which is currently pending. The outcome following such appeal is unpredictable. If Storz Medical were to prevail, we would lose patent protection for our Visiotrack technology, which could result in our competitors and other third parties using our technology to compete with us. Such a loss of patent protection could have a material adverse impact on our business, financial condition and result of operations.

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—ESWL Division—ESWL Division Patents and Intellectual Property.*''

We own or co-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 and/or our ESWL medical equipment, 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.

Our use of "open source" software could negatively affect our ability to sell our products and subject us to possible litigation.

Our products incorporate so-called "open source" software, and we may incorporate additional open source software in the future. Open source software is generally licensed by its authors or other third parties under open source licenses. If we fail to comply with these licenses, we may be subject to certain conditions, including requirements that we offer our products that incorporate the open source software for no cost, that we make available source code for modifications or derivative works we create based upon, incorporating or using the open source software and/or that we license such modifications or derivative works under the terms of the particular open source license. If an author or other third party that distributes such open source software were to allege that we had not complied with the conditions of one or more of these licenses, we could be required to incur significant legal expenses defending against such allegations and could be subject to significant damages, enjoined from the sale of our products that contained the open source software and required to comply with the foregoing conditions, which could disrupt the distribution and sale of our products.

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 afflictions 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.

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 almost 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 the applicable provisions of the French law known as the Sapin II law, and the related implementing decrees, and notably the requirements of Article 8 of the law which requires the establishment of a whistle-blowing policy. These numerous and sometimes conflicting laws and regulations include, among others, data privacy requirements, labor relations laws, tax laws, anti-competition regulations, "Know Your Customer" requirements, import and trade restrictions, export requirements.

We are also subject to healthcare laws and regulations pertaining to physician payment transparency, privacy and data protection 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 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" –updated in 2020- which regulates the provision of gifts, discounts and other incentives to physicians and the "Bertrand law" which imposes disclosure obligations on companies relating to benefits and remunerations granted to, and agreements concluded with, physicians and (iv) the provisions of the French Public Health Code relating to the processing and/or hosting of health-related personal data. Any failure to comply with these regulations may have a material adverse effect on our business, financial condition and results of operations.

Furthermore, in addition to HIPAA we are subject to other data privacy and protection laws and regulations that apply to the collection, transmission, storage and use of personally identifying information, which among other things, impose certain requirements relating to the privacy, security and transmission of personal information. The legislative and regulatory landscape for privacy and data protection continues to evolve in jurisdictions worldwide, and there has been an increasing focus on privacy and data protection issues with the potential to affect our business. There are numerous European, French, U.S. federal and U.S. state laws and regulations related to the privacy and security of personal information. For example, in the European Union, the collection and use of personal data is governed by the provisions of the General Data Protection Regulation ("GDPR") which took effect in May 2018. The GDPR significantly increases the level of data protection and imposes a greater compliance burden on companies. In particular, it treats clinical data as personal data, requiring us or our subcontractors 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. The GDPR is also supplemented by the provisions of the French data protection act (law n°78 17 of 6 January 1978), in particular in respect of the processing of personal data in the field of healthcare. We believe that the GDPR did 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 personal data or to react in due time to address an individual request linked to the GDPR.

Given the high level of complexity of these laws, and the fact that we do business in regions where regulatory compliance is less robust, including in Russia and parts of Asia, there is a risk that we may inadvertently breach some provisions, for example, through fraudulent or negligent behavior of individual employees or business partners, 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 decentralized 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.

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 2020, 74% of our total costs of sales and operating expenses were denominated in euro, while 51% 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, 2020, 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 and are partly dependent on access to sufficient lease financing

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 that 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.

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.

We had in the past identified material weaknesses in our internal controls over financial reporting, which are now fully remediated; however, we may, in the future, identify additional material weaknesses and if we fail to remediate adequately these material weaknesses 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 of December 31, 2020, based on its assessment of our internal control, management concluded that our internal control over financial reporting was effective and that the material weakness reported in our annual report for the year ended December 31, 2019, was fully remediated. During the course of 2020, the Company implemented a formal "Ticketing tool" in order to strengthen the change management process and documentation. The Company also strengthened its IT team to ensure a better segregation of duties upon IT changes implementation. The Company therefore consider that this material weakness has been remediated as of December 31, 2020.

We may in the future identify new material weaknesses in our internal control and we may not be able to fully remediate these material weaknesses. 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.

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 2020 was 107,764, the high and low bid price of our ADSs for the last two financial years ended on December 31, 2020 and December 31, 2019, was $5.28 and $1.46, and $5.42 and $1.78, 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 2019 was 120,648 as opposed to 126,839 for the same period of 2020. 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, general market and economic conditions and results of operations being below analysts' or investors' expectations. Any downward pressure on the price of ADSs caused by the sale of ADS's 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.

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. In February 2021, the Portuguese Presidency of the Council proposed an inclusive discussion among all Member States on tax design issues of the FTT at the EU level.

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% 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. In this respect, a new FTT proposal was submitted in December 2019. Under this new proposal, the FTT would be imposed at a 0.2% rate on the purchase of shares in domestically listed companies with a market capitalization in excess of €1.0 billion, and would also apply to depositary receipts issued domestically and abroad and which are backed by shares in these companies.

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, "*Additional Information—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%. 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.

Our investors may not realize the potential benefits of inspections under the PCAOB's cooperative arrangement until a new cooperative arrangement with the French audit authority is entered into and inspections in France resume.

Our auditor, KPMG S.A., is registered with the Public Company Accounting Oversight Board, or PCAOB, in the United States. The PCAOB's cooperative arrangement with the French audit authority expired in December 2019. The expiration of this cooperation arrangement prevents inspections of registered firms in France until a new arrangement is concluded. Such inspections assess a registered firm's compliance with U.S. law and professional standards in connection with the performance of audits of financial statements filed with the SEC. As a result, our investors may not realize the potential benefits of such inspections until a new cooperative arrangement, which is currently under negotiation, is entered into and inspections in France resume. The current inability of the PCAOB to conduct inspections of auditors in France also makes it more difficult to evaluate the effectiveness of our auditor's audit procedures or quality control procedures as compared to auditors outside France that are subject to PCAOB inspections.

General Risks Factors

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, and particularly the COVID-19 pandemic, has significantly impacted the global, worldwide economies and has affected the level of public and private spending in the healthcare sector generally. A cautious or negative outlook or a COVID-19 crisis which lasts may cause our customers to further delay or cancel investment in medical equipment, which would adversely affect our revenues. *See "-- Worldwide contagious, epidemic diseases may impact our international activities and could have a material adverse effect on our business, results of operations and financial condition."*

We may issue additional securities that may be dilutive to our existing shareholders, in view of funding our new developments and accelerating our business expansion.

On June 28, 2019, our shareholders adopted resolutions allowing the Board of Directors to issue new shares in an aggregate maximum amount of 10 million shares in order to meet any fundraising opportunities that may be necessary to

finance the Company's development, which can be used to finance the acceleration of the roll out of our HIFU activities in the United States, given the CPT Code Category 1 approval for HIFU technology that was confirmed for execution in January 2021. On June 30, 2020, some of these financing resolutions were extended as they came to expiration. On June 28, 2019, our shareholders also adopted a resolution allowing the Board of Directors to issue 1 million new shares under the form of subscription options to motivate and reward the management teams dedicated to successfully implementing our U.S. and worldwide expansion plans. As of December 31, 2020, no additional shares were issued nor options allocated as authorized under the above Plan.

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.

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.

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 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 in part due to a perceived increased vulnerability associated with current remote working conditions. As of the date of this annual report, we have received fraudulent invoices, purportedly from our suppliers, submitted to us using fraudulent email addresses and have made payments in connection with two such fraudulent invoices. While we have protocols in place to protect against such fraudulent transfers, we may fail to identify

fraudulent payment requests that we may receive in the future and may inadvertently provide payment in connection with such requests, which may have a material adverse effect on our business, financial condition or results of operations.

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. As these threats and incidents, 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.

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. 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 electronic 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, section "Investor Relations".

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

In May 2020, we signed an exclusive worldwide agreement with Exact Imaging to distribute their diagnostic micro ultrasound technologies. Their lead product, ExactVu™, delivers diagnostic accuracy similar to MRI in identifying prostate cancer and supports real-time imaging for the prostate. The combination of ExactVu with our Focal One HIFU

soft tissue ablation technology represents what we believe to be the most complete end-to-end solution for the focal management of prostate cancer.

In May 2020, we also initiated a strategic shift after an extensive review of our different businesses, including HIFU, ESWL and Distribution activities. We have decided to strengthen and refocus our development efforts towards HIFU for both prostate application and beyond and hence, to realign our activities and report our financial results in three segments: HIFU, ESWL and Distribution.

In July 2020, we received clearance from French health authorities to initiate a Phase II multi-centric clinical trial evaluating Focal One for the treatment of deep invasive rectal endometriosis. This is a truly debilitating condition for women suffering from this pathology, which is responsible for a significant decline in quality of life. We enrolled our first female subjects in September 2020 and enrollment is proceeding as planned.

Finally, in January 2021, U.S. CPT Code Category 1 reimbursement for HIFU became effective. CMS established, for the first time, a Category 1 CPT code including reimbursement to physicians performing ablation of malignant prostate tissue with HIFU in the United States.

Additional information regarding the principal capital expenditures and divestitures can be found in Item 5, ‘‘Operating and Financial Review and Prospects’’.

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.

We recently implemented organizational changes in our structure and realigned our activity into three divisions: HIFU, ESWL (including lithotripsy activities) and Distribution to better reflect how we view our businesses and how we measure our progress. Through these three divisions, we develop, produce, market and distribute minimally invasive medical devices, mainly for urological diseases. The HIFU division includes sales of Focal One, Ablatherm and related consumables and services, the ESWL division includes revenues generated by the existing installed base of Sonolith range of lithotripters and, the Distribution division includes the sale of complementary products such as lasers, micro-ultrasound systems and other products from third parties.

We believe that these three divisions will help to better support the expansion of our HIFU development and sales activities as well as to maximize the potential of our Distribution activities.

Our three 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 €11.4 million, €14.1 million and €11.0 million for 2020, 2019 and 2018, respectively. Those sales are generated in Europe, the United States and the rest of the world, excluding certain countries in Asia, such as Japan, where our HIFU devices are not approved yet. Total net sales for the ESWL division were €12.9 million (including €6.7 million in Asia and €6.2 million in Europe and the rest of the world), €14.1 million (including €7.1 million in Asia and €7.0 million in Europe and the rest of the world),) and €14.5 million (including €6.1 million in Asia and €8.3 million in Europe and the rest of the world),, each for 2020, 2019 and 2018, respectively. Total net sales for the Distribution division were €17.3 million (including €9.0 million in Asia and €8.3 million in Europe and the rest of the world), €16.6 million (including €10.3 million in Asia and €6.3 million in Europe and the rest of the world), and €13.7 million (including €7.8 million in Asia and €5.9 million in Europe and the rest of the world), each for 2020, 2019 and 2018, respectively.

See Note 29 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 robotic 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 €11.4 million to our consolidated net sales during the fiscal year ended December 31, 2020.

HIFU Division Business Overview

The HIFU division currently develops, manufactures and markets robotic 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 directed at prostate tissue ablation in the treatment of localized organ-confined prostate cancer, referred to as T1-T2 stage. The Focal One high-end device is a HIFU fully robotic device for prostate tissue ablation 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 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. We offer a HIFU mobile treatment option, which 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 installed HIFU devices. As of December 31, 2020, the HIFU division had an active installed base of 122 HIFU devices of which 61 Focal One machines.

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 urology 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 about prostate cancer. 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 that destroy the tumor only (focal therapy) while continuously controlling the disease, HIFU and its focused approach, is well positioned to address this new clinical approach. In addition, within the context of COVID-19 pandemic, as elective procedures are being put on hold, HIFU brings a safer, outpatient and minimally invasive solution to prostate cancer patients. 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. Our strategy is also to accelerate HIFU adoption in the U.S. now that the technology has a CPT Code and an established payment level. We need to work building coverage and market acceptance in order to offer this minimally invasive option to U.S. prostate cancer patients at a broader level. Speed of execution could depend on the amount of resources invested in this strategy. 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 and training 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 in 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 exploring various other applications such as rectal endometriosis, liver and pancreatic cancers, where HIFU could provide an alternative to current therapies. In 2020, the HIFU division increased gross expenses by 17% compared to 2019 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 2021 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 ablation of prostate tissue and is used in 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 by the ablation of prostate tissue. 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, 2020, the HIFU division's patent portfolio contained 33 granted owned or co-owned patents consisting of eight granted patents in the United States, 11 patents in the European Union, eight granted patents in Japan and six patents in China. These patents belong to 12 groups of patents covering technologies related to therapeutic ultrasound principles, systems and associated software.

Additional owned or co-owned patent applications covering certain other aspects of our HIFU technology, including two patent application in the United States, four patent applications in the European Union, two patent applications in Japan and two patent applications in China, are currently pending before the relevant patent offices. During 2020, one such new patent application was filed in France, covering a new ultrasound dynamic focusing technology. 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 collaboration gives rise in some cases to the filing of patent applications, followed by the grant of co-owned patents. We have entered into license agreements with INSERM related to certain patents co-owned with INSERM whereby we commit to pay an amount of royalties to INSERM based on a fixed rate of 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. We have an option to obtain an exclusive license from INSERM relating to other patents co-owned with INSERM.

In July 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 10, 2011, we extended the above license by granting Theraclion exclusivity for the treatment of benign breast tumors and by granting a non-exclusive worldwide 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, if issued, 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

Ablatherm 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. Based on clinical study results, we obtained a CE Marking for Focal One in June 2013, which allowed us to market the Focal One in the European Union and in worldwide territories where CE Marking is required. Our current notified body has recently expanded our Focal One CE certificate until May 2024.

Clinical and Regulatory Status in the United States

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.

On June 7, 2018, based on Ablatherm clearance and European pre-market and post-market clinical data, 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. We will 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, ''*Risk Factors—Our future revenue growth and income depend, among other things, on the success of our HIFU technology"* and "*— 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."*

Clinical and Regulatory Status in China

We did not obtain marketing clearance of our HIFU devices by Chinese authorities due to lengthy and complex processes. We are currently reviewing our regulatory and market access strategy to address the China market.

Clinical and Regulatory Status in the Rest of the World

The Ablatherm is cleared for distribution in Australia, Canada, South Korea, Costa Rica, Ecuador, Russia, Taiwan.

The Focal One device is cleared for distribution in Saudi Arabia, Argentina, Brazil, Canada, South Korea, Costa Rica, United Arab Emirates, Ecuador, Israel, Malaysia, Mexico, U.K, Russia, Switzerland, Ukraine, Uruguay 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 Developments

HIFU in Prostate Cancer

The clinical study initiated in 2015 within the scope of "Forfait Innovation" (the "HIFI" study) and piloted by the French Association of Urology ("AFU") aimed at evaluating the reimbursement of HIFU in France. The patients' inclusion period closed on September 30, 2019. Patients included in the HIFI study will be followed for 30 months ahead of data analysis and results publication. During that follow-up period, we will be able to pursue patient treatments using HIFU under the specific Forfait Innovation coverage process, but these patients will not be followed as part of HIFI Study. In November 2020, the Study Coordinator presented interim results at the AFU annual congress. The results of the interim analysis (non-consolidated results) show a significantly better 24-month recurrence-free survival (i.e., the rate of salvage treatment by external beam radiotherapy and/or hormone therapy) for the patients treated with HIFU compared to the patients undergoing surgery ($p<0.001$). Additionally, urinary continence was significantly better and erectile function was significantly less impacted for the patients undergoing HIFU compared to those in the RP arm.

In July 2017, we, together with our academic, scientific and clinical partners, initiated a collaborative project (the "PERFUSE" project) under the "French National Investment Program for the Future". The overall objective of the PERFUSE project is two-fold: (i) to set-up several clinical studies to assess focal therapy using the Focal One device in view of a better understanding of focal therapy in prostate cancer management and, (ii) to prepare a change of paradigm in the treatment of prostate cancer via technical innovations such as focal therapy. The whole project was awarded funding of €8 million over five years. We, as a partner of the PERFUSE project, are to receive about €1.2 million over the period as a non-refundable grant. As of December 31, 2020, we received refundable grant of a total of €0.6 million.

As part of PERFUSE project, several studies have already been initiated and sponsored by academic partner HCL - Edouard Herriot Hospital. In September 2018, we launched a Phase II multi-centric study to evaluate the efficacy and safety of HIFU focal therapy in patients with intermediate-risk single-lobed prostate cancer (the "FOCALE" study). 170 patients are to be included in the FOCALE study. As of January 2021, 141 patients have already been included in this study within 13 French active centers. In October 2018, we initiated a Phase III, multi-centric, randomized study aiming at evaluating the efficacy of focal HIFU versus active surveillance hence reducing the need for radical treatment for low-risk prostate cancer patients (the "HIFUSA" study). 146 patients are to be included in the study. As of January 2021, 58 patients have been included within 11 French active centers. In February 2020, French regulatory authorities authorized the initiation of a Phase I study aiming at evaluating the use of HIFU guided by a new imaging modality ("PSMA-PET-MRI") to evaluate prostate cancer recurrence after radiotherapy (the "PMSA" study). 40 patients are to be included in the study. The first patient was included in this study in July 2020.

In early 2018, a new data collection collaborative effort, called the Focal Robotic Ultrasound Ablation ("FoR-UsA") Registry, was initiated to collect high quality clinical data of U.S. patients treated with EDAP's HIFU devices in academic institutions in the U.S. Clinical data from Focal One treatments is now being collected as part of this project. 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 such prospective data collection efforts documenting HIFU data from patients in the U.S.

HIFU for Potential Treatment of Liver Cancer

In view of addressing liver cancer using HIFU technology, we entered into a multi-partner liver cancer development project named the HECAM consortium in 2015 to develop a novel HIFU –per operative- approach to treat liver metastasis. The HECAM project was completed in 2020. To fund this development program, EDAP received a total of €1.5 million including €1.0 million as a conditional subsidy and €0.5 million as a non-refundable grant. Despite a first single-center study successfully implemented with Lyon's Centre Leon Bérard cancer center, we decided not to pursue the development of HIFU for liver cancer as a per-operative approach. Additionally, the multi-center Phase II study, which was to be initiated following the single-center study, will not be implemented. We determined that the per-operative approach will not be sufficiently distinct from existing options to be commercially viable at this time and will require

lengthy comparative clinical studies against existing therapeutic solutions to fulfill the requirement of the new European MDR regulations to become effective in May 2021. The company intends to leverage the efforts, knowledge and assets resulting from the HECAM project in two ways: to evaluate the technology and approach for pancreatic cancer for patients with few or even no alternatives and to evaluate the technology and approach as an extracorporeal solution for patients affected by primary or metastatic liver cancer.

HIFU for Potential Treatment of Deep Endometriosis

In 2020, we initiated a Phase II clinical study in France to investigate further the use of Focal One HIFU in the treatment of certain types of deep endometriosis situated in the low rectum. A total of 38 women will be enrolled in the study at five major hospitals in France and assessed over a six-month follow-up period. The intended end-point of this study is to evaluate the safety and efficacy of HIFU for this pathology. This Phase II study complements a Phase I study successfully completed in 2019 which reported promising results with a significant improvement of the outcomes and in patient quality of life at six months. These results were published in November 2019.

HIFU Clinical Publications

To date, clinical results related to our HIFU devices have been published in renowned peer-reviewed journals.

In October 2016, clinical results were published in the *European Urology* journal (Rischmann et al.). They validated a new focal HIFU strategy in the treatment of prostate cancer localized in a single lobe of the prostate (hemi-ablation treatment). The goal of focal treatment as opposed to "radical" treatment is to reduce the complications associated with standard treatments, particularly the risks of incontinence and impotence.

In December 2016, Professor Roland van Velthoven from Institut Bordet Oncology Center, Brussels, Belgium published in *the Journal of Endourology* a matched pair analysis of HIFU Hemi-ablation vs robotic assisted laparoscopic prostatectomy. In this study, 55 patients with prostate cancer localized in a single lobe of the prostate were treated using Ablatherm-HIFU and their outcomes were compared 1:1 with patients having similar clinical criteria but who underwent robotic-assisted laparoscopic prostatectomy.

In 2017, Crouzet et al. from Edouard Herriot Hospital, Lyon, France, reported in the *British Journal of Urology* (BJU), oncological outcomes of salvage HIFU for locally recurrent prostate cancer after External Beam Radiotherapy ("EBRT"). This retrospective study comprises 418 patients from nine centers with local recurrent cancer after EBRT treated with HIFU from 1995 to 2009. The publication is the largest series of salvage treatment confirming very positive oncological outcomes.

More recently, Ganzer & al., Germany, evaluated focal HIFU Hemi-ablation in a prospective trial. Their data were published in the *Journal of Urology* in April 2018. In their conclusion, they reported that focal therapy Hemi-ablation is safe with acceptable oncologic outcome.

In November 2019, Philip CA et al, from Croix Rousse Hospital, Lyon, France, published in *Ultrasound Obstet Gynecology* journal, the results of the treatment of 20 patients with deep rectal endometriosis using Focal One HIFU. This EDAP sponsored study is the first one on the use of HIFU in this indication. The authors reported very promising results with low morbidity and significant efficiency on intestinal and gynecological symptoms as well as in the quality of life.

