edap | Focal·One®
ROBOTIC FOCAL HIFU

The **Global Leader** in **Therapeutic Ultrasound**

2024 **Annual Report**

March 31, 2025

Dear Fellow Shareholders:

In 2024, we made significant progress establishing Focal One® Robotic HIFU as a mainstream treatment option for the management of prostate cancer. During the year, we placed a record number of Focal One Systems and experienced a 51% increase in the number of U.S. Focal One procedures over 2023, which clearly reflects growing adoption and utilization of the Focal One platform.

As Focal One continues to change the treatment paradigm of prostate cancer, we anticipate a growing number of independent studies to emerge that will support the use of the Focal One procedure for early-stage prostate cancer. Without question, the landmark HIFI study is the single most important study to date that demonstrates the effectiveness and safety of Focal One as a front-line treatment option for the treatment of early-state prostate cancer. As announced back in December, the HIFI study was recently published in the prestigious medical journal, *European Urology*, and we expect the widespread dissemination of this publication will help drive further adoption of Focal One. As the number of studies grow, we also expect procedure reimbursement will remain favorable. HIFU procedures continue to be supported with favorable reimbursement from the Center for Medicare and Medicaid Services, which increased its 2025 Medicare Hospital Outpatient payment rate by 5.4% over the 2024 payment amount.

We also remain active in our collaborative activity, which enables us to maintain our technology leading position in the market. In February, EDAP and Cortechs.AI announced the successful completion of the world's first OnQ Prostate-assisted Focal One Robotic HIFU procedure. As the only FDA-cleared solution for Restriction Spectrum Imaging-MRI, OnQ Prostate provides more detailed information about the tissue microstructure that can help urologists identify which patients are the best candidates for focal therapy. Last November, Meridian Hackensack University Medical Center announced the first prostate cancer treatments with Focal One Robotic HIFU using the Philips DynaCAD Urology platform. Both of these collaborations demonstrate our steadfast commitment to expanding the capabilities of Focal One to enable urologists to deliver a precise, customized treatment solution for their prostate cancer patients.

As we further develop the Focal One market in prostate cancer, we also continue to make significant progress advancing the use of therapeutic HIFU to address additional disease states. In January, we announced that the first patient was treated in the PULS Trial to evaluate our proprietary HIFU technology for the treatment of pancreatic tumors. Additionally, in the fourth quarter of 2024, we initiated a Phase I/II study evaluating the Focal One robotic HIFU technology for the treatment of benign prostatic hyperplasia. Finally, the collective data from three clinical studies in the treatment of deep infiltrating endometriosis suggests that HIFU also has the potential to become an alternative to surgical intervention for select patients, enabling us an important opportunity to address a significant unmet need in women's health. These advancing clinical-stage development programs provide us with additional opportunities for strong, long-term growth, with the potential to bring the benefits of therapeutic HIFU to these large and underserved patient populations.

As our investors know, we have been steadily realigning our business to focus exclusively on the multiple high growth opportunities in therapeutic HIFU where we believe the Focal One platform gives us a distinct and sustainable competitive advantage. To help us achieve this objective, we have made notable new appointments to our Board of Directors that provide us with significant added talent, creativity, and industry experience to help us further execute on our strategic growth initiatives. Most recently, we appointed Glen French and Joshua Levine as new EDAP Board members. Both of these highly accomplished individuals will be instrumental in helping us to further drive our Company strategy and direction as the leading market provider in the delivery of therapeutic HIFU.

Looking back, our numerous accomplishments in 2024 position us well for continued success in 2025 and beyond. As always, I would like to thank our dedicated employees and business partners whose collective efforts are making this extraordinary transformation in the management and treatment of prostate cancer a significant reality. While changing long-standing medical practices is not without its challenges, our team's unwavering commitment to customer support and continued education is continuing to raise the equity of the Focal One brand across the global urology community. Together, we are reshaping the treatment paradigm of prostate cancer to better serve patients and their families around the world.

I would like to thank our shareholders for your continued support, and I look forward to sharing with you additional progress throughout 2025.

Sincerely,

Ryan Rhodes
Chief Executive Officer

As filed with the Securities and Exchange Commission on March 27, 2025

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, 2024

OR

☐ TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(D) OF THE SECURITIES EXCHANGE ACT OF 1934

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_____
For the transition period from _____ to _____

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)

Blandine Confort
Legal Affairs Director
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(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, 2024: 37,392,086 ordinary shares

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes __ No X

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

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

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

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

Large accelerated filer __ Accelerated filer X Non-accelerated filer __ Emerging growth company __

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

† The term "new or revised financial accounting standard" refers to any update issued by the Financial Accounting Standards Board to its Accounting Standards Codification after April 5, 2012. Indicate by check mark which basis of accounting the registrant has used to prepare the financial statements included in this filing:

Indicate by check mark whether the registrant has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report. X__

If securities are registered pursuant to Section 12(b) of the Act, indicate by check mark whether the financial statements of the registrant included in the filing reflect the correction of an error to previously issued financial statements. __

Indicate by check mark whether any of those error corrections are restatements that required a recovery analysis of incentive- based compensation received by any of the registrant's executive officers during the relevant recovery period pursuant to §240.10D-1(b). __

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® and 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 applicable federal securities laws, including 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," "can," "contemplate," "could," "plan," "intend," "is designed to," "may," "might," "potential," "objective," "target," "project," "predict," "forecast," "ambition," "aim", "guideline," "should," "will," "estimate," "expect" and "anticipate," or the negative of these and 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:

- insufficient funds to support our operations which may lead to a substantial doubt about our ability to continue as a going concern;
- the success of our High Intensity Focused Ultrasound ("HIFU") technology;
- the uncertainty of market further 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 and our ability to maintain our Intellectual Property protection;
- cybersecurity risks and incidents,
- product liability risk;
- risk of exchange rate fluctuations, particularly between the euro and the U.S. dollar and between the euro and the Japanese yen;
- fluctuations in results of operations due to the cyclical nature of demand for medical devices;
- risks associated with the current worldwide inflationary environment, uncertain worldwide economic, political, social and geopolitical developments, financial changes, and the impact of climate change.
- 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. In light of the significant uncertainties in these forward-looking statements, you should not regard these statements as a representation or warranty by us or any other person that we will achieve our objectives and plans in any specified time frame or at all. Moreover, 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. These forward-looking statements are based upon information, assumptions and estimates available to us as of the date of this annual report, and while we believe such information forms a reasonable basis for such statements, such information may be limited or incomplete, and our statements should not be read to indicate that we have conducted an exhaustive inquiry into, or review of, all potentially available relevant information. In light of these risks, uncertainties and assumptions, you should not place undue reliance on any forward looking statements contained herein.

You should read this annual report and the documents that we reference in this annual report and have filed as exhibits completely and with the understanding that our actual future results may be materially different from what we expect. We qualify all of our forward-looking statements by these cautionary statements.

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

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."

Summary of Key Risks

Our business and our industry are subject to numerous risks described in the following risk factors and elsewhere in this annual report, Investors should carefully consider these risks before making a decision to invest in our securities.

The main risk factors relating to the Company and its business operations are grouped into the seven categories listed below. The most important risk factors have been identified and assessed considering the likelihood of occurrence and the possible negative effect on the Company, in each case also taking into account corrective actions and risk management measures that have been put in place. The occurrence of new events, whether internal or external to the Company, is therefore likely to modify this ranking in the future.

Risks Relating to our Business, Financial Position and Capital Needs

- Our history of losses and our expectation of continuing negative cash flows may raise substantial doubt about our ability to continue as a going concern and may hinder our ability to access the debt and equity capital markets to help meet our cash needs.
- Our future revenue and income growth depends, among other things, on implementing our business strategy, which largely depends on the success of our HIFU technology.
- Our cash flow is highly dependent on cyclical demand for our products.
- Our results of operations have fluctuated significantly from quarter to quarter in the past and may continue to do so in the future.

Risks Related to our Product Candidates and the Industry in which we Operate

- If we do not optimize our sales channels and maintain high product quality, our operating results may be negatively impacted.
- New device developments and introductions may adversely impact our financial results.
- Our future success depends on obtaining and maintaining government regulatory approval of our products.
- Our business depends on the success of our clinical trials related to products using HIFU technology.
- The commercial success of our products depends on whether our products are eligible for reimbursement by national health authorities and third party payers.
- HIFU technology may not be widely adopted by the medical community and may never become a standard of care.
- There is a substantial risk our products or service offerings could become obsolete or uncompetitive.

Risks Related to our Organization and Operations

- Our revenue may be disrupted due to our strategic shift to focus on HIFU activities away from our legacy non-HIFU activities.
- We may face a significant risk of exposure to product liability claims linked to the misuse of our products.
- We depend on a single site to manufacture our products, and any interruption of operations could impact our business.
- We depend on a small number of suppliers who 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 utilize distributors for our sales abroad, which subjects us to a number of risks that could harm our business.
- We are a relatively small company and sales fluctuations and employee turnover may adversely affect our business.
- The loss of key members of our executive management team could adversely affect our business.
- We may have difficulties in attracting and recruiting highly qualified experts in hardware, software, artificial intelligence, design and development of high technology devices.
- We have identified material weaknesses in our internal control over financial reporting with respect to our U.S. subsidiary. If we fail to remediate these material weaknesses or if we experience additional material weaknesses in the future or otherwise fail to achieve an effective system of internal controls, we may not be able to report our financial results accurately or timely. In addition, the trading price of our securities may be adversely affected
- We are exposed to risks related to cybersecurity threats and incidents.
- The expansion of social media platforms and new technologies present risks and challenges for our business and reputation.

Risks Related to Intellectual Property Rights

- Our success largely depends on our ability to establish and protect the intellectual property rights related to our medical devices.
- We may encounter disruption in our Intellectual Property protections due to expiring patents and lack of updated filings.
- U.S. laws relating to the patentability of certain inventions in medical technology industry are uncertain and rapidly changing, which may adversely impact our existing patents or our ability to obtain patents in the future.
- We may not be able to protect or enforce our intellectual property rights throughout the world.
- Our use of "open source" software could negatively affect our ability to sell our products and subject us to possible litigation.

Risks Relating to our Status as a Foreign Private Issuer or a French Company

- Our French and international operations expose us to additional costs, legal and regulatory risks, which could have a material adverse effect on our business, financial condition and results of operations.
- We sell our products in many parts of the world, as a result, our business is affected by fluctuations in currency exchange rates.
- Our by-laws and French corporate law contain provisions that may delay or discourage a takeover attempt.
- The rights of shareholders in companies subject to French corporate law differ in material respects from the rights of shareholders of corporations incorporated in the United States or other countries.
- French law may limit the amount of dividends we are able to distribute, and we do not currently intend to pay dividends.

- We expect to lose our foreign private issuer status in 2026, which will likely result in significant additional costs and expenses.
- 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.

Risks Related to Ownership of our Ordinary Shares and the ADSs

- Our securities may be affected by volume fluctuations, and may fluctuate significantly in price, causing investors to lose some or all of their investment.
- Holders of ADSs have fewer rights than direct shareholders and must act through the Depositary to exercise those rights.
- If securities or industry analysts do not publish research, or publish inaccurate or unfavorable research, about our market or business, our ADS price and trading volume could decline.
- We are subject to different corporate disclosure standards that may limit the information available to holders of our ADSs.
- Preferential subscription rights may not be available for U.S. persons.

General Risk Factors

- Our results of operations and financial condition could be adversely affected by adverse economic changes, political, social and geopolitical developments, financial changes, and the impact of climate change.
- Global potential inflation may 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.
- We may in the future be the target of securities class action or other litigation, which could be costly and time consuming to defend.

Risks Relating to Our Business, Financial Position and Capital Needs

We may in the future face substantial doubt about our ability to continue as a going concern as a result of our history of operating losses and our expectation of continuing negative cash flows, which could hinder our ability to access the debt and equity capital markets to help meet our cash needs.

We have a history of operating losses and expect such losses to continue in the foreseeable future. As of December 31, 2024, we had €29.8 million in cash and cash equivalents, a decrease of €13.6 million from December 31, 2023. We believe we have sufficient funds to support our operations for at least a period of twelve months from the date of issue of our consolidated financial statements. However, we will need to raise substantial additional financing in order to meet our cash flow needs in the subsequent period and until we achieve profitability. We may not be able to raise additional financing on acceptable terms or at all and this condition may in the future raise uncertainty regarding our ability to continue as a going concern. Management is actively exploring various alternatives, including seeking additional funding through the debt and equity capital markets, cost-cutting measures, and restructuring opportunities, but there is no assurance that these efforts will be successful or sufficient to address these liquidity concerns. If we are unable to raise capital when needed on acceptable terms, or at all, we may be forced to restructure our business or delay, reduce, or terminate our research and product development programs, future commercialization efforts or other operations. See Note 1-2 to our consolidated financial statements.

Our future revenue and income growth depends, among other things, on implementing our business strategy, which largely depends on the success of our HIFU technology, and our capacity to scale our operations to manage and sustain our future growth.

Our business strategy depends on the success of our HIFU technology for future revenue growth and net profit generation. We are dependent on the successful development and commercialization of other product lines, such as devices based on HIFU but not limited to the Focal One System, to generate significant additional revenues and to achieve and sustain profitability in the future. To implement our business strategy, we need (among other things) to develop new applications for our HIFU technology, to improve our products and service offerings, and to educate physicians and patients about the clinical and cost benefits of our products, all of which we believe could increase patients' wellbeing and acceptance of our products. Our focus is to primarily expand our HIFU business in the U.S. as HIFU is FDA approved for ablation of prostate tissue and reimbursed at an acceptable level. Although we are particularly dependent on the success of our HIFU technology to grow our business through our 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, contributed to our global revenue in 2024. In 2025, we will

discontinue system sales in our ESWL business, but we will continue to service our existing installed base. This will result in a decline in revenue related to ESWL in 2025 and subsequent periods. In addition, some distribution agreements with third parties expired in December 2024 and were not renewed; the termination of these commitments from such third parties will have a material adverse effect on our revenue, financial condition and results of operations. See Item 4, "Information on the Company—ESWL Division" and "Information on the Company—Distribution Division."

In addition, there can be no assurance that we will be able to manage our future growth efficiently or profitably, and revenue may be less than expected. If we are unable to scale our production capabilities efficiently or maintain pricing, we may fail to achieve expected operating margins, which would have a material and adverse effect on our operating results. Growth may also stress our ability to adequately manage our operations, quality of products, safety, and regulatory compliance. Failure to implement necessary internal quality controls, procedures, equipment, or processes or to hire the necessary personnel in a timely and effective manner could result in higher costs or an inability to meet market demand and could have a material adverse impact on our business, results of operations, financial condition, and prospects. Additionally, our future growth will increase the demands placed on our third-party suppliers, and there is no guarantee that our suppliers will be able to support our anticipated growth. If growth significantly changes, it can negatively impact our cash reserves, and we may be required to obtain additional financing, which may increase indebtedness or result in dilution to shareholders. Further, there can be no assurance that we would be able to obtain additional financing on acceptable terms, if at all.

Although we achieved operating income in 2020, we incurred operating losses in 2021, 2022, 2023 and 2024. We expect that our marketing, selling and research and development expenses will increase as we attempt to further develop and commercialize our HIFU devices and particularly with the planned acceleration of our U.S. HIFU expansion plan. In this respect, we may not generate a sufficient level of revenue to offset these expenses and may not be able to adjust spending in a timely manner to respond to any unanticipated decline in revenue. We cannot guarantee that we will realize sufficient revenue to achieve profitability in the future. See Item 5, "*Operating and Financial Review and Prospects.*"

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

Our operating cash flow has historically been subject to significant fluctuations over the course of any given fiscal year due to cyclical demand for medical devices, in particular with hospital budgets being mostly spent at year-end, 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, in addition to raising additional funding, 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 cash flow is affected by increased expenses in clinical trials, sales efforts and other market costs related to implementing our expanded U.S. and global strategy, which 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 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 financing.

Our results of operations have fluctuated in the past and may continue to fluctuate 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 to purchase and often require the approval of multiple levels of management or Boards of hospitals, purchasing groups and, in some cases, government authorities. In addition, some sales are subject to a public tender offer process with many approvals which could be lengthy to obtain, and, as a result, hospitals may delay their purchase orders according to their timelines and budget allocations. It is difficult to predict the exact timing for closing product sales directly linked to the length of capital expenditure cycles.

In addition, our customers may rely on the credit market to secure dedicated lease financing to purchase or lease our equipment. Due to the limited availability of lending, we may be unable to access sufficient lease financing to support these transactions. Without lease financing, we may be unable to continue the development of our revenue-per-procedure ("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. In addition, the current macro-economic environment with elevated or increasing interest rates as compared to prior years, may make lease financing less attractive and more difficult to implement for our customers.

Risks Related to our Product Candidates and the Industry in which we Operate

If we do not successfully optimize our sales, marketing, and potential future distribution channels or do not effectively expand and update our infrastructure, or maintain high product quality and reliability, our operating results may be negatively impacted.

If we do not adequately predict market demand or otherwise optimize and operate our sales, marketing and potential future distribution channels successfully, it could result in excess or insufficient inventory or fulfillment capacity, increased costs, or immediate shortages in product or component supply, or harm our business in other ways. In addition, if we do not maintain adequate infrastructure to enable us to, among other things, manage our purchasing and inventory levels, it could negatively impact our cash flow and operating results.

Moreover, our future success will depend largely on our ability to continue to hire, train, retain and motivate skilled sales representatives or distributors with significant technical and clinical knowledge about our products. New hires require training, supervision and take time to achieve full productivity. If we fail to train and supervise new hires adequately, or if we experience a high turnover in our sales force or trained professionals in the future, we cannot be certain that we will maintain or increase our sales. If we are unable to expand our sales and marketing capabilities, we may not be able to effectively commercialize our HIFU devices or our other products and service offerings in development, which would adversely affect our business, results of operations, and financial condition.

Our success depends on the quality and reliability of our products. While we subject our devices to stringent quality specifications and processes, our products incorporate mechanical parts, electrical components and computer software, any of which may contain errors or exhibit failures, especially when devices are first introduced. Component failures, manufacturing flaws, design defects, or inadequate disclosure of product-related risks with respect to our products could result in an unsafe condition or injury to, or death of, the patient. In addition, new devices or developments may contain undetected errors or performance problems that, despite testing, are discovered only after commercial placement. Any of the foregoing would adversely affect our business, results of operations, and financial condition.

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

From time to time, we may develop and introduce new devices, hardware and software, with enhanced features, including artificial intelligence ("AI"). These developments may extend a product's 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 approvals 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, European Union 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 U.S. Food and Drug Administration ("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. 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. Such standards may change or evolve, requiring that we change or evolve our manufacturing operations. We may not always 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 corrective or 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.

In the European Union, the regulation of medical devices is being updated by the European Medical Device Regulation ("MDR") imposing stricter requirements on the conformity assessment and the commercialization of our products. A transition period to conform to MDR requirement has been adopted based on MDR classification of devices with an application date of December 31, 2028, at the latest. The extension of the period during which the devices can be placed on the market is subject to certain conditions. To benefit from the new provisions, we were required to, and did, implement a Quality Management System ("QMS") that complies with the MDR requirements. An MDR compliance action plan has been put in place in preparation of MDR enforcement within the expected timelines. We are implementing operational actions and internal audits to ensure our devices may be distributed on the European and international market and conform to MDR requirements, where applicable. However, the uncertainty of continuing healthcare changes, regulations, and our ability to maintain MDR compliance of our products may negatively affect our business.

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 Clinical and Regulatory Status.*"

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 in each intended use. 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. We could suffer significant setbacks in later-stage clinical trials, even after promising results in earlier trials. Furthermore, data obtained from a trial might be insufficient to demonstrate that our products are safe, and effective. 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—HIFU Clinical and Regulatory Status*;"
- slower than expected rates of patient recruitment and enrollment;
- inability to adequately monitor patients 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 preclinical studies, current clinical trials, 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/or efficacy of our products in our clinical trials, we will be unable to obtain regulatory approval to market our products.

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 from management, without any guarantee of success, which could materially adversely affect our business, financial condition and results of operations.

The commercial success of our products depends on whether procedures performed using 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 2022, CMS published its final rules for the calendar year 2023 for ambulatory payment classification ("APC") procedures and physician fee schedule, which established reimbursement rates that recognize both facility or hospital payment and physician professional service payments for HIFU procedures. CMS final rule included a reimbursement level close to surgery, effective on January 1, 2023. The 2025 final rule maintained APC 6 payment level. For private insurers, policy coverage decisions supporting coverage and reimbursement related to HIFU procedures are limited given that HIFU is a new technology. 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 positively or negatively impact reimbursement for procedures performed using our devices and may result in a material adverse effect on our business, financial condition 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.*"

We cannot assure investors that expanded coverage decisions or additional reimbursement approvals will be obtained in the near future, if ever. 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 widely adopted by the medical community and may never become a standard of care, and we may be unable to generate sufficient revenue to sustain our business.

Our success depends on the market's confidence that our HIFU devices can provide reliable, high-quality results or treatments and we believe that physicians are likely to be particularly sensitive to any test defects and errors in our devices. Our robotic HIFU devices represent innovative 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. The failure of our current HIFU devices to perform as expected would significantly impair our reputation. 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.

Competition in the markets in which we operate is intense and is expected to increase in the future, and there is a substantial risk our products or service offerings could become obsolete or uncompetitive.

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, the Focal One system competes with all current treatments for localized tumors, including surgery, external beam radiotherapy, brachytherapy, irreversible electroporation and cryotherapy. See Item 4, "*Information on the Company—HIFU Division— HIFU Competition.*" In our ESWL division, we are also facing competition from lower priced laser systems. 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.

Risks Related to our Organization and Operations

We may experience revenue disruption due to our strategic shift to focus on HIFU activities and away from legacy non-HIFU activities.

Our new strategy is to increase investments in our core proprietary growth HIFU activities and place less emphasis on our non-HIFU distribution and ESWL business activities. As part of this strategy, certain existing distribution agreements with third-party partners have been terminated or may not be renewed. While this strategy aligns with our long-term strategic goals, it carries inherent risks, including:

- a potential reduction in our global near-term revenue as we scale back our distribution activities;
- a possible decline in stock price, particularly if investors perceive the shift as a risk to short-term revenues, if investors do not agree with the strategic change, or if the transition does not proceed as smoothly as anticipated; and
- strained relationships with investors and stakeholders who may be concerned about the potential negative financial and reputational impact of this strategic change, including the potential loss of revenue streams from non-HIFU activities.

While we believe that this strategic focus will position us for stronger, sustainable growth, the execution of this transition may involve significant risks that could materially impact our financial performance and shareholder value in the short term.

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 and our insurance coverage may be inadequate.

Our products are designed to be used safely 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.

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, near Lyon, France. Our facility is Good Manufacturing Practice ("GMP") certified. In the event of a significant interruption in the operations of our sole facility for any reason, such as fire, cyber attack, supply disruption on a critical component, weather conditions, or other natural disasters or potential future pandemics, or a failure to obtain or maintain required regulatory approvals, we would have no other means of manufacturing our products until we would be 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.

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

We purchase most of the components used in our products from a number of suppliers but rely on a small number of suppliers or even one single supplier for some key components. In addition, we rely on a small number of suppliers for certain services. If the supply of these components or services were interrupted for any reason, including geopolitical tensions or instability, global supply chain failures, weather conditions, large-scale cyber attack or infrastructure disruption, a pandemic and implied restrictions, our manufacturing and marketing of the affected products would be delayed. Certain of these key suppliers may be exposed to variations in the costs of raw materials and components, and, consequently, may suffer issues or delays in sourcing these components, which would harm their business and operations. 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 for any reason, including higher energy, raw material or component prices, therefore causing additional charges for us and impacting our margins. For example, a major change in our current ultrasound supplier's strategy resulted in a cost increase to our HIFU systems in 2024. This cost increase has the potential to negatively impact our margins in a short period of time. We have identified a new supplier of ultrasound components, offering a cost-effective solution, and we expect to commercialize HIFU systems based on this technology by the end of 2025. The alternative component may face regulatory approval challenges or cost constraints that could delay its readiness. We expect to continue to depend upon our suppliers for the foreseeable future, while we explore new sourcing alternatives. Failure to obtain adequate supplies of components or services in a timely manner and at an acceptable price could have a material adverse effect on our business, financial condition and results of operations.

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 cases. Moreover, our distributors must be in compliance with all anti-corruption laws and applicable sanctions, such as the U.S. Foreign Corrupt Practices Act ("FCPA"), sanctions imposed by the U.S. Department of the Treasury's Office of Foreign Assets Control, the European Union, His Majesty's Treasury, or other governmental or supranational entities, and other local laws prohibiting improper payments to governmental officials or to customers and we may not be able to trace or be kept informed of such improper payments. 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 and our insurance coverage may be inadequate.*"

We are a relatively small company with a limited number of products and staff. Sales fluctuations and employee turnover may adversely affect our business.

We are a relatively small company. Consequently, compared to larger companies, sales fluctuations could have a greater impact on our revenue and profitability on a quarter-to-quarter and year-to-year basis and delays in customer orders could cause our operating results to vary significantly from quarter-to-quarter and year-to-year. In addition, as a small company we have limited staff and are heavily reliant on certain key personnel to operate our business. If a key employee were to leave our company it could have a material impact on our business and the results of operations as we might not have sufficient depth in our staffing to fill the role that was previously being performed. A delay in filling the vacated position could put a strain on existing personnel or result in a failure to satisfy our contractual obligations or to effectively implement our internal controls and materially harm our business.

The loss of key members of our executive management team could adversely affect our business.

Our success in implementing our business strategy depends largely on the skills, experience and performance of key members of our executive management team and others in key management positions. The collective efforts of each of these people, and others collaborating with them as a team, are critical to us. As a result of the difficulty in locating qualified personnel and new management, the loss or incapacity of existing members of our executive management team could adversely affect our operations. If we were to lose one or more of these key employees, we could experience difficulties in finding qualified successors, competing effectively, developing our technologies and implementing our business strategy.

In addition, we rely on collaborators, consultants and advisors, including scientific and clinical advisors, to assist us in formulating our research and development and commercialization strategy. Our collaborators, consultants and advisors are generally employed by employers other than us and may have commitments, or conflict of interest, or be subject to other agreements with other entities that may limit their availability to us.

We may have difficulties in attracting and recruiting highly qualified experts in hardware, software, artificial intelligence, design and development of high technology devices.

Our devices require highly qualified individuals with a high level of expertise and experience in design, software, artificial intelligence, 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.

We have identified two material weaknesses in our internal control over financial reporting with respect to our U.S. subsidiary. If we fail to remediate these material weaknesses or if we experience additional material weaknesses in the future or otherwise fail to achieve an effective system of internal controls, we may not be able to report our financial results accurately or timely. In addition, the trading price of our securities may be adversely affected.

As a publicly traded company, we are subject to the reporting requirements of the Exchange Act and the Sarbanes-Oxley Act of 2002. We have incurred, and expect to continue to incur, significant continuing costs, including accounting fees and staffing costs, to maintain compliance with the internal control requirements of the Sarbanes-Oxley Act of 2002. As described in Item 15, we have identified two material weaknesses with respect to internal control over financial reporting in our U.S. subsidiary, EDAP Technomed Inc, relating to: (i) an ineffective design and implementation of the subsidiary's control over the recording of third-party vendor invoices, and (ii) inherent IT system limitations, including that the system was not configured to sufficiently ensure data integrity, enforce segregation of duties, prevent erroneous or unauthorized changes to accounting entries made in current or previous reporting periods. Our management has concluded that, as a result, our internal control over financial reporting was not effective as of December 31, 2024. Nevertheless, we have concluded that these material weaknesses did not result in a material misstatement of the consolidated financial statements for the years ended December 31, 2024, and 2023, or require a restatement of consolidated financial statements with respect to any prior period previously reported by us.

Although we have initiated remediation actions to address these material weaknesses, as a small company, we may have insufficient personnel to allow us to segregate duties and consistently execute our internal controls.

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

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

In an effort to remediate the material weaknesses that were identified as of December 31, 2024, and to enhance our overall control environment, we hired new resources in 2024 and plan to hire additional resources in 2025. We are also working at deploying

another IT system in our U.S. subsidiary. We have hired a Global IT Leader to supervise such deployment. We believe this will allow us to remediate these material weaknesses in the near future. See Item 15, "*Controls and Procedures*."

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, and 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 securities to decrease substantially. Inferior controls and procedures could cause investors to lose confidence in our reported financial information, which may give rise to securities claims and have a negative effect on the value of our securities. 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 of 2002.

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 and similar attacks vary in their form and can include the deployment of harmful malware or ransomware, denial-of-services attacks, and other attacks, which may affect business continuity and threaten the availability, confidentiality and integrity of our systems and information. Cybersecurity incidents can also include employee or personnel failures, fraud, phishing or other social engineering attempts or other methods to cause confidential information, payments, account access or access to credentials, or other data to be transmitted to an unintended recipient. Cybersecurity threat actors also may attempt to exploit vulnerabilities through in software including software commonly used by companies in cloud-based services and bundled software. Cybersecurity incidents, such as breaches of data security, disruptions of information technology systems and other cyber attacks, 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, investigations or actions by regulators, 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 partly remote working conditions as well as the use of AI applications, which are subject to manipulation and may result in the unwanted exfiltration of data. While we have protocols in place to protect against such threats, we may fail to identify all threats, 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 incident, 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. While we maintain cyber insurance coverage that is intended to address data security risks, such insurance coverage may be insufficient to cover all losses or claims that may arise and there is no guarantee that such coverage will continue to be available on commercially reasonable terms or at all.

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.

Risks Related to Intellectual Property Rights

Our success largely depends on our ability to establish and protect the intellectual property rights related to our medical devices, and any dispute with respect to these rights could be costly and have an uncertain outcome and may prevent or delay our development and commercialization efforts.

