



**edap tms**  
Bringing New Horizons to Therapy

## EDAP Issues Letter to Shareholders

January 6, 2021

*Recaps progress made in 2020 notwithstanding the ongoing COVID-19 pandemic and previews anticipated 2021 milestones*

LYON, France, January 6, 2021 -- EDAP TMS SA (Nasdaq: EDAP) ("the Company"), the global leader in robotic energy-based therapies, today issued the following letter to shareholders:

To my fellow shareholders:

The year 2020 challenged us in ways we never thought possible and demanded that we continuously adapt to daily life that seemed to constantly evolve. Like most, we are happy to put the year behind us, but at the same time, we thought it would be worthwhile to pause and reflect on the significant progress that we made as a company notwithstanding this very challenging business environment.

The COVID-19 pandemic placed unprecedented strain on healthcare systems around the world, and as hospitals and physicians pivoted to fight the virus, our sales and marketing efforts in the US and elsewhere became more challenging. Travel and other restrictions on in-person meetings necessitated that we quickly adapt to this "new normal", and I am pleased to say that the EDAP team was successful in doing just that.

In May, we announced an exclusive worldwide agreement to distribute Exact Imaging's micro ultrasound technologies. Their lead product, ExactVu™, delivers diagnostic accuracy similar to MRI in identifying prostate cancer. The combination of ExactVu with our Focal One® High Intensity Focused Ultrasound (HIFU) soft tissue ablation technology represents the most complete end-to-end solution for the focal management of prostate cancer. We wasted little time espousing the many benefits of this combined offering, and in July announced combined sales to Edouard Herriot University Hospital in Lyon, France, Ochsner Medical Center in New Orleans, Louisiana, and Mount Sinai Health System in New York. These are three very highly regarded healthcare institutions that we believe will be important reference sales for our Company going forward. Additionally, in December, we were able to exit the year on a strong note by announcing a bundled sale to the University of California, San Francisco Medical Center and a Focal One sale to Cleveland Clinic. We are realizing many synergies from this combination, and our sales pipeline continues to grow as we enter 2021.

My enthusiasm was confirmed by a [Key Opinion Leader \(KOL\) webinar](#) that we hosted in September. The webinar, which was viewed by many healthcare analysts and investors as well as industry participants, featured presentations by Brian Miles, MD of Houston Methodist and Laurence Klotz, MD of Sunnybrook Health Sciences Centre. Drs. Miles and Klotz spoke of the distinct advantages of combining the latest imaging and ablation technologies to deliver accurate MRI and 3D biopsy image fusion as well as precise and efficient HIFU energy to the prostate.

As we have said many times in the past, a key pillar of our long-term growth strategy is to expand HIFU into additional indications beyond the ablation of prostate tissue. To that end, we received clearance from French health regulators to initiate a Phase 2 clinical trial evaluating Focal One for the treatment of deep invasive rectal endometriosis. This is a truly debilitating condition that is responsible for a significant decline in quality of life. We treated our first women patients in September, and enrollment is proceeding as planned. Our research and development team are working on additional indications as we believe HIFU has broad clinical utility.

We ended the year on a high note with final US 2021 reimbursement rules for HIFU. The rules establish, for the first time, a category 1 CPT code as well as reimbursement to physicians performing ablation of malignant prostate tissue with HIFU. Physician reimbursement for HIFU is set approximately 30% higher than both cryotherapy and brachytherapy, and hospital reimbursement increased by approximately 6% over 2020 levels.

More details can be found in a press release [here](#), but suffice it to say that we expect US reimbursement to be a significant catalyst to future adoption of HIFU in both the hospital and clinic settings.

We made meaningful progress in other territories, as well. In November, we announced an exclusive distribution agreement with leading Italian medical device distributor AB Medica. Notably, AB Medica had already been working with Exact Imaging and distributing ExactVu, so they are already familiar with our product line. Italy is the fourth largest medical technology market in Europe, so this agreement is significant for us.

In closing, against a very challenging business backdrop, we are pleased with our progress in 2020. We expanded our cutting-edge product portfolio with the integration of ExactVu and completed several notable sales. We initiated an important study in an additional indication that, if successful, would allow us access to a second large market with a significant unmet medical need. And we were successful in securing reimbursement in the US, our most important market, creating an additional tailwind as we enter the new year. I would like to thank the entire EDAP team for their ability to quickly adapt to this "new normal" and allow us to continue to pursue our mission. I would also like to thank you, our shareholders, for your continued support. I hope you and your families are well, and I look forward to a mutually successful 2021.

Sincerely,

**Marc Oczachowski**  
Chairman & Chief Executive Officer

### About EDAP TMS SA

A recognized leader in the global therapeutic ultrasound market, EDAP TMS develops, manufactures, promotes and distributes worldwide minimally invasive medical devices for various pathologies using ultrasound technology. By combining the latest technologies in imaging and treatment modalities in its complete range of Robotic HIFU devices, EDAP TMS introduced the Focal One® in Europe and in the U.S. as an answer to all requirements for ideal prostate tissue ablation. With the addition of the ExactVu™ Micro-Ultrasound device, EDAP TMS is now the only company

offering a complete solution from diagnostics to focal treatment of Prostate Cancer. EDAP TMS also produces and distributes other medical equipment including the Sonolith® i-move lithotripter and lasers for the treatment of urinary tract stones using extra-corporeal shockwave lithotripsy (ESWL). For more information on the Company, please visit <http://www.edap-tms.com>, and [us.hifu-prostate.com](http://us.hifu-prostate.com).

### **Forward-Looking Statements**

In addition to historical information, this press release contains forward-looking statements. Such statements are based on management's current expectations and are subject to a number of risks and uncertainties, including matters not yet known to us or not currently considered material by us, and there can be no assurance that anticipated events will occur or that the objectives set out will actually be achieved. Important factors that could cause actual results to differ materially from the results anticipated in the forward-looking statements include, among others, the clinical status and market acceptance of our HIFU devices and the continued market potential for our lithotripsy device, as well as the length and severity of the recent COVID-19 outbreak, including its impacts across our businesses on demand for our devices and services. Factors that may cause such a difference also may include, but are not limited to, those described in the Company's filings with the Securities and Exchange Commission and in particular, in the sections "Cautionary Statement on Forward-Looking Information" and "Risk Factors" in the Company's Annual Report on Form 20-F.

### **Company Contact**

Blandine Confort  
Investor Relations / Legal Affairs  
EDAP TMS SA  
+33 4 72 15 31 50  
[bconfort@edap-tms.com](mailto:bconfort@edap-tms.com)

### **Investor Contact**

Jeremy Feffer  
LifeSci Advisors, LLC  
212-915-2568  
[jeremy@lifesciadvisors.com](mailto:jeremy@lifesciadvisors.com)



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