In September 2019, Dupré et al. from Leon Bérard Cancer Center, Lyon, France, published in the *Journal of Visualized Experiments* an evaluation of the feasibility, safety and accuracy of an Intraoperative HIFU device for treating liver metastases. Results are promising and a multi-centric Phase II study is to be initiated.

In February 2020, Tourhino-Barbosa et al. from Institut Mutualiste Monsouris, Paris, France, published in the *Journal of Urology* a retrospective study presenting their results of focal prostate cancer treatments (HIFU and cryotherapy) in their institution.

In September 2020, Nahar et al. from University of Miami Miller School of Medicine, Miami, Florida, published in the *Journal of Urology*, their results on 52 patients after focal treatments using the Ablaterm device (January 2016 to July 2018) on patients with clinically significant cancer profile. They concluded that focal HIFU is safe and effective and may be offered as an alternative to the existing modalities of treatment for select patients with all risk profiles of prostate cancer.

In October 2020, Abreu et al. From USC Institute of Urology, University of Southern California, Los Angeles, California, published in the *Journal of Urology* the first U.S. series of results on a cohort of 100 consecutive men who underwent hemi-gland HIFU ablation (December 2015 to December 2019). They concluded that focal HIFU ablation is safe and provides excellent potency and continence preservation with adequate short-term cancer control and that radical treatment was avoided in 91% of men at two years.

In January 2021, Dr. Castilho Borges et al. from Institut Mutualiste Montsouris, Paris, published in the Journal of Urology their results on 300 patients, a study in which the results compare the impact on functional results (Sexual Function and Urinary Continence) in two groups of patients: 195 patients in Focal Treatment (FT) versus 105 patients in the Whole Gland (WGT) Ablation Prostate Cancer. In the conclusions, FT is associated with better functional outcomes, with an earlier urinary continence recovery, and better sexual function at 3 and 12 months. Moreover, the morbidity associated with focal therapy is substantially lower than that related to whole gland therapy.

HIFU Division Market Potential

Prostate cancer is currently the first (in terms of new cases diagnosed) and second (in terms of number of deaths) 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 to be diagnosed for 2021 to be approximately 248,530, 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.

Management believes that HIFU therapy could be expanded to other medical conditions, such as rectal endometriosis, liver and pancreatic cancers but also to certain localized thyroid, breast, bladder, kidney, brain tumors. We decided to focus on developing HIFU for certain types of pathologies. However, the expansion of the use of HIFU to other areas of treatment will require a significant investment in research and development, an investment that we intend to accelerate as acceptance of HIFU as a treatment for localized prostate cancer is gaining grounds in the medical community.

For example, in 2019, as we decided to expand the development of HIFU beyond prostate cancer, we successfully finalized a clinical Phase I study using Focal One HIFU to address certain types of deep endometriosis located in the low rectum. The study results are promising and show a decrease of symptoms in the treated patients. In 2020, we initiated a Phase II multi-centric study to investigate further the use of HIFU in this pathology. As per the European Society of Human Reproduction and Embryology, endometriosis is estimated to affect approximately one in 10 women of reproductive age.

In addition, in view of addressing liver cancer using HIFU technology, we decided to pursue the development of HIFU for liver cancer as an extracorporeal solution, avoiding open surgery approach.

HIFU Reimbursement status

In the United States, following the AMA's recognition of a new Category 1 CPT code, CMS finalized payment rules for hospitals, facilities, and physicians that facilitates coverage and reimbursement for the ablation of malignant prostate tissue with HIFU technology, effective January 1, 2021. U.S. private insurers are continuing to evaluate and advance coverage and payment policies related to HIFU procedures for prostate tissue ablation. We have engaged Medical Technology Partners (MTP) and Argenta Advisors, two leading reimbursement consultancies, to support us in reimbursement analysis and strategies. As public and private payors expand coverage and payment for HIFU procedures, our Focal One HIFU device and procedure likely will have accelerated market access and demand in the United States.

On the hospital payment side, the final rule maintains the HIFU procedure in the Level 5 Urology Ambulatory Payment Classification (APC) in 2021. This translates into a payment for a hospital performing a HIFU procedure on a Medicare patient of around $4,400 as a national average, adjusted locally based on the wage index. This represents an increase of 5%, from the payment hospitals receive from Medicare for a HIFU procedure in 2020.

In the physician fee schedule final rule, CMS has established for the first time a payment to physicians performing a HIFU procedure in the U.S. In the final rule, CMS has set a total Relative Value Units ("RVUs") for a physician performing a HIFU procedure at 28.57. This translates to an average payment of $997 for a urologist performing a HIFU procedure on a Medicare patient in a facility setting. As a reference, a comparable established minimally invasive therapy

for prostate cancer, cryotherapy, yields 22.28 RVUs, which translates to $786 for the urologist under the same setting and patient conditions. A radical prostatectomy would grant the urologist 34.06 RVUs, which translates to a Medicare payment of $1,188, or 41.95 RVUs and $1,464 if performed laparoscopically.

In the European Union, there is no harmonized procedure for obtaining reimbursement and, consequently, we must seek reimbursement in each Member State. Procedures performed with our HIFU devices are not reimbursed in the European Union with the exception of Italy, Germany, the United Kingdom (where procedures are partially reimbursed by either public healthcare systems or private insurers) and France under certain conditions. In 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.

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 newer 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 it requires a very skilled surgeon. Other therapies for localized prostate cancer include brachytherapy, a therapy that involves the implantation of radioisotopes into the prostate gland, external beam radiation therapy and cryotherapy.

Our robotic 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" or "total" 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—Competition in the markets in which we operate is intense and is expected to increase in the future*."

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.

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 cleared 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, Elbit Medical Imaging and Koch Industries, 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 certain of our HIFU patents, is currently marketing the Echopulse HIFU device to treat thyroid tumors, benign breast tumors and varicose veins. Haifu, a Chinese company, is developing HIFU products addressing various types of cancers.

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, the United States, Germany, Malaysia, South Korea and Russia, which currently represent its largest HIFU markets. Additionally, the HIFU division markets and sells its products through our distribution platform in the rest of Europe, Middle East 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. As HIFU expands in these countries, we intend to strengthen our marketing efforts and further invest in educational and sales programs in these countries.

ESWL Division

The ESWL lithotripsy division is engaged in the manufacturing, marketing and servicing of our installed base of Sonolith range of lithotripters. The ESWL division contributed €12.9 million to our consolidated net sales during the fiscal year ended December 31, 2020.

Our ESWL 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 possible higher selling activity in the last quarter of the year.

ESWL Division Business Overview

The ESWL division's business is producing and marketing certain medical 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 potential for related complications. The ESWL division currently markets one model of lithotripter: the Sonolith i-move. The Company stopped manufacturing the Sonolith i-sys lithotripter in 2020. In addition, as part of the strategic shift we recently implemented, we decided to discontinue our R&D investments in lithotripsy, including the launch of our Endo-Up platform.

As of December 31, 2020, the ESWL division has an actively maintained or otherwise serviced installed base of 731 lithotripters.

ESWL Division Business Strategy

The business strategy for the ESWL division is to capitalize on its expertise in ESWL and its position in urology to maintain our lithotripsy sale and service activity as we intend to maintain this cash generating activity. The ESWL division manufactures its own lithotripsy device, the Sonolith i-move, via EDAP TMS France SAS ("EDAP TMS France"), our wholly owned subsidiary.

ESWL Division Products

The ESWL division offers the Sonolith i-move extracorporeal shockwave lithotripter to small and mid-size hospitals. The ESWL division also sells disposable parts for lithotripters and electrodes of the Sonolith line, which need to be replaced approximately every ten treatments.

The Sonolith i-move relies 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 ESWL division's 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 ESWL division developed the Sonolith i-move, a compact electroconductive lithotripter designed for smaller clinics. The Sonolith i-move offers a wide range of configurations to suit various budgets and various local market needs. Our 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.

ESWL Division Patents and Intellectual Property

As of December 31, 2020, the ESWL division's patent portfolio contained six granted owned and co-owned patents consisting of one granted patent in the United States, four granted patents in the European Union and one granted patent in Japan.

These patents belong to five groups of patents covering technologies relating to ESWL systems and associated software capabilities. The ESWL division's patents cover both piezoelectric and electroconductive technologies associated to ESWL generator, localization systems and device design. The ESWL 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.

ESWL Division Regulatory Status

The Sonolith i-move is cleared and available for commercial distribution in the European Union, Saudi Arabia, Colombia, South Korea, Costa Rica, Egypt, the United States, Indonesia, Japan, Malaysia, Philippines, United Kingdom, Russia, Serbia, Switzerland, Taiwan, Ukraine and Vietnam.

The ESWL division continues to provide disposables, replacement parts and services for the current installed base of Sonolith Praktis, Sonolith Visio and Sonolith i-sys even though we have discontinued the manufacture of these machines.

ESWL Division Market Potential

We estimate that roughly 12% of the world population suffers from kidney or ureteric stones during their lifetime. 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) and buyers looking for simpler and less expensive machines (typically smaller clinics). The market for lithotripters is mature and has become primarily a replacement and service and maintenance market in most of the world. 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 maintain our position in the replacement market for those machines. 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 expect the ESWL division to continue to contribute to the financial results despite the mature nature of the market, due to revenues from consumables, maintenance contracts and demand for replacement machines. See Item 5, ''*Operating and Financial Review and Prospects*''.

ESWL 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 ESWL division expects this trend to continue. See Item 5, ‘‘*Operating and Financial Review and Prospects.*’’ The ESWL division’s major competitors in developed countries are Wolf, Storz Medical and Dornier Medtech.

ESWL Division Sales and Distribution of Products

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

The ESWL 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 its ESWL products under satisfactory conditions.

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

Distribution Division

The Distribution division is engaged in the marketing, distribution and servicing of products complementary to our global activity such as lasers, micro-ultrasound systems and other medical products from third parties. The Distribution division contributed €17.3 million to our consolidated net sales during the fiscal year ended December 31, 2020.

Distribution Division Business Strategy

The Distribution division’s business strategy is to generate revenues from the marketing and distribution of medical devices for the minimally invasive diagnosis or treatment of urological disorders and other various clinical indications. These products include, but are not limited to: micro-ultrasound devices such as the ExactVu product and lasers. The Distribution division also generates revenues from the leasing of devices, as well as from the sale of disposables, spare parts and maintenance contracts for equipment sold under the Distribution division.

We have engaged in exclusive distribution agreements with third parties to distribute and service their products in certain territories, under specific conditions.

The Distribution division strategy is also to distribute products that bring synergies and complementarity to our existing home grown technologies. In May 2020, we signed an exclusive worldwide distribution agreement with Exact Imaging, a developer of high resolution micro-ultrasound imaging technologies. Under the terms of the agreement, we will market Exact Imaging’s micro-ultrasound diagnostic devices alongside our Focal One. In that respect, ExactVu micro-ultrasound complements our Focal One HIFU technology. ExactVu offers all of the steps and procedures that need to be done prior to a treatment for prostate cancer. By distributing the two technologies, EDAP offers the urologist a complete solution for focal prostate cancer management, with full autonomy and capabilities from diagnostic to treatment. This type of complete care is also extremely attractive to patients with prostate cancer as it represents a non-invasive way of managing their disease by using diagnostics to eliminate unnecessary biopsy procedures and allows for a very precise non- invasive HIFU ablation of the suspicious and diagnosed region of the prostate.

Distribution Division Products

The Distribution division currently distributes Holmium lasers (HoLEP) produced by the Israeli company Lumenis Ltd, under an exclusive agreement limited to the French territory. HoLEP Moses Lumenis laser is a groundbreaking, patent-protected pulse delivery technology that remarkably improves energy transmission, resulting in more efficient lithotripsy and BPH treatments compared to the regular Holmium pulse1. The Distribution division also exclusively markets lasers manufactured by Italian company Quanta System Spa in Japan, in certain countries in South-East Asia. Distribution agreements are under renewal in Japan and South-East Asia territories. The Distribution division

also exclusively markets Quanta lasers in certain Middle East territories including Kuwait, Oman, Saudi Arabia, Jordan and Bahrain.

The Distribution division also distributes the ExactVu device, produced by the Canadian company Exact Imaging, under a worldwide and exclusive agreement. ExactVu is an ultrasound-based imaging system that can operate and be used the same way as a standard ultrasound, but it also has the unique capability of operating at a very high frequency of 29MHz. Similar to MRI, it allows urologists to visualize and locate suspicious regions within the prostate and target biopsies in real time. Exact Imaging's technology also includes a solution called FusionVu. Where an MRI is required, FusionVu allows for the quick import, alignment and targeting of MRI-identified lesions. After the MRI image is imported via FusionVu, ExactVu's 70 micron real-time resolution, allows physicians to very precisely targeting lesions.

The Distribution division, through the Group's Japanese subsidiary, exclusively distributes some urology products of the American company Laborie Medical Technologies ("Laborie") in Japan, that includes Urodynamic equipment, Uroflow, and a range of disposable products. Laborie is the world leader of Urodynamic systems and disposables which are used by urologists and gynecologists to diagnose lower urinary tract functions. The Group's Japanese subsidiary also distributes x-ray imaging systems for the diagnosis of musculoskeletal pathologies and orthopedic surgical care in Japan on behalf of French company EOS Imaging and also exclusively distributes urology accessories on behalf of Monaco's company Rocamed in Japan.

Manufacturing

Our current manufacturing operations consist of manufacturing medical products in our facility, which is FDA-registered and certified under international ISO 13485: 2016 and MDSAP standards. We manufacture our own products through our operational subsidiary EDAP TMS France.

We manufacture the critical components for our devices and accessories, unless a subcontractor can manufacture the component more cost-effectively, and we also perform final assembly and quality control processes and maintain our own set of production standards. We purchase the majority of the components used in our products from a number of suppliers, but for several components of our products, we rely on a single source. Most of single source components are secured by contract, by double sourcing or by safety stock. 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 and MDSAP certified which indicates 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, Canadian, Australian, Brazilian and South Korean 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[2]	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).
(2) EDAP Technomed Srl is not operational and is currently in liquidation.

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 which became effective on July 1, 2015. We use this facility to manufacture our device portfolio. 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), Flensburg (Germany), Austin (U.S.), Moscow (Russia), Seoul (South Korea), Fukuoka, Osaka, Sapporo and Tokyo (Japan) and 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 and 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 pre-market approval ("PMA") application 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 Sonolith i-move products is now classified by the FDA as Class II devices. Our Ablatherm and Focal One HIFU devices are also classified as Class II.

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. There are also certain requirements of state, local and foreign governments which must be

complied with in the manufacturing and marketing of our products. We believe that the manufacturing and quality control procedures we employ meet the requirements of these regulations.

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.

Regulation in the European Union

In the European Union, we annually perform ISO 13485: 2016 and MDSAP (Australia, Brazil, Canada, Japan, U.S.) certification audits, showing that we comply with standards for quality assurance, manufacturing and design control.

In 2017, the European Union enacted the new Medical Device Regulation ("MDR"). Manufacturers with currently approved medical devices in their portfolio have had an initial transition time of three years, i.e. until May 26, 2020 to meet new MDR requirements. The transition period was extended to four years, i.e. until May 26, 2021 due to COVID-19 pandemic context. The MDR introduces 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) ("MDD"). We are currently updating our organization and quality system as well as our product development to be able to handle the MDR enforcement within the expected timelines for our existing devices ranges and the devices under development. We have implemented regulatory actions to ensure our devices may be marketed in the European and international markets after May 2021.

The MDD and the MDR provide 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 MDD and MDR as applicable to bear a CE Marking (subject to certain exceptions).

Pursuant to the MDD and MDR, medical devices are classified into different classes 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 a notified 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 I, IIa and IIb devices.

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''). Our Japanese subsidiary has obtained a license as the "Marketing Authorization Holder" as well as specific marketing approvals to import and market our products in Japan. Our Japanese subsidiary is also operating as "Designated Marketing Authorization Holder" on behalf of some companies to market their products in the Japanese Territory. 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 LT-02X, 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, 2020, 2019 and 2018 is based on, and should be read in conjunction with, our consolidated financial statements and the notes thereto included in Item 18, "*Financial Statements.*" The consolidated financial statements have been prepared in accordance with U.S. GAAP.

The following discussion contains certain forward-looking statements that involve risks and uncertainties. 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 generally takes place upon delivery. Consumable revenues included in sales contract are deferred until 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) immaterial 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 services are performed.

Sales of our medical devices and sales of disposables, sales of RPPs and leases, and sales of spare parts and services, are all net of commissions.

The Company invoices its customers based on the billing schedules in its sales arrangements. Payments are generally due between one to three months from the 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 a customer can benefit from the good or service on its own or with other resources that are readily

available to the customer, and (ii) if they are a distinct good or service that is separately identifiable from other items in the multiple-element arrangement. 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 sales net of commission 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 ESWL 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. Such installation related costs are immaterial in the context of the contract with the customer and do not constitute a distinct performance obligation.

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, depending of the geographic area. Over this standard one to two years period, warranty is considered as an extension of such warranty period and constitutes a distinct performance obligation. 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. For RPPs, 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 from leases of machines are considered as immaterial.

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 immaterial 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 a type of spare part is specifically excluded from the maintenance contract terms.

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 equally 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 18.

Contract Balances:

Details on contract liabilities are reported on Note 11.

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.

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., bankruptcy 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

The recent reorganization of our activities into three divisions clarified our vision and enhanced our financial reporting of our three businesses HIFU, ESWL and Distribution. This new structure also allows for an improved measurement of our business progress.

Total revenues of the Company 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 (HIFU devices, ESWL lithotripters and other third-parties devices) and net sales of disposables (mostly Ablapaks and Focalpaks in the HIFU division, electrodes in the ESWL division and disposables from third-parties' devices marketing by the Distribution division). 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 mainly include the revenues recording in the HIFU division 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.

Regarding sales of lithotripters as recorded in our ESWL division, 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 ESWL Division to remain stable in the foreseeable future. In addition, following the discontinuation of our Sonolith i-sys lithotripter in 2020 and of our developments in lithotripsy, including the development of our Endo-UP platform, our ESWL revenues will be mainly stemming from sales of Sonolith i-move lithotripters as well as revenues from sales of maintenance contracts and spare parts.

Revenues recorded in our Distribution division include sales of complementary products such as lasers, micro-ultrasound systems and other products from third parties, including the associated disposables and maintenance contracts.

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

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 38% of our total consolidated net sales in 2020. Net sales of goods in Asia represented 43% of such sales in 2020 and consisted mainly of sales of urology devices and disposables. Net sales of spare parts, supplies and services in Asia represented 39% of such sales in 2020 and related primarily to ESWL lithotripters, reflecting the fact that 51% of the installed base of our ESWL lithotripters that we actively maintain or otherwise serve is located in Asia. See Note 18 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 2020, 74% of our costs of sales and research and development, selling, marketing and general and administrative expenses were denominated in euro, while 49% 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, ''*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 €4.5 million, €3.7 million and €4.1 million in 2020, 2019 and 2018, respectively, representing 10.8%, 8.3% and 10.4% of total revenues in 2020, 2019 and 2018, respectively. Research and development government grants and tax credits are deducted from our consolidated research and development expenses for amounts of €0.7 million, €1.0 million and €0.8 million in 2020, 2019 and 2018, respectively. Research and development expenses included net impact of allowances for depreciation of prototypes and parts in inventory of €0.5 million in 2020, following the decision to discontinue the Endo-Up platform program. Beginning in 2021, management expects the budget for research and development expenses to increase at 11.5% 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 to build reimbursement coverage in key countries and particularly in the U.S., to continue to develop our HIFU 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 €9.3 million in 2020, €10.9 million in 2019 and €10.6 million in 2018. Selling and marketing expenses included net impact of allowances for doubtful accounts of €0.1 million in 2020, €0.1 million in 2019 and €0.4 million in 2018. The €1.6 million or 14.5% decrease in selling and marketing expenses from 2019 to 2020 was primarily a result of the decrease in global sales and marketing activity in a COVID-19 context (cancelation of congresses, limitation of business trips, etc.). Management expects marketing and sales efforts to get back to higher levels as soon as the sanitary situation returns to normal and in the future to consolidate the 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 2021, management expects selling and marketing expenses to increase in connection with the acceleration of HIFU adoption in the U.S.

The novel COVID-19 virus which has profoundly impacted the whole worldwide economy in 2020 represents a new challenge for us all. We continue to closely monitor the situation and have implemented numerous precautions and protective measures to safeguard our employees and to ensure an uninterrupted supply of our devices and disposables, including requiring the majority of our employees to work remotely, adjusting supply chain activity and curtailing all business travel. In the near term, we expect this situation to continue to cause decreased activity in our recurring usual business activity with some cancellations of ESWL and HIFU treatments. We also anticipate that device sales projects may be postponed on a near-term basis as hospital purchase and investment decisions are put on hold. However, our sales cycles are long and we have in inventory several devices and accessories that are ready to be shipped when order activity resumes. The Company therefore believes to be well positioned to resume delivery activities as soon as that becomes possible. Importantly, in this unique and unknown global crisis, EDAP has a solid cash position, which is expected to minimize disruption to the extent possible. See Item 3. ''*Risk Factors*" and "*—Liquidity and Capital Resources*.''