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. We or our licensors may be subject to claims that former employees, collaborators or other third parties have an interest in our owned or in-licensed patents, trade secrets or other intellectual property as an inventor or co-inventor. 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 or amendment to our patents in such a way that they no longer cover our product candidates and existing products or provide any competitive advantage. The outcome of future such challenges is unpredictable, and the loss of patent protection could have a material adverse impact on our business, financial condition and result of operations.

If third parties, including our competitors, believe that our products or technologies infringe, misappropriate or otherwise violate their intellectual property rights, such third parties may seek to enforce against us their intellectual property rights, including patent rights, by filing against us an intellectual property-related lawsuit, including a patent infringement lawsuit. Even if we believe third-party intellectual property claims are without merit, there is no assurance that a court would find in our favor on questions of infringement, validity, enforceability, or priority. If any third parties were to assert these or any other patents against us and we are unable to successfully defend against any such assertions, we may be required, including by court order, to cease the development and commercialization of the infringing products or technology and we may be required to redesign such products and technologies so they do not infringe such patents, which may not be possible or may require substantial monetary expenditures and time. We could also be required to pay damages, which could be significant, including treble damages and attorneys' fees if we are found to have willfully infringed such patents. We could also be required to obtain a license for such patents to continue the development and commercialization of the infringing product or technology. However, such a license may not be available on commercially reasonable terms or at all, including because certain of these patents may be held by or exclusively licensed to our competitors. Even if such a license were available, it may require substantial payments or cross-licenses under our intellectual property rights, and it may only be available on a nonexclusive basis, in which case third parties, including our competitors, could use the same licensed intellectual property to compete with us. Any of the foregoing could have a material adverse effect on our business, financial condition, results of operation and prospects.

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. 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 Patents and Intellectual Property*" and Item 4, "*Information on the Company—ESWL Division—ESWL 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.

Patents have a limited lifespan. In the United States, if all maintenance fees are timely paid, the natural expiration of a utility patent is generally 20 years from its earliest U.S. non-provisional filing date. While extensions may be available, the life of a patent, and the protection it affords, is limited, and certain of our patents may also expire and fall into the public domain, as has already occurred with certain patents in the HIFU division's patent portfolio. See Item 4, "*Information on the Company—HIFU Division—HIFU Patents and Intellectual Property*." See also — *"We may encounter disruption in our Intellectual Property protection due to expiring patents and lack of updated filings*."

As is common in the life sciences and medical industry, we engage the services of consultants and independent contractors to assist us in the development of our products. We 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. We also rely on copyright protection. Litigation may be necessary to protect trade secrets, know-how or copyrights owned by us. In addition, effective copyright and trade secret protection may be unavailable or limited in certain countries.

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

We may encounter disruption in our Intellectual Property protection due to expiring patents and lack of updated filings

Our intellectual property portfolio, including patents, is critical to our competitive position. Certain key global patents included in the HIFU division's patent portfolio are set to expire in the near future, which could expose us to increased competition or the risk of similar products entering the market. Moreover, our ability to maintain a competitive edge is strengthened by our capacity to file new patent applications and keep our existing patent protection up to date. A lapse in our patent coverage or a failure to secure new patents could impact our ability to prevent competitors from copying our current HIFU technology and to maintain or enhance our market position. While we continuously evaluate opportunities for Intellectual Property protection, the failure to timely update or extend our patent coverage could significantly affect our business.

In addition, the disclosure and management of sensitive intellectual property matters, including pending or expired patents, requires careful consideration to avoid unintentionally exposing possible vulnerabilities or weaknesses in our patent portfolio. We rely on our outside Intellectual Property legal counsel and other third party service providers to assist in navigating these risks and ensure that any filings, updates, or communications related to our patents are strategically crafted and properly implemented. However, there can be no assurance that our current patent strategy will adequately mitigate these risks or that we will be able to secure new patent protections as needed.

U.S. laws relating to the patentability of certain inventions in the life sciences and medical technology industry are uncertain and rapidly changing, which may adversely impact our existing patents or our ability to obtain patents in the future.

Changes in either the patent laws or interpretation of the patent laws in the United States or in other jurisdictions could increase the uncertainties and costs surrounding the prosecution of patent applications and the enforcement or defense of issued patents. For instance, under the Leahy-Smith America Invents Act (the "America Invents Act"), enacted in September 2011, the United States transitioned to a first inventor to file system in which, assuming that other requirements for patentability are met, the first inventor to file a patent application is entitled to the patent on an invention regardless of whether a third party was the first to invent the claimed invention. These changes include allowing third-party submission of prior art to the United States Patent and Trademark Office ("USPTO") during patent prosecution and additional procedures to challenge the validity of a patent through USPTO administered post-grant proceedings, including post-grant review, inter partes review, and derivation proceedings.

Various courts, including the U.S. Supreme Court, have rendered decisions that impact the scope of patentability of certain inventions or discoveries relating to life sciences and medical technology. Specifically, these decisions stand for the proposition that patent claims that recite laws of nature, natural phenomena, and abstract ideas are not themselves patentable unless those patent claims

have sufficient additional features that provide practical assurance that the processes are genuine inventive applications of those laws, phenomena, and abstract ideas. What constitutes a "sufficient" additional feature is somewhat uncertain. Furthermore, in view of these decisions, since December 2014, the USPTO has published and continues to publish revised guidelines for patent examiners to apply when examining process claims for patent eligibility.

In addition, U.S. Supreme Court rulings have narrowed the scope of patent protection available in certain circumstances and weakened the rights of patent owners in certain situations. In addition to some degree of uncertainty with regard to the Company's ability to obtain patents in the future, this combination of events has created a degree of uncertainty with respect to the value of patents, once obtained. Depending on relevant laws enacted by the U.S. Congress, and decisions by the federal courts and the USPTO, the laws and regulations governing patents could change in unpredictable ways that may have a material adverse effect on our ability to obtain new patents and to defend and enforce our existing patents and patents that we might obtain in the future.
Our patent portfolio may be negatively impacted by current uncertainties in the state of the law, new court rulings or changes in guidance or procedures issued by the USPTO or other similar patent offices around the world. From time to time, the U.S. Supreme Court, other federal courts, the U.S. Congress or the USPTO may change the standards of patentability, scope and validity of patents within the life sciences and medical technology and any such changes, or any similar adverse changes in the patent laws of other jurisdictions, could have a negative impact on our business, financial condition, prospects and results of operations.

We may not be able to protect or enforce our intellectual property rights throughout the world.

Filing, prosecuting and defending patents and trademarks on all of our current or our planned products throughout the world would be prohibitively expensive to us. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and, further, may export otherwise infringing products to territories where we have patent protection but where enforcement is not as strong as in the U.S. or France. These products may compete with our products in jurisdictions where we do not have any issued patents, and our patent claims or other intellectual property rights may not be effective or sufficient to prevent them from competing. Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents and other intellectual property protection, particularly those relating to the healthcare sector, which could make it difficult for us to stop the infringement of our patents or marketing of competing products in violation of our patents or other intellectual property. Proceedings to enforce our patent rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business.

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. According to certain of 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.

Risks Related to our Status as a Foreign Private Issuer or a French Company

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

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 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 improper 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. EDAP employees can raise any issue by reporting on our hotline at alerteprofessionnelle@edap-tms.com. 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 and 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", 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. 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 our consolidated revenues for the preceding fiscal year, whichever is higher. GDPR is also supplemented by the provisions of the French data protection act (Law No. 78-17 of January 6, 1978), in particular in respect of the processing of personal data in the field of healthcare.

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. See "— General Risk Factors— "*Our results of operations and financial condition could be adversely affected by the adverse economic changes, political, social and geopolitical developments, financial changes, and the impact of climate change."* 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 may make 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 2024, 59% of our total costs of sales and operating expenses were denominated in euro, while 55% of our revenue was 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, 2024, 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 by-laws and French corporate law contain provisions that may delay or discourage a takeover attempt.

Provisions contained in our bylaws and French corporate law could make it more difficult for a third party to acquire our company, even if doing so might be beneficial to its shareholders. In addition, provisions of its bylaws impose various procedural and other requirements, which could make it more difficult for shareholders to affect certain corporate actions. These provisions include the following:

- under French law, a non-resident of France, as well as any French entity controlled by non-residents of France, may have to file a declaration for statistical purposes with the Bank of France (*Banque de France*) within 20 working days following the date of certain direct foreign investments in us, including any purchase of our ADSs. Such filings are required in connection with investments exceeding €15,000,000 that lead to the acquisition of at least 10% of our share capital or voting rights or cross such 10% threshold;
- under French law, certain investments in a French company relating to certain strategic industries by individuals or entities not residents in a Member State of the EU are subject to prior authorization of the Ministry of Economy;
- a merger (i.e., in a French law context, a share for share exchange following which our company would be dissolved into the acquiring entity and our shareholders would become shareholders of the acquiring entity) of our company into a company incorporated in the European Union would require the approval of the Company's Board of Directors, as well as a two-thirds majority of the votes held by the shareholders present, represented by proxy or voting by mail at the relevant meeting;
- a merger of our company into a company incorporated outside of the European Union would require 100% of our shareholders to approve it;
- under French law, a cash merger is treated as a share purchase and would require the consent of each participating shareholder;
- our shareholders may in the future grant our Board of Directors broad authorizations to increase our share capital or to issue additional ordinary shares or other securities (for example, warrants) to our shareholders, the public or qualified investors, including as a possible defense following the launching of a tender offer for our ordinary shares;
- our shareholders have preferential subscription rights proportional to their shareholding in our company on the issuance by us of any additional shares or securities giving the right, immediately or in the future, to new shares for cash or a set-off of cash debts, which rights may only be waived by the extraordinary general meeting (by a two-thirds majority vote) of our shareholders or on an individual basis by each shareholder;
- our Board of Directors can only be convened by its chair or, when no Board meeting has been held for more than two consecutive months, by directors representing at least one-third of the total number of directors;
- our Board of Directors has the right to appoint members to fill a vacancy created by the resignation or death of a member of the Board for the remaining duration of such member's term of office, and subject to the approval by the shareholders of such appointment at the next shareholders' meeting, which prevents shareholders from having the sole right to fill vacancies on our Board of Directors;
- approval of at least a majority of the votes held by shareholders present, represented by a proxy, or voting by mail at the relevant ordinary shareholders' general meeting is required to remove members of the Board of Directors with or without cause;
- pursuant to French law, our by-laws, including the sections relating to the number of members of the Board of Directors, and election and removal of members of the Board of Directors from office may only be modified by a resolution adopted by two-thirds of the votes of our shareholders present, represented by a proxy or voting by mail at the meeting.

The rights of shareholders in companies subject to French corporate law differ in material respects from the rights of shareholders of corporations incorporated in the United States.

We are a French company with limited liability. Our corporate affairs are governed by our by-laws and by the laws governing companies incorporated in France. The rights of shareholders and the responsibilities of members of our Board are in many ways different from the rights and obligations of shareholders in companies governed by the laws of U.S. jurisdictions. For example, in the performance of its duties, our Board of Directors is required by French law to consider the interests of our company, our shareholders, our employees and other stakeholders, rather than solely our shareholders and/or creditors. It is possible that some of these parties will have interests that are different from, or in addition to, the interests of our shareholders.

French law may limit the amount of dividends we are able to distribute, and we do not intend to pay cash dividends for the foreseeable future.

We currently intend to retain our future earnings, if any, to finance the further development and expansion of our business and do not intend to pay cash dividends in the foreseeable future. Any future determination to pay dividends will be at the discretion of our Board of Directors and will depend on our financial condition, results of operations, capital requirements, and future agreements and financing instruments, business prospects and such other factors as our Board of Directors deems relevant.

Further, under French law, the determination of whether we have been sufficiently profitable to pay dividends is made based on our statutory financial statements prepared and presented in accordance with applicable French regulations. Moreover, pursuant to French law, we must allocate 5% of our unconsolidated net profit for each year, if any, to our legal reserve fund before dividends until the amount in the legal reserve is equal to 10% of the aggregate nominal value of our issued and outstanding share capital. Therefore, we may be more restricted in our ability to declare dividends than companies not based in France. Finally, payment of such dividends may subject us to additional taxes.

We expect to lose our foreign private issuer status in 2026, which will likely result in significant additional costs and expenses.

While we currently qualify as a foreign private issuer, the determination of foreign private issuer status is made annually on the last business day of an issuer's most recently completed second fiscal quarter. We do not expect to qualify as foreign private issuer as of the next determination on June 30, 2025, which will require us to comply with all of the periodic disclosure and current reporting requirements of the Exchange Act applicable to U.S. domestic issuers as of January 1, 2026, which are more detailed and extensive than the requirements for foreign private issuers and have shorter deadlines, including with respect to annual and quarterly reports. In particular, Form 10-Q requires quarterly financial statements subject to auditor review.

The regulatory and compliance obligations and costs to us under U.S. securities laws as a U.S. domestic issuer will likely be significantly more than the obligations and costs we currently incur as a foreign private issuer. Once we lose our foreign private issuer status, we will be required to file periodic reports and registration statements on U.S. domestic issuer forms with the SEC, which are more detailed and extensive in certain respects than the forms available to a foreign private issuer. We would be required under current SEC and Nasdaq Global Market ("Nasdaq") rules to modify certain of our policies to comply with corporate governance practices associated with U.S. domestic issuers. In addition, we will lose our ability to rely upon exemptions from certain corporate governance requirements on U.S. stock exchanges that are available to foreign private issuers and exemptions from procedural requirements related to the solicitation of proxies.

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.

Risks Relating to Ownership of our Ordinary Shares and the ADSs

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

Our ADSs, each of which represents one ordinary share, are traded on Nasdaq. The average daily trading volume of our ADSs in 2024 was approximately 75,000, the high and low bid price of our ADSs for the last two fiscal years ended on December 31, 2024, and December 31, 2023, was $8.50 and $12.65, and $2.12 and $3.60, 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, the average daily trading volume of our ADSs in December 2024 was 235,289 as opposed to 217,979 for the same period of 2023. 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 of our ADS 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 investors invest in our ADSs, investors could lose some or all of their investment.

In addition, periods of volatility in the market price of a company's securities often trigger securities class action litigation. 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 the 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.

If securities or industry analysts do not publish research, or publish inaccurate or unfavorable research, about our market or business, our ADS price and trading volume could decline.

The trading market for our ADSs will depend, in part, on the research and reports that securities or industry analysts publish about us or our business. If one or more of the analysts who cover us downgrade our securities or publish inaccurate or unfavorable research about our business, our ADS price would likely decline. In addition, if our operating results fail to meet the expectations of our investors or forecasts of research analysts, our ADS price would likely decline. If one or more of these analysts cease coverage of our company or fail to publish reports on us regularly, demand for our ADSs could decrease, which might cause our ADS price and trading volume to decline.

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.

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.

General Risk Factors

Our results of operations and financial condition could be adversely affected by the adverse economic changes, political, social and geopolitical developments, financial changes, and the impact of climate change.

Political, social and geopolitical conditions in the markets in which our products are sold have been and could continue to be difficult to predict, resulting in adverse effects on our business. The ongoing armed conflict between Russia and Ukraine, and the escalation of violence and potential further conflicts in the Middle East, as well as the global geopolitical situation, may affect regional stability and economic growth throughout the world.

It is difficult to predict the consequences and outcomes of these conflicts, which will depend on developments outside of our control, including, but not limited to the duration and severity of the conflicts, and the consequences of the ongoing and additional financial and economic sanctions imposed by governments in response. As the situation is evolving, and additional sanctions may be implemented, such new restrictions could adversely affect the global economy, prices and energy supply, financial markets, supply chains, and could adversely affect our business, financial condition, and results of operations.

As we evaluated the impact of the consequences related to the conflict between Russia and Ukraine on our business, in 2022, we decided to definitively close our representative office in Moscow to avoid further difficulties in maintaining a direct administrative and operational activity in Russia. Net sales in Russia are not significant as they represented approximately 0.8% in 2023 and 1.0% in 2024 of our consolidated revenues. Our sales in Russia are historically subject to significant variation and long purchase order periods. We have an established exclusive distribution agreement with a business partner with significant experience in marketing and distributing medical equipment in Russia. This partnership will allow us to continue offering a HIFU solution to Russian patients and to maintain our existing installed base in Russia. To date, we have not experienced any material disruptions in our business with Russia, but we cannot predict outcomes that such conflict may have on our future results of operations.

In addition, as a result of the 2024 presidential and legislative elections in the United States, changes to applicable laws and regulations that have been announced, proposed, and/or adopted, or could be made or expanded in the future, may result in new or expanded trade restrictions by the United States and/or other countries, including, but not limited to, tariffs or import taxes being applied to imported goods and services that could affect our operations and exports into the United States. Other countries may implement trade restrictions and/or retaliatory measures as well.

Moreover, uncertain global climate change may result in certain types of more intense and more frequent natural disasters including, but not limited to hurricanes, wildfires or flooding or sustained periods of extreme weather. Such extreme disasters could imply risks to our facilities and disrupt our supply chain or our final customers' sites and may cause us to incur additional operational costs. Such intense events may also trigger internet security threats or damage to global communication networks that would harm our global operations and our customers' operations. Climate change may also result in new regulatory or legal obligations to address the effects of climate change on the environment or the effect of our operations and those of other companies on the environment. Such new obligations could cause increased compliance costs to meet any new regulatory or legal requirements and may adversely affect sourcing, manufacturing operations (such as eco-design), and the distribution of our products. Such natural disasters could have a material adverse impact on our business, financial condition, results of operations, or cash flows.

We may also be unable to meet the future criteria used by rating agencies in their environmental, social and governance ("ESG") assessments process, leading to a downgrading in our rating, when applicable. Financial investments in companies which perform well in ESG assessments are increasingly popular, and major institutional investors have made known their interest in investing in such companies. Depending on ESG assessments and on the rapidly changing views on acceptable levels of action across a range of ESG topics from investors, we may be unable to meet society's or investors' expectations on these matters, which may cause reputational harm, or disappoint the expectations of our stakeholders, and we may face increased compliance or other costs and demand for securities issued by us and our ability to participate in the debt and equity markets may decrease.

Finally, in recent years, "anti-ESG" sentiment has gained momentum across the U.S., with several states and Congress having proposed or enacted "anti-ESG" policies, legislation, or initiatives or issued related legal opinions. The U.S. President recently issued an executive order opposing diversity equity and inclusion ("DEI") initiatives in the private sector. Such anti-ESG and anti-DEI-related policies, legislation, initiatives, litigation, scrutiny and other actions could result in additional compliance obligations, our company becoming the subject of investigations and enforcement actions or otherwise suffering reputational harm.

Global potential inflation may have a material adverse effect on our business, results of operations and financial condition.

Current geopolitical instability including the conflict in the Middle East and in Ukraine and the related sanctions, and other factors including, but not limited to, global supply chain constraints, key components sourcing issues, increase in prices and disruptions of energy supply, and labor shortages, have led to higher worldwide inflation, which is likely, in turn, to lead to an increase in costs and may cause additional changes in tax and governmental policies. We may be unable to raise the prices of our devices and services in a higher inflationary environment and keep up with the rate of inflation. Such inflationary pressures may materially impact our business. We may not be able to adjust pricing, reduce our costs or implement counter measures quickly enough to offset cost increases. Our customers (i.e., hospitals and clinics) are also experiencing financial and operational pressures directly related to this inflationary environment, which may impact their ability or willingness to spend on capital equipment and this may have an adverse impact on our business, financial condition, results of operations, or cash flows.

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.

Our operations have consumed substantial amounts of cash since inception. We expect to use our cash resources to develop and further commercialize our products, develop new products, and for working capital and general corporate purposes. We will require additional capital to further develop and commercialize our products and to develop new products. In addition, our operating plans may change because of many factors that may currently be unknown to us, and we may need to seek additional funds sooner than planned.

On June 28, 2024, our shareholders renewed and extended resolutions allowing the Board of Directors to issue new shares in an aggregate maximum amount of 15 million shares in order to meet any fundraising opportunities that may be necessary to finance our further developments and to address any potential strategic opportunities for our long-term growth. As of December 31, 2024, no shares have been issued related to this resolution.

We cannot guarantee that future financing will be available in sufficient amounts or on terms acceptable to us, if at all. 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. Moreover, the availability of additional capital, whether debt or equity from private capital sources (including banks) or the public capital markets, fluctuates as our financial condition and industry or market conditions change generally. There may be times when the private capital markets and the public debt or equity markets lack sufficient liquidity or when our securities cannot be sold at attractive prices, in which case we would not be able to access capital from these sources on favorable terms, if at all. We can give no assurance as to the terms or availability of additional capital.

On June 28, 2024, our shareholders also adopted resolutions allowing the Board of Directors to issue 2,000,000 new shares under the form of subscription options and 600,000 free shares to motivate and reward the teams dedicated to successfully implementing our worldwide activities. These new resolutions superseded previous resolutions. Based on June 28, 2024, resolutions, a total of 106,000 subscription options were granted to certain employees in late 2024 and 493,000 subscription options were granted in the first half of 2024 based on previous resolutions, under certain conditions. As of December 31, 2024, we had 3,030,913 subscription options outstanding. No free shares were granted to employees in 2024 under June 28, 2024, resolutions. Under French law, only our employees

with an employment contract and corporate officers, such as the Chief Executive Officer and the Chairman of the Board of Directors (*mandataires sociaux*) may receive free shares or stock-options. Non-executive directors may not receive free shares nor stock-options.

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 their 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.

Item 4. Information on the Company

General

We develop, manufacture, promote and distribute advanced non-invasive ultrasound technologies for both diagnosis and treatment of various diseases. We have introduced the Focal One® Robotic HIFU (high-intensity focused ultrasound) system around the world including in the U.S., Europe, Latin America, the Middle East and parts of Asia. We also currently offer customers a complete solution from diagnosis to treatment of prostate disease with the distribution of complementary products on behalf of third parties. Finally, we service systems for the treatment of urinary tract stones. Our technologies include lithotripter systems based on Extracorporeal ShockWave Lithotripsy ("ESWL") technology and advanced surgical laser systems. Recently, we have shifted to a growth strategy aimed at developing our core proprietary HIFU activities and placing less emphasis on our non-HIFU distribution and ESWL business activities.

History and Recent Developments of the Company

Our legal name is EDAP TMS S.A., and our commercial name is Focal One®. In 2023, we elevated the Focal One brand name to further support our growing global sales and marketing activities. This change reflects our focus on our Focal One Robotic HIFU system and enhances our visibility in targeted markets.

EDAP TMS S.A. was incorporated on December 3, 1979, as a *société anonyme* organized under the laws 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. EDAP Technomed, Inc., located at 5321 Industrial Oaks Blvd, Suite 110, Austin, TX 78735, 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 website at http://www.sec.gov or the Company's website at http://www.focalone.com, section "Investor Relations."

In March 2024, our Focal One HIFU platform was granted Breakthrough Device designation by the U.S. Food and Drug Administration ("FDA") for the treatment of deep infiltrating endometriosis.

On October 1, 2024, we announced the first patients treated in a Phase I/II study evaluating the Company's proprietary Focal One® robotic HIFU technology for the treatment of benign prostatic hyperplasia ("BPH").

On December 4, 2024, the full and final results from the HIFI study were published in the prestigious, peer-reviewed journal, European Urology. The HIFI Study, a large, prospective, multicenter, non-inferiority study, compares and evaluates HIFU versus radical prostatectomy as a first line treatment of localized prostate cancer. The HIFI study demonstrated that patients receiving HIFU treatments had better outcomes with respect to urinary continence and erectile function compared to patients receiving radical prostatectomy treatments.

Our capital expenditures in the years ended December 31, 2024, 2023 and 2022 amounted to €4,120 thousand, €4,344 thousand and €2,378 thousand, respectively. These expenditures primarily related to acquisitions and additional considerations linked to purchased licenses, and acquisitions of laboratory equipment. Clinical research and development costs are not capitalized until marketing authorizations are obtained. We expect our capital expenditures to increase in absolute terms in the near term as we continue to advance

our research and development programs and grow our operations. We anticipate our capital expenditure in 2025 to be financed from our cash and cash equivalents on hand. Primarily, these capital expenditures will be made both in France and the United States, where our research and development facilities are currently located. Additional information regarding the principal capital expenditures and divestitures can be found in Item 5, *"Operating and Financial Review and Prospects—Operating Results—Overview."*

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 Company's financial statements, 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 the Company.

Our activity is currently reported through three divisions: HIFU, ESWL and Distribution. The HIFU division includes sales of Focal One, related consumables and services. The ESWL division includes revenues generated by servicing the existing installed base of EDAP's family of lithotripters. The Distribution division includes the sale of complementary products such as ExactVu 29 MHz micro-ultrasound systems, surgical lasers and other products from third parties.

Our global strategy is to expand our HIFU activities in the U.S. and worldwide to accelerate Focal One Robotic HIFU adoption. We are also focusing on our HIFU product and clinical and commercialization efforts, with the goal of expanding clinical indications beyond the management of prostate cancer. Going forward, we intend to focus the majority of our efforts and resources on our core proprietary HIFU activities while maintaining select distribution relationships.

We operate in Europe, the Americas, Asia and the rest of the world. Total net sales for the HIFU division (net contributions to total consolidated sales) were €23.9 million, €20.6 million and €15.6 million for 2024, 2023 and 2022, 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 systems are not approved yet. Total net sales for the ESWL division were €9.0 million, €9.9 million and €11.6 million, each for 2024, 2023 and 2022, respectively. Total net sales for the Distribution division were €31.3 million, €29.9 million and €27.9 million, each for 2024, 2023 and 2022, 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

We are engaged in the development, manufacturing and marketing of the Focal One Robotic HIFU system for the non-invasive focal treatment of urological and other clinical indications. Our HIFU business is cyclical and generally linked to lengthy hospital decisions and investment processes. Hence, our quarterly revenues are often impacted and fluctuate according to these parameters, generally resulting in higher purchasing activity in the last quarter of the year. The HIFU division contributed €23.9 million to our consolidated net sales during the fiscal year ended December 31, 2024.

HIFU Division Business Overview

As of December 31, 2024, the HIFU division had an active installed base of 130 Focal One systems, including 65 in the U.S.

Focal One Robotic HIFU technology uses high-intensity focused ultrasound generated by high power transducers to deliver energy to targeted tissue. HIFU technology allows surgeons to ablate a well-defined area of diseased tissue, without damaging surrounding healthy structures. This non-invasive outpatient treatment option eliminates the need for surgery, blood loss, and overnight hospital stays while also minimizing side effects that impact patients' quality of life. Urologists use Focal One Robotic HIFU to treat a subset of patients diagnosed with prostate cancer who are not candidates for radical treatment including surgery or radiation therapy. In addition, Focal One Robotic HIFU is used by urologists to treat patients who have experienced a recurrence after radiation therapy.

In addition to selling HIFU systems, the HIFU division also records revenues driven from sales of (i) disposables, (ii) equipment leases, (iii) RPP and (iv) equipment service contracts.

In certain regions of the world, we offer a HIFU mobile treatment option, which provides access to our Focal One HIFU systems without requiring hospitals and clinics to make an up-front investment in the equipment. Instead, hospitals and clinics perform treatments using these systems and remunerate us on an RPP basis (i.e., based on 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 Focal One system.

The HIFU division also generates revenues from net sales of maintenance services associated with our installed Focal One HIFU systems.

HIFU Division Business Strategy

Our business strategy is to capitalize on our deep expertise in HIFU to achieve long-term growth as a leader in the development, manufacturing, marketing and distribution of non-invasive robotic HIFU systems for urology-related and other indications. We believe that non-invasive focal HIFU treatments in the management of prostate cancer provide an alternative to current more invasive therapies while reducing costs and lowering morbidity. The key elements of our strategy are:

- *To Provide Non-Invasive Treatment Options for Localized Prostate Cancer using robotic focal HIFU*. Building upon our established position in the urology market, we are striving to become the leading provider of our HIFU treatment option for the management of prostate cancer. We believe there is a large market opportunity due to the large and growing incidence rate of prostate cancer globally. Early detection through increased screenings has led to an increase in early-stage diagnosis and a desire for effective, non-invasive, treatment options with fewer side effects. We also believe, for patients that fit certain criteria, HIFU may represent an excellent alternative to surgery, external beam radiotherapy, brachytherapy and cryotherapy for the treatment of organ-confined prostate cancer while minimizing in-patient hospitalization and adverse side effects associated with those therapies. We are currently focused on strengthening our marketing and commercial teams in order to offer this non-invasive HIFU option to prostate cancer patients around the world. Continued investment is key for effective patient and physician education through focused communication and training programs. We continue to build strong clinical credibility based on clinical articles published in peer-reviewed journals.

- *Achieve Long-Term Growth by Expanding HIFU Indications beyond the Management of Prostate Cancer*. Our long-term growth strategy is to apply our HIFU technology in the treatment of other medical conditions beyond prostate cancer. We are currently developing HIFU for the treatment of deep infiltrating rectal endometriosis and are exploring various other indications such as BPH. We are also conducting clinical research on the treatment of tumors in organs such as the pancreas, where HIFU could provide an effective alternative to current therapies. In 2024, the HIFU division operating expenses grew by 18% compared to 2023, including costs of research and development ("R&D") projects to develop HIFU applications beyond prostate cancer. We are planning to increase our investment levels in operational spending including in R&D in 2025 and future years to strengthen our technological leadership in HIFU while exploring the expansion of applications beyond urology.

HIFU Products

Currently, we commercialize the Focal One Robotic HIFU system. Focal One is an image guided, robotic HIFU system dedicated to delivering focal therapy for the management of prostate cancer. Focal One combines three essential components to efficiently perform a focal treatment of localized prostate cancer: (i) high-quality ultrasound imaging along with imported patient-specific MRI imaging or biopsy information to localize tumors, (ii) high-precision, sub-millimeter accuracy HIFU treatment delivery focused on the identified target areas and (iii) the ability to provide immediate feedback on the delivery of treatment utilizing contrast-enhanced ultrasound imaging.

