



EDAP Issues Letter to Shareholders

Feb 01, 2022

LYON, France, February 1, 2022 -- 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:

As we closed the book on 2021, I am once again pleased by the success of the entire EDAP team in navigating through the ongoing pandemic that has made virtually all business operations far more challenging.

Hitting on a few key highlights, we continued to see strong growth in our US HIFU treatment volumes, which, through December 31, increased 65% over the comparable twelve-month period in 2020. We believe robust year-over-year procedural growth is one of the most important leading indicators, as it directly reflects the increased adoption and utilization of Focal One by urologists even as the pandemic continued to weigh on hospital capital spending and activity for much of the year.

The strategic investments that we are making in our U.S. marketing efforts are clearly driving much of the success we experienced in the fourth quarter of 2021. The addition of our U.S. CEO, Ryan Rhodes, along with the expansion of our U.S. infrastructure, has led to several very noteworthy Focal One placements during the quarter, including UC San Diego, Brigham and Women's Hospital in Boston, Cedars-Sinai Health System in LA, Henry Ford Health System in Detroit, Duke University in North Carolina and Prisma Health in South Carolina. In our view, the relationships we are building with these renowned and highly regarded medical institutions reflect the growing acceptance among physicians that Focal One represents as an important new, cutting-edge technology that more hospitals are likely to adopt over time. We believe these successful recent U.S. placements indicate positive adoption trends for our underlying technology, and we will continue to execute our marketing plan while making the appropriate level of investment to maximize our U.S. growth strategy.

In addition to these successes, we also made meaningful progress advancing our earlier stage research and development activities, as we believe HIFU technology has broad clinical utility in other difficult to treat pathologies. Our Phase 2 study evaluating safety and efficacy of our Robotic Focal One in treating deep rectal endometriosis continues to progress. We expect to finalize patient recruitment in 2022, and diligently work through the six-month follow up period. We look forward to seeing the final results from this study.

More recently, we were pleased to announce the publication of compelling pre-clinical results in the journal *Cancers* which highlighted the possibility of treating locally advanced pancreatic cancers with HIFU. Pancreatic adenocarcinoma is among the most aggressive of all cancers, with an overall five-year survival rate for patients of less than 5%. If ultimately successful, this would be a major breakthrough for these patients who are in desperate need of effective treatment options.

Following our strong fourth quarter momentum and with a solid cash position, EDAP enters 2022 with high expectations. I am excited and optimistic about the many opportunities in front of us, and I am confident that we will deliver another successful year. I would like to thank the entire EDAP team for their tireless work and dedication to get us to this point and you, our shareholders, for your continued support.

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.

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.

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