Fiscal Year Ended December 31, 2020 Compared to Fiscal Year Ended December 31, 2019

We report our segment information on a "net contribution" basis. See Note 29 to our consolidated financial statements.

(in millions of euros)	2020	2019
Total revenues	41.7	44.9
Total net sales	41.6	44.9
Of which HIFU	11.4	14.1
Of which ESWL	12.9	14.2
Of which DISTRIBUTION	17.3	16.6
Total cost of sales	(23.3)	(23.9)
Gross profit	18.4	21.0
Gross profit as a percentage of total net sales	44.1 %	46.8 %
Total operating expenses	(18.1)	(18.8)
Income (loss) from operations	0.3	2.2
Net income (loss)	(1.7)	1.5

Total revenues

Our total revenues decreased 7.2% from €44.9 million in 2019 to €41.7 million in 2020.

HIFU division.

The HIFU division's total revenues decreased by 19.1% from €14.1 million in 2019 to €11.4 million in 2020, reflecting the impact of the ongoing COVID-19 pandemic on both procedure volumes and equipment sales.

The HIFU division's net sales of medical devices decreased 22.7% to €4.5 million in 2020, with two Ablatherm units and ten Focal One units sold, as compared to €5.9 million, with two Ablatherm units and eleven Focal One units sold in 2019.

Treatment-driven revenue, which includes net sales of RPP & leases, net sales of disposables and treatments related services, decreased by 20.1% to €5.6 million in 2020.

Net sales of HIFU maintenance services increased from €1.2 million in 2019 to €1.3 million in 2020 thanks to the increase of the installed base under contract after the warranty period.

Other HIFU-related revenues decreased to €12 thousand in 2020 from €52 thousand in 2019 and were comprised of license-based revenues from Theraclion and training to customers.

ESWL division.

The ESWL division's total revenues decreased 9.2% from €14.2 million in 2019 to €12.9 million in 2020, primarily due to the impact of the COVID-19 pandemic on both procedure volumes and equipment sales.

The ESWL division's net sales of medical devices decreased 4.9% from €5.4 million in 2019 to €5.2 million in 2020 with 33 ESWL devices sold in 2020 compared to 28 ESWL units sold in 2019 due to a change in the mix of products.

Net sales of ESWL-related consumables, spare parts, supplies, RPP, leasing and services decreased 11.9% from €8.7 million in 2019 to €7.7 million in 2020.

Distribution division.

The Distribution division's total revenues increased 4.6% from €16.6 million in 2019 to €17.3 million in 2020, primarily due to the development of Exact Imaging sales and in spite of the adverse impact of the sanitary crisis on the company's activities.

The Distribution division's net sales of medical devices slightly decreased 2.8% from €10.9 million in 2019 to €10.6 million in 2020.

Net sales of Distribution-related consumables, spare parts, supplies, RPP, leasing and services increased 18.7% from €5.7 million in 2019 to €6.8 million in 2020 due to the increase of the installed base under contract after the warranty period.

Cost of sales.

Cost of sales decreased 2.6% from €23.9 million in 2019 to €23.3 million in 2020, and represented 55.9% as a percentage of net sales in 2020, up from 53.3% as a percentage of net sales in 2019. This effect is driven primarily by the decrease in the percentage of HIFU revenue to overall revenue (since HIFU activity has better margin than the former UDS division that combined both ESWL and Distribution); and the effect of the decrease of net sales on the fixed costs.

Operating expenses.

Operating expenses decreased 3.7%, or €0.7 million, from €18.8 million in 2019 to €18.1 million in 2020.

Marketing and sales expenses decreased €1.6 million, or 14.5% to €9.3 million in 2020, reflecting the slowdown in sales and marketing activities in the COVID-19 context.

Research and development expenses increased 20.6% at €4.5 million in 2020 from €3.7 million in 2019, which included non-recurring Endo-up platform program discontinuation cost of €0.5 million, and are net of R&D grants and tax credits of €0.7 million in 2020, €1.0 million in 2019.

General and administrative expenses increased 2.6% to €4.3 million in 2020. General and administrative expenses included net impact of allowances for contingencies linked to bank fraud of €0.1 million in 2020

Operating profit (loss).

As a result of the factors discussed above, we recorded a consolidated operating income of €0.3 million in 2020, as compared to a consolidated operating income of €2.2 million in 2019.

We realized an operating loss in the HIFU division of €0.4 million in 2020, as compared with an operating profit of €0.5 million in 2019, an operating profit in the ESWL division of €1.1 million in 2020, as compared to an operating profit of €1.6 million in 2019, and an operating profit in the Distribution division of €1.1 million in 2020, as compared to an operating profit of €1.4 million in 2019.

Financial (expense) income, net.

Net financial expense was €0.1 million in 2020, compared with a net financial expense of €0.1 million in 2019.

Foreign currency exchange gain (loss), net.

In 2020, we recorded a net foreign currency exchange loss of €1.4 million, mainly due to the variation of the Euro against the U.S. Dollar, compared to an income of €0.1 million in 2019.

Income taxes.

Income tax was an expense of €0.5 million in 2020, compared to an expense of 0.7 million in 2019, reflecting the decrease of the Income before taxes

Net income / (loss).

As a result of the above, we realized a consolidated net loss of €1.7 million in 2020 compared with a consolidated net income of €1.5 million in 2019.

Fiscal Year Ended December 31, 2019 Compared to Fiscal Year Ended December 31, 2018

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 29 to our consolidated financial statements.

(in millions of euros)	2019	2018
Total revenues	44.9	39.2
Total net sales	44.9	39.2
Of which HIFU	14.1	11.0
Of which ESWL	14.2	14.5
Of which Distribution	16.6	13.7
Total cost of sales	(23.9)	(22.3)
Gross profit	21.0	16.9
Gross profit as a percentage of total net sales	46.8 %	43.2 %
Total operating expenses	(18.8)	(18.2)
Income (loss) from operations	2.2	(1.3)
Net income (loss)	1.5	(0.3)

Total revenues

Our total revenues increased 14.6% from €39.2 million in 2018 to €44.9 million in 2019.

HIFU division. The HIFU division's total revenues increased by 28.1% from €11.0 million in 2018 to €14.1 million in 2019.

The HIFU division's net sales of medical devices increased 63.8% to €5.9 million in 2019, with two Ablatherm units and eleven Focal One units sold, as compared to €3.6 million, with one Ablatherm and six Focal One units sold in 2018. This growth is primarily driven by the U.S. market activity since we sold nine HIFU devices in the U.S. in 2019 as compared to two in 2018.

Treatment-driven revenue, which includes net sales of RPP & leases, net sales of disposables and treatments related services, increased by 15.3% to €7.0 million in 2019.

Net sales of HIFU maintenance services slightly decreased from €1.3 million in 2018 to €1.2 million in 2019 in spite of the increase of the installed base, since new sold machines are still under warranty.

Other HIFU-related revenues increased to €52 thousand in 2019 from €19 thousand in 2018 and were comprised of license-based revenues from Theraclion and training to customers.

ESWL division. The ESWL division's total revenues decreased 2.0 % from €14.5 million in 2018 to €14.2 million in 2019, mostly due to the decrease in medical devices revenues.

The ESWL division's net sales of medical devices decreased 7.6% from €5.9 million in 2018 to €5.4 million in 2019 with 28 ESWL devices sold in 2019 compared to 33 ESWL units sold in 2018.

Net sales of ESWL-related consumables, spare parts, supplies, RPP, leasing and services slightly increased 1.9% from €8.6 million in 2018 to €8.7 million in 2019.

Distribution division. The Distribution division's total revenues increased 21.4 % from €13.7 million in 2018 to €16.6 million in 2019, mostly due to the increase in distribution products both in machines and consumables revenues.

The Distribution division's net sales of medical devices increased 15.0% from €9.5 million in 2018 to €10.9 million in 2019. The increase was primarily driven by the growth in the sales of lasers in Japan.

Net sales of Distribution-related consumables, spare parts, supplies, RPP, leasing and services increased 35.7% from €4.2 million in 2018 to €5.7 million in 2019, as a result of the growing installed base of distribution machines.

Cost of sales.

Cost of sales increased 7.4% from €22.3 million in 2018 to €23.9 million in 2019, and represented 53.3% as a percentage of net sales in 2019, down from 56.9% as a percentage of net sales in 2018. This improvement is driven primarily by the increase in the percentage of HIFU revenue to overall revenue (since HIFU activity has better margin than the former UDS division that combined both ESWL and Distribution); and the effect of the increase of net sales on the fixed costs.

Operating expenses.

Operating expenses increased 3.1%, or €0.6 million, from €18.2 million in 2018 to €18.8 million in 2019.

Marketing and sales expenses increased €0.3 million, or 2.8% at €10.9 million, reflecting the sales and marketing efforts on expanding the business.

Research and development expenses decreased 8.8% at €3.7 million in 2019 from €4.1 million in 2018, which included regulatory expenses for the Focal One clearance in the U.S., and are net of R&D grants and tax credits of €1.0 million in 2019 and €0.8 million 2018.

General and administrative expenses increased 17.6% to €4.2 million in 2019, mainly due to the higher level of activity and the implementation of the SAP program.

Operating profit (loss).

As a result of the factors discussed above, we recorded a consolidated operating income of €2.2 million in 2019, as compared to a consolidated operating loss of €1.3 million in 2018.

We realized an operating profit in the HIFU division of €0.5 million in 2019, as compared with an operating loss of €2.3 million in 2018, an operating profit in the ESWL division of €1.1 million in 2019, as compared to an operating profit of €1.8 million in 2018, and an operating profit in the Distribution division of €1.1 million in 2019, as compared to an operating profit of €0.5 million in 2018.

Financial (expense) income, net.

Net financial expense was €0.1 million in 2019, compared with a net financial income of €0.8 million in 2018, including a €0.9 million income due to fair value adjustments of warrants. There were no more outstanding warrants at the end of 2018 and 2019.

Foreign currency exchange gain (loss), net.

In 2019, we recorded a net foreign currency exchange income of €0.1 million, mainly due to the variation of the Euro against the U.S. Dollar and the Japanese Yen, compared to an income of €0.5 million in 2018.

Income taxes.

Income tax was an expense of €0.7 million in 2019, compared to an expense of 0.4 million in 2018, reflecting the growth of the Income before taxes

Net income / (loss).

As a result of the above, we realized a consolidated net income of €1.5 million in 2019 compared with a consolidated net loss of €0.3 million in 2018.

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, 2020.

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. As our expansion plans in the United States are implemented, we anticipate additional capital resources may be needed to implement our strategy.

(in thousands of euros)	2020	2019	2018
Net cash generated by/(used in) in operating activities	1,977	3,800	175
Net cash generated by/(used in) in investing activities	(2,011)	(1,532)	(1,569)
Net cash generated by/(used in) in financing activities	3,201	(664)	1,178
Net effect of exchange rate changes	642	(182)	(323)
Net increase/(decrease) in cash and cash equivalents	3,810	1,422	(539)
Cash and cash equivalents at the beginning of the year	20,886	19,464	20,004
Cash and cash equivalents at the end of the year	24,696	20,886	19,464

Our cash position as of December 31, 2020, 2019 and 2018, was €24.7 million (with no short-term treasury investments), €20.9 million (with no short-term treasury investments) and €19.5 million (with no short-term treasury investments), respectively. We experienced positive cash flows of €3.8 million in 2020, positive cash flows of €1.4 million in 2019 and negative cash flows of €0.5 million in 2018.

In 2020, our positive net cash flow was primarily due to net cash generated by financing activities which included COVID-related assistance loans for €4.6 million. In 2019, our positive net cash flow was primarily due to the high level of cash generated by operating activities, partly offset by cash used in investing activities and net cash used in financing activities which included a repayment of long term borrowing (€1.1 million). 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 2020, net cash generated by operating activities was €2.0 million compared with net cash generated by operating activities of €3.8 million in 2019, and compared with net cash generated by operating activities of €0.2 million in 2018.

In 2020, net cash generated by operating activities reflected principally:

- a net loss of €1.7 million;
- elimination of €3.8 million of net loss without effects on cash, including €2.1 million of depreciation and amortization, €0.7 million of change in allowances for doubtful accounts & slow-moving inventories and €0.5 million in long term provisions and €0.2 million of non-cash compensation linked to stock-options plans; and
- a slight increase in working capital of €0.1 million reflecting the slowdown of activity due to the COVID-19, offset by the high level of net sales recorded in December 2020 as compared to December 2019.

In 2019, net cash generated by operating activities reflected principally:

- a net income of €1.5 million;
- elimination of €2.3 million of net loss without effects on cash, including €1.9 million of depreciation and amortization and €0.3 million of non-cash compensation linked to stock-options plans; and
- an unchanged level in working capital reflecting the growth of activity on the inventories level, offset by the lower level of net sales recorded in December 2019 as compared to December 2018.

In 2018, net cash generated by operating activities reflected principally:

- a net loss of €0.3 million;
- 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; and
- 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 has been collected in 2019.

In 2020, net cash used in investing activities was €2.0 million compared with net cash used in investing activities of €1.5 million in 2019 and compared with net cash used in investing activities of €1.6 million in 2018.

Net cash used in investing activities of €2.0 million in 2020 reflected mainly:

- investments of €1.3 million in capitalized assets produced by the Company: devices for RPP activity (€0.1 million), HIFU treatments probes (€0.9 million) and R&D program (€0.1 million); and
- investment of €0.5 million in property, equipment (including €0.4 million of laser and Exact Imaging equipments for demo and RPP) and IT and offices equipment (€0.1 million).

Net cash used in investing activities of €1.5 million in 2019 reflected mainly:

- investments of €1.0 million in capitalized assets produced by the Company (devices), mostly for RPP activity (€0.3 million), HIFU treatments probes (€0.4 million) and R&D program (€0.3 million); and
- investment of €0.4 million in property, equipment (including €0.2 million of equipment for demo) and IT and offices equipment (€0.2 million).

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);
- 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.

In 2020, net cash generated in financing activities was €3.2 million compared with net cash used in financing activities of €0.7 million in 2019 compared with net cash generated in financing activities of €1.2 million in 2018.

Net cash generated in financing activities of €3.2 million in 2020 reflected principally the net proceeds of €0.1 million from the exercise of stock options, new long terms borrowings for €4.8 million (mainly composed of COVID-19 government assistance programs: € 4.0 million guaranteed by the French government, €0.4 million from Japan and €0.2 million from the U.S. Paycheck Protection Program), the repayments of long-term borrowings and financing lease for €0.8 million and a decrease of short-term borrowings of €0.9 million.

Net cash used in financing activities of €0.7 million in 2019 reflected principally the net proceeds of €0.3 million from the exercise of stock options, the new long term borrowings of €0.7 million in Japan, the repayments of long-term borrowings and financing lease for €1.5 million (including €0.7 million of early repayment in Japan) and a decrease of short-term borrowings of €0.2 million.

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.

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, 2020, 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, 2020 (in thousands of euros)

	Payments Due by Period				
	Total	Less than 1 year	1-3 years	4-5 years	More than 5 years
Short-Term Debt	2,638	2,638	—	—	—
Long-Term Debt	5,675	4,532	732	356	54
Financing Lease Obligations	899	344	456	93	5
Operating Leases Obligations	1,901	802	904	195	—

Recent Accounting Pronouncements

See "*Note 1. Summary of Significant Accounting Policies —1.25 Recent 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 Item 5, "*Operating and Financial Review and Prospects—Operating Results—Overview*" and Item 4, ''*Information on the Company—HIFU Division—HIFU Division Patents and Intellectual Property*'' and ''*Information on the Company—ESWL Division—ESWL 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, 2020, we had no off-balance sheet arrangements.

Item 6. Directors, Senior Management and Employees

Senior Executive Officers

The following table sets forth the name, age and position of each of our Senior Executive Officers as of April 7, 2021. 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 €0.7 million.

Name	Position
Marc Oczachowski Age: 51	Chief Executive Officer of EDAP TMS S.A. and Chairman of the Board of Directors President of EDAP TMS France SAS and EDAP Technomed, Inc. Marc Oczachowski joined EDAP TMS in 1997 as Area Sales Manager. From 2001 to 2004, he was General Manager of EDAP Technomed Malaysia. In 2004, he was appointed Chief Operating Officer of EDAP TMS based in Lyon, France, and became Chief Executive Officer of the Company in 2007. In 2012, he relocated in Austin, Texas (USA), for a five years period, to manage U.S. operations and lead the FDA approval process of the Company's HIFU devices. On March 25, 2020, he was appointed Chairman of the Board of Directors. He started his career as Area Sales Manager for Sodem Systems - power tools for orthopedics. He is graduated from Lyon I University (Molecular Biology), and from Institut Commercial de Lyon, France.
François Dietsch Age: 45	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. He was also appointed Director and treasurer of EDAP Technomed Inc. in January 2020 and Internal Auditor of Edap Technomed Co. Limited in March 2020. 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. On March 25, 2020, the Board of Directors accepted the resignation of Mr. Philippe Chauveau as Chairman of the Board and, upon the recommendation of the Company's Nomination Committee, the Board decided to combine the roles of Chairman of the Board and Chief Executive Officer, as permitted by the Company's by-laws, and elected Mr. Marc Oczachowski as the new Chairman 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 (except for those related to Mr. Oczachowski's position as Chief Executive Officer, provided under his employment agreement). Four Board members out of five are independent within the meaning of NASDAQ Marketplace Rule 5605(2). The mandate of four of our Directors was renewed for a new period of six years at the General Meeting of Shareholders held on June 30, 2020 approving the accounts for the financial year ended December 31, 2019. Their mandate will expire at the end of the ordinary general meeting of

shareholders which will approve the accounts for the financial year ended December 31, 2025, i.e., in the course of 2026. On June 30, 2020, Ms. Marie Meynadier was elected as independent Director in replacement of Mr. Philippe Chauveau.

Marc Oczachowski Age: 51 Mandate: 6 years Appointment: July 1, 2017 Expiration: 2022	Chairman of the Board. See Marc Oczachowski's biography above.
Pierre Beysson Age: 78 Mandate: 6 years Appointment: September 27, 2002 (renewed in 2014 & 2020) Expiration: 2025	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: 73 Mandate: 6 years Appointment: June 25, 2009 (renewed in 2014 & 2020) Expiration: 2025	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. 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 Age: 71 Mandate: 6 years Appointment: July 16, 2009 (renewed in 2014 & 2020) Expiration: 2025	Rob Michiels was elected as a member of the Company's Board of Directors in July 2009. He is a 40-year U.S. veteran of the medical device industry. He most recently served as Chief Executive 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 Conveyor 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.
Marie Meynadier Age: 59 Mandate: 6 years Appointment: June 30, 2020 Expiration: 2025	Marie Meynadier was elected as a member of the Company's Board of Directors in June 2020. Ms. Meynadier currently serves on the Boards of Directors of several medical technology companies in Europe and North America. From 1999 through 2018, she served at EOS Imaging as its CEO and led the company through a period of rapid worldwide sales growth, increasing at a CAGR of 32% from 2012 to 2017. Prior to EOS Imaging, Ms. Meynadier served as CEO at Biospace Lab, a preclinical imaging company she developed and turned to profitability. Ms. Meynadier received a degree in electrical engineering from Sup Télécom, Paris, and her Ph.D. in physics from Ecole Normale Supérieure Ulm, Paris.

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 2020 was €536 thousand including performance bonuses of €99 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 2020. 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."

Compensation Committee

The Compensation Committee is comprised of the following independent members: Mr. Pierre Beysson, Dr. Argil Wheelock, Ms. Marie Meynadier 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, Ms. Marie Meynadier, 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, and

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 the 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 including evaluation of potential candidates, and recommendations to the Board of Directors prior to submitting the candidates to the vote of shareholders. 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 Nomination Committee composed exclusively of independent Directors. The Nomination Committee is comprised

of the following independent members: Mr. Pierre Beysson, Dr. Argil Wheelock, Ms. Marie Meynadier and Mr. Rob Michiels.

Strategic Committee

On August 26, 2020, the Company's Board of Directors created a Strategic Committee which duties are to address the development and implementation of the Company's strategic plan and the risks associated with such plan. Such responsibility has been further formalized by a charter approved by the Board of Directors. The Strategic committee is composed of the following members: Ms. Marie Meynadier, independent Director and Head of the Committee, and Mr. Marc Oczachowski, Chief Executive Officer and Chairman of the Board.

Employees

As of December 31, 2020, we employed 223 individuals on a full-time basis, as follows:

	Sales & Marketing	Manufac-turing	Service	Research & Dvpt	Regula-tory	Clinical Affairs	Adminis-trative	Total
France	25	30	23	22	8	8	17	133
Germany	5	—	3	—	—	—	2	10
Japan	27	—	17	—	2	—	6	52
Malaysia	2	—	4	—	—	—	2	8
South Korea	2	—	4	—	—	—	1	7
USA	6	—	4	—	—	—	3	13
Total	67	30	55	22	10	8	31	223

As of December 31, 2019, we employed 216 individuals on a full-time basis, as follows:

	Sales & Marketing	Manufac-turing	Service	Research & Dvpt	Regula-tory	Clinical Affairs	Adminis trative	Total
France	23	31	24	21	7	9	15	130
Italy	2	—	—	—	—	—	2	4
Germany	7	—	—	—	—	—	2	9
Japan	24	—	16	—	3	—	6	49
Malaysia	2	—	3	—	—	—	2	7
South Korea	2	—	4	—	—	—	1	7
USA	6	—	1	—	—	—	3	10
Total	66	31	48	21	10	9	31	216

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	—	—	—	—	—	2	5
Germany	4	—	3	—	—	—	2	9
Japan	21	—	16	—	3	—	6	46
Malaysia	2	—	3	—	—	—	2	7
South Korea	2	—	3	—	—	—	1	6
USA	7	—	2	—	1	2	4	16
Total	64	32	47	18	10	11	33	215

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

Share Ownership

As of March 30, 2021, the total number of shares issued was 29,488,564 with 292,428 shares held as treasury shares, thus bringing the total number of shares outstanding to 29,196,136.