HIFU Patents and Intellectual Property

As of December 31, 2024, the HIFU division's patent portfolio contained a total of 34 granted, owned or co-owned patents consisting of eight granted patents in the United States, 10 patents in the European Union, eight patents in Japan and eight patents in China. These patents belong to 10 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 one international patent application under the Patent Cooperation Treaty, two patent applications in the United States, five patent applications

in the European Union, three patent applications in Japan and three patent applications in China, are currently pending before the relevant patent offices.

Our ongoing research and development objectives are to maintain our leadership position in the treatment of prostate cancer using HIFU and to extend our HIFU technology to new clinical applications and for future development of new therapeutic ultrasound systems. These research projects are conducted in cooperation and collaboration with the Laboratory of Therapeutic Applications of Ultrasound ("LabTAU"), as part of the French National Institute for Health and Medical Research ("INSERM"). This 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 systems 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.

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 patent applications, if issued, will provide effective protection for the HIFU division's proprietary rights in such technology. HIFU systems, 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 Clinical and Regulatory Status

Clinical and Regulatory Status in Europe

Based on clinical study results, we obtained a CE Marking for Focal One in June 2013, which allowed us to market Focal One in the European Union and in worldwide territories where CE Marking is required. On March 15, 2023, European regulation N°2023/607 extended the validity of our Focal One CE certificate until December 31, 2028. Ablatherm systems previously placed on the market are maintained for use according to applicable regulations. Focal One is the only HIFU system now being commercialized to potential new customers in Europe and territories covered by CE Marking.

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. In October 2017, we were granted a 510(k) clearance for our Ablatherm Fusion system.

On June 7, 2018, we obtained FDA 510(k) clearance for our Focal One system based on the Ablatherm clearance and European pre-market and post-market clinical data.

Clinical and Regulatory Status in Japan

We have initiated discussions with the Japanese authorities ("PMDA") on the process to apply to obtain Japanese approval for our Focal One system. We are initiating a clinical trial in Japan to obtain clearance for the Focal One system. 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 and income growth depends, among other things, on implementing our business strategy, which largely depends on the success of our HIFU technology, and our capacity to scale our operations to manage and sustain our future growth*" 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

After thorough review of the regulatory processes, possible strategies to access the Chinese market and the significant associated costs, we decided to pause further activities related to registration of Focal One in China.

Clinical and Regulatory Status in the Rest of the World

The Focal One system is cleared for distribution in Argentina, Brazil, Canada, Costa Rica, Ecuador, Hong Kong, Israel, Malaysia, Morocco, Serbia, Russia, Singapore, South Korea, Switzerland, Taiwan, Turkey, the United Arab Emirates, the United Kingdom and Uruguay.

See Item 3, "*Risk Factors—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.*"

HIFU Clinical Developments

HIFU in the Management and Treatment of Prostate Cancer

In 2015, a clinical study aiming at evaluating the reimbursement of HIFU in France was initiated within the scope of "Forfait Innovation" (the "HIFI" Study) and piloted by the French Association of Urology ("AFU"). The HIFI Study compares total or sub-total HIFU vs. radical prostatectomy as a first line treatment in grade groups ("GG") <3 localized prostate cancer or as a salvage treatment post radiation. The objectives were to compare oncological efficacy, functionality and safety outcomes. The patients' inclusion period closed on September 30, 2019. The 3,328 patients included in the HIFI Study were followed for 30 months ahead of data analysis and results publication. During that follow-up period, we pursued patient treatments using HIFU under the specific Forfait Innovation coverage process, but these patients were not followed as part of the HIFI Study. In March 2023, the Study Coordinator presented the preliminary results of the HIFI Study at the European Association of Urology congress. Final results were presented at the 2024 Annual Meeting of the European Association of Urology in March as well as the American Urological Association in May. The full results from the HIFI study were published in the prestigious, peer-reviewed journal, European Urology in December 2024. The study shows that Focal One Robotic HIFU is non-inferior to surgery, meeting primary endpoints of non-inferiority for Salvage Treatment-free Survival after HIFU compared to radical prostatectomy at 30 months and that patients receiving HIFU had better outcomes with respect to urinary continence and erectile function compared to patients receiving radical prostatectomy. The publication includes a section titled "What does this study add?" concluding that "This nationwide trial is the first to prospectively compare HIFU and surgery for the treatment of localized prostate cancer. The results demonstrate that medium-term salvage treatment–free outcomes are comparable, with a better safety profile favoring HIFU."

Following the completion and analysis of the HIFI Study submitted to the French National Authority for Health ("HAS"), a positive favorable opinion was issued in late 2023 to include HIFU as a procedure covered under the national universal health, Social Security system ("*Sécurité Sociale"*). This favorable opinion relates to HIFU as a primary treatment of intermediate risk localized prostate cancer as well as a salvage option after failed radiotherapy. Based on this positive opinion from the HAS, the French Social Security authorities can now use this recommendation for including HIFU procedures in its next cycle to determine the procedure's reimbursement rate and the timing for when such reimbursement would go into effect.

In 2017, a clinical study addressing Focal Ablation vs Radical Prostatectomy ("FARP"), sponsored by Oslo University was initiated and aimed at comparing focal ablation and robot-assisted radical prostatectomy for treating patients with unilateral clinically significant prostate cancer. A total of 213 patients were enrolled and randomized to either arm. Patient inclusion was completed in June 2021. According to recent abstracts presented by the Principal Investigator at several major scientific meetings, the rate of treatment failure after two years post procedure in the focal ablation group was found to be non-inferior to that in the radical prostatectomy group. The functional outcomes, in particular the urinary continence rate evaluated with de novo pad use as well as the sexual function evaluated with the International Index of Erectile Function show a statistically significant superiority in favor of HIFU compared to surgery. The FARP study was completed in December 2024.

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 system 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 approximately €1.2 million over the period as a non-refundable grant. As of December 31, 2024, we had received a non-refundable grant of €1.0 million.

As part of the PERFUSE Project, several studies were initiated and sponsored by an academic partner HCL - Edouard Herriot Hospital. In September 2018, a Phase II multi-centric study was launched to evaluate the efficacy and safety of HIFU focal therapy in

patients with intermediate-risk single-lobed prostate cancer (the "FOCALE" study). 172 patients were included in the FOCALE study over 14 centers. The last patient was included in May 2021. Inclusions are now closed, patient follow-up is on-going and the last patient follow-up visit is scheduled for October 2025. In October 2018, a Phase III, multi-centric, randomized study was initiated 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). As of December 31, 2024, 106 patients have been included within 14 French centers. Patient inclusion is now closed. Patient follow-up is on-going and last patient follow-up visit is scheduled for October 2026.

The majority of academic centers using the Focal One system are collecting data following an Investigational Review Board approval in order to continue building clinical evidence and long-term HIFU outcomes. These various sources of clinical data are a basis for individual sites to present abstracts at regional, national or international conferences and submit manuscripts for peer-review to renowned journals and publications. This holds the potential for the FDA, which cleared HIFU for prostate tissue ablation in 2015, to re-evaluate the technology in the future for prostate cancer indication. Likewise, prospective data collection efforts documenting HIFU data from patients in and out of the U.S. may lead to health insurance reimbursements on a wider scale.

HIFU for Potential Treatment of BPH

As part of our exploration of the use of HIFU in other urology related indications, we are studying the use of Focal One in BPH.

In 2021, we initiated a mono-centric Phase I study to investigate the feasibility of BPH HIFU treatment with a Focal One system. A total of nine patients were treated, and the treatment safety was evaluated three months after HIFU treatment.

In 2024, we initiated a combined Phase I/II study evaluating our proprietary Focal HIFU technology for the treatment of BPH. A total of 185 patients are to be included in the study. This Company-sponsored, prospective, multicenter clinical trial is designed as a two-part study. Part 1 of the study is designed to define the optimal treatment parameters to effectively treat BPH and its related symptoms with minimal side effects. Part 2 of the study will expand patient enrollment across a larger number of treatment centers in order to validate the safety and efficacy of the parameters as defined in Part 1 of the study. As of December 31, 2024, six patients have already been treated under this protocol.

HIFU for Potential Treatment of Deep Infiltrating Rectal Endometriosis

As part of our exploration of the use of HIFU outside of urology, we are exploring the use of Focal One in gynecology to treat deep infiltrating endometriosis.

In 2020, we initiated a Phase II multi-center clinical study in France to further investigate the use of Focal One Robotic HIFU in the treatment of certain types of deep endometriosis situated in the low rectum. The study was completed in September 2022: a total of 60 women were enrolled in the study at four major hospitals in France and assessed over a six-month follow-up period. The intended endpoint was to evaluate the safety and efficacy of HIFU for this pathology. Data from this study have been analyzed and final results on safety and efficacy were presented in France at the Pari(s) Santé Femmes Gynecology Congress in early 2023 as well as in a plenary session at the European Society for Gynecological Endoscopy Annual Congress in October 2023 and at the American Association of Gynecology Laparoscopists meeting in November 2023.

In 2021, we initiated a long-term follow-up study aimed at including all patients treated by HIFU for their Rectovaginal endometriosis in the Phase I and II studies. During this study, we will evaluate the quality of life and the symptom levels of the patients up to five years after their HIFU treatment. As of December 31, 2024, 111 patients have accepted to be included in the follow-up study.

In late 2022, we received approval from the French authorities to initiate a Phase III randomized, controlled clinical trial evaluating Focal One HIFU as a potential treatment for deep infiltrating endometriosis. This study is a level 1 multi-center, double blind, randomized, controlled clinical trial. HIFU treatment was compared to a sham treatment. The study enrolled 60 patients across nine centers in France, with 30 patients randomized to each group. The primary efficacy endpoint was acute pelvic pain evolution three months post procedure. Patient inclusions were completed in January 2024. The three-month follow-up data confirmed the safety observed in prior studies. At three months post procedure, the study's primary endpoint of reduced acute pelvic pain in the HIFU treatment arm compared to the sham treatment arm was not met. At the end of 2024, 85% of the patients from the sham treatment arm have elected to cross-over into the open-label extension arm of the study and thus received treatment with robotic HIFU as allowed per protocol. All patients from this Phase III study will be followed during five years and will be included in the Long-Term Follow-Up Study as described above.

HIFU for Potential Treatment of Solid Organ Tumor

As previously announced, the Company supported early exploration of HIFU use to ablate localized tumors of the pancreas.

In 2024, as part of a cooperation with Centre Leon Bérard, Lyon, France, a Phase I-II study was initiated to evaluate the safety and tolerance of intraoperative HIFU treatment in pancreatic tumors, including 26 patients. One patient was treated in December 2024 and discharged without complications.

HIFU Clinical Publications

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

Prostate cancer publications

In February 2022, Hong et al., from Seoul National University Bundang Hospital, Korea, published in the Journal of Society Urological Oncology their results on their retrospective study on 163 patients who underwent Partial Gland HIFU Ablation ("PGA") by Focal One with a median follow up period of 17 months. The results concluded that the PGA with HIFU was safe and showed good preservation of functional outcomes as well as satisfactory oncological control.

In October 2022, De Luca et al., from San Luigi Gonzaga University Hospital, Italy published in the Minerva Urology and Nephrology journal their results on their prospective study on 100 patients with low to intermediate-risk prostate cancer that received customized HIFU ablation by Focal One with 12 months of follow up: 15 patients underwent total ablation, 50 patients hemi-ablation and 35 patients focal ablation. Control biopsy at 12 months of the HIFU-treated zone was negative in 80% for total ablation, 84% for partial and 80% for focal ablation with in-field reoccurrence being less than 10% after hemi-ablation. Patients had postoperative excellent quality of life with lower rate of irritative symptoms and negligible impact on voiding and erectile function scores. 100% of patients that received focal and partial HIFU ablation retained potency.

In December 2022, Jung G, et al., from Seoul National University Bundang Hospital, Korea, published in the journal of Prostate International their results on their propensity score-matched retrospective study on 685 patients who underwent PGA using HIFU with Focal One (137 patients) versus Robot-Assisted Radical Prostatectomy (548 patients) with a median follow-up period of 22 months. The authors confirmed that PGA HIFU preserves urinary and erectile functions, with a slight/minor loss of efficiency, which remained however very satisfactory (80% success rate efficacy). The results concluded that 5.8% underwent salvage treatment with postoperative incontinence and erectile dysfunction being more favourable in PGA compared to Robot-Assisted Radical Prostatectomy.

In July 2023, Mattlet et al, from University of Brussels, Brussels, Belgium published their results in The Prostate Journal from a retrospective analysis on 178 patients that underwent HIFU with Ablatherm (2001-2015) and Focal One (2005-2021). 12% of patients included in the study received neoadjuvant androgen deprivation therapy. Patients received customized ablation based on lesion location with 52% of patients receiving hemi-ablation. Treatment free survival and failure free survival were 89% and 98% respectively, at 60 months without Huber et al criteria. However, for patients with Huber et al. criteria, 23% of patients had treatment failure at 26 months. Therefore, the Huber et al. criteria was found accurate to predict the need for additional treatment.

In September 2023, Debard C et Al., from CHU de Pellegrin, Bordeaux, France published in the journal of *Progrès en urologie* their results on their retrospective and multicenter study on 137 patients with low- or intermediate-risk localized prostate cancer treated with Focal One. 70% of patients had clinical stage T2, 64% had an ISUP score of 2 or 3 on initial biopsies and 61% were treated with "targeted" ablation. According to the authors, the selection of patients treated with focal therapy is a key point for the success of the technique and the inclusion criteria that varied according to the studies. The authors conclude: "Our results are in agreement with those of the literature, seeming to indicate a lower morbidity of the focal treatment by HIFU compared to the radical treatments while offering an acceptable oncological control."

In October 2023, Kaufmann B et al., published in the British Journal of Urology ("BJUI") their results on a study aiming at assessing the oncological and functional outcomes of HIFU in treating low to intermediate risk prostate cancer a 3-year prospective study was undertaken using rigid post-ablation saturation biopsies. Patients with either low (6.6%) or intermediate (93%) risk prostate cancer underwent focal ablation around the lesion(s) of interest. All patients had transperineal template saturation biopsy (>20 cores) in-conjunction with MRI guided fusion biopsy. Over half the patients underwent a follow up biopsy. The Failure-Free Survival ("PROMIS") and Salvage-Free Survival rate at 36 months was 65% and 81% respectively. They concluded that Focal HIFU treatment for localized prostate cancer ("PCa") shows excellent functional outcomes with half of the patients remaining cancer-free after three years. The in-field recurrence (GG2 disease or higher) rate is as follows: 18%, 18%, and 17% at six, 12, and 36 months,

respectively. Urinary and sexual function remained unchanged per the Expanded Prostate Cancer Index Composite. In their conclusions, the authors stated: "Whole-gland treatment was avoided in 81% of patients. Early follow-up biopsies are crucial to change or continue the treatment modality at the right time, while the use of MRI and PSA in detecting PCa recurrence is uncertain."

In November 2023, Mala KS, et al., from Berlin Charité University Medicine, Germany, published in the Journal of the Clinical Medicine their results on their retrospective study on 57 patients with localized PCa using HIFU with Focal One. HIFU treatment was performed as focal, partial, or hemi ablative, depending on the prior histopathology. Out of 26 men that received biopsy, eight (15.8%) had in-field reoccurrence. The rate of post-HIFU complications was low, at 19.3%. Continence was preserved and erectile function was comparatively better than with radical prostatectomy. The study concluded that HIFU as a therapy option for nonmetastatic, significant prostate cancer is effective in the short term for carefully selected patients and shows a low risk of adverse events and side effects.

In November 2023, Rischman P. et al. published in the Progrès en Urologie, their results on salvage HIFU for local recurrence after first-line radiotherapy in 531 patients. This HIFI-2 study was developed as part of the "Forfait Innovation" program to evaluate the efficacy and safety of HIFU in the salvage treatment of localized PCa after failure of first-line radiotherapy. This is a prospective, multicenter, open-label study within the framework of the Forfait Innovation program, promoted by the AFU. Thirty months after post-radiotherapy salvage HIFU, 72% of patients were spared hormonal treatment. Pre-therapy PSA and Gleason score data suggest a better outcome (up to 85% HT-free survival at 30 months) when, in the presence of biological recurrence after radiotherapy, a recommendation is made for earlier management.

In December 2024, Ploussard G. et al. published in the peer-reviewed journal European Urology the full results of the HIFI study. HIFI is the largest, prospective, comparative, multi-center, clinical study ever conducted comparing prostate cancer treatments. The HIFI study showed that Focal One Robotic HIFU is non-inferior to surgery, meeting primary endpoint of non-inferiority for Salvage Treatment-free Survival after HIFU compared to radical prostatectomy at 30 months. The study demonstrated that patients receiving HIFU had better outcomes with respect to urinary continence and erectile function compared to patients receiving radical prostatectomy. This seven-year study (April 2015 - March 2022) enrolled a total of 3,328 patients from 46 treatment centers: 1,967 consecutive patients were treated with EDAP's robotic HIFU technologies, where Focal One was used for 90% of the patients, and 1,361 patients underwent radical prostatectomy surgery. All patients were followed for 30 months.

Endometriosis publications

In September 2020, Philip CA et al, from Croix Rousse Hospital, Lyon, France, published in Ultrasound Obstetric Gynecology journal, the results of the treatment of 20 patients with deep recto vaginal 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 May 2024, Dubernard G. et al, from Croix Rousse Hospital, Lyon, France, published in Human Reproduction journal, the results of a prospective multicentre cohort study. This study was conducted between 2020 and 2022 with 60 patients with symptomatic rectal endometriosis. The study demonstrated the safety of a 30% increase in the intensity of HIFU in the treatment of rectal endometriosis, with no Clavien–Dindo Grade III complications overall, and namely no rectovaginal fistulae.

Pancreas publications

In December 2021, Cilleros et al. from EDAP and LabTAU, INSERM and Centre Leon Bérard, Lyon, published in the journal Cancers positive pre-clinical results using intraoperative HIFU ablation of the pancreas in view of assessing the feasibility HIFU in the pancreas under Doppler guidance to treat the pancreatic parenchyma and tissues surrounding the superior mesenteric vessels *in vivo* in an animal model.

HIFU Market Potential

Prostate cancer is currently the first (in terms of newly diagnosed cases) and second (in terms of number of deaths) as the most common form of cancer amongst men in many populations. In the United States, the American Cancer Society estimates the number of new prostate cancers to be diagnosed for 2025 to be approximately 313,780, of which approximately 70% are diagnosed with localized stage prostate cancer. Additionally, the HIFU division estimates, based on figures provided by the World Health Organization, that the worldwide incidence of localized prostate cancer is approximately 1.5 million new cases. 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.

According to the Focused Ultrasound Foundation, HIFU has the potential to transform the treatment of a variety of serious medical conditions. All indicators point toward the evolution of this platform technology into a robust medical field, including numerous medical conditions, including cardiovascular, neurological, urological or women's health. We decided to focus on developing HIFU for targeted medical conditions. 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.

BPH, another widely spread prostate condition, is potentially addressable with the same approach and Focal One platform. According to the Urologic Clinics of North America Journal, as many as 15 million men in the United States have symptoms of BPH and it is estimated that more than 400,000 surgical procedures are performed every year to treat these symptoms.

The endorectal approach currently delivered by the Focal One Robotic HIFU system, could also benefit patients with rectal endometriosis. The European Society of Human Reproduction and Embryology estimates that endometriosis affects approximately 10% of women of reproductive age. Among them, 5-12% are affected by digestive endometriosis, of which 90% suffer from infiltration of the rectum. As such, we estimate that 1% of the women of reproductive age could possibly benefit from a minimally invasive HIFU treatment.

HIFU Reimbursement Status

In the United States, following the American Medical Association's ("AMA") decision to establish a new Category 1 CPT code (55880) for the ablation of malignant prostate tissue with transrectal HIFU technology, CMS finalized payment rules for hospitals, facilities, and physicians that facilitates coverage and reimbursement, effective January 1, 2021. U.S. private insurers are continuing to evaluate and advance coverage and payment policies related to HIFU procedures for prostate cancer patients. We have engaged Medical Technology Partners ("MTP") and PRIA Healthcare, formerly Argenta Advisors, two leading reimbursement consultants, to support us in reimbursement analysis and strategies.

On the hospital payment side, the 2025 final rule maintained the Urology Ambulatory Payment Classification ("APC") 6 payment level for CPT 55880. This translates into reimbursement to a hospital performing a HIFU procedure on a Medicare patient to $9,247 per procedure as a national average, adjusted locally based on the wage index. This represents a 5.4% increase compared to 2024 and a 105% increase compared to the 2022 payment rate. The CMS will continue to update payment rates for hospitals on a yearly basis as part of the OPPS Rulemaking.

On the physician payment side, CMS first established a payment to physicians performing a HIFU procedure in the U.S. in 2021. The AMA has created a Current Procedure Terminology code and CMS has set the work Relative Value Units for a physician performing a HIFU procedure at 17.73. In the 2025 Final Rule of the Physician Fee Schedule, CMS has set the total facility Relative Value Units ("RVUs") at 29.41. This translates to an average payment of $951 for a urologist performing a HIFU procedure on a Medicare patient in a facility setting in 2025. As a reference, a comparable established minimally invasive therapy for prostate cancer, cryotherapy, yields 23.01 total facility RVUs, which translates to $744 for the urologist under the same setting and patient conditions in 2024. A radical prostatectomy would grant the urologist 35.76 total facility RVUs and $1,157 if performed laparoscopically or robotically.

On December 30, 2024, the AMA released the addition of a new CPT Category 3 code to report the use of transrectal HIFU for the treatment of BPH. The new code, 0950T, currently described for "Ablation of benign prostate tissue, transrectal, with high intensity–focused ultrasound (HIFU), including ultrasound" will become effective on July 1, 2025.

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 systems are not reimbursed in the European Union except in Italy, Germany, the United Kingdom (where procedures are partially reimbursed by either public healthcare systems or private insurers), Switzerland 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. As part of the Forfait Innovation, patients were included in the HIFI Study sponsored by the French Association of Urology. Results and analysis of the study were reviewed by the HAS and a positive favorable opinion was issued in late 2023 to include HIFU as a procedure covered under the national universal health system. More specially, the favorable opinion relates to HIFU as a primary treatment of intermediate risk localized prostate cancer as well as a salvage option after failed radiotherapy. Based on this positive opinion from the HAS, the French Social Security authorities may now use this recommendation for including HIFU procedures in its future reviews to determine the procedure's reimbursement rate and the timing for when such reimbursement would go into effect.

HIFU Competition

Current therapies for prostate cancer are associated with side effects that may seriously affect a patient's quality of life. One of the standard treatments for prostate cancer is radical prostatectomy, which involves the surgical removal of the entire prostate gland and surrounding tissue. A radical prostatectomy may require a hospital stay along with additional recovery time, usually with catheterization, and may result in loss of urinary continence and sexual function. Robotic nerve-sparing radical prostatectomy has been developed to minimize the invasiveness of this surgery; however, radical prostatectomy is still associated with the morbidity of surgery which requires cutting, ligating, dissecting and suturing of tissue leading to blood loss.

Our Focal One Robotic HIFU competes with all current treatments for localized tumors, which include surgery, brachytherapy, radiotherapy, and cryotherapy. We believe that HIFU is a non-invasive, effective, treatment option for patients who seek to manage their cancer while minimizing side effects.

We also believe that Focal One is well positioned to address the growing demand for focal therapy of localized prostate cancer as compared to the radical treatments of surgery or radiation. "Focal" treatment (also known as "partial" or "zonal" treatment, as opposed to "radical" or "total" treatment) delivered with Focal One provides an effective and accurate ablative treatment while preserving patient quality of life.

Other companies are developing and commercializing HIFU technology for the minimally invasive ablation of tissues and/or solid organ tumors. See Item 3, "*Risk Factors—Competition in the markets in which we operate is intense and is expected to increase in the future, and there is a substantial risk our products or service offerings could become obsolete or uncompetitive*."

Certain existing and potential competitors of our HIFU division may have more financial resources to invest in research and development, sales, marketing, and personnel resources than us and may have more experience manufacturing and supporting new products. We believe that an important factor in the potential future market for HIFU treatments will be the ability to make 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 system for the treatment of prostate cancer.

Other companies developing and commercializing HIFU technology for the ablation of tissues and/or solid organ tumors include Sonablate Corporation, a U.S. company that markets the Sonablate® system for the ablation of prostatic tissue. Profound Medical, a Canadian company, markets the Tulsa-Pro® system for transurethral ultrasound ablation for prostate tissue. Insightec, an Israeli private company, markets the Exablate® system to treat uterine fibroids, painful bone tumors, brain disorders and prostate tissue. Theraclion, a French company, markets HIFU systems to treat benign thyroid nodules, benign breast masses and varicose veins. Haifu, a Chinese company, is also developing HIFU products addressing various types of cancers.

HIFU Marketing and Sales

We market and sell our HIFU products through our own direct marketing and sales channels as well as through select third-party distributors and agents in several countries. Using our direct subsidiaries or representative offices network, we maintain a direct marketing and sales force in the United States, France, Germany, Switzerland, Malaysia and South Korea, which currently represent our largest HIFU markets. Additionally, we market and sell our HIFU products through our network of distribution partners in the rest of Europe, Latin America, Middle East, Asia and Southeast Asia.

Our customers are located worldwide and include academic, public, and private hospitals as well as urology clinics. No single customer represents a significant portion of our HIFU installed base.

Our marketing efforts currently include the development of marketing-related resources, activities, and training programs for urologists as well as via traditional, digital and social media programs educating patients on the availability of HIFU technology to treat localized prostate cancer.

ESWL Division

Our ESWL activity consists of maintaining our lithotripters for the treatment of urinary tract stones. ESWL uses extracorporeal shockwaves, focused at a urinary stone within the human body to fragment it into smaller pieces. This technology allows natural elimination of stone fragments and prevents the need for more invasive options including incisions, transfusions, general anesthesia,

and the potential for related complications. We stopped manufacturing the Sonolith i-move lithotripter model in May 2024 in connection with our strategic decision to focus on our core HIFU business.

The ESWL lithotripsy division is engaged in servicing our existing installed base of Sonolith lithotripters while also selling spare parts and disposables such as electrodes for the Sonolith line, which need to be replaced approximately every ten treatments. The ESWL division contributed €9.0 million to our consolidated net sales during the fiscal year ended December 31, 2024.

The ESWL division continues to provide disposables, replacement parts and services for the current installed base of Sonolith range of lithoripters even though we have discontinued the manufacturing of these machines.

ESWL Patents and Intellectual Property

As of December 31, 2024, the ESWL division's patent portfolio included six granted owned and/or co-owned patents consisting of one in the United States, four in the European Union and one in Japan. These patents belong to four 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 with the ESWL generator, localization systems and system design.

Distribution Division

We have been engaged, through our Distribution division, in the marketing, distribution and servicing of third-party medical devices that are complementary to the rest of our product portfolio, such as micro-ultrasound systems, lasers and other medical products from third party manufacturers. We also generate revenues from the sale of disposables, spare parts and maintenance contracts for equipment sold on behalf of third parties. The Distribution division contributed €31.3 million to our consolidated net sales during the fiscal year ended December 31, 2024.

In alignment with our new strategy, we are increasing our focus on investments in our core proprietary HIFU technology and de-emphasizing activities in our ESWL and Distribution divisions, while maintaining select distribution relationships. See Item 3, "*We may experience revenue disruption due to our strategic shift to focus on HIFU activities and away from legacy non-HIFU activities."*

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

In May 2020, we signed an exclusive worldwide distribution agreement with Exact Imaging Inc., a Canadian company and developer of high-resolution micro-ultrasound imaging technologies. Under the terms of the agreement, we have been marketing the ExactVu™ micro-ultrasound diagnostic systems alongside our Focal One Robotic HIFU technology. ExactVu offers advanced technology for performing biopsies and diagnosing prostate cancer. We renewed this agreement in December 2023.

In November 2024, we signed an amendment to terminate the current distribution agreement that will now end on June 30, 2025. Both parties have agreed to enter into a new agreement effective July 1, 2025, providing (a) for the Company's non-U.S. subsidiaries to market and service the ExactVu directly to end-users and (b) for the Company's U.S. subsidiary to continue servicing and supporting customers in the United States based on the expiration dates of existing Service Agreements.

In France, we have been distributing Lumenis® Holmium lasers marketed by Boston Scientific under an exclusive agreement for over ten years. Our distribution agreement with Boston Scientific expired on December 31, 2024, and was not renewed. A termination agreement was signed in December 2024 to transition the Lumenis Lasers activity to Boston Scientific.

In Japan, we have several ongoing distribution agreements under which we exclusively market Quanta Urology Laser Systems. Our Quanta distribution contract was renewed with an expiration date of December 2025. Our Japanese subsidiary also exclusively distributes urology products from Laborie Medical Technologies ("Laborie"), including Urodynamic equipment, Uroflow, and a range of disposable products. The distribution contract with Laborie expires in December 2025. Laborie is the world leader of Urodynamic systems and disposables, which are used by urologists and gynecologists to diagnose lower urinary tract diseases. In addition, our Japanese subsidiary distributes EOS Imaging X-ray imaging systems for the diagnosis of musculoskeletal pathologies and orthopedic surgical care. In addition, we also exclusively distribute urology accessories on behalf of Rocamed and Hugemed.

Manufacturing

Our current manufacturing operations consist of assembling medical products in our facility, which is FDA-registered and certified under international ISO 13485: 2016 standard and Medical Device Single Audit Program ("MDSAP") program. We manufacture our own products through our operational subsidiary, EDAP TMS France.

