

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

August 26, 2020

Commission File Number: 0-29374

EDAP TMS S.A.  
Parc Activite La Poudrette Lamartine  
4/6 Rue du Dauphine  
69120 Vaulx-en-Velin - France

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: August 26, 2020  
EDAP TMS S.A.

/s/ FRANCOIS DIETSCH  
FRANCOIS DIETSCH  
CHIEF FINANCIAL OFFICER

---

## EDAP Reports Second Quarter 2020 Results and Provides Operational Update

- Completed multiple Focal One sales to renowned U.S. and international health care institutions, including multiple Focal One™-ExactVu™ bundled sales
- Announced first two U.S. publications in *Journal of Urology* detailing positive outcomes from U.S. studies of HIFU for the successful partial-gland ablation of prostate tissue
- Maintained a strong cash position of EUR 15.7 million (USD 17.7 million) as of June 30, 2020
- Company to host a conference call tomorrow, August 27<sup>th</sup>, at 8:30 am EDT

LYON, France, August 26, 2020 -- EDAP TMS SA (Nasdaq: EDAP) (the “Company”), the global leader in robotic energy based therapies, announced today financial results for the second quarter of 2020 and provided an update on strategic and operational developments.

Marc Oczachowski, EDAP’s Chairman and Chief Executive Officer, said: “Notwithstanding the significant physician and hospital outreach challenges posed by the COVID-19 pandemic during the second quarter, we continued to advance late-stage discussions, resulting in the completion of several notable deals toward the end of the period. Of particular note, our recent sales momentum, which carried into the current quarter, was characterized by a healthy mix of stand-alone Focal One sales, stand-alone Exact-Vu sales, and bundled sales of both complementary technologies that represent the industry’s first true ‘end-to-end’ solution for the urology suite. These are exactly the types of sales synergies that we envisioned when we announced our worldwide distribution agreement with Exact Imaging in May, and the traction we are seeing continues to exceed our internal forecasts. In parallel with these recent sales announcements, we continue to build our pipeline, assisted by highly regarded reference hospitals that were early adopters of Ablatherm® and continue to champion our Focal One HIFU technology.

“Regarding our financial results, as with the first quarter, we did see an impact on revenue, driven mostly by lower procedure volumes as hospitals focused on treating COVID patients. This was in line with our expectations. However, because of the essential nature of timely prostate cancer screenings and treatments, it is anticipated these procedures must ultimately resume and continue, and we do see signs that our key markets in the U.S. and elsewhere are returning to a more normalized environment. We are optimistic that a gradual return to pre-pandemic procedure volumes, coupled with continued sales successes, will set the stage for improved financial results in the back half of the year and a strong 2021,” Mr. Oczachowski concluded.

As a result of the company’s recent strategic shift toward current and emerging opportunities in HIFU, as well as its recently announced exclusive worldwide distribution agreement with Exact Imaging, beginning with the second quarter of 2020, EDAP is reporting its financial results in three segments: (1) HIFU, which includes sales of Focal One, Ablatherm and related consumables and services, (2) Lithotripsy, which includes revenue generated from the existing Sonolith range, and (3) Distribution, which includes the sale of complementary products such as lasers and micro-ultrasound systems and products from third parties.

EDAP’s new reporting segments align with organizational changes implemented within the company to better support the expansion of its HIFU development and sales activities as well as to maximize the potential of its distribution activities. This improved reporting format will allow for an unbiased comparative analysis of our past, current and future operational results.

---

## Second Quarter 2020 Results

Total revenue for the second quarter 2020 was EUR 9.3 million (USD 10.3 million), a decrease of 26% compared to total revenue of EUR 12.5 million (USD 14.0 million) for the same period in 2019. Second 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 second quarter 2020 was EUR 2.6 million (USD 2.8 million), a 44.2% decrease compared to EUR 4.6 million (USD 5.1 million) for the second quarter of 2019.

Total revenue in the LITHO business for the second quarter 2020 was EUR 2.9 million (USD 3.3 million), a 22.8% decrease compared to EUR 3.8 million (USD 4.3 million) for the second quarter of 2019.

Total revenue in the Distribution business for the second quarter 2020 was EUR 3.8 million (USD 4.2 million), a 8.3% decrease compared to EUR 4.1 million (USD 4.6 million) for the second quarter of 2019.

Gross profit for the second quarter 2020 was EUR 4.3 million (USD 4.8 million), compared to EUR 6.3 million (USD 7.1 million) for the year-ago period. Gross profit margin on net sales was 46.8% in the second quarter of 2020, compared to 50.7% 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 driven primary by COVID-19.