As of March 30, 2021, the Board of Directors and the Senior Executive Officers of the Company held a total of 77,804 Shares. The Board of Directors and Senior Executive Officers beneficially own, in the aggregate less than 1% of the Company's shares.

As of March 30, 2021, Senior Executive Officers held a total of 32,001 Shares and an aggregate of 540,000 options to purchase or to subscribe a total of 540,000 ordinary shares, with a weighted average exercise price of €2.78 per share. Of these options, 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 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.

On June 28, 2019, the shareholders authorized the Board of Directors to grant up to a maximum of 358,528 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 June 28, 2019, the shareholders also authorized the Board of Directors to grant up to 1 million options to subscribe to 1 million new shares at a fixed price to be set by the Board of Directors. No options were granted under these two plans as of March 30, 2021.

As of March 30, 2021, we had sponsored three stock purchase and subscription option plans open to employees of EDAP TMS group.

On December 31, 2020, the expiration of our stock option contracts was as follows:

Date of expiration	Number of Options
January 18, 2023	262,500
April 25, 2026	465,000
April 26, 2027	184,400
August 25, 2028	145,000
April 4, 2029	130,000

As of December 31, 2020, a summary of stock option activity to purchase or to subscribe to shares under these plans is as follows:

	2020		2019		2018	
	Options	Weighted average exercise price (€)	Options	Weighted average exercise price (€)	Options	Weighted average exercise price (€)
Outstanding on January 1,	1,273,900	2.78	1,347,600	2.61	1,207,600	2.61
Granted			155,000	3.90	165,000	2.65
Exercised	(23,750)	2.54	(143,700)	2.16	—	—
Forfeited	(21,250)	2.55	(85,000)	1.94	(25,000)	3.05
Expired	(42,000)	2.38	—	—	—	—
Outstanding on December 31,	1,186,900	2.81	1,273,900	2.78	1,347,600	2.61
Exercisable on December 31,	970,650	2.73	818,900	2.60	772,600	2.44
Share purchase options available for grant on December 31	292,428		250,428		250,428	

The following table summarizes information about options to purchase existing shares held by the Company, or to subscribe to new Shares, as of December 31, 2020:

	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
3.90	130,000	8.8	3.90	42,576	32,500	3.90	13,017
3.22	465,000	5.3	3.22	468,492	465,000	3.22	468,492
2.65	145,000	7.7	2.65	228,739	72,500	2.65	114,369
2.39	184,400	6.3	2.39	338,837	138,150	2.39	253,852
1.91	262,500	2.0	1.91	608,346	262,500	1.91	608,346
1.91 to 3.90	1,186,900	6.0	2.81	1,686,989	970,650	2.73	1,458,076

(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 $5.17 at December 31, 2020, 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 have been or are beneficial owners of more than 5% of our shares over 2018 and 2019. As of April 16, 2020, only Opaleye Management Inc. filed a report showing an increase in its ownership interest in the Company to 1,785,000 ADSs, representing 6.1% of our outstanding ADSs. As of April xx, 2021, Opaleye Management Inc. had decreased its ownership interest in the Company to 657,500 ADSs representing 2.2% of our outstanding ADRs.

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 March 30, 2021, 29,488,564 shares were issued, including 29,196,136 outstanding and 292,428 treasury shares. At March 15, 2021, there were 29,475,814 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

On August 19, 2019, EDAP Technomed Co. Ltd. (Japan) contracted a loan for 80,000,000 JPY. As a current practice in Japan, this loan required a personal guarantee from the representative director, president and CEO of the subsidiary, Mr. Jean-François Bachelard. EDAP TMS S.A., as the parent company, counter-guaranteed this personal loan and agreed to indemnify Mr. Bachelard, in an indemnification letter dated September 12, 2019, expiring upon loan maturity date of August 26, 2026.

On March 27, 2019, EDAP Technomed Sdn Bdh (Malaysia) contracted with Maybank to establish a fixed deposit amounting 65,464.85 MYR. As a current practice in Malaysia, any fixed deposit requires a personal warranty from the representative director, president and CEO of the subsidiary Mr. Hervé de Soultrait. EDAP TMS S.A., as the parent company, counter-warranted this deposit and agreed to indemnify Mr. de Soultrait, in an indemnification letter dated September 13, 2019, which expired upon loan maturity date of March 27, 2020.

On August 2, 2019, EDAP Technomed Inc. contracted a car lease for $28,756.44. This lease required a personal guarantee from the president of the subsidiary, Mr. Marc Oczachowski. EDAP TMS S.A., as the parent company, counter-

guaranteed this personal lease warranty and agreed to indemnify Mr. Marc Oczachowski, in an indemnification letter dated July 1, 2019, expiring upon the car lease maturity date of July 2, 2022.

On April 22, 2020, EDAP Technomed Co. Ltd (Japan) contracted another loan for 50,000,000 JPY requiring a personal guarantee from the representative director, president and CEO of the subsidiary, Mr. Jean-François Bachelard. EDAP TMS S.A., as the parent company, counter-guaranteed this personal loan and agreed to indemnify Mr. Bachelard, in an indemnification letter dated June 2, 2020, expiring upon loan maturity date of April 2, 2025.

On September 2, 2020, a consulting agreement was established between Mr. Philippe Chauveau, Chairman of the Board of the Company until June 23, 2020 (date of expiration of his mandate as a Director) and the Company. As per this agreement, Mr. Chauveau, is to provide Mr. Oczachowski, new Chairman of the Board, with advice and recommendations on various subjects related to the Company's activity and strategic projects. This consulting agreement can be terminated at any time with 30-day's notice. For the period ending December 31, 2020, the Company paid €6,000 under this contract.

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, 2020, total consolidated export net sales, which we define as sales made outside of mainland France, were €31.6 million, which represented 76% 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, we did not invoice any medical equipment to the hospitals in 2018, 2019 and 2020.

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 2015 through 2019, 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 7, 2021

N/A

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. (''The 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 updated on June 30, 2020 to reflect French legal provisions recently implemented and on March 30, 2021 to reflect the latest increases in share capital related to the issuance of additional shares following the exercise of warrants and options.

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 2025. Mr. Marc Oczachowski, Chief Executive Officer, and newly elected Chairman of the Board as of March 25, 2020, 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.

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 or combined. The choice between these two methods of management belongs to the Board of Directors and must be made pursuant to our by-laws and applicable French law.

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.

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. On March 31, 2007, the Board of Directors appointed Mr. Marc Oczachowski

as Chief Executive Officer and on March 25, 2020, the Board of Directors decided to combine the roles of Chairman of the Board and Chief Executive Officer, as allowed by the Company's by-laws, and elected Mr. Marc Oczachowski as the new Chairman of the Board of Directors.

The Chief Executive Officer is vested with the powers to act under all circumstances on behalf of the Company, within the limits set out by the Company's corporate purposes, and subject to the powers expressly granted by the 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, as a company whose shares are not admitted to trading on a regulated market subject to the provisions of Article L. 433-3 II of the French Monetary and Financial Code, may not acquire its own shares except (a) to reduce its share capital under certain circumstances with the approval of the shareholders at an extraordinary general meeting, (b) to provide shares for distribution to employees under a profit sharing or a stock option plan, (c) to offer shares as payment in exchange for assets acquired by the Company in the context of an external growth, merger, demerger or contribution transaction or (d) to provide shares to shareholders as part of a sale procedure organized by the Company. However, the Company may not hold more than 10% of its shares then-issued and 5% for a repurchase of shares to offer them as payment or in exchange for assets acquired by the Company in the context of an external growth, merger, demerger or contribution transaction. 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, 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. Article 4 of Order no. 2020-321 of March 25, 2020, Adapting the Rules for Meetings and Deliberations of the Meetings and Governing Bodies of French Legal Entities and Entities without Legal Personality under Private Law due to the COVID-19 Epidemic, as amended by Decree no. 2021-255 of March 9, 2021, provides that the Shareholders' Meeting may exceptionally be held ''behind closed doors'' without the shareholders and other persons entitled to attend being physically present. These provisions are applicable until July 31, 2021.

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 registered capital or by an interested party under certain circumstances, or, in case of an urgent matter, by the Work Council (*Comité Social et Economique*) 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 to the Company. Under French law, a proxy that is returned without instructions will be counted as present for purposes of the quorum and will be counted (i) in favor of the adoption of the draft resolutions presented or approved by the Board of Directors and (ii) against the adoption of all other draft resolutions which were not expressly presented or approved by the Board of Directors.

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.

As a result of a recent change in French law, as of the General Meeting of Shareholders approving the 2019 accounts, abstention from voting, blank votes and null votes by those present or those represented by proxy or voting by mail are no longer counted as votes against the resolution submitted to a shareholder vote at any of the two types of meetings.

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.

Nevertheless, any investment: (i) by (a) any non-French citizen, (b) any French citizen not residing in France, (c) any non-French entity or (d) any French entity controlled by one of the aforementioned individuals or entities; (ii) that

will result in the relevant investor (a) acquiring control of an entity having its registered office in France, (b) acquiring all or part of a business line of an entity having its registered office in France, or (c) for non-EU or non-EEA investors crossing, directly or indirectly, alone or in concert, a 25% threshold of voting rights in an entity having its registered office in France; and (iii) developing activities in certain strategic industries related to: (a) activities likely to prejudice national defense interests, participating in the exercise of official authority or likely to prejudice public order and public security (including activities related to weapons, dual-use goods and technologies, IT systems, cryptology, data capturing devices, gambling, toxic agents or data storage), (b) activities relating to essential infrastructure, goods or services (including energy, water, transportation, space, telecom, public health, farm products or media), (c) research and development activities related to critical technologies (including cybersecurity, artificial intelligence, robotics, additive manufacturing, semiconductors, quantum technologies, energy storage or biotechnology) or dual-use goods and technologies, is subject to the prior authorization of the French Minister of Economy, which authorization, if granted, may be subject to certain undertakings. This request for prior authorization must be filed with the French Ministry of Economy, which has 30 business days from receipt of the complete file to provide a first decision which may (i) unconditionally authorize the investment or (ii) indicate that further examination is required. In the latter case, the French Ministry of Economy must make a second decision within 45 business days from its first decision. In case of lack of response from the French Ministry of Economy within the above mentioned timeframe, the authorization will be deemed refused. If the authorization is granted, it may be subject to the signature of a letter of undertakings aimed at protecting the French national interests. If an investment requiring the prior authorization of the French Minister of Economy is completed without such authorization having been granted, the French Minister of Economy might direct the relevant investor to (i) submit a request for authorization, (ii) have the previous situation restored at its own expense, or (iii) amend the investment. The relevant investor might also be found criminally liable and might be sanctioned with a fine which cannot exceed the greater of: (i) twice the amount of the relevant investment, (ii) 10% of the annual turnover before tax of the target company and (iii) €5 million (for a company) or €1 million (for an individual).

The French Monetary and Financial Code (CMF) provides for statistical reporting requirements. Transactions by which non-French residents acquire at least 10% of the share capital or voting rights, or cross the 10% threshold, of a French resident company, are considered as foreign direct investments in France and are subject to statistical reporting requirements (Articles R. 152-1; R.152-3 and R. 152-11 of the CMF). When the investment exceeds €15,000,000, companies must declare foreign transactions directly to the Banque de France within 20 business days following the date of certain direct foreign investments in us, including any purchase of ADSs. Failure to comply with such statistical reporting requirement may be sanctioned by five years' imprisonment and a fine of a maximum amount equal to twice the amount which should have been reported, in accordance with Article L 165-1 of the CMF. This amount may be increased fivefold if the violation is made by a legal entity.

Certain Exemptions (US 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. In addition, a substantial portion of our assets is located outside of the United States. As a result, it may be difficult for investors:

- to obtain jurisdiction over us or our non-U.S. resident officers and directors in U.S. courts, or obtain evidence in France or from French citizen or any individual being resident in France or any officer, representative, agent or employee of a legal person having its registered office or an establishment in a territory of France, in connection with those actions in actions predicated on the civil liability provisions of the U.S. federal securities laws;
- to enforce in U.S. courts judgments obtained in such actions against us or our non-U.S. resident officers and directors;

- to bring an original action in a French court to enforce liabilities based upon the U.S. federal securities laws against us or our non-U.S. resident officers or directors; and
- to enforce in U.S. courts against us or our directors in non-U.S. courts, including French courts, judgments of U.S. courts predicated upon the civil liability provisions of the U.S. federal securities laws.

Nevertheless, a final judgment for the payment of money rendered by any federal or state court in the United States based on civil liability, whether or not predicated solely upon the U.S. federal securities laws, would be recognized and enforced in France provided that a French judge considers that this judgment meets the French legal requirement concerning the recognition and the enforcement of foreign judgments and is capable of being immediately enforced in the United States. A French court is therefore likely to grant the enforcement of a foreign judgment without a review of the merits of the underlying claim, only if (i) the judgment was rendered by a court having jurisdiction over the matter as the dispute is clearly connected to the jurisdiction of such court, the choice of the U.S. court was not fraudulent and the French courts did not have exclusive jurisdiction over the matter, (ii) the judgment does not contravene the international public policy rules, both pertaining to the merits and to the procedure of the case, including the defense rights, (iii) the judgment is not tainted with fraud and (iv) the judgment does not conflict with a French judgment or a foreign judgment (or an arbitral award) which has become effective in France. In addition, French law guarantees full compensation for the harm suffered but is limited to the actual damages, so the victim does not suffer or benefit from the situation, it being specified that under French law, the principle of awarding punitive damages is not, *per se*, contrary to public order, provided the amount awarded is not disproportionate to the harm suffered and the defendant's breach.

As a result, the enforcement, by U.S. investors, of any judgments obtained in U.S. courts in civil and commercial matters, including judgments under the U.S. federal securities law against us or members of our Board of Directors, officers or certain experts named herein who are residents of France or countries other than the United States would be subject to the above conditions.

Finally, there may be doubt as to whether a French court would impose civil liability on us, the members of our Board of Directors, our officers or certain experts named herein in an original action predicated solely upon the U.S. federal securities laws brought in a court of competent jurisdiction in France against us or such members, officers or experts, respectively.

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

General

The following generally summarizes the material French and U.S. federal income tax consequences to U.S. holders (as defined below) of purchasing, owning and disposing of ADSs and shares (collectively the "Securities"). 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 the Securities. All of the following is subject to change. Such changes could apply retroactively and could affect the consequences described below.

This summary does not constitute a legal opinion or tax advice. Holders are urged to consult their own tax advisers regarding the tax consequences of the purchase, ownership and disposition of Securities in light of their particular circumstances, including the effect of any U.S. federal, state, local or other national tax laws.

A set of tax rules is applicable to French assets that are held by or in foreign trusts. These rules provide *inter alia* for the inclusion of trust assets in the settlor's net assets for purpose of applying the French real estate wealth tax, for the application of French gift and death duties to French assets held in trust, for a specific tax on capital on the French assets

of foreign trusts not already subject to the French real estate wealth tax and for a number of French tax reporting and disclosure obligations. The following discussion does not address the French tax consequences applicable to Securities held in trusts. *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.*

The description of the French and U.S. federal income tax consequences set forth below is based on the laws (including, for U.S. federal income tax purposes, the Internal Revenue Code of 1986, as amended (the "Code"), final, temporary and proposed U.S. Treasury Regulations promulgated thereunder and administrative and judicial interpretations thereof) in force as of the date of this annual report, 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 any subsequent protocols, including the protocol of January 13, 2009), and the tax regulations issued by the French tax authorities within the *Bulletin Officiel des Finances Publiques-Impôts* (the "Regulations") in force as of the date of this report. *U.S. holders are advised to consult their own tax advisers regarding their eligibility for Treaty benefits, especially with regard to the "Limitations on Benefits" provision, in light of their own particular circumstances.*

No advance ruling has been obtained with respect to the tax consequences of the acquisition, ownership or disposition of the Securities from either the French or U.S. tax authorities. Thus, there can no assurances that one or both of such authorities will not take a position concerning the such tax consequences different from that set out herein or that such a position would not be sustained by a court.

For the purposes of this discussion, a U.S. holder is a beneficial owner of Securities that is (i) an individual who is a U.S. citizen or resident for U.S. federal income tax purposes, (ii) a U.S. domestic corporation or certain other entities created or organized in or under the laws of the United States or any state thereof, including the District of Columbia, or (iii) otherwise subject to U.S. federal income taxation on a net income basis in respect of Securities. A non-U.S. holder is a person other than a U.S. holder.

If a partnership holds Securities, the tax treatment of a partner generally will depend upon 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 adviser regarding the specific tax consequences of acquiring, owning and disposing of Securities.*

This discussion is intended only as a general summary and does not purport to be a complete analysis or listing of all potential tax effects of the acquisition, ownership or disposition of the Securities to any particular investor, and does not discuss tax considerations that arise from rules of general application or that are generally assumed to be known by investors. The discussion applies only to investors that hold the Securities as capital assets that have the U.S. dollar as their functional currency, that are entitled to Treaty benefits under the "Limitation on Benefits" provision contained in the Treaty, and whose ownership of the Securities is not effectively connected to a permanent establishment or a fixed base in France. Certain holders (including, but not limited to, U.S. expatriates, partnerships or other entities classified as partnerships for U.S. federal income tax purposes, banks, insurance companies, regulated investment companies, tax-exempt organizations, financial institutions, persons subject to the alternative minimum tax, persons who acquired the Securities pursuant to the exercise of employee stock options or otherwise as compensation, persons that own (directly, indirectly or by attribution) 5% or more of the Company's voting stock or 5% or more of the Company's outstanding share capital, dealers in securities or currencies, persons that elect to mark their securities to market for U.S. federal income tax purposes, and persons holding Securities as a position in a synthetic security, straddle or conversion transaction) may be subject to special rules not discussed below. *Holders of Securities are advised to consult their own tax advisers with regard to the application of French tax law and U.S. federal tax law to their particular situations, as well as any tax consequences arising under the laws of any state, local or other foreign jurisdiction.*

French Taxes

Estate and gift taxes and transfer taxes

In general, a transfer of Securities by gift or by reason of death of a U.S. holder that would otherwise be subject to French gift or inheritance tax, respectively, will not be subject to such French tax by reason 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 Estates, Inheritances and Gifts, dated November 24, 1978, unless the donor or the transferor is domiciled in France at the time of making the gift or at the time

of his or her death, or the Securities were used in, or held for use in, the conduct of a business through a permanent establishment or a fixed base in France.

Pursuant to Article 235 ter ZD of the French General Tax Code, purchases of certain securities issued by a French company, including 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) 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 French General Tax Code has been published by the French tax authorities in its official guidelines on December 23, 2020 (BOI-ANNX-000467-23/12/2020). The Company was not included in such list as its market capitalization did not exceed €1.0 billion as at December 1, 2020. 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 French Monetary and Financial Code are subject to uncapped registration duties at the rate of 0.1% notwithstanding the existence of a written statement (*acte*). As shares of the Company are not listed, their transfer should be subject to uncapped registration duties at the rate of 0.1% notwithstanding the existence of a written agreement (*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.

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. French real estate wealth tax applies only to individuals and does not generally apply to the Securities if the holder is a U.S. resident, as defined pursuant to the provisions of the Treaty, provided that the individual does not own directly or indirectly a shareholding exceeding 10% of the financial rights and voting rights.

U.S. Taxes

Ownership of the securities

Deposits and withdrawals by a U.S. holder of shares in exchange for ADSs, will not be taxable events for U.S. federal income tax purposes. For U.S. tax purposes, holders of ADSs will be treated as owners of the shares represented by such ADSs. Accordingly, the discussion that follows regarding the U.S. federal income tax consequences of acquiring, owning and disposing of shares is equally applicable to ADSs.

Information reporting and backup withholding tax

Distributions made to holders and proceeds paid from the sale, exchange, redemption or disposal of Securities may be subject to information reporting to the Internal Revenue Service. Such payments may be subject to backup withholding taxes 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 to establish that it is an exempt recipient. Backup withholding is not an additional tax. Amounts withheld as backup withholding may be credited against a holder's U.S. federal income tax liability. A holder may obtain a refund of any excess amounts withheld under the backup withholding rules by filing the appropriate claim for refund with the Internal Revenue Service and furnishing any required information.

Foreign asset reporting

In addition, a U.S. holder that is an individual (and, to the extent provided in future regulations, an entity), may be subject to recently-enacted reporting obligations with respect to shares and ADSs if the aggregate value of these and certain other "specified foreign financial assets" exceeds $50,000. If required, this disclosure is made by filing Form 8938 with the U.S. Internal Revenue Service. Significant penalties can apply if holders are required to make this disclosure and

fail to do so. In addition, a U.S. holder should consider the possible obligation to file online a FinCEN Form 114 - Foreign Bank and Financial Accounts Report as a result of holding shares or ADSs. Holders are encouraged to consult their U.S. tax advisors with respect to these and other reporting requirements that may apply to their acquisition of shares and ADSs.