We perform final assembly and quality control processes and maintain production standards. We purchase most of the components used in our products from several suppliers, but for some components of our products, we rely on a single source. Most of our components are secured by contract or dual sourcing manufacturing strategies. Furthermore, we conduct regular quality audits of suppliers' manufacturing facilities. Our principal suppliers are located in France, Germany and Denmark. To date, our procurement and manufacturing strategy has not led to any material impact on our ability to deliver systems and services to our customers. Management believes that the relationships with our suppliers at the current time are satisfactory.

Suppliers provide us with some key materials and components which can expose us to the risk of a supply shortage, obsolescence or interruption if these suppliers are unable to manufacture our products in line with our quality standards or encounter other challenges. For example, a major change in our current ultrasound supplier's strategy resulted in a cost increase to our HIFU systems. This cost increase has the potential to negatively impact our margins in a short period of time. We have identified a new supplier of ultrasound components, offering a cost-effective solution, and we expect to commercialize HIFU systems based on this technology by the end of 2025. This new technology will allow us to innovate new ultrasound-based features going forward.

From time to time, we experience challenges in obtaining some materials or components used in our systems, including electronic parts, computers, plastics, mechanical parts due to supply shortage directly linked to logistics challenges. In order to address these risks, we have put in place safety stock and have modified our order management for long lead time critical components. See Item 3. "*Risk Factors— Risks Related to our Organization and Operations*."

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, Brazilian and South Korean regulations, as well as with the U.S. Quality System Regulation. See "—Government Regulation—Regulation in the United States" and "—Government Regulation—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 Switzerland GmbH	Switzerland	100 %
EDAP TMS GmbH	Germany	100 %

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

Property and Equipment

We have one main facility, which is in Vaulx-en-Velin, near Lyon, France. The premises comprise 4,150 square meters and were leased to us under a renewable ten-year commercial lease agreement that became effective on July 1, 2015. The lease was renewed in November 2024 under a 9-year commercial lease term, with an effective date of July 1, 2025. This contract permits termination of

the lease at 3 or 6 years. We use this facility to manufacture our medical device systems and consumables. We believe the terms of the lease reflect current 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), Wollerau (Switzerland), Austin, Texas and Los Altos, California (U.S.), Seoul (South Korea), Fukuoka, Osaka, Sapporo and Tokyo (Japan).

Government Regulation

Government regulation in our major markets, particularly 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. Our products and operations are subject to regulation by the FDA and the countries where we market our products. We must meet the requirements governing the design, manufacture, sourcing, testing, certification, packaging, installation, use, and disposal (including recycling) of our products. See Item 3, "*Risk Factors— Risks Related to our Product Candidates and the Industry in which we Operate*."

Regulation in the United States

Our products are regulated in the United States by the FDA under several 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 - based on 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 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 using general controls and "special controls," such as special labeling requirements, mandatory performance standards, and post-market surveillance. Class II medical devices typically require 510(k) submission and clearance based on a demonstration of substantial equivalence to an identified predicate device. A successful 510(k) may also require the submission of clinical data as part of the 510(k) for some Class II devices. For novel devices that present low to moderate risk but where there is no suitable predicate device to support a standard 510(k) submission, the FDA has what is known as the De Novo process. 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 an advisory committee before FDA approval. Our Focal One HIFU is classified by the FDA as a Class II device.

The FDC Act also regulates quality and manufacturing procedures by requiring us to demonstrate and maintain compliance with current Quality System Regulations ("QSR"). We believe our manufacturing facilities meet the requirements of the QSR. There are also certain requirements of state, local and foreign governments that 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 by the U.S. Federal Trade Commission.

Regulation in the European Union

In the European Union, we annually perform ISO 13485: 2016 and MDSAP (which covers the following countries 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 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. An amendment to modify the transitional provisions has been adopted. The schedule is defined based on the MDR classification of devices with an updated application date of December 31, 2028. The extension of the period during which the devices can be placed on the market is subject to certain terms and conditions. To benefit from the new provisions, the manufacturer must have implemented a QMS that complies with MDR requirements. This 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. This MDR will replace the EU's current Medical Device Directive (93/42/EEC) ("MDD"). We implemented a QMS compliant with MDR provisions and obtained a QMS certification according to MDR in September 2024. All provisions to ensure the extension of MDD CE marking until 2028 according to

MDR transitional clauses were implemented and confirmed by the notified body. Devices manufactured by us are currently under evaluation for CE marking under MDR or have already obtained MDR certification.

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 based on their invasiveness and the duration of their use. This classification serves as a basis for determining the conformity assessment procedures that apply to medical devices that are eligible to receive a CE Mark. The conformity assessment procedures for Class I devices can be carried out, generally, 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 a 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 ("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 a "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 list of reimbursable prices applicable to certain medical devices under national health insurance programs. Until a new device is included in this list, its costs are not covered by the programs. 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.

Human Capital

Overview

Our employees are the driving force behind our success, and we are committed to nurturing and investing in our teams. We are proud of our dedicated workforce, which is instrumental in achieving our strategic objectives. In 2024, we continued to enhance our recruitment and retention efforts, with a focus on fostering a culture of inclusion, professional development, and employee wellbeing. Through targeted learning initiatives, leadership development programs, and a competitive compensation and benefits package, we strive to provide an environment where our employees can thrive. As we look ahead, we remain committed to these efforts.

We have never experienced a work stoppage or interruption due to labor disputes. We believe our relations with our employees are quite good. Our global workforce consists of experienced and highly skilled employees at all levels.

Employee Talent and Retention

Our business and future operating results are dependent upon the continued contributions of our senior management team and key personnel. Our ability to continue to attract and retain key talent for our operations is essential for our continued success.

Ensuring fair and equitable pay for our employee base is essential. We regularly review and benchmark our total compensation offers to ensure our pay structure is appropriate and fair to ensure our ability to compete in a competitive job market.

Employees are encouraged to share any pay equity concerns with management, Human Resources, or confidentially through our whistleblower hotline.

Culture

We believe in a high-performance culture. Fostering and maintaining a strong and collaborative culture is a key component of our strategy. We also have policies that instill a commitment to ethical behavior and legal compliance. Employees are encouraged to approach their manager and/or Human Resources Representative if they believe violations of policies have occurred. Employees may also report any such violations confidentially and anonymously through our whistleblower process.

Talent Development

We value our employees and the strengths, passion, and commitment they bring to our success. To foster a culture of high performance, we offer comprehensive learning and development opportunities that support personal growth, professional advancement, and clinical technical expertise.

The Executive Sales Training Program serves as an onboarding continuum, equipping new team members with the foundational knowledge and skills aligned to their role-specific core competencies. Established U.S. commercial employees participate in bi-monthly development seminars designed to reinforce existing knowledge, enhance skills, and introduce new tools and initiatives. Additionally, the U.S. commercial organization attends two national sales training meetings annually to deepen knowledge, share best practices with peers, and refine skills aligned with the commercial strategy.

On a global scale, the Global Leaders Executive Sales Training Program prepares the Company's global commercial leaders to train non-direct partners on the Focal One sales philosophy and process. Complementing this, the Global Partners Executive Training Program provides distributors with a condensed, focused curriculum to execute the Focal One sales process effectively.

We also offer various additional education and development programs, including leadership development, compliance and ethical behavior training, and specialized technical skills training to ensure our team members excel in their roles to drive the Company's continued success.

Health, Safety and Wellness

Protecting the health, safety, and well-being of our employees around the world is a top priority. We incorporate workplace health and safety programs into each of our sites. Through our benefits offerings, we provide our employees with access to a variety of progressive, flexible, and convenient health and wellness programs. These programs are to provide our employees a peace of mind and sense of security. We continue to adapt our programs to respond to the ever-changing needs of our workforce that support employee time away from work, family care, mental health, or financial wellbeing. Ensuring a safe and healthy work environment continues to be one of our top priorities.

Item 4A. Unresolved Staff Comments

None.

Item 5. Operating and Financial Review and Prospects

The following discussion of our results of operations, liquidity and capital resources for the fiscal years ended December 31, 2024, and 2023 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 Estimates

Management has not identified any estimates made in accordance with generally accepted accounting principles that involve a significant level of estimation uncertainty and have had or are reasonably likely to have a material impact on the financial condition or results of operations of the registrant.

Operating Results

Overview

Our activities are organized into three divisions: HIFU, ESWL and Distribution. Recently, we have shifted to a growth strategy focused on developing our core proprietary HIFU activities and placing less emphasis on our non-HIFU distribution and ESWL business activities. We expect this new strategy to impact our accounts. See Item 3. "*Risk Factors— Risks Related to our Organization and Operations.*"

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 third-party distributor and agent 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 Focalpaks in the HIFU division, electrodes in the ESWL division and disposables from third parties' devices sold 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 recorded in the HIFU division from the sale of Focal One treatment procedures and from leasing Focal One devices or treatment probes. We provide Focal One systems to clinics and hospitals at no charge for a limited period, rather than selling the systems. These hospitals and clinics perform treatments using the systems 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 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 systems, this business model initially generates a smaller, although more predictable stream of revenue and, if successful, should lead to more purchases of Focal One systems by hospitals and clinics in the long term.

Regarding the ESWL division, and in line with our growth strategy, we have made the decision to stop selling the Sonolith i-move lithotripsy product line. Final system sales are currently scheduled to conclude in the second half of calendar year 2025. Going forward, we will continue to service our installed base of ESWL systems by providing consumable electrodes, spare parts and repair services to customers on active service agreements as well as customers purchasing electrodes, parts and services outside of standard service agreements. This will result in a decline in revenue related to ESWL in 2025 and subsequent periods.

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. Some distribution agreements with third parties expired in December 2024 and were not renewed; the termination of these commitments from such third parties will have a material adverse effect on our revenue, financial condition and result of operations.

Sales of spare parts and services include revenues arising from maintenance services furnished by us for the installed base of ESWL lithotripters, HIFU systems 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 30% of our total consolidated net sales in 2024. Net sales of goods in Asia represented 34% of such sales in 2024 and consisted mainly of sales of urology devices and disposables. Net sales of spare parts, supplies and services in Asia represented 29% of such sales in 2024 and related primarily to ESWL lithotripters. We also derive a significant portion of net sales of medical devices and disposables from our operations in the U.S., through our wholly owned subsidiary (Edap Technomed. Inc). Net sales derived from our operations in the U.S. represented 28% of our total consolidated net sales in 2024. Net sales of goods in the U.S. represented 28% of such sales in 2024 and consisted mainly of sales of urology devices and disposables. 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 2024, 59% of our costs of sales and research and development, selling, marketing and general and administrative expenses were denominated in euro, while 55% of our sales were denominated in currencies other than euros (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 that 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 systems 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 €7.7 million and €7.0 million in 2024 and 2023, respectively, representing 12.1% and 11.5% of total revenues in 2024 and 2023, respectively. This increase was mainly driven by our HIFU development programs and clinical studies. Research and development government grants and tax credits are deducted from our consolidated research and development expenses for amounts of €0.7 million and €0.6 million in 2024 and 2023, respectively. Beginning in 2025, management expects the budget for research and development expenses to increase to 15% 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 €25.3 million in 2024 and €22.6 million in 2023. The €2.7 million or 11.9% increase in selling and marketing expenses from 2023 to 2024 was primarily a result of the implementation of the HIFU expansion plan in the U.S. Beginning in 2025, management expects selling and marketing expenses to increase in connection with the acceleration of HIFU adoption in the U.S.

Consolidated general and administrative expenses decreased €0.6 million or 3.7% to €14.1 million in 2024, reflecting the impact of the HIFU expansion plan in the U.S., which includes the impact of share-based compensation plans for €1.7 million in 2024 and for €2.9 million in 2023 and non-recurring expenses linked to the leadership succession plan for €3.4 million in 2023, which includes the impact of share-based compensation plan for €1.3 million. Beginning in 2025, management expects general and administrative expenses to increase in connection with the development of the U.S. activity.

Fiscal Year Ended December 31, 2024 Compared to Fiscal Year Ended December 31, 2023

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

(in millions of euros)	2024	2023
Total revenues	64.1	60.4
Total net sales	64.1	60.4
HIFU	23.8	20.6
ESWL	9.0	9.9
DISTRIBUTION	31.3	29.9
Total cost of sales	(37.6)	(36.0)
Gross profit	26.6	24.4
Gross profit as a percentage of total net sales	41.42 %	40.40 %
Total operating expenses	(47.1)	(44.2)
Loss from operations	(20.5)	(19.8)
HIFU	(17.5)	(14.8)
ESWL	1.2	(0.2)
DISTRIBUTION	(0.6)	(0.2)
Net loss	(19.0)	(21.2)

Total revenues

Our total revenues increased 6.1% from €60.4 million in 2023 to €64.1 million in 2024.

HIFU division.

The HIFU division's total revenues increased by 15.7% from €20.6 million in 2023 to €23.8 million in 2024, reflecting growth of equipment sales and treatment-driven revenue in the U.S.

The HIFU division's net sales of medical devices were stable with €9.7 million in 2024, with 22 Focal One units sold (including 12 in the U.S.), as compared to €9.8 million in 2023, with 21 Focal One units sold (including 15 in the U.S.). Treatment-driven revenue, which includes net sales of RPP & leases, net sales of disposables and treatments related services, increased by 31.4% to €11.9 million in 2024.

Net sales of HIFU maintenance services increased by 25.2% to €2.2 million in 2024.

ESWL division.

The ESWL division's total revenues decreased 9.3% from €9.9 million in 2023 to €9.0 million in 2024, primarily due to the decrease in sales of equipment and maintenance services, consistent with our strategic shift to de-emphasize our ESWL division.

The ESWL division's net sales of medical devices decreased 9.2% from €2.8 million in 2023 to €2.5 million in 2024 with 13 ESWL devices sold in 2024 compared to 16 ESWL units sold in 2023.

Net sales of ESWL-related consumables, spare parts, supplies, RPP, leasing and services decreased 8.8% from €7.1 million in 2023 to €6.5 million in 2024.

Distribution division.

The Distribution division's total revenues increased 4.6% from €29.9 million in 2023 to €31.3 million in 2024, primarily due to the increase of consumables and maintenance revenues linked to the development of the installed base.

The Distribution division's net sales of medical devices decreased 3.8% from €15.6 million in 2023 to €15.0 million in 2024, consistent with our strategy to de-emphasize our Distribution division.

Net sales of Distribution-related consumables, spare parts, supplies, leasing and services increased 13.7% from €14.4 million in 2023 to €16.3 million in 2024, reflecting the growth of the installed base.

Cost of sales.

Cost of sales increased 4.3% from €36.0 million in 2023 to €37.6 million in 2024 and represented 58.6% as a percentage of net sales in 2024, down from 59.6% as a percentage of net sales in 2023. This effect was primarily due to segment mix and a better absorption of our fixed costs mainly due to the growth of the HIFU revenues, which carry a lower cost of sales as a percentage of revenue.

Operating expenses.

Operating expenses increased 6.5%, or €2.9 million, from €44.2 million in 2023 to €47.1 million in 2024.

Marketing and sales expenses increased €2.7 million, or 11.9% to €25.3 million in 2024, reflecting the impact of the HIFU expansion plan in the U.S.

Research and development ("R&D") expenses increased 11.0% to €7.7 million in 2024 from €7.0 million in 2023. R&D expenses are net of R&D grants and tax credits of €0.7 million in 2024 and €0.6 million in 2023. This increase was mainly driven by the increase in research and development activities associated with our HIFU development programs and clinical studies.

General and administrative expenses decreased €0.6 million or 3.7% to €14.1 million in 2024. This reduction reflects the impact of non-recurring expenses linked to the leadership succession plan for €3.4 million in 2023, which includes the impact of share-based compensation plan for €1.3 million. This is offset by the HIFU expansion plan in the U.S., which includes the impact of share-based compensation plans for €1.7 million in 2024 and for €2.9 million in 2023.

Operating profit (loss).

As a result of the factors discussed above, particularly the expansion of our activities in the U.S. to accelerate HIFU adoption, we recorded a consolidated operating loss of €20.5 million in 2024, as compared to a consolidated operating loss of €19.8 million in 2023.

We recorded an operating loss in the HIFU division of €17.5 million in 2024, as compared with an operating loss of €14.8 million in 2023, an operating profit in the ESWL division of €1.2 million in 2024, as compared to an operating loss of €0.2 million in 2023, and an operating loss in the Distribution division of €0.6 million in 2024, as compared to an operating loss of €0.2 million in 2023.

Interest (expense) income, net.

Net interest income was €0.6 million in 2024, compared with a net interest income of €1.1 million in 2023.

The interest income was mainly generated by short-term deposits net of interest expenses generated by long-term debt and short-term borrowings.

Foreign currency exchange gain (loss), net.

In 2024, we recorded a net foreign currency exchange gain of €1.2 million, mainly due to the variation of the Euro against the U.S. Dollar, compared to a loss of €1.8 million in 2023.

Income taxes.

Income tax expenses in the consolidated statement of operations was an expense of €0.3 million in 2024, compared to an expense of €0.6 million in 2023.

Net loss.

As a result of the above, we realized a consolidated net loss of €19.0 million in 2024 compared with a consolidated net loss of €21.2 million in 2023.

For comparison between the fiscal year ended December 31, 2023 and the fiscal year ended December 31, 2022, please refer to our annual report on Form 20-F filed with the SEC on March 28, 2024.

Effect of Inflation

In 2023 and 2024, geopolitical instability and other factors have led to higher worldwide inflation leading to a global increase in costs. We are constantly addressing this cost increase by mitigating the impact on our margins, in particular by adjusting our prices, reducing our costs or implementing counter measures to ensure the minimum residual impact.

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, 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 have a history of operating losses and expect such losses to continue in the foreseeable future. As of December 31, 2024, we had €29.8 million in cash and cash equivalents, a decrease of €13.6 million from December 31, 2023. We believe we have sufficient funds to support our operations for at least a period of twelve months from the date of issue of our consolidated financial statements. However, we will need to raise substantial additional financing in order to meet our cash flow needs in the subsequent period and until we achieve profitability. We may not be able to raise additional financing on acceptable terms or at all and this condition may in the future raise uncertainty regarding our ability to continue as a going concern. Management is actively exploring various alternatives, including seeking additional funding through the debt and equity capital markets, cost-cutting measures, and restructuring opportunities, but there is no assurance that these efforts will be successful or sufficient to address these liquidity concerns. If we are unable to raise capital when needed on acceptable terms, or at all, we may be forced to restructure our business or delay, reduce, or terminate our research and product development programs, future commercialization efforts or other operations. See Note 1-2 to our consolidated financial statements.

Material Cash Requirements

The following table discloses aggregate information about material contractual obligations and periods in which payments were due as of December 31, 2024.

	Payments Due by Period				
	Total	Less than 1 year	1-3 years	4-5 years	More than 5 years
Short-Term Debt	6,243	6,243	—	—	—
Long-Term Debt	4,571	2,409	2,152	10	—
Financing Lease Obligations	519	168	258	78	15
Operating Leases Obligations	2,588	999	1,374	215	—

The commitment amounts in the table above are associated with contracts that are enforceable and legally binding and that specify all significant terms, excluding interest on long-term debt. Future events could cause actual payments to differ from these estimates.

Long term debts represent a €4.2 million cash requirement as of December 31, 2024 and are mainly related to the two loans taken out from French banks, in the form of the loans guaranteed by the French State for a total amount of €4.0 million at inception in the context of the Covid-19 pandemic, and a new loan taken out from a French bank in December 2024, for a total amount of €2.2 million at inception, to finance the purchase of ultrasound technology. This loan will reach maturity in December 2026. The first two loans taken out in August 2020 with initial maturity in August 2021 have been extended until August 2026. The amendments provide for reimbursements to be made over four years, beginning in August 2022.

Operating and financing leases represent a €3.1 million cash requirement as of December 31, 2024, with a repayment horizon up to 2030.

Cash Flows

We anticipate that cash flow in future periods will be derived mainly from ongoing operations. However, as noted above, we will need to raise additional substantial financing to meet our future cash needs. As of the date of this annual report, we do not employ any off-balance sheet financing. An inability to raise additional financing, 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 to meet our cash needs.

(in thousands of euros)	2024	2023
Net cash generated by/(used in) in operating activities	(13,584)	(14,678)
Net cash generated by/(used in) in investing activities	(4,120)	(4,344)
Net cash generated by/(used in) in financing activities	4,635	(911)
Net effect of exchange rate changes	(566)	268
Net increase/(decrease) in cash and cash equivalents	(13,635)	(19,665)
Cash and cash equivalents at the beginning of the year	43,471	63,136
Cash and cash equivalents at the end of the year	29,836	43,471

Our cash position as of December 31, 2024, and 2023 was €29.8 million (with no short-term treasury investments) and €43.5 million (with no short-term treasury investments), respectively. We experienced a decrease in cash and cash equivalents of €13.6 million in 2024 and a decrease of €19.7 million in 2023.

In 2024, our negative net cash flow was primarily due to net cash used in operating activities of €13.6 million and in investing activities of €4.1 million.

In 2023, our negative net cash flow was primarily due to net cash used in operating activities of €14.7 million and in investing activities of €4.3 million.

In 2024, net cash used in operating activities was €13.6 million compared with net cash used in operating activities of €14.7 million in 2023.

In 2024, net cash used in operating activities reflected principally:

- a net loss of €19.0 million;
- elimination of €7.4 million of net loss without effects on cash, including €2.6 million of depreciation and amortization, €1.0 million of change in allowances for doubtful accounts & slow-moving inventories, which includes €0.6 million of allowances for inventories related to the termination agreement for the Lumenis Lasers activity, €0.2 million of change in long term provisions, €0.5 million of net capital loss on disposals of assets and €3.3 million of non-cash compensation linked to stock-based compensation plans and free shares; and
- an increase in working capital of €2.0 million primarily reflecting the increase in inventory linked to the advanced purchasing related to ultrasound technology.

In 2023, net cash used in operating activities was €14.7 million compared with net cash used in operating activities of €3.0 million in 2022.

In 2023, net cash used in operating activities reflected principally:

- a net loss of €21.2 million;
- elimination of €9.4 million of net loss without effects on cash, including €1.9 million of depreciation and amortization, €0.4 million of change in allowances for doubtful accounts & slow-moving inventories and €0.2 million of change in long term provisions ; and €6.9 million of non-cash compensation linked to stock-based compensation plans and free shares; and
- an increase in working capital of €2.9 million primarily reflecting the increase in inventory and trade receivables linked to the higher level of sales.

In 2024, net cash used in investing activities was €4.1 million compared with net cash used in investing activities of €4.3 million in 2023.

Net cash used in investing activities of €4.1 million in 2024 reflected mainly:

- investments of €2.6 million in capitalized assets produced by the Company including devices for RPP and lease activities (€0.7 million), HIFU treatments probes (€1.8 million) and R&D programs (€0.2 million);
- investment of €1.3 million in property and equipment (including €0.6 million of laser and ExactVu equipment for demo, €0.7 million for IT, offices and industrial equipment); and
- investment of €0.2 million in intangible assets (licences and development of IT softwares).

Net cash used in investing activities of €4.3 million in 2023 reflected mainly:

- investments of €2.6 million in capitalized assets produced by the Company including devices for RPP and lease activities (€0.8 million), HIFU treatments probes (€1.5 million) and R&D programs (€0.4 million) ;
- investment of €1.2 million in property and equipment (including €0.3 million of laser and ExactVu equipment for demo, €0.7 million for IT, offices and industrial equipment and €0.1 million for vehicles); and
- investment of €0.5 million in intangible assets (licences and development of IT softwares).

In 2024, net cash generated by financing activities was €4.6 million compared with net cash used in financing activities of €0.9 million in 2023.

Net cash generated by financing activities of €4.6 million in 2024 reflected principally the net proceeds of €0.1 million from the exercise of stock options, the net proceeds of €2.6 million from long term borrowings, the repayments of long-term borrowings and financing leases for €1.8 million and an increase of short-term borrowings of €3.7 million.

Net cash used in financing activities of €0.9 million in 2023 reflected principally the net proceeds of €0.3 million from the exercise of stock options, the repayments of long-term borrowings and financing leases for €1.8 million and an increase of short-term borrowings of €0.7 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. Currently the short-term debt consists of account receivables factored and for which the Company is supporting the collection risk and credit lines. 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, 2024, there were no outstanding hedging instruments. See Notes 13 and 14 to the consolidated financial statements for further information on our borrowings.

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 Patents and Intellectual Property*" and "*Information on the Company—ESWL Division—ESWL 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 is refundable in cash.

Off-Balance Sheet Arrangements

At December 31, 2024, we had no off-balance sheet arrangements.

Item 6. Directors, Senior Management and Employees

Senior Management

The following table sets forth the name, age and position of each of our senior executive officers as of March 15, 2025 (the "Senior Management"). The Senior Management listed below have entered into employment agreements 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 agreement by the Company without cause, the members of Senior Management are entitled to receive severance packages totaling €1.7 million.

Name	Position
Ryan Rhodes Age: 63	Chief Executive Officer of EDAP TMS S.A. Member of the Board of Directors Chief Executive Officer of EDAP Technomed Inc. Mr. Ryan Rhodes was appointed as Chief Executive Officer of the Company in May 2023. Mr. Rhodes was appointed as a member of the Board of Directors in August 2023. Mr. Rhodes has over 30 years of leadership experience in market development in the medical device industry, including 20 years dedicated to medical robotics. Prior to joining EDAP, Mr. Rhodes served as the Chief Executive Officer of Restoration Robotics, a global leader in robotic aesthetic medicine, where he led the company to a successful merger with Venus Concept Inc. in 2019. Prior to Restoration Robotics, Mr. Rhodes spent over 13 years at Intuitive Surgical, the global leader in medical robotics, where he was a key architect of the company's multi-procedure market focus and development efforts, including the successful launch of the global Urology franchise. Prior to Intuitive Surgical, he spent over 11 years in various management positions in sales, marketing, professional education, and market development at Ethicon Inc., a Johnson & Johnson Company. Mr. Rhodes holds a B.A. in Public Administration from San Diego State University.
Ken Mobeck Age: 54	Chief Financial Officer of EDAP TMS S.A. Ken Mobeck was appointed as the Company's Chief Financial Officer in January 2024. Prior to that position, Mr. Mobeck held the position of Chief Financial Officer of EDAP's U.S. subsidiary since joining the company in December 2022. Prior to joining EDAP, Mr. Mobeck served as Vice President of Finance and Investor Relations at medical device manufacturer Accuray Inc., a leading global radiation therapy company. Prior to joining Accuray, Mr. Mobeck served as Vice President, Finance with an optical networking leader, Lumentum. Before Lumentum, he spent over two decades in positions with increasing levels of responsibility at some of Silicon Valley's most innovative companies including Silicon Graphics, Hewlett Packard, KLA and Intel Corporation. Mr. Mobeck holds an MBA and a BSC in Finance from the Leavey School of Business at Santa Clara University.
François Dietsch Age: 49	Chief Accounting Officer of EDAP TMS S.A. François Dietsch was appointed as the Company's Chief Accounting Officer in January 2024. Prior to that position, Mr. Dietsch held the position of Chief Financial Officer of the Company since July 2015. Mr. Dietsch joined EDAP in 2005 as Internal Audit and Consolidation Manager and in 2012 was promoted to Group Financial Control Manager and Finance Manager of EDAP's French subsidiary. 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.

Frédéric Pech Age: 56	President of EDAP TMS France S.A.S. Frédéric Pech joined EDAP TMS France S.A.S. in January 2021, as Chief Operating Officer and was appointed as President of EDAP TMS France on May 1, 2023. Prior to joining EDAP TMS France, he served as Chief Operating Officer at Metal Global Concept, a company specialized in the design and manufacturing of medical instrumentation containers for operating rooms, from 2018 to 2021. Prior to this position, he served as Human Resources Director, mainly in the medical devices industry at companies including Stryker, Tornier and Wright Medical, from 2000 to 2018. Frédéric holds a master's degree in accounting, a master's degree in organization from the CNAM (Conservatoire National des Arts et Métiers), an MBA from IGS Paris (Institut de Gestion Social) and a double degree from EM Lyon business school (Certificate in Business Management and Executive Advanced Management program).
Jean-François Bachelard Age: 61	President and Chief Executive Officer of Edap Technomed Co. Ltd. (Japan) Jean-François Bachelard was appointed President & Chief Executive Officer of Edap Technomed Co., Ltd. (Japan) in 2009. Jean-François Bachelard started his career at EDAP TMS Group in 1987 as Service Engineer. In 1989, he became Service Manager for Asia Pacific (APAC) area based in Tokyo. From 1993 to 1998, he worked for Inamed Corp. as Product Manager France (Bioenterics, gastric implants). In 1999, he reintegrated EDAP TMS Group as Area Manager Northen Europe and General Manager of EDAP TMS Moscow office. He graduated from Grenoble University with a degree in Electrotechnics and Robotics.

Board of Directors

The following table sets forth the names and backgrounds of the members of the Board of Directors as of March 15, 2025. Since May 1, 2023, we have separated the offices of Chairman of the Board and Chief Executive Officer.

None of the directors have service contracts with the Company or any of its subsidiaries providing for benefits upon termination of employment (except for those related to Mr. Rhodes's current position as Chief Executive Officer, as provided under his employment agreement). Five of the six Board members are independent within the meaning of Nasdaq Marketplace Rule 5605(2). The mandate of our directors, was reduced to a period of two years at the General Meeting of Shareholders held on June 28, 2024. The directors' mandates 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, to be held in 2026.

