

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 6-K

REPORT OF FOREIGN PRIVATE ISSUER

PURSUANT TO RULE 13a-16 OR 15d-16
UNDER THE SECURITIES EXCHANGE ACT OF 1934

May 13, 2020

Commission File Number: 0-29374

EDAP TMS S.A.
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Indicate by check mark whether the registrant files or will file annual reports under cover of Form 20-F or Form 40-F.

Form 20-F [x] Form 40-F []

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(1): ____

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(7): ____

SIGNATURES

Pursuant to the requirements of the Securities Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

Date: May 13, 2020
EDAP TMS S.A.

/s/ FRANCOIS DIETSCH
FRANCOIS DIETSCH
CHIEF FINANCIAL OFFICER

EDAP Reports First Quarter 2020 Results and Provides Operational Update

- Maintains strong balance sheet with EUR 18.5 million (USD 20.3 million) in cash as of March 31, 2020
- Signs exclusive worldwide distribution agreement with Exact Imaging to combine their innovative micro-ultrasound technology with Focal One to offer an end-to-end focal therapy solution for the diagnosis and management of prostate cancer
- Announces strategic refocusing of future development programs towards high intensity focused ultrasound (HIFU) and related growth opportunities
- Company to host a conference call tomorrow, May 14 at 8:30 am EDT

LYON, France, May 13, 2020 -- EDAP TMS SA (Nasdaq: EDAP) (the "Company"), the global leader in robotic energy based therapies, announced today financial results for the first quarter of 2020 and provided an update on strategic and operational developments.

Marc Oczachowski, EDAP's Chief Executive Officer, said: "Through the first months of 2020, we continued to advance toward our goal of becoming the leading developer of therapeutic ultrasound solutions in urology while also implementing strategic initiatives intended to provide a superior customer offering and drive long-term growth. We are very pleased to have announced a global exclusive distribution agreement with Exact Imaging, a leading innovator in advanced ultrasound technologies. In addition to representing a real advancement in the precise and reliable diagnosis of lesions within the prostate, their ExactVu™ product and its unique micro-ultrasound technology perfectly complements our state-of-the-art Focal One therapeutic offering. By combining these, EDAP is the first and only company to offer urologists a complete end-to-end solution from diagnosis through treatment in the modern management of prostate cancer.

"Regarding our first quarter results, we expected and did experience a deceleration in both procedure volumes and new system sales as hospitals around the world worked to fight the COVID-19 pandemic. However, we are seeing early signs that certain markets are returning to a more normalized business environment, an indication that prostate cancer procedures that had been previously delayed will now resume. As far as system sales, Focal One represents a significant capital outlay for a hospital and as a result, hospitals have been postponing significant technology investments during the COVID outbreak. We strongly believe that many of these sales will ultimately be completed this year. In the meantime, we have continued to grow our pipeline of projects and leads during the worst of the pandemic.

"After an extensive review of our different businesses, including HIFU, Distribution and ESWL, we have decided to strengthen and refocus our development efforts towards HIFU for both prostate applications and beyond. As a part of this initiative, we will be revisiting our lithotripsy R&D investment strategy (to include discontinuation of Endo-UP platform). Based on recent trends, we believe it is important to shift and narrow our R&D focus and marketing towards HIFU and Distribution, as these have shown strong growth and have the potential for future growth and contribution. Importantly, our Lithotripsy business generates significant and steady cash flow for the company that can finance future HIFU development, and we intend to sustain this cash flow by continuing to sell and support our state of the art Sonolith range of devices. But given the opportunities in HIFU that are in front of us, and our technology leadership position, we believe now is the right time to pivot more fully toward that business and to accelerate HIFU expansion," Mr. Oczachowski concluded.

First Quarter 2020 Results

Total revenue for the first quarter 2020 was EUR 7.6 million (USD 8.4 million), a 24.9% decrease compared to EUR 10.1 million (USD 11.5 million) for the first quarter of 2019. First quarter 2020 revenue reflects the impact of the ongoing COVID-19 pandemic on both procedure volumes and equipment sales.

Total revenue in the HIFU business for the first quarter 2020 was EUR 1.9 million (USD 2.1 million), a 50.2 % decrease compared to EUR 3.9 million (USD 4.4 million) for the first quarter of 2019. The year-over-year decline was due to no Focal One units sold during the first quarter of 2020 compared to four sold in the year ago period.

For the three months ended March 31, 2020, total revenue for the UDS division was EUR 5.7 million (USD 6.3 million), a 9.2 % decrease compared to EUR 6.3 million (USD 7.1 million) during the year-ago period.

Gross profit for the first quarter 2020 was EUR 3.1 million (USD 3.4 million), compared to EUR 4.9 million (USD 5.5 million) for the year-ago period. Gross profit margin on net sales was 40.2% in the first quarter of 2020, compared to 48.0% in the year-ago period. The decline in gross profit year-over-year was due to in part to lower sales in HIFU business as compared to the year-ago period.

Operating expenses were EUR 4.5 million (USD 5.0 million) for the first quarter of 2020, compared to EUR 4.7 million (USD 5.3 million) for the same period in 2019.