State and local taxes

In addition to U.S. federal income tax, U.S. holders of Securities may be subject to U.S. state and local taxes with respect to such Securities. *Holders of Securities are advised to consult their own tax advisers with regard to the application of U.S. state and local income tax law to their particular situation.*

ADSs and Shares

French Taxes

Taxation of dividends

Under French law, dividends paid by a French corporation, such as the Company, to non-residents of France are generally subject to French withholding tax at a rate of 26.5% (12.8% for distributions made to 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 paragraph 2 of the French General Tax Code if its head office were located in France and which meet the criteria set forth in the Regulations BOI-RPPM-RCM-30-30-10-70-24/12/2019, nº 130). Dividends paid by a French corporation, such as the Company, towards non-cooperative States or territories, as defined in Article 238-0 A of the French General Tax Code, will generally 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; however, eligible U.S. holders entitled to Treaty benefits under the "Limitation on Benefits" provision contained in the Treaty who are U.S. residents, as defined pursuant to the provisions of the Treaty and who receive dividends in non-cooperative States or territories, will not be subject to this 75% withholding tax rate.

Under the Treaty, the rate of French withholding tax on dividends paid to an eligible U.S. holder who is a U.S. resident as defined pursuant to the provisions of the Treaty and whose ownership of the shares or ADSs 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 but are U.S. residents, as defined pursuant to the provisions of the Treaty, the requirements for eligibility for Treaty benefits, including the reduced 5% or 15% withholding tax rates contained in the "Limitation on Benefits" provision of the Treaty, are complicated, and certain technical changes were made to these requirements by 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.

Dividends paid to an eligible U.S. holder may immediately be subject to the reduced rates of 5% or 15% provided that such holder establishes before the date of payment that it is a U.S. resident under the Treaty by completing and providing the depositary with a treaty form (Form 5000). Dividends paid to a U.S. holder that has not filed the Form 5000 before the dividend payment date will be subject to French withholding tax at the rate of 26.5% and then reduced at a later date to 5% or 15%, provided that such holder duly completes and provides the French tax authorities with the treaty forms Form 5000 and Form 5001 before December 31 of the second calendar year following the year during 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.

The depositary agrees to use reasonable efforts to follow the procedures established, or that may be established, by the French tax authorities (i) to enable eligible U.S. holders to qualify for the reduced withholding tax rate provided by the Treaty, if available at the time the dividends are paid, or (ii) to recover any excess French withholding taxes initially withheld or deducted with respect to dividends and other distributions to which such U.S. holders may be eligible from the French tax authorities and (iii) to recover any other available tax credits. In particular, associated forms (including Form 5000 and Form 5001, together with their instructions), will be made available by the depositary to all U.S. holders registered with the depositary, and are also generally available from the U.S. Internal Revenue Service.

The withholding tax refund, if any, ordinarily is paid within 12 months of filing the applicable French Treasury Form, but not before January 15 of the year following the calendar year in which the related dividend is paid.

Tax on sale or other disposition

In general, under the Treaty, a U.S. holder who is a U.S. resident for purposes of the Treaty will not be subject to French tax on any capital gain from the redemption (other than redemption proceeds characterized as dividends under French domestic law), sale or exchange of shares or ADSs unless the shares or the ADSs form part of the business property of a permanent establishment or fixed base that the U.S. holder has in France. Special rules apply to holders who are residents of more than one country.

U.S. Taxes

Taxation of dividends

For U.S. federal income tax purposes, the gross amount of any distribution paid to U.S. holders (that is, the net distribution received plus any tax withheld therefrom) will be treated 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). Dividends paid by the Company will not be eligible for the dividends-received deduction generally allowed to corporate U.S. holders.

Subject to certain exceptions for short-term and hedged positions, the U.S. dollar amount of dividends received by an individual U.S. holder with respect to the ADSs or shares is currently subject to taxation at a maximum rate of 20% if the dividends are "qualified dividends". Dividends paid on the shares or ADSs will be treated as qualified dividends if (i) the issuer is eligible for the benefits of a comprehensive income tax treaty with the United States that the Internal Revenue Service has approved for the purposes of the qualified dividend rules and (ii) the issuer 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 ("PFIC"). The Treaty has been approved for the purposes of the qualified dividend rules. Based on the Company's financial statements and relevant market and shareholder data, the Company believes it was not a PFIC for U.S. federal income tax purposes with respect to its 2020 taxable year. In addition, based on its current expectations regarding the value and nature of its assets, the sources and nature of its income, and relevant market and shareholder data, the Company does not anticipate that it will become a PFIC for its 2021 taxable year. See "Passive Foreign Investment Company Rules", below. *Holders of shares and ADSs should consult their own tax advisers regarding the availability of the reduced dividend tax rate in light of their own particular circumstances.*

Dividend income received by a U.S. Holder with respect to ADSs or shares generally will be treated as foreign source income for foreign tax credit purposes. The limitation on foreign taxes eligible for credit is calculated separately with respect to specific classes of income. Distributions out of earnings and profits with respect to the ADSs or shares generally will be treated as "passive category" income (or, in the case of certain U.S. holders, "general category" income). Subject to certain limitations, French income tax withheld in connection with any distribution with respect to the ADSs or shares 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. *The U.S. federal income tax rules governing the availability and computation of foreign tax credits are complex. U.S. holders should consult their own tax advisers concerning the implications of these rules in light of their particular circumstances.*

To the extent that an amount received by a U.S. holder exceeds the allocable share of the Company's current and accumulated earnings and profits, such excess will be applied first to reduce such U.S. holder's tax basis in its shares or ADSs and then, to the extent it exceeds the U.S. holder's tax basis, it will constitute capital gain from a deemed sale or exchange of such shares or ADSs (see "- T*ax on Sale or Other Disposition*", below).

The amount of any distribution paid in euros will be equal to the U.S. dollar value of the euro amount distributed, calculated by reference to the exchange rate in effect on the date the dividend is received by a U.S. holder of shares (or by the depositary, in the case of ADSs) regardless of whether the payment is in fact converted into U.S. dollars on such date. *U.S. holders should consult their own tax advisers regarding the treatment of foreign currency gain or loss, if any, on any euros received by a U.S. holder that are converted into U.S. dollars on a date subsequent to receipt.*

Distributions to holders of additional shares (or ADSs) with respect to their shares (or ADSs) that are made as part of a pro rata distribution to all shareholders generally will not be subject to U.S. federal income tax. However, if a U.S. holder has the option to receive a distribution in shares (or ADSs) or to receive cash in lieu of such shares (or ADSs), the distribution of shares (or ADSs) will be taxable as if the holder had received an amount equal to the fair market value of the distributed shares (or ADSs), and such holder's tax basis in the distributed shares (or ADSs) will be equal to such amount.

Tax on sale or other disposition

In general, for U.S. federal income tax purposes, a U.S. holder that sells, exchanges or otherwise disposes of its shares or ADSs will recognize capital gain or loss in an amount equal to the U.S. dollar value of the difference between the amount realized for the shares or ADSs and the U.S. holder's adjusted tax basis (determined in U.S. dollars and under U.S. federal income tax rules) in the shares or ADSs. Such gain or loss generally will be U.S.-source gain or loss, and will be treated as long-term capital gain or loss if the U.S. holder's holding period in the shares or ADSs exceeds one year at the time of disposition. If the U.S. holder is an individual, any capital gain generally will be subject to U.S. federal income tax at preferential rates (currently a maximum of 20%) if specified minimum holding periods are met. The deductibility of capital losses is subject to significant limitations.

Medicare tax

Certain U.S. holders who are individuals, estates or trusts are required to pay a Medicare tax of 3.8% (in addition to taxes they would otherwise be subject to) on their "net investment income" which would include, among other things, dividends and capital gains from the shares and ADSs.

Passive Foreign Investment Company Rules

Unfavorable U.S. tax 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, based on the Company's financial statements and relevant market and shareholder data, the Company believes it was not a PFIC with respect to its 2020 taxable year. In addition, based on its current expectations regarding the value and nature of its assets, the sources and nature of its income, and relevant market and shareholder data, the Company does not anticipate that it will become a PFIC for its 2021 taxable year. However, as discussed in our Annual Report on 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 hold Securities at any time during years when the Company is a PFIC and do 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.

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 2020 and as of December 31, 2020, 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 2020, 74% of our total costs of sales and operating expenses were denominated in euro. During the same period, 51% of our net 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, 2020 relative to the U.S. dollar and the Japanese yen would have resulted in an increase in income before taxes of approximately €65,000 for the year ended December 31, 2020, compared to an increase of approximately €67,000 for the year ended December 31, 2019. A uniform 10% decrease in the value of the euro as of December 31, 2020 relative to the U.S. dollar and the Japanese yen would have resulted in a decrease in income before taxes of approximately €71,000 for the year ended December 31, 2020 as compared to an increase of approximately €73,000 for the year ended December 31, 2019. 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, 2020, 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. €0.9 million, €0.6 million and €0.6 million of our outstanding indebtedness at December 31, 2020, 2019 and 2018, respectively, were denominated in Japanese yen. €0.2 million, €0 million and €0 million of our outstanding indebtedness at December 31, 2020, 2019 and 2018, respectively, were denominated in U.S. dollars. In addition, we had €6.0 million, €4.0 million and €1.3 million of cash denominated in U.S. dollars at December 31, 2020, 2019 and 2018, respectively, and €2.7 million, €1.3 million and €3.7 million of cash denominated in Japanese yen at December 31, 2020, 2019 and 2018, respectively.

Equity Price Risk

Not applicable.

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 – Cable, telex and facsimile transmissions (when expressly provided in the de posit agreement)
Expenses of the Depositary	– 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, 2020 to March 15, 2021, the following amounts were paid by the Depositary to the Company: $90,000 and $13,656 respectively for the administration of the ADR program and for expenses linked to the assistance in identifying shareholders of the Company.

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(e) 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, 2020. Based on this evaluation, the Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures were effective as of December 31, 2020 and that the material weakness reported in our annual report for the year ended December 31, 2019 was fully remediated. During the course of 2020, the Company implemented a formal "Ticketing tool" in order to strengthen the change management process and documentation. The Company also strengthened its IT team to ensure a better segregation of duties upon IT changes implementation. The Company therefore considers that this material weakness has been remediated as of December 31, 2020.

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, 2020 based upon the internal control framework as set forth by the Committee of Sponsoring Organizations of the Treadway Commission (2013 COSO). Based on management's assessment, management concluded that the Company's internal control over financial reporting was effective as of December 31, 2020.

Remediation Activities

In our Annual Report on Form 20-F for the year ended December 31, 2018, we reported 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 resulted from several significant deficiencies in the development and change program which, considered in aggregation, gave rise to the conclusion that our internal control over financial reporting was not effective as of December 31, 2018 and that this material weakness was not considered fully remediated as of December 31, 2019, although certain new controls were implemented during 2019.

During the course of 2020, the Company implemented a formal "Ticketing tool" in order to strengthen the change management process and documentation. The Company also strengthened its IT team to ensure a better segregation of duties upon IT changes implementation. The Company, therefore, considers that this material weakness has been remediated as of December 31, 2020.

Change in Internal Control over Financial Reporting

Other than the remediation, there were no changes in the Company's internal control over financial reporting during 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, 2020, 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.

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 firm, billed to us for the fiscal years ended December 31, 2020 and December 31, 2019 for audit and other services. KPMG S.A. ("KPMG") served as the Company's independent registered accounting firm for the fiscal years ended December 31, 2020 and 2019.

Nature of the Fees	Fees for 2020 (in €)	Fees for 2019 (in €)
Audit fees [(1)]	375,829	358,902
Audit-related fees	8,000	5,000
Tax fees	—	—
All other fees	—	—
Total	**383,829**	**363,902**

(1) "Audit fees" for 2019 include €13,000 paid to PriceWaterhouseCoopers Audit in relation with their consent and audit report related to the Annual Report on Form 20-F for the fiscal year ended December 2019.

As the Company has exceeded certain levels of revenues and balance sheet set under French law, the appointment of a joint-auditor, as well as the production of consolidated accounts under International Financial Reporting Standards, is required for the fiscal year 2020. On June 30, 2020, the shareholders appointed the audit firm of Agili(3F) as our independent joint-auditors starting with the 2020 fiscal year for the audit of the statutory consolidated financial statements prepared in accordance with International Financial Reporting Standards. Audit fees to be billed to us by Agili(3F) for fiscal year ended December 31, 2020 are as follows:

Nature of the Fees	Fees for 2020 (in €)
Audit fees	37,000
Audit-related fees	—
Tax fees	—
All other fees	—
Total	**37,000**

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 consist 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

None.

Item 16F. Change in Registrant's Certifying Accountant

Not applicable.

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 The NASDAQ Listing Rules.

On August 26, 2020, the Board of Directors approved the creation of a Strategic Committee to address strategic issues and governed by a charter which sets forth its composition and defines its scope of authority.

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.

Exhibit Number:	**Description**
1.1	By-laws (*statuts*) of EDAP TMS S.A. as amended as of March 30, 2021
2.3	Description of securities registered under Section 12 of the Exchange Act
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 S.A. 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)]
8.1	List of subsidiaries of EDAP TMS S.A. as of April 7, 2021
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.
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 7, 2021

/s/ Marc Oczachowski

Marc Oczachowski
Chief Executive Officer

Dated: April 7, 2021

/s/ François Dietsch

François Dietsch
Chief Financial Officer

INDEX TO FINANCIAL STATEMENTS

Report of Independent Registered Public Accounting Firm

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

Opinion on the Consolidated Financial Statements

We have audited the accompanying consolidated balance sheets of EDAP TMS S.A. and subsidiaries (the Company) as of December 31, 2020 and 2019, the related consolidated statements of income (loss), comprehensive income (loss), shareholders' equity, and cash flows for each of the years in the three-year period ended December 31, 2020, 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, 2020 and 2019, and the results of its operations and its cash flows for each of the years in the three-year period ended December 31, 2020, 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, 2020, 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 7, 2021 expressed an unqualified opinion on the effectiveness of the Company's internal control over financial reporting.

Change in Accounting Principle

As discussed in Notes 1.25 to the consolidated financial statements, the Company has changed its method of accounting for leases in 2019 due to the adoption of ASU No. 2016-02 Leases (Topic 842).

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 audits. 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 audits 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.

Critical Audit Matter

The critical audit matter communicated below is a matter arising from the current period audit of the consolidated financial statements that was communicated or required to be communicated to the audit committee and that: (1) relates to accounts or disclosures that are material to the consolidated financial statements and (2) involved our especially challenging, subjective, or complex judgments. The communication of a critical audit matter does not alter in any way our opinion on the consolidated financial statements, taken as a whole, and we are not, by communicating the critical audit matter below, providing a separate opinion on the critical audit matter or on the accounts or disclosures to which it relates.

Revenue recognition – Identification of distinct performance obligations in multiple-element arrangements related to sales of medical devices produced by the Company

As discussed in Note 1.5 to the consolidated financial statements, the Company's sale arrangements may contain multiple elements, including medical devices produced by the Company, consumables, and services such as maintenance or warranty extensions. The Company identifies goods or services within the contract that constitute distinct performance obligations.

We identified the identification of distinct performance obligations included in the contracts with customers for the sales of medical devices produced by the Company as a critical audit matter, because each customer contract is a specific contract, with distinct

performance obligations. Challenging auditor judgment was required in evaluating the impact of the terms and conditions in contracts with multiple elements to assess the identification of distinct performance obligations.

The following are the primary procedures we performed to address this critical audit matter. We evaluated the design and tested the operating effectiveness of an internal control over the Company's revenue recognition process related to the identification of distinct performance obligations included in multiple-element arrangements. For a sample of medical device sales we obtained and read the executed contracts and assessed the Company's identification of distinct performance obligations.

Lyon April 7, 2021

KPMG Audit
A division of KPMG S.A.

/s/ Sara Righenzi de Villers
Partner

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

Report of Independent Registered Public Accounting Firm

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. and subsidiaries' (the Company) internal control over financial reporting as of December 31, 2020, based on criteria established in Internal Control – Integrated Framework (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission. In our opinion, the Company maintained, in all material respects, effective internal control over financial reporting as of December 31, 2020, 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 sheets of the Company as of December 31, 2020 and 2019, the related consolidated statements of income (loss), comprehensive income (loss), shareholders' equity, and cash flows for each of the years in the three-year period ended December 31, 2020, and the related notes (collectively, the consolidated financial statements), and our report dated April 7, 2021 expressed an unqualified opinion 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 7, 2021

KPMG Audit
A division of KPMG S.A.

/s/ Sara Righenzi de Villers
Partner

EDAP TMS S.A. AND SUBSIDIARIES
CONSOLIDATED BALANCE SHEETS
As of December 31, 2020 and 2019
(in thousands of euros unless otherwise noted)

ASSETS	Notes	2020	2019
Current assets			
Cash and cash equivalents	2	24,696	20,886
Current portion of net trade accounts and notes receivable	3	11,307	11,328
Other receivables	4	1,031	1,259
Inventories	5	7,989	8,178
Other assets, current portion	6	369	447
Total current assets		45,393	42,097
Non-current assets			
Property and equipment, net	7	3,704	4,069
Operating lease right-of-use assets	8	1,895	2,647
Intangible assets, net	9	761	770
Goodwill	9	2,412	2,412
Deposits and other non-current assets		655	640
Deferred tax assets	23-3	374	432
Net Trade accounts and notes receivable, non-current	3	—	2
Total assets		**55,193**	**53,068**
LIABILITIES AND SHAREHOLDERS' EQUITY			
Current liabilities			
Trade accounts and notes payable	10	5,708	6,046
Deferred revenues, current portion	11	2,701	1,892
Social security and other payroll withholdings taxes		1,176	1,207
Employee absences compensation		698	634
Income taxes payable		129	280
Other accrued liabilities	12	2,774	2,109
Short-term borrowings	14	2,638	3,513
Current obligations under finance leases	13-1	344	392
Current portion of operating lease obligations	13-2	802	958
Current portion of long-term debt	15-1	4,532	462
Total current liabilities		21,504	17,493
Non-current liabilities			
Deferred revenues, non-current	11	926	1,313
Obligations under finance leases	13-1	555	653
Operating lease obligations, non-current	13-2	1,099	1,726
Long-term debt, non-current	15-1	1,143	957
Other long-term liabilities	16	3,720	3,567
Total liabilities		28,945	25,710
Shareholders' equity			
Common stock, €0.13 par value; 29,457,744 shares issued and 29,165,316 shares outstanding at December 31, 2020; €0.13 par value; 29,433,994 shares issued and 29,141,566 shares outstanding at December 31, 2019		3,830	3,826
Additional paid-in capital		66,548	66,331
Retained earnings		(40,139)	(38,435)
Cumulative other comprehensive loss		(3,064)	(3,436)
Treasury stock, at cost; 292,428 at December 31, 2020 and at December 31, 2019	17	(928)	(928)
Total shareholders' equity	17	26,248	27,359
Total liabilities and shareholders' equity		**55,193**	**53,068**

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

EDAP TMS S.A. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF INCOME (LOSS)
For the years ended December 31, 2020, 2019 and 2018
(in thousands of euros except share and per share data)

	Note	2020	2019	2018
Sales of goods		27,523	30,111	25,070
Sales of RPPs & leases		4,745	5,747	5,086
Sales of spare parts and services		9,382	9,001	9,007
Total sales	18	41,649	44,859	39,163
Other revenues	19	12	52	19
Total revenues		41,662	44,912	39,183
Cost of goods		(14,951)	(15,442)	(14,053)
Cost of RPPs & leases		(2,601)	(3,000)	(2,557)
Cost of spare parts and services		(5,732)	(5,467)	(5,655)
Total cost of sales	20	(23,283)	(23,909)	(22,266)
Gross profit		18,379	21,002	16,917
Research and development expenses	21	(4,496)	(3,728)	(4,088)
Selling and marketing expenses		(9,279)	(10,850)	(10,551)
General and administrative expenses		(4,335)	(4,224)	(3,593)
Income (loss) from operations		269	2,201	(1,315)
Financial (expense) income, net	22	(98)	(146)	797
Foreign currency exchange gain (loss), net		(1,359)	136	538
Income (loss) before taxes	23-1	(1,188)	2,191	20
Income tax (expense) benefit	23-2	(516)	(679)	(358)
Net income (loss)		(1,704)	1,512	(338)
Basic income (loss) per share	24	(0.06)	0.05	(0.01)
Diluted income (loss) per share	24	(0.06)	0.05	(0.01)
Basic Weighted average shares outstanding	24	29,148,108	29,016,118	28,997,866
Diluted Weighted average shares outstanding	24	29,148,108	29,615,466	28,997,866

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

EDAP TMS S.A. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF COMPREHENSIVE INCOME (LOSS)
For the years ended December 31, 2020, 2019 and 2018
(in thousands of euros unless otherwise noted)

		2020	2019	2018
Net income (loss)		(1,704)	1,512	(338)
Other comprehensive income (loss):				
Foreign currency translation adjustments	17-6	410	(61)	(146)
Provision for retirement indemnities	17-6	(38)	374	—
Comprehensive income (loss), net of tax		(1,332)	1,825	(483)