Lance Willsey Age: 63 Mandate: 2 years Appointment: December 6, 2023 Expiration: 2026	Interim Chairman of the Board Dr. Lance Willsey, M.S., M.D. joined the Board of Directors in December 2023 and was appointed Interim Chairman of the Board in September 2024. Dr. Willsey is a urologist who has 36 years of private and public board experience focused in the area of cancer diagnostics and therapeutics. He completed his surgical and urology training at the Massachusetts General Hospital and additional postgraduate training in the Steele Lab, Harvard University and the Dana Farber Cancer Institute. Dr. Willsey is a founding Partner of the healthcare fund DCF Capital. He also actively participated on boards of directors as a director of Exact Sciences from 1999 to 2009 and of Exelixis from 1997 to 2023. He also has extensive experience in corporate governance, having served on audit, compensation, finance and scientific advisory committees. Dr. Lance Willsey holds an MS and MD from Wayne State University.
Marie Meynadier Age: 63 Mandate: 2 years Appointment: June 30, 2020 Expiration: 2026	Marie Meynadier joined the 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. Ms. Meynadier has been serving as a director of Pixium Vision since 2019 and as a director of Alphatec Spine since 2021. From 1999 through 2018, she served at EOS Imaging as its Chief Executive Officer and led the company through a period of rapid worldwide sales growth prior to its sale to Alphatec Holdings in 2021. Prior to EOS Imaging, Ms. Meynadier served as the Chief Executive Officer of 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. Marie Meynadier informed the Board of her resignation from the Board of Directors effective March 31, 2025
Fran Schulz Age: 61 Mandate: 2 years Appointment: June 28, 2024 Expiration: 2026	Fran Schulz joined the Board of Directors in June 2024. Ms. Schulz is a seasoned executive with over 35 years of experience with EY who has spent her career working with large public and emerging private companies in the life sciences industry. Ms. Schulz also has significant experience working on U.S. SEC and International Financial Reporting Standards ("IFRS") matters. She is qualified to serve as a financial expert under SEC, NYSE and NASDAQ rules. Ms. Schulz currently also serves as a Board Member of Senti Biosciences and Menlo College. Previously, she served as a Board Member for the National Board of Women in Bio (2013 – 2023) and for the California Life Sciences Industry Association. Ms. Schulz is a licensed certified public accountant (CPA) licensed in California. Ms. Schulz received her B.S. in Business Administration from Menlo College.
Josh Levine Age: 64 Mandate: 2 years Appointment: December 19, 2024 Expiration: 2026	Josh Levine joined the Board of Directors in December 2024. From 2012 to 2022, Mr. Levine served as President, Chief Executive Officer, and Director of Accuray Incorporated. Concurrent with his Accuray roles, Mr. Levine served as an independent director from 2018-2022 and later as Non-Executive Chairman of the board of Natus Medical from 2022-2023. Prior to that Mr. Levine served as President, Chief Executive Officer, and Board Member of Immucor, Inc. in 2011. From 2004 to 2010, Mr. Levine served as President, Chief Executive Officer and Board Member of Mentor Corporation, where he played an instrumental role in repositioning the company by executing a strategic transformation. Mr. Levine has completed executive management programs at UCLA Anderson School of Business, Stanford University, and University of Pennsylvania, and he received his bachelor's degree in communications from the University of Arizona.

Glen French Age: 62 Mandate: 2 years Appointment: February 27, 2025 Expiration: 2026	Glen French joined the Board of Directors in February 2025. Mr. French has been a member of the Pulmonx Corporation board of directors since December 2014. Mr. French serves or has served on many private medical device company boards. He served as President and CEO of Pulmonx Corporation from December 2014 to March 2024. From January 2014 to November 2014, Mr. French served as President, CEO and Director of ApniCure, a medical device company. From October 2010 to December 2012, Mr. French served as President, Pulmonary Endoscopy for Boston Scientific Corporation, a medical device company. From December 2003 to October 2010, Mr. French served as President, CEO, Co-Founder and Director of Asthmatx, Inc., a medical device company. From March 1997 to December 2003, he served as President, CEO, Co-Founder, and Director of Broncus Technologies. Mr. French served as the Executive Chairman of the board of directors of Levita Magnetics, a medical device company, from August 2013 to January 2022. Mr. French holds a B.A. in History from Dartmouth College and an M.B.A. from the Wharton School at the University of Pennsylvania.
Ryan Rhodes Age: 62 Mandate: 6 years Appointment: August 23, 2023 Expiration: 2026	Chief Executive Officer. See Ryan Rhodes' biography above.

Compensation

Aggregate compensation paid or accrued for services in all capacities by the Company and its subsidiaries to senior management and to the Board of Directors as a group (for those individuals in office during the course of the year) for the fiscal year 2024 was €2,227 thousand including performance bonuses of €322 thousand and benefits in kind of €49 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 management and to the Board of Directors as a group (for those individuals in office during the course of the year) for the fiscal year 2024 other that the legal retirement indemnity for French senior executives. On November 8, 2023, the Board of Directors adopted the Company's Clawback Policy which is filed as exhibit 97.1 to this annual report. For information regarding compensation paid in the form of stock options or free shares, see *"—Share Ownership*" and "*Options to Purchase or Subscribe for Securities—Free shares*."

Compensation Committee

The Compensation Committee is comprised of the following independent members: Dr. Lance Willsey, Mr. Glen French, Mr. Josh Levine, Ms. Marie Meynadier and Ms. Fran Schulz. Ms. Marie Meynadier, resigning from the Board of Directors as of March 31, 2025, will no longer be a member of the Compensation Committee from this date. The Compensation Committee gathers at least once a year to review the compensation of our Chief Executive Officer 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. The Compensation Committee operates pursuant to a charter. The principal duties and responsibilities of our Compensation Committee include, but are not limited to:

- Make recommendations and proposals to the Board of Directors regarding compensation programs, including benefits in kind and equity compensation, for the Chief Executive Officer and members of the Board of Directors;
- Define methods used to calculate variable compensation and set objectives and assist the Board of Directors in determining whether the objectives have been met for bonuses and other types of equity or non-equity compensation plans; and
- Formulate general policies on the granting of equity compensation and recommend to the Board of Directors the granting of options and other stock awards thereunder.

Audit Committee

The Board of Directors' Audit Committee is comprised of the following independent members of the Board: Ms. Fran Schulz, acting as Chairperson of the Audit Committee and financial expert, Mr. Glen French, Mr. Josh Levine, Ms. Marie Meynadier and Dr. Lance Willsey. Ms. Marie Meynadier, resigning from the Board as of March 31, 2025, will no longer be a member of the Audit Committee from this date. The Audit Committee operates pursuant to a charter. The principal duties and responsibilities of our Audit Committee include, but are 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;
- Approve all services provided by the 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 the 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.

Nomination Committee

The Nomination Committee is comprised of the following independent members: Mr. Glen French, Mr. Josh Levine, Ms. Marie Meynadier, Ms. Fran Schulz and Dr. Lance Willsey. Ms. Marie Meynadier, resigning from the Board as of March 31, 2025, will no longer be a member of the Nomination Committee from this date. The Nomination Committee recommends director nominees to the Board, which then submits its nominees to the shareholders for election. 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.

The Nomination Committee operates pursuant to a charter, the terms of which apply to the Board of Directors when considering director nominees, including in the evaluation of potential candidates and in recommendations to the Board of Directors prior to submitting the candidates to the vote of shareholders. The principal duties and responsibilities of our Nomination Committee include, but are not limited to:

- Develop and recommend to the Board of Directors appropriate criteria for the selection of individual director candidates (such as, independence, industry knowledge, fields of expertise, ability to serve as "financial expert," leadership, diversity, etc.) and executive officers;
- Evaluate candidates in light of appropriate criteria and conduct all necessary and appropriate inquiries into the backgrounds and qualifications of potential candidates;
- Assist the Board of Directors in evaluating director independence, conflicts of interest and re-election of current directors;
- Make recommendations to the Board of Directors concerning the size and composition of the Board of Directors in order to ensure it has the necessary expertise and diversity;
- Make recommendations to the Board of Directors concerning appointees to be selected by the Board of Directors for service on its committees or removal of any member of any committee; and
- Assist the Board of Directors in ensuring adequate succession planning for our executive bodies, in particular, through the establishment of a succession plan for the chairman and Chief Executive Officer.

Employees

As of December 31, 2024, we employed 310 individuals on a full-time basis, as follows:

	Sales & Marketing	Manufac-turing	Service	Research & Dvpt	Regula-tory	Clinical Affairs	Adminis-trative	Total
France	25	31	26	34	8	15	22	161
Germany	7	—	4	—	—	—	2	13
Japan	22	—	21	—	3	—	7	53
Malaysia	2	—	4	—	—	—	2	8
South Korea	2	—	5	—	—	—	2	9
Switzerland	1	—	—	—	—	—	1	2
USA	35	—	17	—	—	—	12	64
Total	94	31	77	34	11	15	48	310

As of December 31, 2023, we employed 307 individuals on a full-time basis, as follows:

	Sales & Marketing	Manufac-turing	Service	Research & Dvpt	Regula-tory	Clinical Affairs	Adminis trative	Total
France	25	35	24	33	11	15	21	164
Germany	6	—	3	—	—	—	2	11
Japan	21	—	23	—	3	—	8	55
Malaysia	2	—	3	—	—	—	2	7
South Korea	2	—	5	—	—	—	2	9
Switzerland	—	—	—	—	—	—	—	—
USA	36	—	17	—	—	—	8	61
Total	92	35	75	33	14	15	43	307

As of December 31, 2022, we employed 264 individuals on a full-time basis, as follows:

	Sales & Marketing	Manufac-turing	Service	Research & Dvpt	Regula-tory	Clinical Affairs	Adminis-trative	Total
France	24	29	26	26	9	12	21	147
Germany	5	—	4	—	—	—	2	11
Japan	27	—	20	—	3	—	9	59
Malaysia	1	—	3	—	—	—	2	6
South Korea	2	—	4	—	—	—	2	8
Switzerland	—	—	—	—	—	—	—	—
USA	18	—	11	—	—	—	4	33
Total	77	29	68	26	12	12	40	264

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

Share Ownership

As of March 15, 2025, the total number of shares issued was 37,661,619 with 269,533 shares held as treasury shares, thus bringing the total number of shares outstanding to 37,392,086.

As of March 15, 2025, the Board of Directors and members of the Company’s administrative, supervisory and management bodies during 2024 held a total of 1,072,713 shares. The Board of Directors and members of the Company’s administrative, supervisory and management bodies during 2024 beneficially own, in the aggregate less than 3% of the Company’s outstanding shares.

As of March 15, 2025, the members of the Company's administrative, supervisory and management bodies during 2024 held a total of 33,333 free shares and an aggregate of 1,707,500 options to purchase or to subscribe to a total of 1,707,500 ordinary shares, with a weighted average exercise price of €5.66 per share. Of these options, 40,000 will expire on April 26, 2026; 20,000 expire on April 25, 2027; 20,000 expire on August 29, 2028; 15,000 expire on April 4, 2029; 837,500 expire on June 11, 2031; 375,000 expire on December 15, 2032; 200,000 expire on May 2, 2033, 100,000 expire on January 18, 2034, and 100,000 expire on March 26, 2034.

Options to Purchase or Subscribe for Securities – Free Shares

Options

On June 28, 2024, the shareholders authorized the Board of Directors to grant up to 2,000,000 options to subscribe to 2,000,000 new shares at a fixed price to be set by the Board of Directors and 600,000 free shares. These new resolutions superseded the June 30, 2021 and 2022 resolutions, cancelling the unused portion of the 2021 and 2022 resolutions.

As of March 15, 2025, we had sponsored four stock purchase and subscription option plans open to employees of EDAP TMS group and two free share plans.

On December 31, 2024, the expiration of our stock options contracts was as follows:

Date of expiration	Number of Options
April 25, 2026	152,500
April 26, 2027	81,080
August 25, 2028	57,500
April 4, 2029	70,000
June 11, 2031	954,533
November 17, 2031	83,300
May 17, 2032	76,000
November 2, 2032	20,000
December 15, 2032	395,000
April 5, 2033	69,000
May 2, 2033	200,000
May 31, 2033	50,000
August 23, 2033	150,000
September 20, 2033	53,000
November 8, 2033	10,000
December 6, 2033	34,000
January 18, 2034	142,000
February 28, 2034	12,000
March 26, 2034	160,000
June 3, 2034	167,000
August 21, 2034	34,000
November 6, 2034	60,000

As of December 31, 2024, a summary of stock option activity to purchase or to subscribe to shares under these plans is as follows:

	2024		2023		2022	
	Options	Weighted average exercise price (€)	Options	Weighted average exercise price (€)	Options	Weighted average exercise price (€)
Outstanding on January 1,	3,198,913	6.26	2,613,886	5.66	2,408,508	4.38
Granted	599,000	5.34	686,000	8.53	571,000	9
Exercised	(24,584)	4.71	(55,973)	4.66	(320,622)	2
Forfeited	(742,416)	4.92	(45,000)	7.99	(45,000)	5.34
Expired	—	—	—	—	—	—
Outstanding on December 31,	3,030,913	6.42	3,198,913	6.26	2,613,886	5.66
Exercisable on December 31,	2,130,107	6.17	1,997,666	5.23	1,362,205	4.35
Share purchase options available for grant on December 31,	25,000		25,000		20,000	

As of December 31, 2024, 1,894,000 options to subscribe for new shares are available for future grants.

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, 2024:

	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
10.32	20,000	7.8	10.32	—	13,889	10.32	—
10.10	200,000	8.3	10.10	—	105,556	10.10	—
9.96	69,000	8.3	9.96	—	38,333	9.96	—
9.94	395,000	8.0	9.94	—	263,333	9.94	—
9.32	50,000	8.4	9.32	—	26,389	9.32	—
7.53	150,000	8.7	7.53	—	66,667	7.53	—
6.83	160,000	9.3	6.83	—	40,000	6.83	—
6.64	10,000	8.8	6.64	—	3,611	6.64	—
6.41	76,000	7.3	6.41	—	65,444	6.41	—
6.08	53,000	8.8	6.08	—	22,083	6.08	—
5.59	954,533	6.4	5.59	—	954,533	5.59	—
5.48	167,000	9.5	5.48	—	27,833	5.48	—
5.46	12,000	9.2	5.46	—	3,333	5.46	—
5.29	142,000	9.1	5.29	—	43,389	5.29	—
5.18	83,300	6.8	5.18	—	83,300	5.18	—
4.98	34,000	8.9	4.98	—	11,333	4.98	—
3.90	70,000	4.8	3.90	—	70,000	3.90	—
3.80	34,000	9.7	3.80	—	—	—	—
3.22	152,500	1.3	3.22	—	152,500	3.22	—
2.65	57,500	3.7	2.65	—	57,500	2.65	—
2.53	60,000	9.8	2.53	—	—	—	—
2.39	81,080	2.3	2.39	—	81,080	2.39	—
2.39 to 10.32	3,030,913	7.51	—	—	2,130,107	—	—

(1) Fully vested options are all exercisable options.

(2) Aggregate intrinsic value represents the total pre-tax intrinsic value, based on the Company's closing stock price of $2.21 at December 31, 2024, which would have been received by the option holders had all in-the-money option holders exercised their options as of that date.

Free Shares

On March 30, 2022, 40,000 free shares were granted to the Chief Executive Officer of the Company. On March 30, 2023, all 40,000 free shares were vested and became subject to a 12-month holding period.

On November 8, 2022, 291,500 free shares were granted to certain officers and employees of the Company. On November 8, 2024, 181,604 free shares were vested. As of December 31, 2024, 82,984 free shares remain outstanding.

On March 29, 2023, 150,000 free shares were granted to the Chief Executive Officer of the Company. On March 29, 2024, all 150,000 free shares were acquired and became subject to a 12-month holding period.

On May 2, 2023, 50,000 free shares were granted to the President of the French subsidiary EDAP TMS France SAS. On May 2, 2025, all 50,000 free shares will have vested, as long as the conditions set forth in the free share plan are met and will be subject to a 12-month holding period.

See Note 17-5 of the consolidated financial statements.

Disclosure of any action to recover erroneously awarded compensation

Not applicable.

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.

On the basis of the notifications received or filed with the SEC and information from the Bank of New York Mellon, as of March 15, 2025, (i) Soleus GP, LLC, filed a report showing beneficial ownership of 7,309,254 ADSs, representing 19.7% of our outstanding ADSs and (ii) Morgan Stanley filed a report showing beneficial ownership of 3,367,685 ADSs, representing 9.01% of our outstanding ADSs. There are no arrangements known to us whereby we are directly or indirectly owned or controlled by another corporation or government, or by any other natural or legal persons, nor are we aware of any arrangement] that 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 15, 2025, 37,661,619 shares were issued, including 37,392,086 outstanding and 269,533 treasury shares. As of March 15, 2025, there were 37,638,613 ADSs, each representing one Share, all of which were held of record by 20 registered holders (including The Depository Trust Company).

As of December 31, 2024, we estimate that approximately 13 million shares, or 35% of our outstanding ordinary shares, were held by U.S. institutional investors.

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 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.

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, 2024, total consolidated export net sales, which we define as sales made outside of mainland France, were €52.9 million, which represented 82% of total net sales.

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. We do not have any pending legal proceedings.

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 recommendations 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 dated as of July 31, 1997, as amended and restated as of April 7, 2008, among our company, The Bank of New York Mellon, as Depositary, and all owners and beneficial owners from time to time of ADSs issued thereunder (the "Deposit Agreement").

No dividends have ever been paid to shareholders 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 a 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 the shareholders.

Significant Changes as of March 15, 2025

None.

Item 9. The Offer and Listing

Description of Securities

Our ordinary shares are traded solely in the form of ADSs, each representing one ordinary share. The ADSs are evidenced by American Depositary Receipts, which are issued by The Bank of New York Mellon, our Depositary. Our ADSs are traded on Nasdaq under the symbol "EDAP."

Item 10. Additional Information

Share Capital

Not applicable.

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, an English 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 where such shareholders hold at least 33 1/3% of the shares with voting rights, we file copies of our by-laws 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.

Our by-laws were updated on December 19, 2024, to reflect the latest increases in share capital related to the issuance of additional shares following the exercise of options or definitive acquisition of free shares.

Corporate Purposes

Pursuant to Article 2 of our 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 six members, one of which (Ms. Meynadier) will have her term expire March 31, 2025, which is the date of her resignation from the Board of Directors, and the remaining terms will expire on the date of the annual general shareholders' meeting approving the accounts for fiscal year 2025, i.e. in June 2026. During the shareholders' general meeting dated June 28, 2024, the shareholders decided to reduce the directors' term from six years to two years in order to align the Company's by-laws with Nasdaq rules applicable to U.S. companies and domestic issuers. 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 (*sociétés anonymes*) registered in France; directorships held in controlled companies (as defined by Article 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, provided that the number of directors still in office is not below the required legal minimum of directors (three). 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.

Our employees may be appointed to serve as directors. Such an employee's employment contract must include actual work obligations. In this case, such an employee 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. Decisions of the Board of Directors are made by a majority vote; in case of a tie, the Chairman of the Board has a casting vote.

French law provides that the functions of Chairman of the Board of Directors 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. Mr. Lance Willsey was appointed as interim Chairman of the Board of Directors on September 30, 2024, replacing Marc Oczachowski who resigned from his position as Chairman of the Board of Directors and from his term of office as director. See Item 6, "*Directors, Senior Management and Employees.*"

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. 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.

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 an individual elected by the Board of Directors and bearing the title of Chief Executive Officer (*directeur général*). On March 29, 2023, the Board of Directors decided to separate the roles of Chairman of the Board of Directors and Chief Executive Officer, as allowed by the Company's by-laws, and elected Mr. Ryan Rhodes as the Chief Executive Officer, effective May 1, 2023, for an indefinite term.

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 the recommendation of the Compensation Committee. See Item 6, "*Directors, Senior Management and Employees–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 Article 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.

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

Provisions With Respect to Directors (French Law)

Transactions in Which Directors Are Materially Interested

Under French law, any agreement entered into (directly or through an intermediary) between the Company and any one of the members of the Board of Directors that is not entered into (i) in the ordinary course of our business and (ii) under normal conditions, is subject to the prior authorization of the Board of Directors with only the disinterested members of the Board of Directors voting. This provision applies in particular to any undertaking taken by our Company for the benefit of our Chairman, Chief Executive Officer or his delegates (*délégués*) pursuant to which such persons will or may be granted compensation, benefits or any other advantages as a result of the termination of or a change in their offices or following such termination or change.

The same provision applies to agreements between our Company and another company if one of the members of the Board of Directors is the owner, general partner, manager, director, general manager or member of the executive or supervisory board of the other company, as well as to agreements in which one of the members of the Board of Directors has an indirect interest.

In accordance with Article L. 225-38 of the French Commercial Code, each related-party agreement entered into during the fiscal year is submitted for approval by our shareholders at the annual general shareholders' meeting; the interested director (directly or through an intermediary), if he/she is a shareholder of the Company, may not take part in the vote and the shares held by the interested director are not taken into account for the calculation of the majority vote count.

Directors' Compensation

The aggregate amount of compensation of the Board of Directors is determined at the ordinary general shareholders' meeting. The Board of Directors then divides this aggregate amount among its members by a simple majority vote. In addition, the Board of Directors may grant exceptional compensation (*rémunérations exceptionnelles*) to individual directors on a case-by-case basis for special assignments following the procedures described above at "- *Transactions in which directors are materially Interested*." The Board of Directors may also authorize the reimbursement of travel and accommodation expenses, as well as other expenses incurred by Directors in the corporate interest. See also Item 6, "*Directors, Senior Management and Employees.*"

Board of Directors' Borrowing Powers

All loans or borrowings on behalf of the Company may be decided by the Board of Directors within the limits, if any, imposed by the extraordinary meeting of the shareholders. There are currently no limits imposed on the amounts of loans or borrowings that the Board of Directors may approve.

Enforceability of Civil Liabilities (French Law)

We are a *société anonyme*, or limited liability corporation, organized under the laws of France. A substantial portion of our assets are 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 citizens 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 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 international public policy rules, as applied by French courts, whether such rules pertain to the merits or to the procedure of the case, including any defense rights, (iii) the judgment is not tainted with fraud, (iv) the judgment does not conflict with a French judgment or a foreign judgment (or an arbitral award) on the same matter which has become effective in France and (v) that judgment is enforceable in the jurisdiction of the U.S. court which rendered it. 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.

In addition, French law guarantees full compensation for the harm suffered but is limited to the actual damages, so that 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, our 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 directors, officers or experts, respectively.

Listing

Our ADSs are listed on Nasdaq under the symbol "EDAP."

Transfer Agent and Registrar

The transfer agent and registrar for our ADSs is The Bank of New York Mellon.

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 (subject to the absence of any specific decision taken by the government otherwise). 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. There is a reporting obligation to customs officers for the transfer of cash in banknotes and coins of €10,000 or more carried in, or out of, the European Union.

Taxation

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.

In particular, the French Finance Bill for 2025 (*Loi de Finances pour 2025*), enacted on February 14, 2025, contains certain measures that affect the French taxation of U.S. holders purchasing, owning and disposing of ordinary shares or ADSs.

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 the 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 U.S. tax authorities. Thus, there can be no assurance that one or both of such authorities will not take a position concerning 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, (iii) an estate whose income is subject to U.S. federal income tax regardless of its source, or (iv) a trust if (1) a U.S. court can exercise primary supervision over the trust's administration and one or more U.S. persons are authorized to control all substantial decisions of the trust or (2) has a valid election in effect under applicable U.S. Treasury Regulations to be treated as a U.S. person for U.S. federal income tax purposes. 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 currently subject in France to a 0.3% tax on financial transactions, or the TFT (according to Article 26 *quater* of the French Finance Bill for 2025, the rate of the TFT will be increased to 0.4% for purchases of Securities as from the first day of the second month following the enactment of the French Finance Bill for 2025), 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, 2024 (BOI-ANNX-000467-23/12/2024). The Company was not included in such list as its market capitalization did not exceed €1.0 billion as at December 1, 2024. 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 in 2025 are not subject to the TFT.

In the case where the TFT is not applicable, transfers of shares issued by a French company and that 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 statement (*acte*). Although the official guidelines published by the French tax authorities are silent on this point, ADSs should remain outside of the scope of the aforementioned 0.1% registration duties.

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 certain entities may be subject to reporting obligations with respect to shares and ADSs if the aggregate value of these and certain other "specified foreign financial assets" exceeds $50,000 on the last day of the tax year or more than $75,000 at any time during the tax year. 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 corporations that are the beneficial owners and are not domiciled in France are generally subject to French withholding tax at a rate of 25% for payments benefitting legal persons who are the beneficial owners and are not French tax residents (12.8% for distributions made to individuals who are beneficial owners and are not French tax residents, 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, n° 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 (other than those mentioned in 2° of 2 *bis* of the same 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 subject to specific conditions, 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 25% 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 U.S. holders are advised to consult their own tax advisors in this respect). 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.

In addition, please note that, pursuant to Article 235 *quater* of the French General Tax Code and under certain conditions (in particular, in addition to certain reporting obligations, the interest held in the distributing company must not enable the beneficiary to participate effectively in the management or control of that company and the beneficiary company must be located in a country that has signed an administrative assistance agreement with France to combat tax evasion and avoidance, as well as an administrative assistance agreement on tax collection, and that is not a non-cooperative country), a corporate U.S. holder who is in a tax loss position or whose tax result is nil due to offset of tax losses for the fiscal year during which the dividend is received may be entitled to a deferral regime, and obtain a withholding tax refund. The tax deferral ends in respect of the first financial year during which this U.S. holder is in a profit making position, as well as in the cases set out in Article 235 *quater* of the French General Tax Code. The refund must be claimed within the same period applicable to claim related to taxes other than local taxes. Also, pursuant to Article 235 *quinquies* of the French General Tax Code and under certain conditions, a corporate U.S. holder may be entitled to a refund of a fraction of the withholding tax, up to the difference between the withholding tax paid (on a gross basis) and the withholding tax based on the dividend net of the expenses incurred for the acquisition and conservation directly related to the income, provided (i) that these expenses would have been tax deductible had the U.S. holder been established in France, and (ii) that the tax rules in the United States do not allow the U.S. holder to offset the withholding tax.

Given the special features of the ADSs, U.S. holders are urged to consult their own tax advisor about the possible application to ADSs of such provisions in light of their own circumstances.

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

This subsection only addresses certain U.S. federal income tax consequences of ownership of the ADSs or shares to U.S. holders.

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%.

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 2024 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 2025 taxable year. However, as discussed in the Company's annual reports on Form 20-F filed 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 remainder of this discussion assumes that the Company is not a PFIC.

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 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 The Treaty has been approved for the purposes of the qualified dividend rules. *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 and the Foreign Tax Credit Regulations (as defined below), 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. Further, certain Treasury regulations addressing foreign tax credits (the “Foreign Tax Credit Regulations”) impose additional requirements for foreign taxes to be eligible for a foreign tax credit if the relevant taxpayer does not elect to apply the benefits of an applicable income tax treaty, and there can be no assurance that those requirements will be satisfied. Recent notices from the Internal Revenue Service provide temporary relief by allowing taxpayers that comply with applicable requirements to apply many aspects of the foreign tax credit regulations as they previously existed (before the release of the current Foreign Tax Credit Regulations) for taxable years ending before the date that a notice or other guidance withdrawing or modifying the temporary relief is issued (or any later date specified in such notice or other guidance). 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, including the Foreign Tax Credit Regulations and the related temporary relief in the Internal Revenue Service notices, 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 “—Tax on Sale or Other Disposition”, below).

The amount of any distribution paid in euro 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.

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.

Dividends and Paying Agents

Not applicable.

Statement by Experts

Not applicable.

Documents on Display

We file annual, periodic, and other reports and information with the U.S. Securities and Exchange Commission (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.

Annual Report to Security Holders

If we are required to provide an annual report to security holders in response to the requirements of Form 6-K, we will submit the annual report to security holders in electronic format in accordance with applicable requirements.

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 2023, 2024 and as of December 31, 2024, 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 2024, 59% of our total costs of sales and operating expenses were denominated in euro. During the same period, 45% 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, 2024, relative to the U.S. dollar and the Japanese yen would have resulted in a decrease in loss before taxes of approximately €1,274 thousand for the year ended December 31, 2024, compared to a decrease in loss before taxes of approximately €1,118 thousand for the year ended December 31, 2023. A uniform 10% decrease in the value of the euro as of December 31, 2024, relative to the U.S. dollar and the Japanese yen would have resulted in an increase in loss before taxes of approximately €1,401 thousand for the year ended December 31, 2024, as compared to an increase in loss before taxes of approximately €1,230 thousand for the year ended December 31, 2023. 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, 2024, we had no outstanding hedging instruments.

Financial Instruments and Indebtedness in Foreign Currencies

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. €1.9 million, €0.4 million and €1.0 million of our outstanding indebtedness (excluding lease obligations) at December 31, 2024, 2023 and 2022, respectively, were denominated in Japanese yen. €1.4 million, €0.0 million and €0.0 million of our outstanding indebtedness (excluding lease obligations) at December 31, 2024, 2023 and 2022, respectively, were denominated in U.S. dollars . In addition, we had €16.4 million, €27.1 million and €28.8 million of cash denominated in U.S. dollars at December 31, 2024, 2023 and 2022, respectively, and €3.4 million, €3.6 million and €3.9 million of cash denominated in Japanese yen at December 31, 2024, 2023 and 2022, respectively.

Equity Price Risk

Not applicable.

Item 12. Description of Securities Other than Equity Securities

Debt Securities

Not applicable.

Warrants and Rights

Not applicable.

Other Securities

Not applicable.

American Depositary Shares

For general information on our ADSs, please refer to Exhibit 2.3 “Description of securities registered under Section 12 of the Exchange Act” of this annual report.

Fees Payable by ADS Holders

The Bank of New York Mellon, 240 Greenwich Street, New York, NY 10286, 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.

A deposit agreement among us, the Depositary and the owners and beneficial owners of ADS sets out the ADS holder rights as well as the rights and obligations of the Depositary. New York law governs the deposit agreement and the ADSs. A copy of the deposit agreement is incorporated by reference as an exhibit to this annual report.

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.

Pursuant to the deposit agreement, holders of our ADSs may have to pay to the Depositary, either directly or indirectly, fees, charges and expenses up to the amounts set forth in the table below.

