# EDAP Issues Letter to Shareholders

Jan 09, 2020

***Recaps significant progress made in 2019 and previews expectations for accelerating global growth in 2020***

LYON, France, January 9, 2020 -- 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 turn the page on 2019, I thought this would be a good opportunity to recap our recent progress as well as to preview what we expect to be a very exciting 2020 and beyond. Recall that our latest generation high Intensity Focused Ultrasound (HIFU) robotic device, Focal One®, was cleared by FDA in 2018 for the targeted ablation of cancerous prostate tissue. Focal One addresses the significant unmet medical need that exists between the two extremes in prostate cancer treatment: active surveillance (watchful waiting) and radical prostatectomy surgery. The latter is highly invasive and can often result in devastating side effects, including incontinence and impotence. With Focal One, the prostate is preserved. The development of Focal One extends our long-standing position as a leading innovator in the field of therapeutic ultrasound, and this is reflected in the growing sales traction that we are seeing in the U.S. and other key markets around the world.

We have conducted extensive research on the global addressable market for HIFU, and specifically Focal One, and have concluded that the opportunity in front of us is substantial. Around the world, it is estimated that there are roughly 680,000 newly diagnosed cases of localized prostate cancer (PCa) annually, of which approximately 180,000 occur in the United States. Even if we employ modest assumptions regarding HIFU and Focal One market share and procedure volumes per device, we believe we are poised to embark on a significant growth trajectory that at its peak, could take a significant share in of a multi-billion dollar PCa treatment market. A significant percentage of this would be recurring, driven by procedure-related disposable kits and device service contracts. Needless to say, this analysis easily justifies our growing optimism.

In the United States, despite being in the early stages of our physician outreach and educational programs, and while the number of sales is of course an important metric, it is the quality of the institution – a hospital's ability to act as a reference center to help drive awareness – where initial sales are clearly having an impact. Our Focal One customers include such highly-regarded institutions as Mayo Clinic, Houston Methodist Hospital, University of California at Irvine Medical Center and University of Chicago Medicine, among others. These Focal One sales, combined with our presence at important medical meetings such as the American Urology Association Annual Meeting, are driving accelerating growth in our pipeline of potential U.S. customers. Leading urology centers around the country are realizing that this technology is a key differentiator that helps drive increased patient throughput.

A significant catalyst to further adoption of Focal One in the U.S. occurred in June of last year, when we learned that the American Medical Association's CPT® Editorial Panel accepted our application to establish a new Category 1 CPT code that will facilitate reimbursement for the ablation of malignant prostate tissue with HIFU technology. Having a definitive path to reimbursement for the Focal One procedure in the U.S. removes significant financial uncertainty on the part of the hospital, as Focal One represents a meaningful capital investment. The AMA's decision will go a long way toward helping close additional sales ahead of January 2021, when reimbursement commences.

In parallel with these activities, outside of the United States, we continue to further penetrate existing markets such as Brazil, where we now have five installed Focal One devices. At the same time, we opened substantial new markets with sales to Moscow State University of Medicine, a top urology center in Russia and our first in the region, and Farrer Park Hospital in Singapore, our first in Southeast Asia. We are successfully executing on our multi-faceted growth plan, and as a result, we have now recorded four consecutive quarters of profitability as of September 30, 2019.

Longer term, we see opportunity to leverage our state-of-the-art ablation technology into new indications as well. One example is using robotic Focal One HIFU to treat deep rectal endometriosis. We are in ongoing discussions with French regulators to initiate a Phase 2 clinical trial designed to show the safety and efficacy of our technology.

We also successfully expanded our product portfolio with the recent introduction of our brand-new Endo-UP Endourology Platform at the 2019 World Congress of Endourology and Lithotripsy. Endo-UP is designed for the complete management of urinary stones by combining a fully dedicated endourology table with X-ray and ultrasound imaging systems, an integrated shockwave generator and holmium laser source. We believe combining all the tools available to surgeons provides them with the ability to select the best approach or combination of approaches depending on the patient and the stone. This represents a true breakthrough in urinary stone management and again reflects our robust research and development capabilities.

As a result of the solid foundation that we built over the past several years, we enter 2020 with significant momentum and an

opportunity to offer our disruptive breakthrough technologies to patients and physicians around the world.

In closing, I would like to thank the EDAP team who have gotten us to this point, and you, our shareholders, for your continued support. We are very optimistic about the future and look forward to keeping you apprised of our progress as we work to bring new non-invasive therapeutic options to patients while increasing the long-term value of our company.

Sincerely,

**Marc Oczachowski**
**Chief Executive Officer**

**About EDAP TMS SA**

A global leader in Robotic Energy-based therapies for 40 years, EDAP TMS develops, manufactures, promotes and distributes worldwide minimally invasive medical devices for urology 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 2013 in Europe and in 2018 in the US as the answer to all requirements for ideal prostate tissue ablation as a complement to the existing FDA-cleared Ablatherm® Robotic HIFU and Ablatherm® Fusion. As a pioneer and key player in the field of extracorporeal shock wave lithotripsy (ESWL), EDAP TMS exclusively utilizes the latest generation of shock wave source in its Sonolith® range of ESWL systems. 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 may contain 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, regulatory approvals, market acceptance and the continued market potential for our HIFU and lithotripsy devices. 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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