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

EDAP TMS S.A. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF SHAREHOLDERS' EQUITY
For the years ended December 31, 2020, 2019 and 2018
(in thousands of euros unless otherwise noted)

	Number of shares	Common stock	Additional paid-in capital	Retained Earnings / (Loss)	Other comprehensive income (loss)	Treasury stock	Total
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	28,997,886	3,818	65,983	(39,947)	(3,748)	(1,142)	24,964
Net (loss) / income	—	—	—	1,512	—	—	1,512
Translation adjustment	—	—	—	—	(61)	—	(61)
Stock-Options granted or exercised	—	—	232	—	—	—	232
Capital increase	65,600	8	116	—	—	—	124
Treasury stock disposition	78,100	—	—	—	—	214	214
Provision for retirement indemnities	—	—	—	—	374	—	374
Balance as of December 31, 2019	29,141,566	3,826	66,331	(38,435)	(3,436)	(928)	27,359
Net (loss) / income	—	—	—	(1,704)	—	—	(1,704)
Translation adjustment	—	—	—	—	410	—	410
Stock-Options granted or exercised	—	—	160	—	—	—	160
Capital increase	23,750	3	57	—	—	—	60
Treasury stock disposition	—	—	—	—	—	—	—
Provision for retirement indemnities	—	—	—	—	(38)	—	(38)
Balance as of December 31, 2020	29,165,316	3,830	66,548	(40,139)	(3,064)	(928)	26,248

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, 2020, 2019 and 2018
(in thousands of euros unless otherwise noted)

	2020	2019	2018
Cash flows from operating activities			
Net income (loss)	(1,704)	1,512	(338)
Adjustments to reconcile net income (loss) to net cash generated by (used in) operating activities:			
Depreciation and amortization	2,105	1,879	1,610
Change in warrants fair value		—	(889)
Other non-cash compensation	160	260	289
Change in allowances for doubtful accounts & slow-moving inventories	734	176	591
Change in long-term provisions	455	(6)	300
Net capital loss on disposals of assets	291	79	37
Deferred tax expense (benefit)	45	(106)	(153)
Operating cash flow	2,087	3,794	1,447
Increase/Decrease in operating assets and liabilities:			
Decrease (Increase) in trade accounts and notes and other receivables	1,137	908	(983)
Decrease (Increase) in inventories	(554)	(1,036)	(704)
Decrease (Increase) in other assets	69	(60)	115
(Decrease) Increase in trade accounts and notes payable	(422)	(249)	(70)
(Decrease) Increase in accrued expenses, other current liabilities	(339)	445	370
Net change in operating assets and liabilities	(110)	6	(1,272)
Net cash generated by (used in) operating activities	**1,977**	**3,800**	**175**
Cash flows from investing activities:			
Additions to capitalized assets produced by the Company	(1,339)	(1,020)	(827)
Proceeds from sale of leased back assets	—	—	359
Acquisitions of property and equipment	(531)	(396)	(604)
Acquisitions of intangible assets	(103)	(35)	(438)
Acquisitions of other financial assets	(2)	(14)	—
Increase in deposits and guarantees	(36)	(67)	(59)
Net cash generated by (used in) investing activities	**(2,011)**	**(1,532)**	**(1,569)**
Cash flow from financing activities:			
Proceeds from capital increase	—	—	—
Proceeds from stock-option exercise	60	310	—
Proceeds from long term borrowings, net of financing costs	4,848	688	1,032
Repayment of long term borrowings	(519)	(1,087)	(443)
Repayment of obligations under financing leases in 2020 and 2019 and capital leases in 2018	(321)	(396)	(358)
Increase (decrease) in bank overdrafts and short-term borrowings	(867)	(179)	946
Net cash generated by (used in) financing activities	**3,201**	**(664)**	**1,178**
Net effect of exchange rate changes on cash and cash equivalents	642	(182)	(323)
Net increase (decrease) in cash and cash equivalents	**3,810**	**1,422**	**(539)**
Cash and cash equivalents at beginning of year	20,886	19,464	20,004
Cash and cash equivalents at end of year	**24,696**	**20,886**	**19,464**

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

1— SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

1-1 Nature of operations

EDAP TMS S.A. and its subsidiaries (‘‘the 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.

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 operations.

Since the occurrence in 2020 of the COVID-19 virus, we have taken steps to require the majority of our employees to work remotely, maintain minimum supply chain and development activity and curtail most business travels. The pandemic has resulted in further postponement and/or cancelation of the sale and installation of new devices and disposables in hospitals or clinics as investment decisions are put on hold or their resources are refocused on COVID-19. During this period, we benefited from covid related assistance loans from French, Japanese and US authorities.

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).

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, duration and interest rate of operating leases, 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. In particular regarding the estimate of future sales in our business plans, the prolonged impact of the COVID19 pandemic and lack of visibility on the return to normal sales cycles has created a higher level of uncertainty. 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 after elimination of intercompany balances and transactions. We do not have any significant interests in any variable interest entities.

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 generally takes place upon delivery. Consumables revenues included in sales contract are deferred until 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) immaterial 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.

Sales of our medical devices and sales of disposables, sales of RPPs and leases, and sales of spare parts and services, are all net of commissions.

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 a customer can benefit from the good or service on its own or with other resources that are readily available to the customer, and (ii) if they are a distinct good or service that is separately identifiable from other items in the multiple-element arrangement. 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 goods 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 sales net of commission 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 ESWL 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 goods to provide services or sell or exchange the good), and based on contractual incoterms. Such installation-related costs are immaterial in the context of the contract with the customer and do not constitute a distinct performance obligation.

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 depending of the geographic area. Over this standard one to two years period, it is considered as an extension of such warranty period and constitutes a distinct performance obligation. 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. For RPP, 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 from leasing of machine are considered as immaterial.

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 immaterial 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 a type of spare part is specifically excluded from the maintenance contract terms.

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 equally 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 agents and distributors. Such agents 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 when the control is transferred to the related agent or distributor which generally occurs 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 18.

Contract Balances:

Details on contract liabilities are reported on Note 11.

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.

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. There is no short-term investment at December 31, 2020.

1-9 Accounts Receivable

The Company maintains an allowance for doubtful accounts for estimated losses inherent in its accounts receivable portfolio. In establishing the required allowance, management considers historical losses adjusted to take into account current market conditions and the Company's customers' financial condition, the amount of receivables in dispute, and the current receivables aging and current payment patterns. The Company reviews its allowance for doubtful accounts quarterly. Past due balances over 90 days and over a specified amount are reviewed individually for collectability. Account balances are charged off against the allowance after all means of collection have been exhausted and the potential for recovery is considered remote. Write-offs for 2020 and 2019 approximated €827 thousands and €15 thousands, respectively. The Company does not have any off-balance-sheet credit exposure related to its customers. 2020 write-offs are linked to the liquidation of the Italian' subsidiary.

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, net of accumulated depreciation and impairment. 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.

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.

When imparement indicators are identified, the impairment test is performed by comparing the fair value of a reporting unit with its carrying amount, including goodwill. 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. 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. The warranty expense is incurred at time of accrual and not when paid. Warranty expense amounted to €266 thousand, €131 thousand and €433 thousand for the years ended December 31, 2020, 2019 and 2018, 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.

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 €291 thousand, €739 thousand and €719 thousand for the years ended December 31, 2020, 2019 and 2018, 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 (loss) 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 recorded in the statement of income (loss).

Presentation in the Statement of Income (loss)

Aggregate foreign currency transactions gains and losses are disclosed in a single caption in the Statement of Income (loss) 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.

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 (loss). As of December 31, 2020, there are no derivative instruments.

1-22 Employee stock option plans

At December 31, 2020, the Company had three 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. Since December 31, 2018, there were no more warrants outstanding.

1-24 Leases

Leases as a Lessee

In accordance with ASC 842, Leases, and as from January 1, 2019, the Company classifies all leases at the inception of a contract and assess whether the contract is, or contains, a lease. The assessment is based on: (1) whether the contract involves the use of a distinct identified asset, (2) whether the company controls the use of the identified asset (e.g. whether the company has the right to obtain substantially all of the economic benefits from the use of the asset throughout the period, and whether the company has the right to direct the use of the asset).

Leases are classified as either finance leases or operating leases. Substantially all our operating leases are comprised of office space leases, and substantially all our finance leases are comprised of office furniture and technology equipment.

The Company recognizes a right-of-use ("ROU") asset and a lease liability at the lease commencement date. The right-of-use asset is initially measured at cost, which primarily comprises the initial amount of the lease liability, plus any initial direct costs incurred, plus prepaid lease payments, less any lease incentives received. All ROU assets are reviewed for impairment. For operating leases, the lease liability is initially measured at the present value of the unpaid lease payments at lease commencement date, discounted using the incremental borrowing rate for assets of same duration or characteristics. For finance leases the lease liability is initially measured in the same manner and date as for operating leases and is subsequently measured at amortized cost using the effective interest method

For operating leases, the ROU asset is subsequently measured throughout the lease term at the carrying amount of the lease liability, plus initial direct costs, plus (minus) any prepaid (accrued) lease payments, less the unamortized balance of lease incentives received. Lease expense for lease payments is recognized on a straight-line basis over the lease term.

For finance leases, the ROU asset is subsequently amortized using the straight-line method from the lease commencement date to the earlier of the end of its useful life or the end of the lease term unless the lease transfers ownership of the underlying asset to the Company or the Company is reasonably certain to exercise an option to purchase the underlying asset. In those cases, the ROU asset is amortized over the useful life of the underlying asset. Amortization of the ROU asset is recognized and presented separately from interest expense on the lease liability.

Lease payments included in the measurement of the lease liability comprise the following: the fixed payments, including in-substance fixed payments over the lease term (which includes termination penalties the Company would owe if the lease term assumes the Company's exercise of a termination option), variable lease payments that depend on an index or ratepayments for optional renewal periods where it is reasonably certain the renewal period will be exercised, the exercise price of an option to purchase the underlying asset if the company is reasonably certain to exercise the option, and

amounts expected to be paymable under a Company provided residual value guarantee. Documentation of the discount rates used is provided by a credit simulation carried out by the bank for similar goods and duration.

Variable lease payments associated with the Company's leases are recognized when the event, activity, or circumstance in the lease agreement on which those payments are assessed occurs. Variable lease payments are presented as operating expenses in the Company's consolidated statements of income in the same line item as expenses arising from fixed lease payments (operating leases) or amortization of the ROU asset (finance leases).

Our real estate leases generally include non-lease maintenance services. The consideration in the contract is allocated to the lease and non-lease components based on standalone selling prices.

Some of our real estate leases contain variable lease payments, including payments based on an index or rate. Variable lease payments based on an index or rate are initially measured using the index or rate in effect at lease commencement, and changes to index and rate-based variable lease payments are recognized in profit or loss in the period of the change. Variable payments that do not depend on an index or rate, such as rental payments based on the use of the underlying asset or property taxes and insurance reimbursement, are recorded as operating expense when incurred. Lease modifications result in remeasurement of the lease payments when that modification is not accounted for as a separate contract.

Lease expense for operating leases consists of the lease payments plus any initial direct costs, primarily brokerage commissions, and is recognized on a straight-line basis over the lease term. Included in lease expense are any variable lease payments incurred in the period that were not included in the initial lease liability. Lease expense for finance leases consists of the amortization of the right-of-use asset on a straight-line basis over the lease term and interest expense determined on an amortized cost basis. The lease payments are allocated between a reduction of the lease liability and interest expense.

The lease term for all of the Company's leases includes the non-cancellable period of the lease plus any additional periods covered by either a Company option to extend (or not to terminate) the lease that the Company is reasonably certain to exercise, or an option to extend (or not to terminate) the lease controlled by the lessor .

We have elected not to recognize right-of-use assets and lease liabilities for short-term leases that have a term of 12 months or less. The effect of short-term leases on our right-of-use asset and lease liability was not material. We have elected not to review the classification for expired or existing leases, prior to January 1, 2019.

Leases as a Lessor:

A lessor shall classify a lease as a sales-type lease when the lease meets any of the following criteria at lease commencement:

- The lease transfers ownership of the underlying asset to the lessee by the end of the lease term.
- The lease grants the lessee an option to purchase the underlying asset that the lessee is reasonably certain to exercise.
- The lease term is for the major part of the remaining economic life of the underlying asset. However, if the commencement date falls at or near the end of the economic life of the underlying asset, this criterion shall not be used for purposes of classifying the lease.
- The present value of the sum of the lease payments and any residual value guaranteed by the lessee that is not already reflected in the lease payments in accordance with paragraph 842-10-30-5(f) equals or exceeds substantially all of the fair value of the underlying asset.
- The underlying asset is of such a specialized nature that it is expected to have no alternative use to the lessor at the end of the lease term.

When none of the criteria are met:

A lessor shall classify the lease as either a direct financing lease or an operating lease. A lessor shall classify the lease as an operating lease unless both of the following criteria are met, in which case the lessor shall classify the lease as a direct financing lease:

- The present value of the sum of the lease payments and any residual value guaranteed by the lessee that is not already reflected in the lease payments in accordance with paragraph 842-10-30-5(f) and/or any other third party unrelated to the lessor equals or exceeds substantially all of the fair value of the underlying asset;

- It is probable that the lessor will collect the lease payments plus any amount necessary to satisfy a residual value guarantee.

1-25 Recent accounting pronouncements

Recently Adopted Accounting Pronouncements

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. The Company adopted 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. and for Company’s equipment, vehicles and IT equipment. The last category has been determined as being below the threshold and not material.

The Company adopted ASC 842 using a modified retrospective transition approach for all leases existing at or entered into after, the beginning of the earliest comparative period presented in the financial statements. The Company adopted the new standard as of January 1, 2019 with practical expedients, and did not restate comparative prior periods. The adoption of ASC 842 had a material effect on our consolidated balance sheet, but did not materially affect the consolidated statement of income (loss). The most significant impact was the recognition of the operating lease right-of-use assets and the liability for operating leases. The accounting for finance leases (capital leases) was substantially unchanged. Accordingly, upon adoption, leases that were classified as operating leases under ASC 840 were classified as operating leases under ASC 842, and we recorded an adjustment of €3.5 million to operating lease right-of-use assets and the related lease liability in 2019. The lease liability is based on the present value of the remaining minimum lease payments, determined under ASC 840, discounted using our secured incremental borrowing rate at the effective date of January 1, 2019, using the original lease term as the tenor. As permitted under ASC 842, we elected several practical expedients that permit us to not reassess (1) whether a contract is or contains a lease, (2) the classification of existing leases, and (3) whether previously capitalized costs continue to qualify as initial indirect costs. The application of the practical expedients did not have a significant impact on the measurement of the operating lease liability. As a result, the Company adapted its internal controls to identify contracts and apply the new GAAP.

In June 2016, the FASB issued ASU 2016-13, Financial Instruments - Credit Losses: Measurement of Credit Losses on Financial Instruments, or ASU 2016-13, which changes the impairment model for most financial assets. This standard has been amended with codification improvements in ASU 2018-19, 2019-04, 2019-05, 2019-11. The new model uses a forward-looking expected loss method, which generally results in earlier recognition of allowances for losses. ASU 2016-13 was effective for annual and interim periods beginning after December 15, 2019 and early adoption was permitted for annual and interim periods beginning after December 15, 2018. The Company adopted ASU 2016-13 on January 1, 2020. The application of ASU 2016-3 did not have a significant impact on our accounts.

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 was effective for the Company in the first quarter of 2020. Early adoption was permitted for interim or annual goodwill impairment tests performed on testing dates after January 1, 2017. The application of ASU 2016-3 did not have a significant impact on our accounts.

2— CASH EQUIVALENTS

Cash equivalents at December 31, 2020 and 2019 only comprise cash investments which are highly liquid and have initial maturities of 90 days or less.

3— TRADE ACCOUNTS AND NOTES RECEIVABLE, NET

Trade accounts and notes receivable consist of the following:

	2020	2019
Trade accounts receivable	11,363	11,807
Notes receivable	667	1,013
Less: allowance for doubtful accounts	(722)	(1,490)
Total	11,307	11,330
Less current portion	(11,307)	(11,328)
Total long-term portion	—	2

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

Bad debt expenses amount to a net cost of €87 thousand, a net cost of €84 thousand and €362 thousand, respectively for the years ended December 31, 2020, 2019 and 2018.

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

4— OTHER RECEIVABLES

Other receivables consist of the following:

	December 31,	
	2020	2019
Research and development tax credit receivable from the French State	492	766
Value-added taxes receivable	403	422
Other receivables from Government and public authorities	64	26
Others	72	46
Total	1,031	1,259

5— INVENTORIES

	December 31,	
	2020	2019
Components, spare parts	6,050	4,959
Work-in-progress	226	584
Finished goods – own manufactured products	1,283	1,737
Finished goods – distribution products	1,994	1,981
Total gross inventories	9,552	9,262
Less: allowance for slow-moving inventory and net realizable value	(1,563)	(1,085)
Total	7,989	8,178

The provision for slow moving inventory relates to components and spare parts. The allowance for slow moving inventory (excluding exchange rate impact), the increases in which are classified within cost of sales, amounted to a cost of €651 thousand for the year ended December 31, 2020, a cost of €168 thousand for the year ended December 31, 2019, and a cost of €227 thousand for the year ended December 31, 2018, respectively.

6— OTHER ASSETS

Other assets consist of the following:

	December 31,	
	2020	2019
Prepaid expenses, current portion	369	447
Total	369	447

Prepaid expenses mainly consist of rental and future congresses and conferences expenses.

7— PROPERTY AND EQUIPMENT, NET

Property and equipment consist of Property and equipment purchased or capitalized by the Company and finance leases for 2020 and 2019.

7-1 Property and Equipment, net

Property and equipment consist of the following:

	2020	2019
Equipment	8,405	7,002
Furniture, fixture, and fittings and other	2,736	2,776
Total gross value	11,141	9,778
Less: accumulated depreciation and amortization	(8,142)	(6,644)
Total	3,000	3,134

Depreciation expense related to property and equipment amounted to €1,695 thousand, €1,511 thousand and €981 thousand for the years ended December 31, 2020, 2019 and 2018, respectively.

Assets leased to customers:

Capitalized costs on equipment leased to customers of €264 thousand and €342 thousand are included in property and equipment at December 31, 2020 and 2019, respectively. Accumulated amortization of these assets leased to third parties was €102 thousand and €95 thousand, at December 31, 2020 and 2019, respectively.

Depreciation expense on equipment leased to customer is included in total depreciation expense and amounted to €240 thousand, €23 thousand and €51 thousand, for the years ended December 31, 2020, 2019 and 2018, respectively.

7-2 Finance leases

Finance lease right-of-use assets in 2020 and previous years consist of the following:

	2020	2019
Equipment	359	713
Vehicles and IT equipment	1,196	1,582
Total gross value	1,554	2,295
Less: accumulated depreciation and amortization	850	1,360
Total	704	935

Depreciation expense related to finance lease right-of-use assets amounted to €401 thousand, €448 thousand and €386 for the years ended December 31, 2020, 2019, 2018, respectively.

The reduction to right-of-use assets resulting from reductions to finance lease obligations amounted €670 thousand and €122 thousand for the years ended December 31, 2020 and 2019 respectively.

8— OPERATING LEASE RIGHT-OF-USE ASSETS

Operating lease right-of-use assets consist of the following:

	2020	2019
Facilities	1,584	2,387
Equipment	237	58
Furniture, fixture, and fittings and other	74	202
Total net operating lease right of use	1,895	2,647

The reduction to right-of-use assets resulting from reductions to operating lease obligations amounted to €931 thousand and €836 thousand for the years ended December 31, 2020 and 2019 respectively.

Variable lease costs related to above contracts amounted to €101 thousand and €108 thousand for the years ended December 31, 2020 and 2019 respectively.

Non-recognized lease liabilities for short term leases amounted to €71 thousand and €71 thousand for the years ended December 31, 2020 and 2019 respectively.

9— 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), Urology Devices and Services (ESWL) and Distribution services (DIST) — to be its reporting units for purposes of testing for impairment. Goodwill amounts to €496 thousand for the ESWL division, 1,271 thousand for the DIST division and to €645 thousand for the HIFU division, at December 31, 2020.

Following the change of reporting segments in 2020, the previous UDS goodwill amount has been split between ESWL and Distribution according to the fair value of each segment measured at December 31, 2020.

The Company completed the required annual impairment test in the fourth quarter of 2020. To determine the fair value of the Company's reporting units, the Company used the discounted cash flow approach for each of the three reportable units. In all three cases, the fair value of the reporting unit was in excess of the reporting unit's book value, which resulted in no goodwill impairment.

Intangible assets consist of the following:

	2020	2019
Licenses	1,570	1,466
Trade name and trademark	412	427
Patents	412	412
Organization costs	225	320
Total gross value	2,619	2,625
Accumulated amortization for licenses	(813)	(699)
Accumulated amortization for trade name and trademark	(409)	(424)
Accumulated amortization for patents	(412)	(412)
Accumulated amortization for organization costs	(225)	(320)
Less: Total accumulated amortization	(1,858)	(1,855)
Total	761	770

Amortization expenses related to intangible assets amounted to €113 thousand, €113 thousand and €110 thousand, for the years ended December 31, 2020, 2019 and 2018, respectively.