Fees:	**Depositary Services:**
$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.
$0.02 (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 De positary or its agent when you deposit or withdraw shares
	– Cable, telex and facsimile transmissions (when expressly provided in the deposit agre ement)
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, 2024, to December 31, 2024, the following amounts were paid by the Depositary to the Company: $90,000 and $9,568.06 respectively for the administration of the ADR program and for expenses linked to the preparation of our Assembly meeting of shareholders and 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 Exchange Act, of the effectiveness of our disclosure controls and procedures as of December 31, 2024. Based on this evaluation, the Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures were not effective as of December 31, 2024, because of the material weaknesses described below.

In response to the identification of the material weaknesses described below, the Company performed additional analysis. Based upon the work performed, management believes that the Company's consolidated financial statements for the periods covered by and included in this annual report fairly present in all material respects the Company's financial position, results of operations and cash flows, in conformity with U.S. GAAP.

Disclosure controls and procedures means controls and other procedures that are designed to ensure that information required to be disclosed by the Company in the reports that the Company files or submits 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 the Company in the reports that it files or submits under the Exchange Act is accumulated and communicated to the Company's management, including its 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, 2024, 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 not effective as of December 31, 2024, because of the material weaknesses described below.

Based on this evaluation, management identified two material weaknesses with respect to internal control in our U.S. subsidiary, EDAP Technomed Inc. related to:

- Ineffective design and implementation of the subsidiary's control over the recording of third-party vendor invoices.
- Inherent IT system limitations, including that the system was not configured to sufficiently ensure data integrity, enforce segregation of duties, prevent erroneous or unauthorized changes to accounting entries made in current or previous reporting periods.

Management has concluded that, as a result, the Company's internal control over financial reporting was not effective as of December 31, 2024.

A material weakness is a deficiency, or combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of our annual or interim financial statements will not be prevented or detected on a timely basis.

Management plan for the remediation of the current material weaknesses

In the Company's annual report on Form 20-F for the year ended December 31, 2023, it reported a material weakness with respect to internal controls in its U.S. subsidiary, EDAP Technomed Inc. related to an ineffective design and implementation of the subsidiary's control over the recording of third-party vendor invoices, which was due to insufficient resources in the finance department of the subsidiary and IT environment limitations.

In an effort to remediate the material weakness, management has developed and started to implement the following remediation plans at the U.S. subsidiary:

- Hired IT and accounting personnel with sufficient internal controls experience, including a Global IT Leader to supervise the deployment of IT systems and an experienced controller.
- Engaged external consultants to assist management with the design and implementation of internal controls.

Due to the inherent system limitations described above, management has not yet fully remediated this material weakness at December 31, 2024.

In an effort to remediate these material weaknesses identified as of December 31, 2024, management is in the process of developing and implementing the following remediation plans at the U.S. subsidiary in addition to the remedial actions performed or in process as described above:

- Implementing SAP, an Enterprise Resource Planning (ERP) system designed to ensure data integrity and enforce segregation of duties. This ERP system should be deployed by the second half of 2025 in the U.S. subsidiary (SAP was already implemented in France in 2018).
- Hiring additional resources in 2025 to strengthen financial oversight and reporting accuracy.
- Engaging external consultants to assist in the transition to a more secure IT infrastructure and improve IT governance practices.

Management is committed to remediating the material weaknesses in a timely fashion and to making continuous improvements to the Company's internal control over financial reporting. Management believes the measures described above will strengthen the Company's internal control over financial reporting. Management will continually assess the effectiveness of the remediation efforts and may determine to take additional measures to address control deficiencies or modify the remediation plan described above.

The material weaknesses did not result in a material misstatement of the consolidated financial statements for the years ended December 31, 2024 and 2023, or restatement of any prior period previously reported by the Company. However, there is a reasonable possibility that a material misstatement of the consolidated financial statements would not have been prevented or detected on a timely basis due to the failure in designing and implementing appropriate controls over the recording of third-party vendor invoices and inherent IT systems limitations, and therefore, our management has determined these deficiencies constitute material weaknesses.

Change in Internal Control over Financial Reporting

Other than the material weaknesses and remediation activities described above, there were no changes in the Company's internal control over financial reporting during the period covered by this annual 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, 2024, has been audited by KPMG S.A. ("KPMG"), an independent registered public accounting firm, as stated in its report on the Company's internal control over financial reporting included on page F-4 of this annual report.

Its report expresses an opinion that the Company did not maintain effective internal control over financial reporting as of December 31, 2024 because of the effect of the material weaknesses described above.

Item 16. [Reserved]

Item 16A. Audit Committee Financial Expert

Our Board of Directors has determined that the chair of the Board's Audit Committee, Ms. Fran Schulz, 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, Chief Accounting Officer, principal accounting officers, to any persons performing similar functions as well as to all of our employees as soon as they join us. The code of ethics is regularly reviewed and updated as needed. Our code of ethics has been made available on our website at http://www.edap-tms.com. The contents of our website are not incorporated by reference or otherwise included in this annual report. You may request a copy of our code of ethics free of charge upon request by contacting compliance@edap-tms.com. We expect that any amendments to the code of ethics, or any waivers of its requirements, will be disclosed on our website.

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, 2024, and December 31, 2023, for audit and other services. KPMG served as the Company's independent registered accounting firm for the fiscal years ended December 31, 2024, and 2023.

Nature of the Fees	Fees for 2024 (in €)	Fees for 2023 (in €)
Audit fees	1,118,000	830,000
Audit-related fees	—	—
Tax fees	—	—
All other fees	—	—
Total	**1,118,000**	**830,000**

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 and beyond. 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 billed to us by Agili(3F) for fiscal years ended December 31, 2024 and 2023 are as follows:

Nature of the Fees	Fees for 2024 (in €)	Fees for 2023 (in €)
Audit fees	31,700	30,500
Audit-related fees	—	—
Tax fees	—	—
All other fees	—	—
Total	**31,700**	**30,500**

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.

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

All services that are to be performed by our independent auditors are pre-approved according to our Audit Committee Pre-Approval Policy for services obtained from the Independent Auditor. All services performed by the independent auditors were subjected to the Audit Committee's pre-approval.

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 Nasdaq, under 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 Nasdaq corporate governance rules.

EDAP currently follows Nasdaq's Listing Rule 5620(c), which provides that the minimum quorum requirement for a meeting of shareholders is 33 1⁄3% of the outstanding common voting shares of the company. In accordance with the provisions of the French Commercial Code, the required majority for the adoption of a decision is a simple majority (for an ordinary general meeting of the shareholders) or a two-thirds majority (for an extraordinary general meeting) of the votes cast by the shareholders present or represented.

Under French law, the committees of our Board of Directors are advisory only, and where 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 shareholders' meeting of the Company that is competent to appoint our auditors upon the proposal of our Board of Directors. Our Compensation Committee is composed of five members who meet the definition of independence contained in Nasdaq Listing Rule 5602(a) and is governed by a charter that 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.

Nasdaq rules require shareholder approval in certain circumstances, including in connection with the issuance of shares as part of an acquisition of stock or assets of another company (Rule 5635(a)), a company change of control within the meaning of Nasdaq's rules (Rule 5635(b)), when a plan or other equity compensation arrangement is established or materially amended (Rule 5635(c)), and in connection with certain issuances involving 20% or more of the ordinary shares or voting power outstanding before the issuance at a price lower than a minimum price specified in the Nasdaq Listing Rules (Rule 5635(d)). Under French law our shareholders must decide any issuance of equity, as a general matter. Such shareholder approval is typically provided by the adoption of authorizing resolutions at the Company's annual shareholders' meeting at which shareholders approve delegations of authority to the Executive Board to increase the Company's share capital within specified parameters, which may include specified price limitations and/or specific or aggregate limitations on the size of the share capital increase. While the Company views such shareholder approvals to be consistent with the purpose of the Nasdaq shareholder approval rules, it is not certain that Nasdaq would accept the Company's shareholder-approved resolutions as sufficient to satisfy the Nasdaq shareholder approval rules in connection with a specific transaction. Accordingly, we follow our French home country practice and obtain shareholder approval for delegations of authority (i) to issue equity to our directors, officers and employees, subject to the limitations of such approvals, and (ii) to define the final terms of such transactions (including the final terms of any equity compensation plan or arrangements) to our directors, officers and employees. The Company may, from time to time, ask for our shareholders' approval in respect of a specific transaction or we may seek subsequent approval of an equity compensation arrangement in order to obtain advantageous tax treatment or otherwise. In addition, under French law, we must obtain the prior approval of our shareholders before issuing equity or establishing or amending a compensatory plan or arrangement that would exceed the limits of the shareholder-granted delegations.

Because we are a "foreign private issuer" as described above, our Chief Executive Officer and our Chief Financial Officer issue the certifications required by Section 302 and Section 906 of the Sarbanes-Oxley Act of 2002 on an annual basis (with the filing of our annual report on Form 20-F) rather than on a quarterly basis as would be the case of a U.S. corporation filing quarterly reports on Form 10- Q.

French corporate law provides that the Board of Directors must vote to approve a broadly defined range of related-party transactions (*conventions réglementées*) between the Company on the one hand and its directors and Chief Executive Officer on the other hand, which are then presented to shareholders for approval at the next annual meeting. This legal safeguard operates in place of certain provisions of the Nasdaq Listing Rules.

Item 16H. Mine Safety Disclosure

Not applicable.

Item 16I. Disclosure Regarding Foreign Jurisdictions that Prevent Inspections.

Not applicable.

Item 16J. Insider Trading Policy

The Company has adopted a policy on the prevention of insider trading governing the purchase, sale and other dispositions of securities by directors, senior management and employees that is reasonably designed to promote compliance with applicable insider trading laws, rules and regulations. This "Insider Trading Policy" was approved by the Board of Directors on November 6, 2024, and is filed as Exhibit 11.1 to this annual report on Form 20-F.

Item 16K. Cybersecurity

Cybersecurity Risk Management and Strategy

We have developed and implemented a cybersecurity risk management program designed to safeguard sensitive information and ensure the integrity of our operations. We have a framework of policies and procedures, encompassing governance, risk

management, and compliance, to address cybersecurity threats in a manner commensurate with the size and complexity of our operations and organizational structures. As part of this program, we address risks linked to network security, data encryption and other measures to protect our systems and data from unauthorized access or misuse. In addition, we also take measures to meet the information security standards that our customers require from time to time. To protect our systems and information from cybersecurity threats, we use a variety of security tools and techniques generally available for entities of our size.

Since hiring a Vice President of Information Technology, we have made significant improvements in centralizing our IT organization at group level and implementing a group wide framework of IT policies and procedures and a cybersecurity risk management program. Our Vice President of Information Technology has five years of experience with cybersecurity.

Our cybersecurity risk management processes include:

- an incident response plan that ensures detection, mitigation and resolution of cybersecurity incidents;
- risk management criteria that adapt to the specific cybersecurity risk, including feedback from cybersecurity incidents that have occurred in the past;
- protocols that protect against specific cybersecurity threats identified by our cyber risk assessments;
- continuous assessments and upgrades of our IT and related systems;
- processes to ensure business continuity and ongoing operations upon the occurrence of a cyber attack;
- the use of a specialized third-party firm to conduct periodic assessments of our cybersecurity policies and procedures;
- the use of third parties for certain cybersecurity defense measures, including firewalls, antivirus solutions and system back-up solutions;
- periodic cyber-awareness campaigns for employees and cybersecurity training for our incident response personnel and senior management.

We have not identified risks from known cybersecurity threats, including as a result of any prior cybersecurity incidents that have materially affected or are reasonably likely to materially affect us, including our operations, business strategy, results of operations, or financial condition. See Item 3.D. “Risk Factors—We are exposed to risks related to cybersecurity threats and incidents.”

Cybersecurity Governance

Our board of directors considers cybersecurity risk as part of its risk oversight function and has delegated to the Audit Committee oversight of our cybersecurity risk management program.

Our Internal Audit organization reports on a quarterly basis on the prevention, detection, mitigation and remediation of cybersecurity incidents to our Senior management team, Audit Committee and Board of Directors depending on the materiality of the incident. Materiality is primarily assessed both in terms of criticality of the data and overall amount at risk. In addition to any reports from the Audit Committee to our full Board of Directors regarding cybersecurity, the Chairman of the Audit Committee informs and updates the full Board of Directors about any significant cybersecurity incidents.

Our management team, which is led by our Chief Executive Officer and Chief Financial Officer, is responsible for assessing and managing material risks from cybersecurity threats.

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 December 19, 2024.
2.1#	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).
2.2	Form of American Depositary Receipt (included in Exhibit 2.1).
2.3	Description of securities registered under Section 12 of the Exchange Act.
4.1	English version of Commercial Lease dated November 26, 2024, between Maison Antoine Baud and EDAP TMS France, effective July 1, 2025.
4.2†#	2016 Form of Stock Option Plan (incorporated herein by reference to Exhibit 4.2 to Form S-8 dated April 5, 2017, SEC File Number 333-217160).
4.3†#	2019 Form of Stock-Option Subscription Plan (incorporated herein by reference to Exhibit 4.2 to Form S-8 dated June 16, 2021, SEC File Number 333-257142).
4.4†#	2019 Form of Stock-Option Purchase Plan (incorporated herein by reference to Exhibit 4.3 to Form S-8 dated June 16, 2021, File Number 333-257142).
4.5†#	2021 Form of Free Share Plan (incorporated herein by reference to Exhibit 4.2 to Form S-8 dated September 28, 2021, SEC File Number 333-259857).
4.6†#	2021 Form of Share Subscription Option Plan (incorporated herein by reference to Exhibit 4.2 to Form S-8 dated November 18, 2021, SEC File Number 333-261182).
4.7†#	2022 Form of Free Share Plan (incorporated herein by reference to Exhibit 4.2 to Form S-8 dated November 9, 2022, SEC File Number 333-268265).
4.9†#	2024 Form of Share Subscription Option Plan (incorporated herein by reference to Exhibit 4.2 to Form S-8 dated August 22, 2024, SEC File Number 333-281720).
8.1	List of significant subsidiaries, see "*Item 4. Information on the Company — C. Organizational Structure*" of this annual report on Form 20-F.
11.1	Company's Insider Trading Policy.
12.1	Certification by the Principal Executive Officer pursuant to Securities Exchange Rules 13a-14(a) and 15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
12.2	Certification by the Principal Financial Officer pursuant to Securities Exchange Rules 13a-14(a) and 15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
13.1	Certification by the Principal Executive Officer and Principal Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
15.1	Consent of KPMG.
97.1#	Clawback Policy of EDAP TMS S.A. (incorporated herein by reference to Exhibit 97.1 to Form 20-F dated March 28, 2024, SEC File No. 000-29374).
101.INS	Inline XBRL Instance Document.
101.SCH	Inline XBRL Taxonomy Extension Schema Document.
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document.

101.DEF	Inline XBRL Taxonomy Definition Linkbase Document.
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document.
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document.
104	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101).

† Indicates a management contract or any compensatory plan, contract or arrangement.
Indicates a document previously filed with the Commission.

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: March 27, 2025

/s/ Ryan Rhodes

Ryan Rhodes
Chief Executive Officer

Dated: March 27, 2025

/s/ Ken Mobeck

Ken Mobeck
Chief Financial Officer

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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, 2024 and 2023, the related consolidated statements of operations, comprehensive loss, shareholders' equity, and cash flows for each of the years in the three-year- period ended December 31, 2024, 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, 2024 and 2023, and the results of its operations and its cash flows for each of the years in the three-year- period ended December 31, 2024, 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, 2024, 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 March 27, 2025, expressed an adverse opinion on the effectiveness of the Company's internal control over financial reporting.

Basis for Opinion

These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these consolidated financial statements based on our 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 Matters

The critical audit matters communicated below are matters arising from the current period audit of the consolidated financial statements that were communicated or required to be communicated to the audit committee and that: (1) relate 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 critical audit matters 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 matters below, providing separate opinions on the critical audit matters or on the accounts or disclosures to which they relate.

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 certain internal controls over the Company's revenue recognition process related to the identification of distinct performance obligations included in multiple-element arrangements. For certain medical device sales, we obtained and read the executed contracts and assessed the Company's identification of distinct performance obligations.

Going concern assessment

As discussed in note 1-2 to the consolidated financial statements, the Company has a history of operating losses and expects such losses to continue in the foreseeable future. As of December 31, 2024, the Company had €29.8 million in cash and cash equivalents and believes it has sufficient funds to support its operations for at least a period of twelve months from the date of issue of these consolidated financial statements. However, the Company believes that it will need to raise substantial additional financing in order to meet its cash needs in subsequent periods.

We identified the evaluation of the Company's assessment of its ability to continue as a going concern and related disclosures as a critical audit matter. A high degree of subjective auditor judgment was required to evaluate the Company's forecasted cash flows used in its going concern analysis due to uncertainty in certain assumptions, specifically forecasted revenue and the feasibility of the Company's planned expense and working capital management activities for the twelve-month period subsequent to the issuance of the consolidated financial statements.

The following are the primary procedures we performed to address this critical audit matter. We evaluated the design and tested the operating effectiveness of certain internal controls related to the Company's assessment of its ability to continue as a going concern and related disclosures. This included controls related to the development of certain assumptions, including forecasted revenue and the feasibility of the Company's planned expense and working capital management activities. We compared the Company's historical forecasted cash flows to actual results to assess the Company's ability to accurately forecast. We assessed the reasonableness of forecasted revenue and the feasibility of the Company's planned expense and working capital management activities used in management's forecasted cash flows by (1) conducting interviews with management to gain an understanding of the Company's operations, strategy, research and development, and selling and marketing activities, (2) evaluating the consistency of information used in management's analysis with management's plans for expense and working capital management activities presented to the Board of Directors and other public information disseminated by the Company and (3) assessing their consistency with evidence obtained in other areas of the audit. We performed sensitivity analyses on forecasted revenue by evaluating the impact of changes in forecasted revenue on the Company's going concern assessment. We assessed the Company's disclosures related to its going concern assessment by comparing the disclosures to the audit evidence obtained.

Lyon, March 27, 2025

KPMG S.A.

Stéphane Gabriel Devin
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, 2024, based on criteria established in Internal Control – Integrated Framework (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission. In our opinion, because of the effect of the material weaknesses, described below, on the achievement of the objectives of the control criteria, the Company has not maintained effective internal control over financial reporting as of December 31, 2024, 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, 2024 and 2023, the related consolidated statements of operations, comprehensive loss, shareholders' equity, and cash flows for each of the years in the three-year period ended December 31, 2024, and the related notes (collectively, the consolidated financial statements), and our report dated March 27, 2025 expressed an unqualified opinion on those consolidated financial statements.

A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of the company's annual or interim financial statements will not be prevented or detected on a timely basis. Material weaknesses at the Company's U.S. subsidiary have been identified and included in management's assessment related to an ineffective design and implementation of the subsidiary's control over the recording of third-party vendor invoices and inherent IT system limitations.

The material weaknesses were considered in determining the nature, timing, and extent of audit tests applied in our audit of the 2024 consolidated financial statements, and this report does not affect our report on those consolidated financial statements.

Basis for Opinion

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

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

Definition and Limitations of Internal Control Over Financial Reporting

A company's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting

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

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

Lyon, March 27, 2025

KPMG S.A.

Stéphane Gabriel Devin
Partner

EDAP TMS S.A. AND SUBSIDIARIES
CONSOLIDATED BALANCE SHEETS
As of December 31, 2024 and 2023
(in thousands of euros unless otherwise noted)

ASSETS	Notes	2024	2023
Current assets			
Cash and cash equivalents	2	29,836	43,471
Current portion of net trade accounts and notes receivable	3	18,601	17,858
Other receivables	4	1,688	1,380
Inventories	5	18,495	15,112
Other assets, current portion	6	1,258	659
Total current assets		69,876	78,480
Non-current assets			
Property and equipment, net	7	7,782	6,471
Operating lease right-of-use assets	8	2,554	1,722
Intangible assets, net	9	1,085	1,084
Goodwill	9	2,412	2,412
Deposits and other non-current assets	10	1,522	651
Deferred tax assets	23-3	833	729
Net Trade accounts and notes receivable, non-current	3	—	—
Total assets		**86,063**	**91,548**
LIABILITIES AND SHAREHOLDERS' EQUITY			
Current liabilities			
Trade accounts and notes payable	11	12,611	11,297
Deferred revenues, current portion	12	6,641	4,049
Social security and other payroll withholdings taxes		2,243	1,695
Employee absences compensation		981	860
Income taxes payable		(8)	77
Other accrued liabilities	13	5,523	4,506
Short-term borrowings	15	6,243	2,466
Current obligations under finance leases	14-1	168	195
Current portion of operating lease obligations	14-2	999	898
Current portion of long-term debt	16-1	2,409	1,553
Total current liabilities		37,811	27,596
Non-current liabilities			
Deferred revenues, non-current	12	358	643
Obligations under finance leases	14-1	350	433
Operating lease obligations, non-current	14-2	1,589	882
Long-term debt, non-current	16-1	2,162	1,997
Other long-term liabilities	17	2,897	3,075
Total liabilities		45,167	34,626
Shareholders' equity			
Common stock, €0.13 par value; 37,661,619 shares issued and 37,392,086 shares outstanding at December 31, 2024 €0.13 par value 37,373,312 shares issued and 37,103,779 shares outstanding at December 31, 2023		4,888	4,851
Additional paid-in capital		124,269	120,908
Accumulated deficit		(82,567)	(63,549)
Cumulative other comprehensive loss		(4,894)	(4,487)
Treasury stock, at cost 269,533 shares at December 31, 2024 and 269,533 shares at December 31, 2023	18	(800)	(800)
Total shareholders' equity	18	40,896	56,922
Total liabilities and shareholders' equity		**86,063**	**91,548**

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

EDAP TMS S.A. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF OPERATIONS
For the years ended December 31, 2024, 2023 and 2022
(in thousands of euros except share and per share data)

	Note	2024	2023	2022
Sales of goods		44,037	42,333	38,462
Sales of RPPs & leases		7,610	6,176	5,617
Sales of spare parts and services		12,468	11,914	11,030
Total revenues	19	64,114	60,423	55,108
Cost of goods		(24,599)	(23,302)	(20,528)
Cost of RPPs & leases		(4,964)	(4,541)	(3,387)
Cost of spare parts and services		(7,996)	(8,169)	(7,000)
Total cost of sales	20	(37,558)	(36,012)	(30,916)
Gross profit		26,556	24,411	24,193
Research and development expenses	21	(7,726)	(6,963)	(4,920)
Selling and marketing expenses		(25,281)	(22,626)	(16,379)
General and administrative expenses		(14,083)	(14,634)	(7,152)
Loss from operations		(20,534)	(19,813)	(4,257)
Interest (expense) income, net	22	560	1,079	236
Foreign currency exchange gain (loss), net		1,246	(1,799)	1,925
Loss before taxes	23-1	(18,729)	(20,533)	(2,096)
Income tax expense	23-2	(289)	(644)	(837)
Loss		(19,018)	(21,178)	(2,933)
Basic loss per share	24	(0.51)	(0.57)	(0.09)
Diluted loss per share	24	(0.51)	(0.57)	(0.09)
Basic Weighted average shares outstanding	24	37,286,446	36,996,722	34,392,598
Diluted Weighted average shares outstanding	24	37,286,446	36,996,722	34,392,598

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

EDAP TMS S.A. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS
For the years ended December 31, 2024, 2023 and 2022
(in thousands of euros unless otherwise noted)

		2024	2023	2022
Net loss		(19,018)	(21,178)	(2,933)
Other comprehensive loss				
Foreign currency translation adjustments	18-6	(495)	(478)	(596)
Provision for retirement indemnities	18-6	68	(141)	282
Deferred tax for retirement indemnities	18-6	20	(39)	73
Comprehensive loss, net of tax		(19,425)	(21,836)	(3,173)

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, 2024, 2023 and 2022
(in thousands of euros unless otherwise noted)

	Number of shares	Common stock	Additional paid-in capital	Retained Earnings / Accumulated deficit	Other comprehensive income (loss)	Treasury stock	Total
Balance as of December 31, 2021	33,466,136	4,389	89,621	(39,439)	(3,589)	(928)	50,054
Net loss	—	—	—	(2,933)	—	—	(2,933)
Translation adjustment	—	—	—	—	(596)	—	(596)
Stock-based compensation	—	—	2,103	—	—	—	2,103
Capital increase net of issuance costs of €1,954 thousand	3,444,789	388	22,228	—	—	—	22,616
Treasury stock disposition	—	—	—	—	—	31	31
Provision for retirement indemnities	—	—	—	—	282	—	282
Deferred tax for retirement indemnities	—	—	—	—	73	—	73
Balance as of December 31, 2022	36,910,925	4,776	113,952	(42,372)	(3,829)	(897)	71,632
Net loss	—	—	—	(21,178)	—	—	(21,178)
Translation adjustment	—	—	—	—	(478)	—	(478)
Stock-based compensation	—	—	6,865	—	—	—	6,865
Capital increase	192,854	74	90	—	—	—	164
Treasury stock disposition	—	—	—	—	—	97	97
Provision for retirement indemnities	—	—	—	—	(141)	—	(141)
Deferred tax for retirement indemnities	—	—	—	—	(39)	—	(39)
Balance as of December 31, 2023	37,103,779	4,851	120,908	(63,549)	(4,487)	(800)	56,922
Net loss	—	—	—	(19,018)	—	—	(19,018)
Translation adjustment	—	—	—	—	(495)	—	(495)
Stock-based compensation	—	—	3,283	—	—	—	3,283
Capital increase	288,307	37	78	—	—	—	116
Provision for retirement indemnities	—	—	—	—	68	—	68
Deferred tax for retirement indemnities	—	—	—	—	20	—	20
Balance as of December 31, 2024	37,392,086	4,888	124,269	(82,567)	(4,894)	(800)	40,896

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, 2024, 2023 and 2022
(in thousands of euros unless otherwise noted)

	2024	2023	2022
Cash flows from operating activities			
Net loss	(19,018)	(21,178)	(2,933)
Adjustments to reconcile net loss to net cash generated by (used in) operating activities:			
Depreciation and amortization	2,565	1,913	1,605
Share based compensation	3,283	6,865	2,103
Change in allowances for doubtful accounts & slow-moving inventories	955	422	124
Change in long-term provisions	173	159	79
Net capital loss on disposals of assets	515	1	266
Deferred tax expense (benefit)	(97)	42	48
Operating cash flow before changes in working capital	(11,623)	(11,775)	1,292
Increase/Decrease in operating assets and liabilities:			
Decrease (Increase) in trade accounts and notes and other receivables	(139)	(4,910)	(1,974)
Decrease (Increase) in inventories	(4,042)	(4,212)	(4,482)
Decrease (Increase) in other assets	(572)	(12)	(82)
(Decrease) Increase in trade accounts and notes payable	1,236	5,281	1,143
(Decrease) Increase in accrued expenses, other current liabilities	1,555	950	1,079
Net change in operating assets and liabilities	(1,961)	(2,903)	(4,316)
Net cash generated by (used in) operating activities	**(13,584)**	**(14,678)**	**(3,024)**
Cash flows from investing activities:			
Additions to capitalized assets produced by the Company	(2,556)	(2,583)	(1,570)
Acquisitions of property and equipment	(1,315)	(1,179)	(613)
Acquisitions of intangible assets	(230)	(534)	(137)
Decrease (Increase) of other financial assets	—	1	—
Increase in deposits and guarantees	(19)	(50)	(58)
Net cash generated by (used in) investing activities	**(4,120)**	**(4,344)**	**(2,378)**
Cash flow from financing activities:			
Proceeds from capital increase [(1)]	—	—	21,960
Proceeds from stock-option exercise	116	261	688
Proceeds from long term borrowings, net of financing costs	2,585	—	286
Repayment of long term borrowings	(1,549)	(1,586)	(803)
Repayment of obligations under financing leases	(232)	(242)	(350)
Increase (decrease) in bank overdrafts and short-term borrowings	3,716	656	(38)
Net cash generated by (used in) financing activities	**4,635**	**(911)**	**21,741**
Net effect of exchange rate changes on cash and cash equivalents	(566)	268	(388)
Net increase (decrease) in cash and cash equivalents	**(13,635)**	**(19,665)**	**15,952**
Cash and cash equivalents at beginning of year	43,471	63,136	47,183
Cash and cash equivalents at end of year	**29,836**	**43,471**	**63,136**

[(1)] The net proceeds from capital increase of €21,960 thousand relate to the Company's successful common stock offering in September 2022 – refer to Note 18-1.

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, manufacturing, promotion and distribution of advanced non-invasive ultrasound technologies for both diagnosis and treatment various diseases. We have introduced the Focal One® Robotic HIFU (high-intensity focused ultrasound) system around the world including Europe, U.S., Latin America, the Middle East and parts of Asia. We also currently offer customers a complete solution from diagnosis to treatment of prostate disease with the distribution of complementary products on behalf of third parties. Finally, we service systems for the treatment of urinary tract stones. Our technologies include lithotripter systems based on Extracorporeal ShockWave Lithotripsy ("ESWL") technology and advanced surgical laser systems. 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. Our new growth strategy is to develop our core proprietary HIFU activities and place less emphasis on our non-HIFU distribution and ESWL business activities.

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.

1-2 Basis of preparation and financial condition

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

We have a history of operating losses and expect such losses to continue in the foreseeable future. As of December 31, 2024, we had €29.8 million in cash and cash equivalents, a decrease of €13.6 million from December 31, 2023. We believe we have sufficient funds to support our operations for at least a period of twelve months from the date of issue of these consolidated financial statements. However, we will need to raise substantial additional financing in order to meet our cash flow needs in the subsequent period and until we achieve profitability. We may not be able to raise additional financing on acceptable terms or at all and this condition may in the future raise uncertainty regarding our ability to continue as a going concern. Management is actively exploring various alternatives, including seeking additional funding through the debt and equity capital markets, cost-cutting measures, and restructuring opportunities, but there is no assurance that these efforts will be successful or sufficient to address these liquidity concerns. If we are unable to raise capital when needed on acceptable terms, or at all, we may be forced to restructure our business or delay, reduce, or terminate our research and product development programs, future commercialization efforts or other operations.