Operating loss for the first quarter of 2020 was EUR 1.5 million (USD 1.6 million), compared to an operating profit of EUR 0.2 million (USD 0.2 million) in the first quarter of 2019. The financial impact related to discontinuation of R&D lithotripsy programs is under evaluation and will be reflected in the future quarters.

Net loss for the first quarter of 2020 was EUR 1.3 million (USD 1.4 million), or EUR (0.04) per diluted share, as compared to net income of EUR 0.3 million (USD 0.4 million), or EUR 0.01 per diluted share in the year-ago period.

As of March 31, 2020, the Company recorded a strong cash position of EUR 18.5 million (USD 20.3 million).

Conference Call

An accompanying conference call and webcast will be conducted by management to review the results. The call will be held at 8:30am EDT on Thursday, May 14, 2020. Please refer to the information below for conference call dial-in information and webcast registration.

Conference Call & Webcast

Thursday, May 14, 2020 @ 8:30am Eastern Time

Domestic: 877-451-6152
International: 201-389-0879
Passcode: 13703225
Webcast: <http://public.viavid.com/index.php?id=139678>

Following the live call, a replay will be available on the Company's website, www.edap-tms.com under "Investors Information."

About EDAP TMS SA

A recognized leader in the global therapeutic ultrasound market for almost 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 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 devices, 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 may also 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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EDAP TMS S.A.
UNAUDITED CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
(Amounts in thousands of Euros and U.S. Dollars, except per share data)

	Three Months Ended:		Three Months Ended:	
	March 31, 2020 Euros	March 31, 2019 Euros	March 31, 2020 \$US	March 31, 2019 \$US
Sales of medical equipment	4,125	6,546	4,551	7,432
Net Sales of RPP and Leases	1,255	1,371	1,385	1,556
Sales of spare parts, supplies and Services	2,228	2,215	2,458	2,515
TOTAL NET SALES	7,608	10,131	8,394	11,503
Other revenues	2	-	2	-
TOTAL REVENUES	7,610	10,131	8,295	11,503
Cost of sales	(4,548)	(5,266)	(5,018)	(5,979)
GROSS PROFIT	3,062	4,865	3,378	5,523
Research & development expenses	(1,042)	(1,013)	(1,150)	(1,150)
S, G & A expenses	(3,480)	(3,644)	(3,839)	(4,137)
Total operating expenses	(4,522)	(4,657)	(4,989)	(5,287)
OPERATING PROFIT (LOSS)	(1,460)	208	(1,611)	236
Interest (expense) income, net	(20)	(31)	(22)	(35)
Currency exchange gains (loss), net	289	265	319	301
INCOME (LOSS) BEFORE TAXES AND MINORITY INTEREST	(1,191)	443	(1,315)	503
Income tax (expense) credit	(116)	(115)	(128)	(131)
NET INCOME (LOSS)	(1,308)	328	(1,443)	372
Earning per share – Basic	(0.04)	0.01	(0.05)	0.01
Average number of shares used in computation of EPS	29,141,566	28,997,866	29,141,566	28,997,866
Earning per share – Diluted	(0.04)	0.01	(0.05)	0.01
Average number of shares used in computation of EPS for positive net income	29,141,566	29,656,133	29,141,566	29,656,133

NOTE: Translated for convenience of the reader to U.S. dollars at the 2020 average three months' noon buying rate of 1 Euro = 1.1033 USD, and 2019 average three months noon buying rate of 1 Euro = 1.1353 USD

EDAP TMS S.A.
UNAUDITED CONSOLIDATED BALANCE SHEETS HIGHLIGHTS
(Amounts in thousands of Euros and U.S. Dollars)

	Mar. 31, 2020 Euros	Dec. 31, 2019 Euros	Mar. 31, 2020 \$US	Dec. 31, 2019 \$US
Cash, cash equivalents and short-term investments	18,450	20,886	20,323	23,449
Total current assets	39,188	42,097	43,168	47,263
Total current liabilities	16,664	17,493	18,356	19,640
Shareholders' Equity	25,896	27,359	28,526	30,716

NOTE: Translated for convenience of the reader to U.S. dollars at the noon buying rate of 1 Euro = 1.1016 USD, on March 31, 2020 and at the noon buying rate of 1 Euro = 1.1227 USD, on December 31, 2019

EDAP TMS S.A.
UNAUDITED CONDENSED STATEMENTS OF OPERATIONS BY DIVISION
THREE MONTHS ENDED MARCH 31, 2020
(Amounts in thousands of Euros)

	HIFU Division	UDS Division	Reconciling Items	Total After Consolidation
Sales of goods	578	3,547		4,125
Sales of RPPs & Leases	924	331		1,255
Sales of spare parts & services	421	1,808		2,228
TOTAL NET SALES	1,922	5,686		7,608
Other revenues	2	-		2
TOTAL REVENUES	1,924	5,686		7,610
GROSS PROFIT				
(% of Total Revenues)	783 40.7%	2,279 40.1%		3,062 40.2%
Research & Development	(543)	(499)		(1,042)
Total SG&A plus depreciation	(1,262)	(1,820)	(397)	(3,479)
OPERATING PROFIT (LOSS)	(1,023)	(39)	(397)	(1,460)