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

	December 31, 2020
2021	113
2022	106
2023	94
2024	87
2025	87
Total	488

10— TRADE ACCOUNTS AND NOTES PAYABLE

Trade accounts and notes payable consist of the following:

	2020	2019
Trade accounts payable	5,708	6,034
Notes payable	—	12
Total	5,708	6,046

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.

11— DEFERRED REVENUES

Deferred revenues consist of the following:

	2020	2019
Deferred revenues on maintenance contracts	1,761	1,741
Deferred revenue on RPP	255	243
Deferred revenue on sale of devices	135	115
Deferred revenue on extension of warranty, included in sales contracts	782	837
Deferred research and development grants	693	269
Total	3,627	3,205
Less long term portion	(926)	(1,313)
Current portion	2,701	1,892

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

	December 31, 2020
2021	300
2022	314
2023	143
2024	18
2025	8
Total	782

Changes in deferred revenue on extension of warranty are as follows:

	Total
Balance as of December 31, 2018	855
New extension of warranty	254
Recognition of revenue	(272)
Balance as of December 31, 2019	837
New extension of warranty	206
Recognition of revenue	(261)
Balance as of December 31, 2020	782

12— OTHER ACCRUED LIABILITIES

Other accrued liabilities consist of the following:

	2020	2019
Retirement indemnities	2,665	2,444
Provision for warranty costs	368	370
Accruals for payroll and associated taxes	734	738
Conditional government advances	1,097	1,071
Value added tax payable	420	557
Advances received from customers	551	—
Provision for Asset Retirement Obligation (Japan)	113	117
Provision for employee termination indemnities (Korea)	69	56
Others	477	323
Total	6,494	5,676
Less non-current portion	(3,720)	(3,567)
Current portion	2,774	2,109

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.

Despite a first mono-centric study successfully implemented with Lyon's Centre Leon Bérard cancer center, we decided not to pursue the development of HIFU for liver cancer as a per-operative approach. The multi-centric Phase II study, which was to be initiated following the mono-centric study, will not be implemented. We considered that the per-operative approach initially targeted will not offer the breakthrough innovation expected by the market and will lead to comparative lengthy clinical studies with existing therapeutic solutions to fulfill the requirement of the new European MDR regulations to become effective in May 2021.

In 2020, the Company decided to reorient the efforts, knowledge and assets resulting from the HECAM project in two directions. The first one, with a technology and approach very similar to the one developed for liver cancer, will focus on pancreatic cancer for patients with few or even no alternatives. The second one will still target liver cancer application but through an extracorporeal solution to offer to patients affected by primary or metastatic liver cancer an undisputable benefit compared to the existing alternatives. In 2021, the Company will discuss with BPI France whether 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, 2020 mature as follows, should the underlying Research Program advance as per contract:

2021	6
2022	214
2023	214
2024	214
2025 and thereafter	447
Total	1,097

Changes in the provision for warranty costs are as follows:

	2020	2019
Beginning of year	370	547
Amount used during the year	(268)	(308)
New warranty expenses	266	131
End of year	368	370
Less current portion	(262)	(260)
Long term portion	106	110

13— LEASE OBLIGATIONS

13-1 Financing leases

The Company leases certain of its equipment under finance leases. At December 31, 2020, this equipment consists of medical devices for a liability amount of €223 thousand and vehicles and other IT equipment for a liability amount of €676 thousand.

Maturities of finance leases liabilities for the years ending December 31, 2020 are as follows:

	December 31, 2020
2021	360
2022	280
2023	190
2024	72
2025 and thereafter	28
Total undiscounted minimum lease payments	930
Less: amount representing interest	(33)
Present value of minimum lease payments	899
Less: current portion	(344)
Long-term portion	555

	December 31, 2019
2020	415
2021	299
2022	221
2023	122
2024 and thereafter	30
Total undiscounted minimum lease payments	1,086
Less: amount representing interest	(41)
Present value of minimum lease payments	1,044
Less: current portion	(392)
Long-term portion	653

Interest paid under finance lease obligations was €33and €29 thousand the years ended December 31, 2020 and 2019 respectively.

The weighted average remaining lease term and the weighted average discount rate for finance leases at December 31, 2020 was: 2.38 years and 3.06% and at December 31, 2019 was: 3.2 years and 2.44%.

13-2 Operating leases

Maturities of operating leases liabilities consist of the following amounts:

	December 31, 2020
2021	803
2022	523
2023	381
2024	195
2025 and thereafter	—
Total undiscounted minimum lease payments	1,901
Less: current portion	(802)
Long-term portion	1,099

	December 31, 2019
2020	980
2021	758
2022	474
2023	349
2024 and thereafter	171
Total undiscounted minimum lease payments	2,732
Less: amount representing interest	(48)
Present value of minimum lease payments	2,684
Less: current portion	(958)
Long-term portion	1,726

The weighted average remaining lease term and the weighted average discount rate for operating leases at December 31, 2020 was : 2.80 years and 1.45% and at December 31, 2019 was : 3.51 years and 1.56%.

Total rent expenses under operating leases amounted to €941 thousand, €828 thousand and €1,002 thousand, for the years ended December 31, 2020, 2019 and 2018, respectively. These total rent expenses are related to office rentals, office equipment and car rentals.

14— SHORT-TERM BORROWINGS

As of December 31, 2020 short-term borrowings consist mainly of €2,638 thousand of factored account receivables and for which the Company maintains the effective control.

As of December 31, 2019 short-term borrowings consist mainly of €3,185 thousand of factored account receivables and for which the Company is bearing the collection risk and €328 thousand of short borrowing in Japan.

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

15-1 Long-term debt:

	December 31,	
	2020	2019
France term loan	4,394	351
Japanese term loan (YEN)	900	617
Germany term loan	193	438
USA term loan	180	—
Malaysia term loan	8	13
Total long term debt	5,675	1,420
Less current portion	(4,532)	(462)
Total long-term portion	1,143	957

As of December 31, 2020, long-term debt in Japan consists of two loans in Yen subscribed with the following conditions:

	Initial Amount	Maturity	Fixed Interest rate	Frequency of principal payments
EDAP Technomed Co. Ltd	80,000,000	August 2, 2026	1.98 %	Monthly instalment
EDAP Technomed Co. Ltd	50,000,000	April 2, 2025	1.8 %	Monthly instalment

As of December 31, 2019, 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	80,000,000	August 2, 2026	1.98 %	Monthly instalment
EDAP Technomed Co. Ltd	40,000,000	April 15, 2020	2.91 %	Monthly instalment

The long-term debt of 40,000,000 has been fully reimbursed in April 2020.

As of December 31, 2020 , long-term debt in Germany consists of one loan in euro 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 was pledged against an HIFU equipment with a purchase value of €438 thousand.

As of December 31, 2019, long-term debt in Germany consists of this previous loan in euro and another loan with the following conditions :

	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 against a ESWL equipment with a purchase value of €136 thousand. This loan has been fully reimbursed in last quarter of 2020.

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

This loan was pledged against an HIFU equipment with a purchase value of €450 thousand, it has been fully reimbursed in November 2020.

As of December 31, 2020, long-term debt in France consists of a loan in Euro to finance the ERP project and three new loans in Euro subscribed in 2020 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

This loan is related to ERP SAP project. This four-year loan will be fully reimbursed in October 2021.

	Initial Amount	Maturity	Fixed Interest rate	Frequency of principal payments
EDAP TMS FRANCE	218,000	April 1, 2025	0.99 %	Monthly instalment

This new loan is pledged against the countervalue in dollars on the loan. This loan constitutes a complete financial package of €1,530,000, of which €218,000 was drawn at the end of December to finance HIFU treatment probes.

	Initial Amount	Maturity	Fixed Interest rate	Frequency of principal payments

EDAP TMS FRANCE	2,000,000	August 11, 2021	0.25 %	Monthly instalment

This new loan is COVID-related loan guaranteed by the French government with initially one year repayment term but which can be extended to five years (conditions not yet defined).

	Initial Amount	Maturity	Fixed Interest rate	Frequency of principal payments
EDAP TMS FRANCE	2,000,000	August 4, 2021	0.25 %	Monthly instalment

This new loan is COVID-related loan guaranteed by the French government with initially one year repayment term but which can be extended to five years (conditions not yet defined).

As of December 31, 2019, long-term debt in France consists of one loan in Euro to finance the ERP (SAP) 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

As of December 31, 2020 and 2019, long-term debt in Malaysia consists of a 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

As of December 31, 2020, long-term debt in USA consists of a loan in USD with the following conditions:

	Initial Amount	Maturity	Fixed Interest rate	Frequency of principal payments
EDAP TECHNOMED INC	221,217	May 14, 2022	1 %	Monthly instalment

This loan has been received from the US Paycheck Protection Program and may be forgivable in the future if certain conditions are met.

15-2 Financial instruments carried at fair value:

As of December 31, 2020, there is no financial instruments such as warrants.

Refer to Note 26 for more details on the fair value of other Financial Instruments.

15-3 Long-term debt maturity:

Long-term debt carried at fair value at December 31, 2020 matures as follows:

2021	4,532
2022	504
2023	228
2024	200
2025 and thereafter	210
Total	5,675

16— OTHER LONG-TERM LIABILITIES

Other long-term liabilities consist of the following:

	2020	2019
Provision for retirement indemnities (Japan & France), less current portion	2,273	2,167
Provision for employee termination indemnities (Korea) less current portion	69	56
Provision for Asset Retirement Obligation (Japan) less current portion	113	117
Provision for warranty costs, less current portion	106	110
Conditional government advances, less current portion	1,097	1,071
Accrued interest less current portion	62	46
Total	3,720	3,567

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, 2020 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's best estimate based on the following assumptions as of year-end :

	Pension benefits France	
	2020	2019
Discount rate	0.60 %	0.90 %
Salary increase	2.50 %	2.50 %
Retirement age	65	65
Average retirement remaining service period	24	24

	Pension benefits Japan	
	2020	2019
Discount rate	0.60 %	0.60 %
Salary increase	2.50 %	2.50 %
Retirement age	60	60
Average retirement remaining service period	14	14

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 2020, provision presentation according to ASC 715 in thousands of euros :

	France	Japan
Non-current liabilities	1,032	1,241
Current liabilities	80	69
Accumulated other comprehensive income (loss)	(111)	(130)
Total	1,000	1,181

In 2019, provision presentation according to ASC 715 in thousands of euros:

	France	Japan
Non-current liabilities	960	1,207
Current liabilities	10	22
Accumulated other comprehensive income (loss)	(67)	(136)
Total	903	1,093

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, 2020 is as follows :

France	2020	2019	2018
Change in benefit obligations:			
Benefit obligations at beginning of year	969	976	895
Service cost	88	68	67
Interest cost	9	16	14
Net loss or (gain)	—	2	—
Actuarial (gain) or loss	45	(93)	
Amortization of net prior service cost	1	1	1
Benefits paid	—	—	—
Benefit obligations at end of year [1]	1,111	969	976
Unrecognized actuarial (gain) loss [2]	94	48	141
Unrecognized prior service cost [2]	17	18	20
Accrued pension cost	1,000	903	815

(1) The accumulated benefit obligation was €800 thousand and €693 thousand at December 31, 2020 and 2019 respectively.
(2) The amount in accumulated other comprehensive income (loss) to be recognized as components of net periodic benefit costs in 2020 is €1 thousand.

Japan	2020	2019	2018
Change in benefit obligations:			
Benefit obligations at beginning of year	1,230	1,311	1,182
Service cost	123	140	131
Interest cost	7	6	6
Amortization of net loss	1	27	26
Actuarial (gain) / loss	(1)	(294)	—
Benefits paid	(5)	(3)	(94)
Exchange rate impact	(44)	42	(60)
Benefit obligations at end of year[1]	1,310	1,230	1,311
Unrecognized actuarial (gain) loss [2]	130	136	416
Unrecognized prior service cost [2]	—	—	—
Accrued pension cost	1,181	1,093	895

(1) The accumulated benefit obligation was €1,134 thousand and €1,062 thousand at December 31, 2020 and 2019, respectively.
(2) The amount in accumulated other comprehensive income (loss) to be recognized as components of net periodic benefit costs in 2020 is €1 thousand.

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
2021	80	70
2022	—	105
2023	67	114
2024	—	157
2025	—	167
2026-2030	318	397
	465	1,008

17— SHAREHOLDERS' EQUITY

17-1 Common stock

As of December 31, 2020, EDAP TMS S.A.'s common stock consisted of 29,457,744 issued shares fully paid and with a par value of €0.13 each. 29,165,316 of the shares were outstanding.

17-2 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.

17-3 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 €16,172 thousand. Dividend distributions, if any, will be made in euros. The Company has no plans to distribute dividends in the foreseeable future.

17-4 Treasury stock

As of December 31, 2020, all 292,428 shares held as treasury stock consisted of (i) 112,138 shares acquired between August and December 1998 and (ii) 180,290 shares acquired in June and July 2001 for a total of €928 thousand. All treasury stocks have been acquired to cover stock purchase options (see Note 17-5).

17-5 Stock-option plans

As of December 31, 2020, the 292,428 ordinary shares held as treasury stock were dedicated to serve stock purchase option plans that may be allocated by the Board of Directors in the future, as per June 28, 2019 shareholders' approval. The June 25, 2010 purchase option plan expired on June 25, 2020.

As of December 31, 2020, EDAP TMS S.A. sponsored three stock purchase and subscription option plans open to employees of EDAP TMS group:

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 to new 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). Under this plan, 262,500 options are outstanding and exercisable at December 31, 2020.

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 to new 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 were 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 has been 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 to new 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 to new 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).

Conforming to this February 18, 2016 stock option plan, the Board of Directors granted 155,000 options to subscribe to new shares to certain employees of EDAP TMS on April 4, 2019. Forfeited options corresponding to employees' departures were re-allocated. The exercise price was fixed at €3.90 per share. Options were to begin vesting one year after the date of grant and all options will be fully vested as of April 4, 2023 (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 4, 2029 (i.e., ten years after the date of grant) or when employment with the Company ceases, whichever occurs earlier. At December 31, 2019, the total fair value of the options granted on April 4, 2019 under this plan was €299 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).

The impact of this February 18, 2016 Plan on operating income, in accordance with ASC 718, was €289 thousand, €260 thousand and €160 thousand in 2018, 2019 and 2020, respectively.

Under this 2016 plan, 924,400 options are outstanding, 708,150 options are exercisable and 13,750 options are exercised at December 31, 2020.

On June 28, 2019, the shareholders authorized the Board of Directors to grant up to a maximum of 358,528 options to purchase pre-existing shares and to grant 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 December 31, 2020, 292,428 pre-existing shares are available for future purchase option grants and none of the options authorized under this Plan have been allocated.

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:

	2020	2019	2018
Weighted-average expected life (years)	— [2]	6.25	6.25
Expected volatility rates[1]	—	49.45 %	52.6 %
Expected dividend yield	—	0 %	0 %
Risk-free interest rate	—	(0.08)%	0.18 %
Weighted-average exercise price (€)	—	3.90	2.65
Weighted-average fair value of options granted during the year (€)	—	1.93	1.33

(1) Historical volatility calculated over 10 years.

(2) There was no new plan for the year 2020.

As of December 31, 2020, a summary of stock option activity to purchase or to subscribe to Shares under these plans is as follows:

	2020		2019		2018	
	Options	Weighted average exercice price (€)	Options	Weighted average exercice price (€)	Options	Weighted average exercice price (€)
Outstanding on January 1,	1,273,900	2.78	1,347,600	2.61	1,207,600	2.61
Granted	—	—	155,000	3.90	165,000	2.65
Exercised	(23,750)	2.54	(143,700)	2.16	—	—
Forfeited	(21,250)	2.55	(85,000)	1.94	(25,000)	3.05
Expired	(42,000)	2.38	—	—	—	—
Outstanding on December 31,	1,186,900	2.81	1,273,900	2.78	1,347,600	2.61
Exercisable on December 31,	970,650	2.73	818,900	2.60	772,600	2.44
Share purchase options available for grant on December 31,	292,428		250,428		250,428	

The following table summarizes information about options to purchase existing Shares held by the Company, or to subscribe to new Shares, at December 31, 2020:

	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)
3.90	130,000	8.8	3.90	42,576	32,500	3.90	13,017
3.22	465,000	5.3	3.22	468,492	465,000	3.22	468,492
2.65	145,000	7.7	2.65	228,739	72,500	2.65	114,369
2.39	184,400	6.3	2.39	338,837	138,150	2.39	253,852
1.91	262,500	2.0	1.91	608,346	262,500	1.91	608,346
1.91 to 3.90	1,186,900	6.0	2.81	1,686,989	970,650	2.73	1,458,076

(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 $5.17 at December 31, 2020, which would have been received by the option holders had all in-the-money option holders exercised their options as of that date.

A summary of the status of the non-vested options to purchase shares or to subscribe to new shares as of December 31, 2020, and changes during the three years ended December 31, 2020, is presented below:

	Options	Weighted average Grant-Date Fair Value (€)
Non-vested at January 1, 2018	593,750	1.53
Granted	165,000	1.33
Vested	(180,000)	1.56
Forfeited	(3,750)	1.29
Non-vested at December 31, 2018	575,000	1.47
Non-vested at January 1, 2019	575,000	1.47
Granted	155,000	1.93
Vested	(204,000)	1.52
Forfeited	(70,600)	1.58
Non-vested at December 31, 2019	455,000	1.58
Non-vested at January 1, 2020	455,000	1.58
Granted	0	0
Vested	(235,000)	1.58
Forfeited	(3,750)	1.54
Non-vested at December 31, 2020	216,250	1.59

As of December 31, 2020, there were €105 thousand of total unrecognized compensation expenses related to non-vested stock-options, over a period of 3.25 years.

17-6 Accumulated other comprehensive income (loss)

The components of accumulated other comprehensive income (loss) net of tax, for the years ended December 31, 2020, and 2019, are as follows:

	Year Ended December 31, 2020		
	Foreign currency translation adjustment	Provision for retirement indemnities	Total
Beginning balance	(3,234)	(203)	(3,436)
Other comprehensive income (loss) before reclassifications	—	—	—
Reclassified from accumulated other comprehensive loss	—	—	—
Net current-period other comprehensive income (loss)	410	(38)	372
Ending balance	(2,824)	(241)	(3,064)

	Year Ended December 31, 2019		
	Foreign currency translation adjustment	Provision for retirement indemnities	Total
Beginning balance	(3,173)	(577)	(3,748)
Other comprehensive income (loss) before reclassifications	—	—	—
Reclassified from accumulated other comprehensive loss	—	—	—
Net current-period other comprehensive income (loss)	(61)	374	313
Ending balance	(3,234)	(203)	(3,436)

As there is an allowance recorded against deferred tax assets, there is no net impact of tax.

18— TOTAL SALES

Amount of net sales derived from our operations in Asia, France, the United States. and other geographical areas, are as follows:

Primary geographical markets (€)	2020	2019	2018
Asia	15,872	17,939	14,119
France	10,021	11,350	11,577
United States	5,611	5,194	2,048
Others geographical areas	10,146	10,377	11,419
	41,649	44,859	39,163

The amount of net sales is recognized following the timing above:

Timing of revenue recognition	2020	2019	2018
Products transferred at a point in time	32,862	36,767	31,373
Products and services transferred over time	8,787	8,092	7,790
	41,649	44,859	39,163

19— OTHER REVENUES

Other revenues consist of the following:

	2020	2019	2018
Licenses and others	12	52	19
Total	12	52	19

In 2020, 2019 and 2018, other revenues mainly consist of sales of a license to Theraclion and training to customers.

20— COSTS OF SALES

Costs of sales consist of the following:

	2020	2019	2018
Direct costs of sales	(14,058)	(14,919)	(13,683)
Indirect costs of sales	(9,225)	(8,990)	(8,583)
Total costs of sales	(23,283)	(23,909)	(22,266)

21— RESEARCH AND DEVELOPMENT EXPENSES

Research and development expenses consist of the following:

	2020	2019	2018
Gross research and development expenses	(5,173)	(4,727)	(4,863)
Research Tax Credit	492	762	685
Grants	184	236	90
Net Research and development expenses	(4,496)	(3,728)	(4,088)

In 2020 and 2019 grants consisted mainly of national grants for the assessment and optimization of the focal treatments of prostate cancer (Perfuse development project).

In 2018 grants mainly consisted of European, national and regional grants for the development of innovative imaging solutions for the focal treatment of liver cancer (HECAM Development project).

Research and development costs are expensed as incurred and include amortization of assets, costs of prototypes, salaries, benefits and other headcount related costs, contract and other outside service fees, and facilities and overhead costs.