1-3 Management estimates

The preparation of financial statements in conformity with 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 contracts 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.

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's revenue consists of:

- Sales of goods (devices and consumables), where invoicing generally takes place upon delivery. Consumables revenues included in sales contracts 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) 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 third-party distributor and agent 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 Focalpaks in the HIFU division and electrodes in the ESWL division). Sales of goods also includes products such as micro-ultrasound devices, urology lasers 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, 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. 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 on the geographic area. Over this standard one to two-year 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 at no cost for a limited period, rather than selling the devices. These hospitals and clinics perform treatments using the devices and usually pay us based on the number of individual treatments provided.

Revenues related to the sale of treatments invoiced on a 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.

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 19.

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

Contract Balances:

Details on contract liabilities are reported on Note 12.

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 classified as short-term investments. There are no short-term investments at December 31, 2024.

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 2024 and 2023 approximated none and €1 thousand, respectively. The Company does not have any off-balance-sheet credit exposure related to its customers.

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

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

Equipment includes industrial equipment and research equipment that has alternative future uses. Equipment also includes devices and treatment probes that are manufactured by the Company and leased to customers through operating leases related to RPP transactions. This equipment is generally depreciated over a period of five to 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 impairment 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 €52 thousand, €134 thousand and €112 thousand for the years ended December 31, 2024, 2023 and 2022, 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 operations. Advertising costs amounted to €1,740 thousand, €1,352 thousand and €929 thousand for the years ended December 31, 2024, 2023 and 2022, 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 operations 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 operations.

Presentation in the Statement of Operations

Aggregate foreign currency transactions gains and losses are disclosed in a single caption in the Statement of Operations 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 Operations. As of December 31, 2024, there are no derivative instruments.

1-22 Employee stock option and free shares plan

The accounting for stock-based awards is based on the fair value of the award measured at the grant date. Accordingly, stock-based compensation cost is recognized in the consolidated statements of operations and comprehensive loss as an operating expense over the requisite service period. The fair value of stock options is determined using the Black-Scholes option-pricing model. The Company determines the fair value of stock option awards on the date of grant using assumptions regarding expected term, share price volatility over the expected term of the awards, risk-free interest rate, and dividend rate. The fair value of free shares is measured using the fair value of the Company's shares as if the free shares were vested and issued on the grant date. Forfeited stock-options and free shares are recognized as they occur, in accordance with ASU 2016-09. The Company recognizes compensation cost for employee awards with only service conditions that have a graded vesting schedule on a straight-line basis over the requisite service period for each separately vesting portion of the award as if the award was, in-substance, multiple awards.

At December 31, 2024, the Company had four stock-based employee compensation plans and two free shares plans.

1-23 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 rate payments 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 payable under a Company provided residual value guarantee. The company assesses the discount rate by requesting credit simulation from certain banks.

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 operations 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 expenses 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.

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

- 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.

1-24 Recent accounting pronouncements

Recently Adopted Accounting Pronouncements

As of November 27, 2023, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ASU 2023-07 (Segment reporting: Improvements to reportable segment disclosures) that improves disclosures about a public entity's reportable segments and addresses requests from investors and other allocators of capital for additional, more detailed information about a reportable segment's expenses. This Topic provides guidance "on how to report certain information about operating segments in complete sets of financial statements of the public entity and in condensed financial statements of interim periods issued to shareholders." This ASU also requires disclosure of the title and position of the individual identified as the Chief Operating Decision Maker ("CODM") and an explanation of how the CODM uses the reported measures of a segment profit or loss in assessing segment performance and deciding how to allocate resources. This standard is effective for the Company in fiscal years beginning after December 15, 2023. The Company evaluated this guidance and does not believe the impact of the new guidance and related codification improvements had a material impact to its financial position, results of operations and cash flows.

2— CASH EQUIVALENTS

Cash equivalents at December 31, 2024 and 2023 only comprise cash investments which are highly liquid and have initial maturities of 90 days or less.

	December 31,	
	2024	2023
Total cash and cash equivalents	29,836	43,471
Short term investment	—	—
Total cash and cash equivalents	29,836	43,471

Please refer to *Note 15 – Short-term borrowings* and *Note 16-1 – Long-term debt* as €3,853 thousand of indebtedness tied to investments for which the Company has access at all times.

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

3— TRADE ACCOUNTS AND NOTES RECEIVABLE, NET

Trade accounts and notes receivable consist of the following:

	December 31,	
	2024	2023
Trade accounts receivable	18,667	17,186
Notes receivable	306	896
Less: allowance for doubtful accounts	(372)	(224)
Total	18,601	17,858
Less current portion	(18,601)	(17,858)
Total long-term portion	—	—

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

Bad debt expenses amount to a net cost of €115 thousand, a net cost of €68 thousand and €32 thousand, respectively for the years ended December 31, 2024, 2023 and 2022.

4— OTHER RECEIVABLES

Other receivables consist of the following:

	December 31,	
	2024	2023
Research and development tax credit receivable from the French State	—	411
Settlement fees	1,000	—
Grants	194	—
Value-added taxes receivable	371	863
Other receivables from Government and public authorities	19	22
Others	105	84
Total	1,688	1,380

Settlement fees for the year ended December 31, 2024, are linked to the termination agreement signed with Boston Scientific. These fees are to be settled in two payments upon fulfilled terms and conditions by the Company. In the Consolidated Statements of Operations, these settlement fees are allocated to the respective lines of expenses generated by the Settlement agreement.

5— INVENTORIES

	December 31,	
	2024	2023
Components, spare parts	13,814	8,973
Work-in-progress	1,019	512
Finished goods – own manufactured products	2,783	2,115
Finished goods – distribution products	2,933	4,775
Total gross inventories	20,549	16,375
Less: allowance for slow-moving inventory and net realizable value	(2,054)	(1,263)
Total	18,495	15,112

The provision for slow moving inventory relates to components and spare parts. The increase in the allowance for slow moving inventory (excluding exchange rate impact), which are classified within cost of sales, amounted to €809 thousand for the year ended December 31, 2024, €354 thousand for the year ended December 31, 2023, and €93 thousand for the year ended December 31, 2022. The increase in the allowance for slow moving inventory linked to the Boston Scientific contract amounted to

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

€570 thousand for the year ended December 31, 2024. During 2023, the Company wrote off obsolete inventory, which was fully reserved for an amount of €301 thousand.

6— OTHER ASSETS

Other assets consist of the following:

	December 31,	
	2024	2023
Prepaid expenses, current portion	1,258	659
Total	1,258	659

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 2024 and 2023.

7-1 Property and Equipment, net

Property and equipment consist of the following:

	December 31,	
	2024	2023
Equipment	13,624	11,900
Furniture, fixture, and fittings and other	4,171	3,672
Total gross value	17,795	15,573
Less: accumulated depreciation and amortization	(10,509)	(9,686)
Total	7,286	5,887

Depreciation expense related to property and equipment (inclusive of depreciation expense on equipment leased to customers) amounted to €2,168 thousand, €1,557 thousand and €1,194 thousand for the years ended December 31, 2024, 2023 and 2022, respectively.

Assets leased to customers:

Capitalized costs on equipment leased to customers of €1,480 thousand and €885 thousand are included in property and equipment at December 31, 2024 and 2023, respectively. Accumulated amortization of these assets leased to third parties was €337 thousand and €207 thousand, at December 31, 2024 and 2023, respectively.

Depreciation expense on equipment leased to customers amounted to €22 thousand, €13 thousand and €37 thousand, for the years ended December 31, 2024, 2023 and 2022, respectively.

7-2 Finance leases

Finance lease right-of-use assets in 2024 and previous years consist of the following:

	December 31,	
	2024	2023
Facilities	—	242
Equipment	220	220
Vehicles and IT equipment	1,015	828
Total gross value	1,235	1,290
Less: accumulated depreciation and amortization	(739)	(705)
Total	496	585

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

Depreciation expense related to finance lease right-of-use assets amounted to €204 thousand, €193 thousand and €303 for the years ended December 31, 2024, 2023 and 2022, respectively.

8— OPERATING LEASE RIGHT-OF-USE ASSETS

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

	December 31,	
	2024	2023
Facilities	2,334	1,534
Equipment	10	30
Furniture, fixture, and fittings and other	209	157
Total net operating lease right of use	2,554	1,722

Operating lease cost amounted to €1,047 thousand and €1,053 thousand for the years ended December 31, 2024 and 2023, respectively.

Variable lease costs related to above contracts amounted to €188 thousand and €243 thousand for the years ended December 31, 2024 and 2023, respectively.

Non-recognized lease liabilities for short term leases amounted to €68 thousand and €71 thousand for the years ended December 31, 2024 and 2023, 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 segments — High Intensity Focused Ultrasound (HIFU), Lithotripsy (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, 2024.

The Company completed the required annual impairment test in the fourth quarter of 2024. 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.

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

Intangible assets consist of the following:

	December 31,	
	2024	2023
Licenses	2,322	2,119
Trade name and trademark	320	333
Patents	412	412
Organization costs	225	225
Total gross value	3,278	3,089
Accumulated amortization for licenses	(1,239)	(1,038)
Accumulated amortization for trade name and trademark	(317)	(331)
Accumulated amortization for patents	(412)	(412)
Accumulated amortization for organization costs	(225)	(225)
Less: Total accumulated amortization	(2,193)	(2,005)
Total	1,085	1,084

Amortization expenses related to intangible assets amounted to €220 thousand, €175 thousand and €141 thousand, for the years ended December 31, 2024, 2023 and 2022, respectively.

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

	December 31, 2024
2025	214
2026	211
2027	194
2028	107
2029	81
2030 and thereafter	209
Total	1,016

10— DEPOSITS AND OTHER NON-CURRENT ASSETS

Deposits and other non-current assets consist of the following:

	December 31,	
	2024	2023
Deposits	653	650
Research and development tax credit receivable from the French State	869	—
Other non-current assets	1	1
Total	1,522	651

Research and development tax credit receivable from the French State is recognized in current assets for the year ended December 31, 2023.

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

11— TRADE ACCOUNTS AND NOTES PAYABLE

Trade accounts and notes payable consist of the following:

	December 31,	
	2024	2023
Trade accounts payable	12,557	11,236
Notes payable	54	61
Total	12,611	11,297

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.

12— DEFERRED REVENUES

Deferred revenues consist of the following:

	December 31,	
	2024	2023
Deferred revenues on maintenance contracts	2,335	1,809
Deferred revenue on RPP	667	492
Deferred revenue on sale of devices	137	104
Deferred revenue on extension of warranty, included in sales contracts	503	591
Deferred revenue on treatment probe lease and other	3,357	1,696
Total	6,999	4,693
Less long term portion	(358)	(643)
Current portion	6,641	4,049

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

	December 31, 2024
2025	344
2026	89
2027	44
2028	13
2029	3
2030 and thereafter	12
Total	503

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

	Total
Balance as of December 31, 2022	535
New extension of warranty	238
Recognition of revenue	(181)
Balance as of December 31, 2023	591
New extension of warranty	175
Recognition of revenue	(263)
Balance as of December 31, 2024	503

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

13— OTHER ACCRUED LIABILITIES

Other accrued liabilities consist of the following:

	December 31,	
	2024	2023
Retirement indemnities	2,323	2,310
Provision for warranty costs	126	172
Accruals for payroll and associated taxes	3,313	2,256
Conditional government advances	436	463
Value added tax payable	914	758
Advances received from customers	478	860
Provision for Asset Retirement Obligation (Japan)	200	91
Provision for employee termination indemnities (Korea)	169	149
Others	461	522
Total	8,420	7,581
Less non-current portion	(2,897)	(3,075)
Current portion	5,523	4,506

Conditional government advances are linked to prospecting sales insurance that is financially sponsored by French government. Maturity of the repayment is conditioned by the sales projections over five years after the end of the prospection period.

Conditional advances as of December 31, 2024, mature as follows:

2025	—
2026	19
2027	19
2028	19
2029	—
2030 and thereafter	378
Total	436

Changes in the provision for warranty costs are as follows:

	2024	2023
Beginning of year	172	162
Amount used during the year	(98)	(124)
New warranty expenses	52	134
End of year	126	172
Less current portion	(108)	(107)
Long term portion	18	65

14— LEASE OBLIGATIONS

14-1 Financing leases

The Company leases certain of its equipment under finance leases. At December 31, 2024, the corresponding liability associated with this lease equipment amounts to €519 thousand for vehicles and other IT equipment.

Maturities of finance leases liabilities for the years ended December 31, 2024 and 2023 are as follows:

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

	December 31, 2024
2025	187
2026	156
2027	112
2028	80
2029	14
2030 and thereafter	1
Total undiscounted minimum lease payments	550
Less: amount representing interest	(31)
Present value of minimum lease payments	519
Less: current portion	(168)
Long-term portion	350

	December 31, 2023
2024	214
2025	170
2026	134
2027	86
2028	52
2029 and thereafter	2
Total undiscounted minimum lease payments	659
Less: amount representing interest	(33)
Present value of minimum lease payments	627
Less: current portion	(195)
Long-term portion	433

Interest paid under finance lease obligations was €18 thousand, €7 thousand and €12 thousand for the years ended December 31, 2024, 2023 and 2022 respectively.

The weighted average remaining lease term and the weighted average discount rate for finance leases were respectively 3.85 years and 3.37% at December 31, 2024 and 3.75 years and 3.67% at December 31, 2023.

14-2 Operating leases

Maturities of operating lease liabilities consist of the following amounts:

	December 31, 2024
2025	999
2026	729
2027	645
2028	215
2029	—
2030 and thereafter	—
Total undiscounted minimum lease payments	2,588
Less: current portion	(999)
Long-term portion	1,589

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

	December 31, 2023
2024	898
2025	485
2026	240
2027	157
2028	—
2029 and thereafter	—
Total undiscounted minimum lease payments	1,780
Less: current portion	(898)
Long-term portion	882

The weighted average remaining lease term and the weighted average discount rate for operating leases were respectively 3.12 years and 5.02% at December 31, 2024 and 2.35 years and 4.98% at December 31, 2023.

Total rent expenses under operating leases amounted to €1,321 thousand, €1,017 thousand and €912 thousand, for the years ended December 31, 2024, 2023 and 2022, respectively. These total rent expenses are related to office rentals, office equipment and car rentals.

15— SHORT-TERM BORROWINGS

As of December 31, 2024 and 2023, short-term borrowings consist mainly of €4,492 thousand and €2,466 thousand of factored account receivables and for which the Company maintains the effective control, respectively.

	2024	2023
Japanese and France Factored account	4,492	2,466
USA Credit line	1,444	—
Japanese Other Short-term borrowings	307	—
Total	6,243	2,466

The U.S. credit line is tied to an investment for which the Company has access at all times for an amount equal to $2,400,000. If the investment is not maintained, the principal amount loaned along with interest and all amounts due to the lender for any reason will become immediately due and payable.

16— LONG TERM DEBT

16-1 Long-term debt:

	December 31,	
	2024	2023
France term loan	4,431	3,222
Japanese term loan	138	323
Germany term loan	—	—
USA term loan	—	—
Korea term loan	2	5
Switzerland term loan	—	—
Malaysia term loan	—	—
Total long-term debt	4,571	3,551
Less current portion	(2,409)	(1,553)
Total long-term portion	2,162	1,997

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

As of December 31, 2024 and 2023, long-term debt in Japan consists of two loans denominated in Yen and 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 installment
EDAP Technomed Co. Ltd	50,000,000	April 2, 2025	1.8 %	Monthly installment

As of December 31, 2024, long-term debt in France consists of two loans denominated in euro, which were originally subscribed in 2020 which terms and maturity were amended, with a loan denominated in euro, which was subscribed in 2021, and three loans denominated in euro, which were subscribed in 2024, with the following terms:

	Initial Amount	Maturity	Fixed Interest rate	Frequency of principal payments
EDAP TMS FRANCE	2,200,000	December 18, 2026	3.60 %	Monthly installment

This loan, denominated in euro, is tied to an investment for which the Company has access at all times for an amount equal to the countervalue of €1,100,000 in USD. This loan is related to the advanced purchasing of ultrasound technology. If the investment is not maintained, the principal amount loaned along with interest and all amounts due to the lender for any reason will become immediately due and payable.

	Initial Amount	Maturity	Fixed Interest rate	Frequency of principal payments
EDAP TMS FRANCE	56,000	August 5, 2028	4.16 %	Monthly installment

This loan, denominated in euro, is related to the acquisition of a medical equipment for ESWL mobile RPP.

	Initial Amount	Maturity	Fixed Interest rate	Frequency of principal payments
EDAP TMS SA	328,650	December 31, 2027	4.60 %	Full reimbursement at termination date

This loan, denominated in euro, is related to the Research and development tax credit receivable from the French State.

	Drawn Amount	Maturity	Fixed Interest rate	Frequency of principal payments
EDAP TMS FRANCE	1,066,081	July 1, 2025	0.99 %	Monthly installment

This loan is tied to an investment for which the Company has access at all times for an amount equal to the countervalue of the loan in USD. This loan constitutes a complete financial package of €1,530,000, of which €1,066,081 was drawn to finance HIFU treatment probes. This drawn amount will be reimbursed over three years until July 1, 2025.

	Initial Amount	Maturity	Fixed Interest rate	Frequency of principal payments
EDAP TMS FRANCE	2,000,000	July 30, 2026	0.73 %	Monthly installment

This loan, denominated in euro, is a COVID-related loan guaranteed by the French government entered into in 2020 with an initial one-year repayment term subsequently extended to six years.

	Initial Amount	Maturity	Fixed Interest rate	Frequency of principal payments
EDAP TMS FRANCE	2,000,000	August 4, 2026	0.73 %	Monthly installment

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

This loan, denominated in euro, is a COVID-related loan guaranteed by the French government in 2020 with an initial one year repayment term subsequently extended to six years.

As of December 31, 2023, long-term debt in France consists of three loans denominated in euro, which were originally subscribed in 2020 which terms and maturity were amended and a loan denominated in euro, which was subscribed in 2021 with the following terms:

	Drawn Amount	Maturity	Fixed Interest rate	Frequency of principal payments
EDAP TMS FRANCE	1,066,081	July 1, 2025	0.99 %	Monthly installment

This loan is pledged against the Company's cash in USD for an amount equal to the countervalue of the loan in USD. This loan constitutes a complete financial package of €1,530,000, of which €1,066,081 was drawn to finance HIFU treatment probes. This drawn amount will be reimbursed over three years until July 1, 2025.

	Initial Amount	Maturity	Fixed Interest rate	Frequency of principal payments
EDAP TMS FRANCE	2,000,000	July 30, 2026	0.73 %	Monthly installment

This loan, denominated in euro, is a COVID-related loan guaranteed by the French government entered into in 2020 with an initial one-year repayment term subsequently extended to six years.

	Initial Amount	Maturity	Fixed Interest rate	Frequency of principal payments
EDAP TMS FRANCE	2,000,000	August 4, 2026	0.73 %	Monthly installment

This loan, denominated in euro, is a COVID-related loan guaranteed by the French government in 2020 with an initial one-year repayment term subsequently extended to six years.

	Initial Amount	Maturity	Fixed Interest rate	Frequency of principal payments
EDAP TMS FRANCE	72,222	July 5, 2024	0.45 %	Monthly installment

This loan is related to the acquisition of computer servers.

16-2 Long-term debt maturity:

Long-term debt carried at amortized cost at December 31, 2024 matures as follows:

2025	2,409
2026	1,809
2027	343
2028	10
2029	—
2030 and thereafter	—
Total	4,571

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

17— OTHER LONG-TERM LIABILITIES

Other long-term liabilities consist of the following:

	December 31,	
	2024	2023
Provision for retirement indemnities (Japan & France), less current portion	2,178	2,241
Provision for employee termination indemnities (Korea) less current portion	169	149
Provision for Asset Retirement Obligation (Japan) less current portion	30	91
Provision for warranty costs, less current portion	18	65
Provision for guarantee given to customer, less current portion	66	66
Conditional government advances, less current portion	436	463
Accrued interest less current portion	—	—
Total	2,897	3,075

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 plans in place. The provision for retirement indemnities at December 31, 2024 represents an accrual for lump-sum retirement benefit 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:

	Retirement indemnities France	
	2024	2023
Discount rate	3.35%	3.19%
Salary increase	3.00%	3.00%
Retirement age	65	65
Average retirement remaining service period	23	23

	Retirement indemnities Japan	
	2024	2023
Discount rate	1.70%	1.30%
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.

At December 31, 2024, the provision which represents the projected benefit obligation in accordance with ASC 718 consists of:

	France	Japan
Non-current liabilities	1,123	1,055
Current liabilities	—	145
Total projected benefit obligation	1,123	1,200

At December 31, 2023, the provision which represents the projected benefit obligation in accordance with ASC 718 consists of:

	France	Japan
Non-current liabilities	1,084	1,157
Current liabilities	—	70
Total projected benefit obligation	1,084	1,227

The Company does not have a funded benefit plan. A detailed reconciliation of pension cost components (in thousands of euros) during fiscal year for each of the three years ending December 31, 2024 is as follows:

France	**2024**	**2023**	**2022**
Change in benefit obligations:			
Projected Benefit obligations at beginning of year	1,084	934	1,080
Service cost	75	67	84
Interest cost	35	34	11
Net loss or (gain)	—	—	—
Actuarial (gain) or loss	(20)	66	(241)
Amortization of net prior service cost	—	—	—
Benefits paid	(51)	(17)	—
Projected Benefit obligations at end of year [1]	1,123	1,084	934
Unrecognized actuarial (gain) loss [2]	(163)	(146)	(219)
Unrecognized prior service cost [2]	12	13	14

(1) The accumulated benefit obligation was €824 thousand and €805 thousand at December 31, 2024 and 2023 respectively.
(2) The amount in accumulated other comprehensive loss to be recognized as components of net periodic benefit costs in 2024 is €152 thousand.

Japan	**2024**	**2023**	**2022**
Change in benefit obligations:			
Projected Benefit obligations at beginning of year	1,227	1,219	1,302
Service cost	110	114	112
Interest cost	15	13	7
Amortization of net loss	—	—	—
Actuarial (gain) / loss	(35)	4	(30)
Benefits paid	(65)	(76)	(75)
Plan Amendments	—	74	—
Exchange rate impact	(51)	(122)	(95)
Projected Benefit obligations at end of year [1]	1,200	1,227	1,219
Unrecognized actuarial (gain) loss [2]	43	81	86
Unrecognized prior service cost [2]	64	74	—

(1) The accumulated benefit obligation was €1,011 thousand and €1,030 thousand at December 31, 2024 and 2023, respectively.
(2) The amount in accumulated other comprehensive loss to be recognized as components of net periodic benefit costs in 2024 is €106 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**
2025	—	146
2026	129	137
2027	85	65
2028	85	44
2029	85	17
2030-2034	408	1,005
	793	1,414

18— SHAREHOLDERS' EQUITY

18-1 Common stock

As of December 31, 2024, EDAP TMS S.A.'s common stock consisted of 37,661,619 issued shares fully paid and with a par value of €0.13 each. 37,392,086 of the shares were outstanding.

18-2 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.

18-3 Dividend rights

Dividends may be distributed from the statutory retained earnings, subject to the requirements of French law and the Company's by-laws. The Company has not distributed any dividends since its inception as the result of an accumulated statutory deficit of €15,630 thousand. Dividend distributions, if any, will be made in euros. The Company has no plans to distribute dividends in the foreseeable future.

18-4 Treasury stock

As of December 31, 2024, all 269,533 shares held as treasury stock consisted of (i), 89,243 shares acquired between August and December 1998 and (ii) 180,290 shares acquired in June and July 2001 for a total of €590 thousand. All treasury stocks have been acquired to cover stock purchase options (see Note 18-5).

18-5 Stock-option and free share plans

As of December 31, 2024, EDAP TMS S.A. sponsored four stock purchase and subscription option plans open to employees of EDAP TMS group:

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). The options will expire on April 26, 2026 (i.e., ten years after the date of grant) or when employment with the Company ceases, whichever occurs earlier. The total fair value of the options granted under this plan was €960 thousand. This non-cash compensation expense was 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 were fully vested as of April 25, 2021 (i.e., four years after the date of grant). The options will expire on April 25, 2027 (i.e., ten years after the date of grant) or when employment with the Company ceases, whichever occurs earlier. The total fair value of the options granted on April 25, 2017 under this plan was €335 thousand. This non-cash compensation expense was 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 were fully vested as of August 29, 2022 (i.e., four years after the date of grant). The options will expire on August 29, 2029 (i.e., ten years after the date of grant) or when employment with the Company ceases, whichever occurs earlier. The total fair value of the options granted on August 29, 2018 under this plan was €219 thousand. This non-cash compensation expense was 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 were fully vested as of April 4, 2023 (i.e., four years after the date of grant). The options will expire on April 4, 2029 (i.e., ten years after the date of grant) or when employment with the Company ceases, whichever occurs earlier. The total fair value of the options granted on April 4, 2019 under this plan was €299 thousand. This non-cash compensation expense is 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 €25 thousand and €3 thousand in 2022 and 2023, respectively.

Under this 2016 plan, 361,080 options are outstanding and are exercisable at December 31, 2024.

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. Conforming to this June 28, 2019 stock option plan, the Board of Directors granted 292,428 options to purchase pre-existing shares and 1,000,000 options to subscribe to new shares to certain employees of EDAP TMS on June 11, 2021. The exercise price was fixed at €5.59 per share. Options were to begin vesting six months after the date of grant and most options will be fully vested as of June 11, 2024 (i.e., three years after the date of grant). On March 29, 2023, the vesting of 270,000 of these options was accelerated and such options may vest immediately. The options will expire on June 11, 2031 (i.e., ten years after the date of grant) or when employment with the Company ceases, whichever occurs earlier. The total fair value of subscription options granted on June 11, 2021 under this plan was €681 thousand and the total fair value of purchase options was €2,371 thousand. This non-cash compensation expense is recognized in the Company's operating expenses over a period of 36 months (using the graded vesting method).

The impact of this June 28, 2019 Plan on operating income, in accordance with ASC 718, was €1,104 thousand, €410 thousand and €32 thousand in 2022, 2023 and 2024, respectively.

Under this 2019 plan, 954,533 options are outstanding and are exercisable at December 31, 2024.

On June 30, 2021, the shareholders authorized the Board of Directors to grant up to a maximum of 2,000,000 options to subscribe to 2,000,000 new shares at a fixed price to be set by the Board of Directors. Conforming to this June 30, 2021 stock-option plan, the Board of Directors granted:

(i) 100,000 options to subscribe to new shares to certain employees of EDAP TMS on November 17, 2021. The exercise price was fixed at €5.18 per share. Options were to begin vesting six months after the date of grant and all options will be fully vested as of November 17, 2024 (i.e., three years after the date of grant). The options will expire on November 17, 2031 (i.e., ten years after the date of grant) or when employment with the Company ceases, whichever occurs earlier. The total fair value of the options granted on November 17, 2021 under this plan was €229 thousand. This non-cash compensation expense is recognized in the Company's operating expenses over a period of 36 months (using the graded vesting method).

(ii) 144,000 options to subscribe to new shares to certain employees of EDAP TMS on May 17, 2022. The exercise price was fixed at €6.41 per share. Options were to begin vesting six months after the date of grant and all options will be fully vested as of May 17, 2025 (i.e., three years after the date of grant). The options will expire on May 17, 2032 (i.e., ten years after the date of grant) or when employment with the Company ceases, whichever occurs earlier. The total fair value of the options granted on May 17, 2022 under this plan was €450 thousand. This non-cash compensation expense is recognized in the Company's operating expenses over a period of 36 months (using the graded vesting method).

(iii) 32,000 options to subscribe to new shares to certain employees of EDAP TMS on November 8, 2022. The exercise price was fixed at €10.32 per share. Options were to begin vesting six months after the date of grant and all options will be fully vested as of November 8, 2025 (i.e., three years after the date of grant). The options will expire on November 8, 2032 (i.e., ten years after the date of grant) or when employment with the Company ceases, whichever occurs earlier. The total fair value of the options granted on November 8, 2022 under this plan was

€161 thousand. This non-cash compensation expense was recognized in the Company's operating expenses over a period of 36 months (using the graded vesting method).

(iv) 395,000 options to subscribe to new shares to certain employees of EDAP TMS on December 15, 2022. The exercise price was fixed at €9.94 per share. Options were to begin vesting six months after the date of grant and all options will be fully vested as of December 15, 2025 (i.e., three years after the date of grant). The options will expire on December 15, 2032 (i.e., ten years after the date of grant) or when employment with the Company ceases, whichever occurs earlier. The total fair value of the options granted on December 15, 2022 under this plan was €1,858 thousand. This non-cash compensation expense is recognized in the Company's operating expenses over a period of 36 months (using the graded vesting method).

(v) 125,000 options to subscribe to new shares to certain employees of EDAP TMS on April 5, 2023. The exercise price was fixed at €9.96 per share. Options were to begin vesting six months after the date of grant and all options will be fully vested as of April 5, 2026 (i.e., three years after the date of grant). The options will expire on April 5, 2033 (i.e., ten years after the date of grant) or when employment with the Company ceases, whichever occurs earlier. The total fair value of the options granted on April 5, 2023 under this plan was €687 thousand. This non-cash compensation expense is recognized in the Company's operating expenses over a period of 36 months (using the graded vesting method).

(vi) 200,000 options to subscribe to new shares to certain employees of EDAP TMS on May 2, 2023. The exercise price was fixed at €10.10 per share. Options were to begin vesting six months after the date of grant and all options will be fully vested as of May 2, 2026 (i.e., three years after the date of grant). The options will expire on May 2, 2033 (i.e., ten years after the date of grant) or when employment with the Company ceases, whichever occurs earlier. The total fair value of the options granted on May 2, 2023 under this plan was €1,183 thousand. This non-cash compensation expense is recognized in the Company's operating expenses over a period of 36 months (using the graded vesting method).

(vii) 50,000 options to subscribe to new shares to certain employees of EDAP TMS on May 31, 2023. The exercise price was fixed at €9.32 per share. Options were to begin vesting six months after the date of grant and all options will be fully vested as of May 31, 2026 (i.e., three years after the date of grant). The options will expire on May 31, 2033 (i.e., ten years after the date of grant) or when employment with the Company ceases, whichever occurs earlier. The total fair value of the options granted on May 31, 2023 under this plan was €270 thousand. This non-cash compensation expense is recognized in the Company's operating expenses over a period of 36 months (using the graded vesting method).

(viii) 177,000 options to subscribe to new shares to certain employees of EDAP TMS on August 23, 2023. The exercise price was fixed at €7.53 per share. Options were to begin vesting six months after the date of grant and all options will be fully vested as of August 23, 2026 (i.e., three years after the date of grant). The options will expire on August 23, 2033 (i.e., ten years after the date of grant) or when employment with the Company ceases, whichever occurs earlier. The total fair value of the options granted on August 23, 2023 under this plan was €774 thousand. This non-cash compensation expense is recognized in the Company's operating expenses over a period of 36 months (using the graded vesting method).

(ix) 80,000 options to subscribe to new shares to certain employees of EDAP TMS on September 20, 2023. The exercise price was fixed at €6.08 per share. Options were to begin vesting six months after the date of grant and all options will be fully vested as of September 20, 2026 (i.e., three years after the date of grant). The options will expire on September 20, 2033 (i.e., ten years after the date of grant) or when employment with the Company ceases, whichever occurs earlier. The total fair value of the options granted on September 20, 2023 under this plan was €296 thousand. This non-cash compensation expense is recognized in the Company's operating expenses over a period of 36 months (using the graded vesting method).

(x) 20,000 options to subscribe to new shares to certain employees of EDAP TMS on November 8, 2023. The exercise price was fixed at €6.64 per share. Options were to begin vesting six months after the date of grant and all options will be fully vested as of November 8, 2026 (i.e., three years after the date of grant). The options will expire on November 8, 2033 (i.e., ten years after the date of grant) or when employment with the Company ceases, whichever occurs earlier. The total fair value of the options granted on November 8, 2023 under this plan was €81

thousand. This non-cash compensation expense is recognized in the Company's operating expenses over a period of 36 months (using the graded vesting method).

(xi) 34,000 options to subscribe to new shares to certain employees of EDAP TMS on December 6, 2023. The exercise price was fixed at €4.98 per share. Options were to begin vesting six months after the date of grant and all options will be fully vested as of December 6, 2026 (i.e., three years after the date of grant). The options will expire on December 6, 2033 (i.e., ten years after the date of grant) or when employment with the Company ceases, whichever occurs earlier. The total fair value of the options granted on December 6, 2023 under this plan was €103 thousand. This non-cash compensation expense is recognized in the Company's operating expenses over a period of 36 months (using the graded vesting method).

(xii) 154,000 options to subscribe to new shares to certain employees of EDAP TMS on January 18, 2024. The exercise price was fixed at €5.29 per share. Options were to begin vesting six months after the date of grant and all options will be fully vested as of January 18, 2027 (i.e., three years after the date of grant). The options will expire on January 18, 2034 (i.e., ten years after the date of grant) or when employment with the Company ceases, whichever occurs earlier. The total fair value of the options granted on January 18, 2024 under this plan was €521 thousand. This non-cash compensation expense is recognized in the Company's operating expenses over a period of 36 months (using the graded vesting method).

(xiii) 12,000 options to subscribe to new shares to certain employees of EDAP TMS on February 28, 2024. The exercise price was fixed at €5.46 per share. Options were to begin vesting six months after the date of grant and all options will be fully vested as of February 28, 2027 (i.e., three years after the date of grant). The options will expire on February 28, 2034 (i.e., ten years after the date of grant) or when employment with the Company ceases, whichever occurs earlier. The total fair value of the options granted on February 28, 2024 under this plan was €38 thousand. This non-cash compensation expense is recognized in the Company's operating expenses over a period of 36 months (using the graded vesting method).

(xiv) 160,000 options to subscribe to new shares to certain employees of EDAP TMS on March 26, 2024. The exercise price was fixed at €6.83 per share. Options were to begin vesting six months after the date of grant and all options will be fully vested as of March 26, 2027 (i.e., three years after the date of grant). The options will expire on March 26, 2034 (i.e., ten years after the date of grant) or when employment with the Company ceases, whichever occurs earlier. The total fair value of the options granted on March 26, 2024 under this plan was €630 thousand. This non-cash compensation expense is recognized in the Company's operating expenses over a period of 36 months (using the graded vesting method).

(xv) 167,000 options to subscribe to new shares to certain employees of EDAP TMS on June 3, 2024. The exercise price was fixed at €5.48 per share. Options were to begin vesting six months after the date of grant and all options will be fully vested as of June 3, 2027 (i.e., three years after the date of grant). The options will expire on June 3, 2034 (i.e., ten years after the date of grant) or when employment with the Company ceases, whichever occurs earlier. The total fair value of the options granted on June 3, 2024 under this plan was €473 thousand. This non-cash compensation expense is recognized in the Company's operating expenses over a period of 36 months (using the graded vesting method).

The impact of this June 30, 2021, Plan on operating income, in accordance with ASC 718, was €442 thousand, €2,936 thousand and €2,502 thousand in 2022, 2023 and 2024, respectively.

Under this 2021 plan, 1,621,300 options are outstanding at December 31, 2024 and 814,494 are exercisable.

On June 28, 2024, the shareholders authorized the Board of Directors to grant up to a maximum of 2,000,000 options to subscribe to 2,000,000 new shares at a fixed price to be set by the Board of Directors. Conforming to this June 28, 2024 authorization, the Board of Directors granted:

(i) 34,000 options to subscribe to new shares to certain employees of EDAP TMS on August 21, 2024. The exercise price was fixed at €3.80 per share. Options were to begin vesting six months after the date of grant and all options will be fully vested as of August 21, 2027 (i.e., three years after the date of grant). The options will expire on August 21, 2034 (i.e., ten years after the date of grant) or when employment with the Company ceases, whichever

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

occurs earlier. The total fair value of the options granted on August 21, 2024 under this plan was €74 thousand. This non-cash compensation expense is recognized in the Company's operating expenses over a period of 36 months (using the graded vesting method).

(ii) 72,000 options to subscribe to new shares to certain employees of EDAP TMS on November 6, 2024. The exercise price was fixed at €2.53 per share. Options were to begin vesting six months after the date of grant and all options will be fully vested as of November 6, 2027 (i.e., three years after the date of grant). The options will expire on November 6, 2034 (i.e., ten years after the date of grant) or when employment with the Company ceases, whichever occurs earlier. The total fair value of the options granted on November 6, 2024 under this plan was €114 thousand. This non-cash compensation expense is recognized in the Company's operating expenses over a period of 36 months (using the graded vesting method).

The impact of this June 28, 2024 stock-option plan on operating income, in accordance with ASC 718, was €37 thousand in 2024.

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:

	Nov-2024	Aug-2024	Jun-2024	Mar-2024	Feb-2024	Jan-2024
Weighted-average expected life (years)	5.79	5.79	5.79	5.79	5.79	5.79
Expected volatility rates[(1)]	60.31 %	60.27 %	60.52 %	60.18 %	63.24 %	63.30 %
Expected dividend yield	0 %	0 %	0 %	0 %	0 %	0 %
Risk-free interest rate	4.34 %	3.76 %	4.42 %	4.24 %	4.29 %	4.08 %
Weighted-average exercise price (€)	2.53	3.80	5.48	6.83	5.46	5.29
Weighted-average fair value of options granted during the year (€)	1.58	2.18	2.83	3.94	3.19	3.38

(1) Historical volatility calculated over the weighted-average expected life.

As of December 31, 2024, a summary of stock option activity to purchase or to subscribe to shares under these plans is as follows:

	2024		2023		2022	
	Options	Weighted average exercice price (€)	Options	Weighted average exercice price (€)	Options	Weighted average exercice price (€)
Outstanding on January 1,	3,198,913	6.26	2,613,886	5.66	2,408,508	4.38
Granted	599,000	5.34	686,000	8.53	571,000	9.07
Exercised	(24,584)	4.71	(55,973)	4.66	(320,622)	2.14
Forfeited	(742,416)	4.92	(45,000)	7.99	(45,000)	5.34
Expired	—	—	—	—	—	—
Outstanding on December 31,	3,030,913	6.42	3,198,913	6.26	2,613,886	5.66
Exercisable on December 31,	2,130,107	6.17	1,997,666	5.23	1,362,205	4.35
Share purchase options available for grant on December 31,	25,000		25,000		20,000	

As of December 31, 2024, 1,894,000 options to subscribe to new shares are available for future grants.

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

The following table summarizes information about options to purchase existing shares held by the Company, or to subscribe to new shares, at December 31, 2024:

	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)
10.32	20,000	7.8	10.32	—	13,889	10.32	—
10.10	200,000	8.3	10.10	—	105,556	10.10	—
9.96	69,000	8.3	9.96	—	38,333	9.96	—
9.94	395,000	8.0	9.94	—	263,333	9.94	—
9.32	50,000	8.4	9.32	—	26,389	9.32	—
7.53	150,000	8.7	7.53	—	66,667	7.53	—
6.83	160,000	9.3	6.83	—	40,000	6.83	—
6.64	10,000	8.8	6.64	—	3,611	6.64	—
6.41	76,000	7.3	6.41	—	65,444	6.41	—
6.08	53,000	8.8	6.08	—	22,083	6.08	—
5.59	954,533	6.4	5.59	—	954,533	5.59	—
5.48	167,000	9.5	5.48	—	27,833	5.48	—
5.46	12,000	9.2	5.46	—	3,333	5.46	—
5.29	142,000	9.1	5.29	—	43,389	5.29	—
5.18	83,300	6.8	5.18	—	83,300	5.18	—
4.98	34,000	8.9	4.98	—	11,333	4.98	—
3.90	70,000	4.8	3.90	—	70,000	3.90	—
3.80	34,000	9.7	3.80	—	—	—	—
3.22	152,500	1.3	3.22	—	152,500	3.22	—
2.65	57,500	3.7	2.65	—	57,500	2.65	—
2.53	60,000	9.8	2.53	—	—	—	—
2.39	81,080	2.3	2.39	—	81,080	2.39	—
2.39 to 10.32	3,030,913	7.5	—	—	2,130,107	—	—

(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 $2.21 at December 31, 2024, which would have been received by the option holders had all in-the-money option holders exercised their options as of that date. If closing stock price is under exercise price, then the aggregate intrinsic value is not considered.

A summary of the status of the non-vested options to purchase shares or to subscribe to new shares as of December 31, 2024, and changes during the three years ended December 31, 2024, is presented below:

	Options	Weighted average Grant-Date Fair Value (€)
Non-vested at January 1, 2022	1,259,107	2.32
Granted	571,000	4.33
Vested	(543,426)	2.32
Forfeited	(35,000)	2.80
Non-vested at December 31, 2022	1,251,681	2.32
Granted	686,000	4.95
Vested	(691,434)	3.22
Forfeited	(45,000)	3.98
Non-vested at December 31, 2023	1,201,247	4.18
Granted	599,000	3.09
Vested	(461,526)	4.45
Forfeited	(437,916)	2.99
Non-vested at December 31, 2024	900,806	3.89

As of December 31, 2024, there were €1,352 thousand of total unrecognized compensation expenses related to non-vested stock-options, over a period of 2.9 years.

On June 30, 2021, the shareholders authorized the Board of Directors to grant up to a maximum of 200,000 free shares to certain employees. Conforming to this June 30, 2021 authorization, the Board of Directors granted:

(i) 61,500 free shares to certain employees of EDAP TMS on September 28, 2021. Free shares shall be definitively acquired by the relevant beneficiaries at the end of the vesting period (minimum one year period starting on the allocation date and ending on the acquisition date, i.e. two years starting on the allocation date). On September 28, 2022, 57,500 free shares were definitely acquired by French resident beneficiaries. The total fair value of the free shares granted on September 28, 2021 under this plan was €340 thousand. This non-cash compensation expense was recognized in the Company's operating expenses upon allocation.

(ii) 40,000 free shares to the CEO of EDAP TMS on March 30, 2022. Free shares shall be definitively acquired by the relevant beneficiaries at the end of the vesting period (minimum one year period starting on the allocation date and ending on the acquisition date, i.e. two years starting on the allocation date). The total fair value of the free shares granted on March 30, 2022 under this plan was €259 thousand. This non-cash compensation expense was recognized in the Company's operating expenses upon allocation.

Under this 2021 plan, no free shares are outstanding at December 31, 2024.

On June 30, 2022, the shareholders authorized the Board of Directors to grant up to 600,000 free shares. This new resolution superseded the June 30, 2021 resolution, cancelling the unused portion of the 2021 resolution. Conforming to this June 30, 2022 authorization, the Board of Directors granted:

(i) 291,500 free shares to certain employees of EDAP TMS on November 8, 2022. Free shares shall be definitively acquired by the relevant beneficiaries at the end of the vesting period, which begins six months after the date of grant and all shares will be fully vested as of November 8, 2025 (i.e. three years after the date of the grant). The total fair value of the free shares granted on November 8, 2022, under this plan was €2,963 thousand. This non-cash compensation expense is recognized in the Company's operating expenses over a period of 36 months (using the graded vesting method).

(ii) 150,000 free shares to Mr. Marc Oczachowski, Chairman and Chief Executive Officer EDAP TMS on March 29, 2023. All free shares shall be definitively acquired one year after the date of the grant. All free shares will be subject to the required 12-month conservation period following the acquisition of the shares. The total fair value of the free shares granted on March 29, 2023 under this plan was €1,542 thousand. This non-cash compensation expense was recognized in the Company's operating expenses upon allocation.

(iii) 50,000 free shares to the President of EDAP TMS France, Mr. Frédéric Pech on May 2, 2023. Free shares shall be definitively acquired at the end of the vesting period, which begins six months after the date of grant and all shares will be fully vested as of May 2, 2026 (i.e. three years after the date of the grant). The total fair value of the free shares granted on May 2, 2023, under this plan was €508 thousand. This non-cash compensation expense is recognized in the Company's operating expenses over a period of 36 months (using the graded vesting method).

Under this 2022 plan, 107,984 free shares are outstanding at December 31, 2024.

On June 28, 2024, the shareholders authorized the Board of Directors to grant up to 600,000 free shares. This new resolution superseded the June 30, 2022 resolution, cancelling the unused portion of the 2022 resolution. No free shares were granted under this authorization as of December 31, 2024.

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

18-6 Accumulated other comprehensive income (loss)

The components of accumulated other comprehensive income (loss) net of tax, for the years ended December 31, 2024, and 2023, are as follows:

	Year Ended December 31, 2024		
	Foreign currency translation adjustment	Provision for retirement indemnities (net of tax)	Total
Beginning balance	(4,451)	(37)	(4,487)
Other comprehensive income (loss) before reclassifications	—	—	—
Reclassified from accumulated other comprehensive loss	—	—	—
Net current-period other comprehensive income (loss)	(495)	88	(407)
Ending balance	(4,946)	51	(4,894)

	Year Ended December 31, 2023		
	Foreign currency translation adjustment	Provision for retirement indemnities (net of tax)	Total
Beginning balance	(3,973)	144	(3,829)
Other comprehensive income (loss) before reclassifications	—	—	—
Reclassified from accumulated other comprehensive loss	—	—	—
Net current-period other comprehensive income (loss)	(478)	(180)	(658)
Ending balance	(4,451)	(37)	(4,487)

19— TOTAL SALES

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

	Year Ended December 31,		
Primary geographical markets (€)	2024	2023	2022
Asia	19,041	17,841	17,936
France	11,240	11,999	10,637
United States	18,220	16,717	15,036
Others geographical areas	15,613	13,865	11,500
Total Net Sales	64,114	60,423	55,108

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

	Year Ended December 31,		
Timing of revenue recognition	2024	2023	2022
Products transferred at a point in time	50,619	48,646	44,173
Products and services transferred over time	13,495	11,777	10,935
Total Net Sales	64,114	60,423	55,108

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

20— COSTS OF SALES

Costs of sales consist of the following:

	Year Ended December 31,		
	2024	2023	2022
Direct costs of sales	(23,894)	(22,624)	(19,814)
Indirect costs of sales	(13,664)	(13,388)	(11,102)
Total costs of sales	(37,558)	(36,012)	(30,916)

21— RESEARCH AND DEVELOPMENT EXPENSES

Research and development expenses consist of the following:

	Year Ended December 31,		
	2024	2023	2022
Gross research and development expenses	(8,413)	(7,596)	(5,751)
Research Tax Credit	458	411	581
Grants	229	222	250
Net Research and development expenses	(7,726)	(6,963)	(4,920)

In 2024, 2023 and 2022, grants consisted mainly of national grants for the assessment and optimization of the focal treatments of prostate cancer (Perfuse 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— INTEREST INCOME, NET

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

	Year Ended December 31,		
	2024	2023	2022
Interest income	796	1,311	404
Interest expense	(236)	(232)	(168)
Total	560	1,079	236

23— INCOME TAXES

23-1 Income / (Loss) before income taxes

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

	Year Ended December 31,		
	2024	2023	2022
France	(5,352)	(9,026)	(418)
Other countries	(13,377)	(11,507)	(1,678)
Total	(18,729)	(20,533)	(2,096)

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

23-2 Income tax (expense)/ benefit

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

	Year Ended December 31,		
	2024	2023	2022
Current income tax expense:			
France	(46)	(77)	(485)
Other countries	(355)	(533)	(251)
Sub-total current income tax expense	(401)	(610)	(736)
Deferred income tax (expense) benefit:			
France	5	3	(8)
Other countries	107	(37)	(93)
Sub-total deferred income tax (expense) benefit	112	(34)	(101)
Total	(289)	(644)	(837)

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 :

	2024	2023
Net operating loss carry forwards	20,744	16,356
Elimination of intercompany profit in inventory	452	689
Elimination of intercompany profit in fixed assets	412	396
Provisions for retirement indemnities	689	663
Capital leases treated as operating leases for tax	7	10
Other items	356	354
Total deferred tax assets	22,660	18,468
Total deferred tax liabilities	—	—
Net deferred tax assets	22,660	18,468
Valuation allowance for deferred tax assets	(21,828)	(17,739)
Deferred tax assets (liabilities), net of allowance	833	729

Net operating loss carryforwards available amount to €91,795 thousand as of December 31, 2024, of which €35,657 thousand relates to EDAP TMS SA, €55,688 thousand relates to Edap Technomed Inc., €293 thousand relates to Edap TMS Gmbh and €158 thousand relates to Edap Technomed Co Ltd Japan. These net operating losses generate deferred tax assets of €20,744 thousand as at December 31, 2024. Realization of these tax assets is contingent on future taxable earnings in the applicable tax jurisdictions. As of December 31, 2024, €91,637 thousand out of these €91,795 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 in 2025. 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.

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

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:

	2024	2023	2022
Theoretical income tax (expense) benefit at French statutory tax rate	4,682	5,133	524
Income of foreign subsidiaries taxed at different tax rates	(546)	(546)	(174)
Effect of net operating loss carry-forwards and valuation allowances	(4,431)	(4,439)	(643)
Non-taxable debt fair value variation	—	—	—
Permanent differences	(282)	(263)	(99)
Effect of cancellation of intra-group positions	267	(476)	(366)
French business tax included in income tax (CVAE)	(40)	(74)	(99)
Other	62	20	20
Effective income tax (expense) benefit	(289)	(644)	(837)

The valuation allowances for deferred taxes presented on the line "Effect of net operating loss carry-forwards and valuation allowances" include some additional categories compared to note 23-3 and include mainly R&D tax credit, stock options and foreign exchange rates.

23-5 Uncertainty in Income Taxes

According to ASC 740, the Company reviewed the tax positions of each subsidiary. On December 31, 2024 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 2024, 2023 and 2022.

24— LOSS PER SHARE

	Year Ended December 31,		
	2024	2023	2022
Loss available to common shareholders (in euro)	€ (19,017,804)	€ (21,177,772)	€ (2,933,058)
Weighted average number of shares for the computation of basic EPS	37,286,446	36,996,722	34,392,598
Basic EPS (in euro)	€ (0.51)	€ (0.57)	€ (0.09)
Effect of dilutive securities	903,889	2,653,050	2,502,171
Weighted average number of shares for the computation of diluted EPS	37,286,446	36,996,722	34,392,598
Diluted EPS loss (in euro)	€ (0.51)	€ (0.57)	€ (0.09)

Diluted EPS 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, 2024 and 2023 were excluded from the calculation of diluted earnings per share as a net loss was reported in this period.

25— COMMITMENTS AND CONTINGENCIES

25-1 Commitments

The Company currently has commitments regarding its operating leases as described in Note 14-2.

25-2 Contingencies

The Company currently has contingencies relating to standard warranties provided to customers for products as described in Note 1-15 and Note 13.

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.

The recorded amount of cash and cash equivalents, accounts receivable, accounts payable, accrued liabilities and short-term borrowings are a reasonable estimate of their fair value due to the short-term maturities of these instruments. As of December 31, 2024 and December 31, 2023, the Company did not have any other asset or liability measured at fair value.

As of December 31, 2024, the fair value of the Company’s long-term debt was not materially different from the carrying value.

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 unknown 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 €0.4 million and €0.2 million, for the years ended December 31, 2024 and 2023, 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 2024, 2023 and 2022, 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 may engage in foreign exchange hedging activities when deemed 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, 2024, there were no outstanding hedging instruments.

29— SEGMENT INFORMATION

Our activity is organized into three divisions: HIFU, ESWL (including lithotripsy activities) and Distribution. Through these three divisions, we develop, produce, market and distribute non-invasive medical devices, mainly for urological diseases. HIFU division includes sales of Focal One, Ablatherm and related consumables and services, ESWL division includes revenues

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

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 non-invasive medical devices, primarily for the treatment of urological diseases. The segments derive their revenues from this activity.

The following tables set forth the key Statement of loss figures, by segment for fiscal years 2024, 2023 and 2022 and the key balance sheet figures, by segment, for fiscal years 2024, 2023 and 2022. 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. The CODM uses operating income (loss) as the measure of profit or loss to allocate resources, assess performance, and monitor budgets against actual results. 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:

	Year Ended December 31,		
	2024	2023	2022
Segment operating loss	(20,534)	(19,813)	(4,257)
Interest income (expense), net	560	1,079	236
Foreign Currency exchange (losses) gains, net	1,246	(1,799)	1,925
Income tax (expense) benefit	(289)	(644)	(837)
Consolidated net loss	(19,018)	(21,178)	(2,933)

A summary of the Company's operations by segment is presented below for years ended December 31, 2024, 2023 and 2022:

2024	HIFU Division	ESWL Division	DISTRIB Division	Reconciling Items	Total consolidated
Sales of goods	14,825	3,481	25,731	—	44,037
Sales of RPPs & leases	6,273	1,033	304	—	7,610
Sales of spare parts and services	2,741	4,468	5,258	—	12,468
Total sales	23,839	8,982	31,293	—	64,114
External other revenues	—	—	—	—	—
Total revenues	23,839	8,982	31,293	—	64,114
Total COS	(11,567)	(5,496)	(20,495)	—	(37,558)
Gross profit	12,272	3,486	10,798	—	26,556
R&D expenses	(6,693)	(365)	(668)	—	(7,726)
Selling and marketing expenses	(15,546)	(1,305)	(8,429)	—	(25,281)
G&A expenses	(7,492)	(606)	(2,271)	(3,714)	(14,083)
Total expenses	(29,731)	(2,276)	(11,368)	(3,714)	(47,090)
Operating income (loss) from operations	(17,459)	1,210	(571)	(3,714)	(20,534)
Total Assets	29,954	11,623	32,770	11,716	86,063
Capital expenditures	3,096	306	718	—	4,120
Non-current assets	8,962	1,467	4,888	—	15,318
Goodwill	645	496	1,271	—	2,412

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

2023	HIFU Division	ESWL Division	DISTRIB Division	Reconciling Items	Total consolidated
Sales of goods	13,510	3,844	24,980	—	42,333
Sales of RPPs & leases	4,935	955	286	—	6,176
Sales of spare parts and services	2,152	5,109	4,653	—	11,914
Total sales	20,596	9,908	29,919	—	60,423
External other revenues	—	—	—	—	—
Total revenues	20,596	9,908	29,919	—	60,423
Total COS	(10,112)	(6,268)	(19,632)	—	(36,012)
Gross profit	10,484	3,640	10,287	—	24,411
R&D expenses	(5,755)	(764)	(444)	—	(6,963)
Selling and marketing expenses	(13,524)	(1,636)	(7,466)	—	(22,626)
G&A expenses	(5,983)	(1,471)	(2,625)	(4,556)	(14,634)
Total expenses	(25,262)	(3,871)	(10,535)	(4,556)	(44,224)
Operating income (loss) from operations	(14,778)	(232)	(248)	(4,556)	(19,813)
Total Assets	22,443	12,798	31,400	24,908	91,548
Capital expenditures	3,577	288	479	—	4,344
Non-current assets	6,516	2,105	4,448	—	13,069
Goodwill	645	496	1,271	—	2,412

2022	HIFU Division	ESWL Division	DISTRIB Division	Reconciling Items	Total consolidated
Sales of goods	9,437	4,880	24,145	—	38,462
Sales of RPPs & leases	4,287	1,058	272	—	5,617
Sales of spare parts and services	1,909	5,630	3,491	—	11,030
Total sales	15,634	11,568	27,907	—	55,108
External other revenues	—	—	—	—	—
Total revenues	15,634	11,568	27,907	—	55,108
Total COS	(6,788)	(6,732)	(17,396)	—	(30,916)
Gross profit	8,846	4,836	10,511	—	24,193
R&D expenses	(3,525)	(950)	(444)	—	(4,920)
Selling and marketing expenses	(8,083)	(1,887)	(6,409)	—	(16,379)
G&A expenses	(2,131)	(1,077)	(1,690)	(2,254)	(7,152)
Total expenses	(13,739)	(3,914)	(8,543)	(2,254)	(28,450)
Operating income (loss) from operations	(4,894)	922	1,968	(2,254)	(4,257)
Total Assets	16,293	12,997	26,407	45,426	101,123
Capital expenditures	1,715	307	356	—	2,378
Non-current assets	4,269	2,149	4,187	—	10,605
Goodwill	645	496	1,271	—	2,412

30— VALUATION ACCOUNTS

	Allowance for deferred tax assets	Allowance for doubtful accounts	Slow-moving inventory	Warranty reserve
Balance as of December 31, 2021	14,341	742	1,470	252
Charges to costs and expenses	1,538	32	93	112
Deductions: write-off and others	(1,135)	(613)	(300)	(202)
Balance as of December 31, 2022	14,744	161	1,262	162
Charges to costs and expenses	3,175	85	354	134
Deductions: write-off and others	(180)	(21)	(353)	(124)
Balance as of December 31, 2023	17,739	224	1,263	172
Charges to costs and expenses	4,114	146	809	52
Deductions: write-off and others	(25)	2	(18)	(98)
Balance as of December 31, 2024	21,828	372	2,054	126

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

31— SUPPLEMENTAL DISCLOSURES OF CASH FLOW INFORMATION

Interest and income taxes paid are as follows:

	Year Ended December 31,		
	2024	2023	2022
Income taxes paid (refunds received)	377	509	410
Interest paid	281	265	168
Interest received	796	1,311	403

Non-cash transactions:

	Year Ended December 31,		
	2024	2023	2022
Financing lease obligations incurred	140	358	162
Operating lease obligations incurred	1,915	1,098	1,162

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

	Year Ended December 31,		
	2024	2023	2022
Operating cash flow used in operating leases	1,074	1,009	900
Operating cash flow used in finance leases	18	7	12
Financing cash flow used in finance leases	232	242	350

32— RELATED PARTY TRANSACTIONS

On August 19, 2019, EDAP Technomed Co. Ltd. (Japan) contracted a loan amounting to JPY 80,000,000. 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 April 22, 2020, EDAP Technomed Co. Ltd (Japan) contracted another loan amounting to JPY 50,000,000 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.

33— SUBSEQUENT EVENTS

On March 26th, 2025, the Company’s Focal One Robotic HIFU System received CE Mark certification from GMED, the Company’s notified body, for the treatment of posterior deep endometriosis infiltrating the rectum and surrounding structures.

EDAP TMS S.A.
Senior Executive Officers

Ryan Rhodes
Chief Executive Officer

Kenneth S. Mobeck
Chief Financial Officer

François Dietsch
Chief Accounting Officer

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Chairman

Glen French
Director

Josh Levine
Director

Ryan Rhodes
Director
Chief Executive Officer

Fran Schulz
Director
Audit Committee Chair

EDAP TMS S.A. Subsidiary Officers

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Chief Executive Officer
EDAP Technomed, Inc.
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Frédéric Pech
President
EDAP TMS France S.A.S.
Lyon, France

Jean-François Bachelard
Asia Operations Supervisor
Chief Executive Officer
EDAP Technomed Co. Ltd
Tokyo, Japan

Alex Fromm
General Manager
EDAP Switzerland GmbH
Zurich, Switzerland
and
General Manager
EDAP TMS GmbH
Flensburg, Germany

Hervé de Soultrait
General Manager
EDAP Technomed (M) Sdn, Bhd
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EDAP TMS S.A. Branch Officer

Jeon Jon-Hyeon
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