22— FINANCIAL INCOME, NET

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

	2020	2019	2018
Interest income	10	20	19
Interest expense	(108)	(165)	(111)
Warrants exercised / forfeited	—	—	889
Total	(98)	(146)	797

23— INCOME TAXES

23-1 Income / (Loss) before income taxes

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

	2020	2019	2018
France	(2,042)	1,803	1,687
Other countries	854	388	(1,667)
Total	(1,188)	2,191	20

23-2 Income tax (expense)/ benefit

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

	2020	2019	2018
Current income tax expense:			
France	(158)	(237)	(163)
Other countries	(312)	(550)	(351)
Sub-total current income tax expense	(471)	(787)	(515)
Deferred income tax (expense) benefit:			
France	8	(1)	2
Other countries	(53)	109	155
Sub-total deferred income tax (expense) benefit	(45)	108	157
Total	(516)	(679)	(358)

23-3 Deferred income taxes:

Deferred income taxes reflect the impact of temporary differences between the amounts of assets and liabilities reported for financial reporting purposes and such amounts as measured in accordance with tax laws. The tax effects of temporary differences which give rise to significant deferred tax assets (liabilities) are as follows by nature :

	2020	2019
Net operating loss carry forwards	14,014	13,642
Elimination of intercompany profit in inventory	161	269
Elimination of intercompany profit in fixed assets	244	349
Provisions for retirement indemnities	634	577
Capital leases treated as operating leases for tax	56	29
Other items	775	544
Total deferred tax assets	15,883	15,410
Total deferred tax liabilities	—	—
Net deferred tax assets	15,883	15,410
Valuation allowance for deferred tax assets	(15,508)	(14,977)
Deferred tax assets (liabilities), net of allowance	374	432

Net operating loss carryforwards available amounts to €59,052 thousand as of December 31, 2020, of which €34,225 thousand at EDAP TMS SA, €21,134 thousand at Edap Technomed Inc., €1,884 thousand at Edap Technomed Co Ltd Japan, €1,789 thousand at EDAP Technomed Italia S.R.L and €20 thousand at Edap TMS Gmbh. These net operating losses generate deferred tax assets of €14,014 thousand as at December 31, 2020. Realization of these tax assets is contingent on future taxable earnings in the applicable tax jurisdictions. As of December 31, 2020, €57,168 thousand out of these €59,052 thousand net operating loss carry-forwards have no expiration date but the amount of the net operating loss carry-forward, which can be used each year to offset taxable earnings, is limited in all jurisdictions. The remaining tax loss carry-forwards expire from years 2020 through 2030. In accordance with ASC 740, 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 asset will not be realized.

The 2017 U.S. Tax Act was enacted on December 22, 2017. The 2017 U.S. Tax Act includes a number of changes in existing tax law which impacted our business in the U.S. Starting with tax year 2018, the U.S. corporate tax rates changed from a graduated system ranging from 15% to 39% to a flat 21% of taxable net income. For taxable net income of $100K and greater for years 2018 and following, EDAP's U.S. subsidiary would pay significantly lower taxes than with the previous tax law.

Starting from tax year 2019, the French corporate tax rates of taxable net income will gradually decrease from 28% to 25% in 2022.

23-4 Effective tax income (expense)

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

	2020	2019	2018
Theoretical tax income / (loss) at French statutory tax rate	333	(614)	(6)
Income of foreign subsidiaries taxed at different tax rates	9	(51)	(124)
Effect of net operating loss carry-forwards and valuation allowances	(858)	189	(210)
Non-taxable debt fair value variation	—	—	235
Permanent differences	(159)	(251)	(392)
Effect of cancellation of intra-group positions	152	(54)	35
French business tax included in income tax (CVAE)	(156)	(159)	(161)
Other	164	263	265
Effective income (loss) tax	(516)	(679)	(358)

23-5 Uncertainty in Income Taxes

According to ASC 740, the Company reviewed the tax positions of each subsidiary. On December 31, 2020 the Company believes that there is no significant uncertainty in the Company's tax positions.

The Company remains subject to examination by major tax jurisdictions.

Interest and penalties on income taxes are classified as a component of the provision for income taxes. There were no interest or penalties in 2020, 2019 and 2018.

24— EARNINGS (LOSS) PER SHARE

	December 31, 2020	December 31, 2019	December 31, 2018
Income (loss) available to common shareholders (in Euros)	€ (1,703,668)	€ 1,512,056	€ (338,382)
Number of shares for the computation of basic EPS	29,148,108	29,016,118	28,997,866
Basic EPS (in Euros)	€ (0.06)	€ 0.05	€ (0.01)
Effect of dilutive securities	622,723	604,238	347,500
Number of shares for the computation of diluted EPS	29,148,108	29,615,466	28,997,866
Diluted EPS income / (loss) (in Euros)	€ (0.06)	€ 0.05	€ (0.01)

Diluted EPS income / (loss) available to common shareholders is computed including all dilutive securities that are in the money.

The effects of dilutive securities for the years ended December 31, 2020 and 2018 were excluded from the calculation of diluted earnings per share as a net loss was reported in these periods.

25— COMMITMENTS AND CONTINGENCIES

25-1 Commitments

The Company currently has commitments regarding its operating leases as described in Note 12-2.

25-2 Contingencies

The Company currently has contingencies relating to warranties provided to customers for products as described in Note 1-15 and Note 11.

26— FAIR VALUE OF FINANCIAL INSTRUMENTS

The following disclosure of the estimated fair value of financial instruments was made in accordance with the requirements of ASC 820 ‘‘Disclosure about fair value of financial instruments’’ and indicates the fair value hierarchy of the valuation techniques utilized to determine such fair value.

ASC 820 defines three levels of inputs that may be used to measure fair value and requires that the assets or liabilities carried at fair value be disclosed by the input level under which they were valued. The input levels are defined as follows:

Level 1: Quoted (unadjusted) prices in active markets for identical assets and liabilities that the reporting entity can access at the measurement date.

Level 2: Inputs other than quoted prices included within Level 1 that are observable for the asset or liability, either directly or indirectly.

Level 3: Unobservable inputs for the asset or liability.

	ASC 820 Level	December 31, 2020	December 31, 2019
Assets:			
Cash and cash equivalents	Level 1	24,696	20,886
Liabilities:			
Short-term borrowings	Level 1	2,638	3,513
Long-Term Debt	Level 1	5,675	1,420

The recorded amount of cash and cash equivalents and short-term borrowings are a reasonable estimate of their fair value due to the short-term maturities of these instruments.

The fair market value (Level 1 measurement) of the Company’s long-term debt is estimated using interest rate available to the Company in corresponding markets for debt with similar terms and maturities (see note 15-1 Long-term debt).

27— CONCENTRATION OF CREDIT RISK

Financial instruments, which potentially subject the Company to concentrations of credit risk, consist principally of cash and cash equivalents and trade accounts and notes receivable from customers, primarily located in France, Japan and the United States. The Company maintains cash deposits with major banks. Management periodically assesses the financial condition of these institutions and believes that credit risk is limited.

The Company has implemented procedures to monitor the creditworthiness of its customers. The Company obtains bank guarantees for first time or infrequent customers, and in certain cases obtains insurance against the risk of a payment default by the customer. The Company reviewed individual customer balances considering current and historical loss experience and general economic conditions in determining the allowance for doubtful accounts receivable of €0.7 million and €1.5 million, for the years ended December 31, 2020 and 2019, respectively.

Actual losses may vary from the current estimates, and any adjustments are reported in earnings in the periods in which they become known.

In 2020, 2019 and 2018, the Company did not generate more than 10% revenue with a single customer.

28— FOREIGN CURRENCY TRANSACTIONS

The Company generates a significant percentage of its revenues, and of its operating expenses, in currencies other than the euro. The Company's operating profitability could be materially adversely affected by large fluctuations in the rate of exchange between the euro and such other currencies. The Company engages in foreign exchange hedging activities when it deems necessary, but there can be no assurance that hedging activities will be offset by the impact of movements in exchange rates on the Company's results of operations. As of December 31, 2020, there were no outstanding hedging instruments.

29— SEGMENT INFORMATION

We recently implemented organizational changes in our structure and realigned our activity into three divisions: HIFU, ESWL (including lithotripsy activities) and Distribution to better reflect how we view our businesses and how we measure our progress. Through these three divisions, we develop, produce, market and distribute minimally invasive medical devices, mainly for urological diseases. HIFU division includes sales of Focal One, Ablatherm and related consumables and services, ESWL division includes revenues generated by the existing Sonolith range of lithotripters and, Distribution division includes the sale of complimentary products such as lasers, micro-ultrasound systems and other products from third parties.

The organization of our activities into three divisions better clarified our vision and enhanced our financial reporting of our three businesses HIFU, ESWL and Distribution. This new structure also allows for an improved measurement of our business progress.

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

The following tables set forth the key Statement of income (loss) figures, by segment for fiscal years 2020, 2019 and 2018 and the key balance sheet figures, by segment, for fiscal years 2020, 2019 and 2018. Segment operating profit or loss and segment assets are determined in accordance with the same policies as those described in the summary of significant accounting policies and they are reviewed by the CODM, who is the CEO. Interest income and expense, current and deferred income taxes are not allocated to individual segments. A reconciliation of segment operating profit or loss to consolidated net loss is as follows:

	2020	2019	2018
Segment operating income (loss)	269	2,201	(1,315)
Financial income (expense), net	(98)	(146)	797
Foreign Currency exchange (losses) gains, net	(1,359)	136	538
Income tax (expense) credit	(516)	(679)	(358)
Consolidated net profit (loss)	(1,704)	1,512	(338)

A summary of the Company's operations by segment is presented below for years ending December 31, 2020, 2019 and 2018:

2020	HIFU Division	ESWL Division	DISTRIB Division	Reconciling Items	Total consolidated
Sales of goods	6,000	6,248	15,274		27,523
Sales of RPPs & leases	3,594	927	224		4,745
Sales of spare parts and services	1,831	5,707	1,844		9,382
Total sales	11,425	12,882	17,342		41,649
External other revenues	12	—	—		12
Total revenues	11,438	12,882	17,342		41,662
Total COS	(5,144)	(7,232)	(10,906)		(23,283)
Gross profit	6,293	5,649	6,436		18,379
R&D expenses	(2,583)	(1,555)	(358)		(4,496)
Selling and marketing expenses	(3,151)	(2,052)	(4,076)		(9,279)
G&A expenses	(1,005)	(964)	(900)	(1,465)	(4,335)
Total expenses	(6,738)	(4,572)	(5,335)	(1,465)	(18,110)
Operating income (loss) from operations	(445)	1,078	1,102	(1,465)	269
Total Assets	16,279	15,567	20,795	2,551	55,193
Capital expenditures	1,144	309	557	—	2,011
Non-current assets	3,706	2,466	3,628	—	9,801
Goodwill	645	496	1,271	—	2,412

2019	HIFU Division	ESWL Division	DISTRIB Division	Reconciling Items	Total consolidated
Sales of goods	8,311	6,715	15,084	—	30,111
Sales of RPPs & leases	4,162	1,426	158	—	5,747
Sales of spare parts and services	1,618	6,048	1,335	—	9,001
Total sales	14,092	14,190	16,578	—	44,859
External other revenues	52	—	—	—	52
Total revenues	14,144	14,190	16,578	—	44,912
Total COS	(6,152)	(7,816)	(9,941)	—	(23,909)
Gross profit	7,991	6,374	6,637	—	21,002
R&D expenses	(1,962)	(1,394)	(372)	—	(3,728)
Selling and marketing expenses	(4,402)	(2,441)	(4,008)	—	(10,850)
G&A expenses	(1,168)	(904)	(854)	—	(4,224)
Total expenses	(7,533)	(4,738)	(5,233)	—	(18,802)
Operating income (loss) from operations	459	1,635	1,404	—	2,201
Total Assets	16,665	15,892	16,500	4,012	53,068
Capital expenditures	915	298	319	—	1,532
Non-current assets	4,096	4,448	2,427	—	10,971
Goodwill	645	450	1,317	—	2,412

2018	HIFU Division	ESWL Division	DISTRIB Division	Reconciling Items	Total consolidated
Sales of goods	5,494	7,069	12,505	—	25,070
Sales of RPPs & leases	3,750	1,254	82	—	5,086
Sales of spare parts and services	1,780	6,157	1,070	—	9,007
Total sales	11,025	14,480	13,657	—	39,163
External other revenues	19	—	—	—	19
Total revenues	11,044	14,480	13,657	—	39,183
Total COS	(5,312)	(8,178)	(8,775)	—	(22,266)
Gross profit	5,732	6,302	4,882	—	16,917
R&D expenses	(2,394)	(1,410)	(285)	—	(4,088)
Selling and marketing expenses	(4,628)	(2,357)	(3,566)	—	(10,551)
G&A expenses	(1,036)	(731)	(580)	(1,247)	(3,593)
Total expenses	(8,057)	(4,498)	(4,431)	(1,247)	(18,232)
Operating income (loss) from operations	(2,325)	1,804	451	(1,247)	(1,316)
Total Assets	13,648	16,700	13,149	5,243	48,740
Capital expenditures	1,154	451	324	—	1,928
Non-current assets	2,855	3,697	1,462	—	8,013
Goodwill	645	403	1,364	—	2,412

30— VALUATION ACCOUNTS

	Allowance for deferred tax assets	Allowance for doubtful accounts	Slow-moving inventory	Warranty reserve
Balance as of December 31, 2017	14,266	1,029	723	449
Charges to costs and expenses	515	365	355	433
Deductions: write-off and others	(228)	10	(104)	(334)
Balance as of December 31, 2018	14,553	1,404	974	548
Charges to costs and expenses	859	94	333	131
Deductions: write-off and others	(435)	(9)	(223)	(308)
Balance as of December 31, 2019	14,977	1,490	1,085	370
Charges to costs and expenses	596	90	651	266
Deductions: write-off and others	(65)	(858)	(172)	(268)
Balance as of December 31, 2020	15,508	722	1,563	368

31— SUPPLEMENTAL DISCLOSURES OF CASH FLOW INFORMATION

Interest and income taxes paid are as follows:

	2020	2019	2018
Income taxes paid (refunds received)	377	289	407
Interest paid	124	87	49
Interest received	10	17	12

Non-cash transactions:	2020	2019	2018
Financing lease obligations incurred	192	203	427
Operating lease obligations incurred	317	3,483	—

Cash paid for amounts included in the measurement of lease liabilities:

	2020
Operating cash flow used in operating leases	941
Operating cash flow used in finance leases	18
Financing cash flow used in finance leases	321

32— RELATED PARTY TRANSACTIONS

On August 19, 2019, 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 parent company, counter-warranted this personal loan and agreed to indemnify Mr. Bachelard, in an indemnification letter dated September 12, 2019 expiring upon loan maturity date of August 26, 2026.

On March 27, 2019, EDAP Technomed Sdn Bdh (Malaysia) contracted with Maybank to establish a fixed deposit amounting 65,464.85 MYR. As a current practice in Malaysia, any fixed deposit requires a personal warranty from the representative director, president and CEO of the subsidiary Mr. Hervé de Soultrait. EDAP TMS S.A., as the parent company, counter-warranted this deposit and agreed to indemnify Mr. de Soultrait, in an indemnification letter dated September 13, 2019, which expired upon loan maturity date of March 27, 2020.

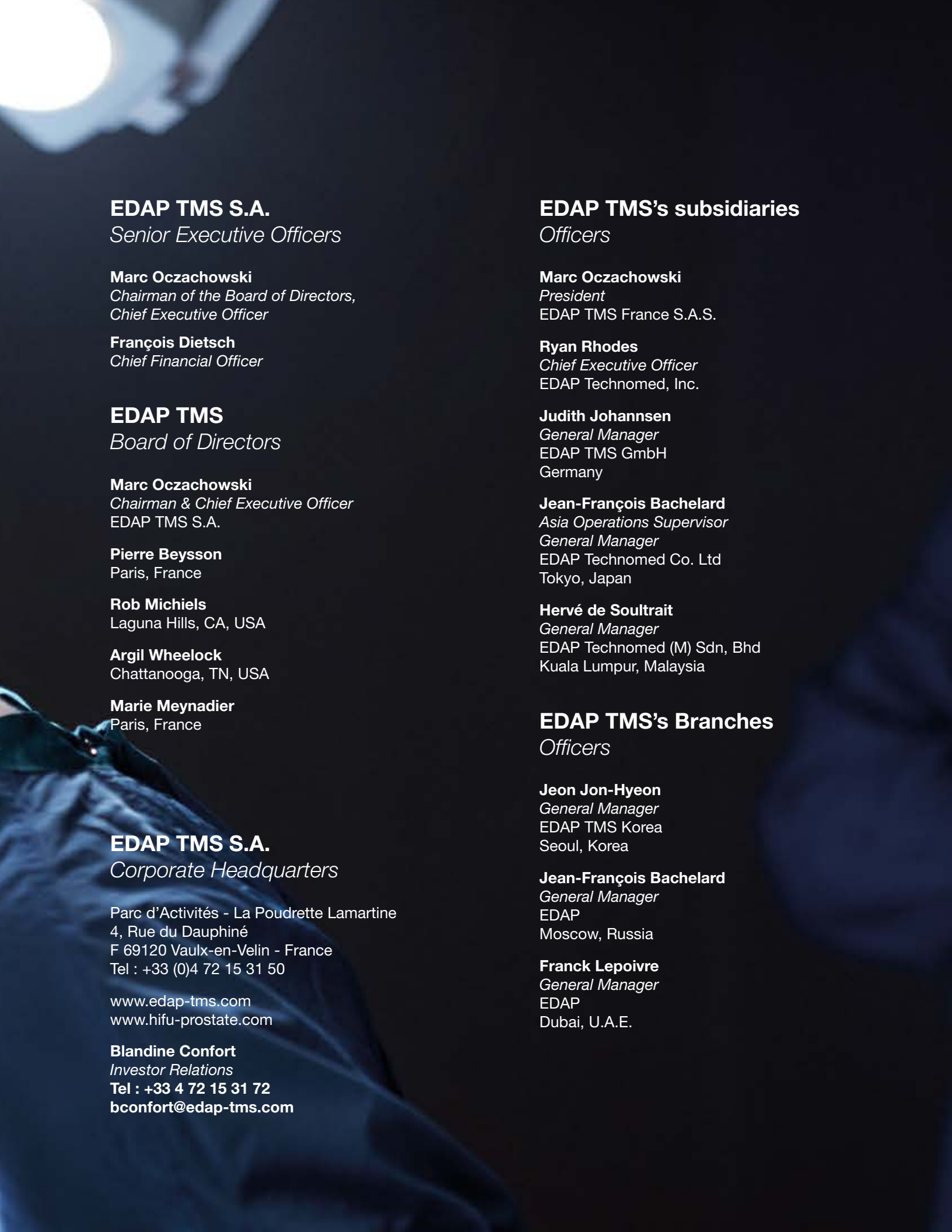
On August 2, 2019, EDAP Technomed Inc. contracted a car lease amounting $28,756.44. This lease required a personal warranty from the president of the subsidiary Mr. Marc Oczachowski. EDAP TMS S.A., as the parent company, counter-warranted this personal lease warranty and agreed to indemnify Mr. Marc Oczachowski, in an indemnification letter dated July 1, 2019, expiring upon car lease maturity date of July 2, 2022.

On April 22, 2020, EDAP Technomed Co. Ltd (Japan) contracted another loan amounting 50,000,000 JPY requiring a personal warranty from the representative director, president and CEO of the subsidiary Mr. Jean-François Bachelard. EDAP TMS S.A., as the parent company, counter-warranted this personal loan and agreed to indemnify Mr. Bachelard, in an indemnification letter dated June 2, 2020, expiring upon loan maturity date of April 2, 2025.

On September 2, 2020, a consulting agreement was established between Mr. Philippe Chauveau, Chairman of the Board of the Company up to June 23, 2020 (date of expiration of his mandate as a Director) and the Company. As per this agreement, Mr. Chauveau, is to provide Mr. Oczachowski, new Chairman of the Board, with advice and recommendations on various subjects related to the Company's activity and strategic projects. This consulting agreement can be terminated at any time with 30 days notice. For the period ending 2020, the Company paid €6,000 under this contract.

33— SUBSEQUENT EVENTS

N/A



EDAP TMS S.A.
Senior Executive Officers

Marc Oczachowski
Chairman of the Board of Directors,
Chief Executive Officer

François Dietsch
Chief Financial Officer

EDAP TMS
Board of Directors

Marc Oczachowski
Chairman & Chief Executive Officer
EDAP TMS S.A.

Pierre Beysson
Paris, France

Rob Michiels
Laguna Hills, CA, USA

Argil Wheelock
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General Manager
EDAP TMS GmbH
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Jean-François Bachelard
Asia Operations Supervisor
General Manager
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Hervé de Soultrait
General Manager
EDAP Technomed (M) Sdn, Bhd
Kuala Lumpur, Malaysia

EDAP TMS's Branches
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Jeon Jon-Hyeon
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EDAP TMS Korea
Seoul, Korea

Jean-François Bachelard
General Manager
EDAP
Moscow, Russia

Franck Lepoivre
General Manager
EDAP
Dubai, U.A.E.

by edap tms

EDAP TMS is a high-tech medical company listed on the Nasdaq (EDAP) which develops, manufactures and markets minimally invasive medical devices using ultrasound technology for various medical applications and offers a wide portfolio of complementary distribution products in urology.

By strongly investing in R&D activities and partnering with renowned medical research institutions since its inception in 1979, EDAP TMS today's development efforts are focused on making High Intensity Focused Ultrasound (HIFU) a standard therapy for soft tissue ablation.

Based near Lyon-France, the company is actively operating worldwide with subsidiaries and offices in USA, Japan, Germany, Malaysia, South Korea, UAE and Russia, as well as through more than 70 distribution partners.

The HIFU and ESWL divisions market products developed and manufactured by EDAP TMS for the treatment of Prostate Cancer and Urinary Stones. To complete EDAP's product offering, the distribution division also markets third-party devices in the urology space.

edap tms
Bringing New Horizons to Therapy

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