Operating expenses were EUR 4.0 million (USD 4.5 million) for the second quarter of 2020, compared to EUR 4.7 million (USD 5.3 million) for the same period in 2019.

Operating profit for the second quarter of 2020 was EUR 0.3 million (USD 0.3 million), compared to an operating profit of EUR 1.7 million (USD 1.9 million) in the second quarter of 2019.

Net loss for the second quarter of 2020 was EUR 0.2 million (USD 0.2 million), or EUR (0.01) per diluted share, as compared to net income of EUR 1.4 million (USD 1.6 million), or EUR 0.05 per diluted share in the year-ago period.

## For the first six months 2020 Results

Total revenue for the first half of 2020 was EUR 16.9 million (USD 18.7 million), a decrease of 25% compared to total revenue of EUR 22.6 million (USD 25.6 million) for the same period in 2019. As mentioned, first half 2020 revenue reflects the impact of the ongoing COVID-19 pandemic on the company's activities.

Total revenue in the HIFU business for the first six months of 2020 was EUR 4.5 million (USD 5.0 million), a 47.0% decrease compared to EUR 8.4 million (USD 9.5 million) for the first six months of 2019.

Total revenue in the LITHO business for the first six months of 2020 was EUR 5.9 million (USD 6.5 million), a 13.0% decrease compared to EUR 6.7 million (USD 7.6 million) for the first six months of 2019.

Total revenue in the Distribution business for the first six month of 2020 was EUR 6.5 million (USD 7.2 million), a 12.3% decrease compared to EUR 7.4 million (USD 8.4 million) for the first six month of 2019.

Gross profit for the first six months of 2020 was EUR 7.4 million (USD 8.2 million), compared to EUR 11.2 million (USD 12.6 million) for the year-ago period. Gross profit margin on net sales was 43.9% for the first six months of 2020, compared to 49.5% in the year-ago period. The decline in gross profit year-over-year was due in part to lower sales in the HIFU business driven by COVID-19.

Operating expenses were EUR 8.5 million (USD 9.5 million) for the first six months of 2020, compared to EUR 9.3 million (USD 10.5 million) for the same period in 2019.

Operating loss for the first six months of 2020 was EUR 1.2 million (USD 1.3 million), compared to an operating profit of EUR 1.9 million (USD 2.1 million) for the same period of 2019.

Net loss for the first six months of 2020 was EUR 1.5 million (USD 1.6 million), or EUR (0.05) per diluted share, as compared to a net income of EUR 1.7 million (USD 1.9 million), or EUR 0.06 per diluted share in the year-ago period.

As of June 30, 2020, the Company recorded a strong cash position of EUR 15.7 million (USD 17.6 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, August 27, 2020. Please refer to the information below for conference call dial-in information and webcast registration.

### Conference Call & Webcast

**Thursday, August 27, 2020 @ 8:30am Eastern Time**

Domestic: 877-451-6152

International: 201-389-0879

Passcode: 13707833

Webcast: <http://public.viavid.com/index.php?id=141080>

Following the live call, a replay will be available on the Company's website, [www.edap-tms.com](http://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](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 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.

### 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)

---

**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:	
	June 30, 2020 Euros	June 30, 2019 Euros	June 30, 2020 \$US	June 30, 2019 \$US
Sales of medical equipment	5,975	8,716	6,628	9,797
Net Sales of RPP and Leases	947	1,429	1,050	1,606
Sales of spare parts, supplies and Services	2,311	2,341	2,564	2,631
<b>TOTAL NET SALES</b>	<b>9,233</b>	<b>12,485</b>	<b>10,242</b>	<b>14,035</b>
Other revenues	23	-	25	-
<b>TOTAL REVENUES</b>	<b>9,255</b>	<b>12,485</b>	<b>10,267</b>	<b>14,035</b>
Cost of sales	(4,931)	(6,154)	(5,470)	(6,918)
<b>GROSS PROFIT</b>	<b>4,324</b>	<b>6,331</b>	<b>4,797</b>	<b>7,117</b>
Research & development expenses	(926)	(986)	(1,027)	(1,108)
S, G & A expenses	(3,096)	(3,691)	(3,434)	(4,149)
Total operating expenses	(4,022)	(4,677)	(4,461)	(5,257)
<b>OPERATING PROFIT (LOSS)</b>	<b>303</b>	<b>1,654</b>	<b>336</b>	<b>1,860</b>
Interest (expense) income, net	(19)	(32)	(21)	(36)
Currency exchange gains (loss), net	(346)	(161)	(384)	(181)
Other income, net	(1)	0	(1)	0
<b>INCOME (LOSS) BEFORE TAXES AND MINORITY INTEREST</b>	<b>(63)</b>	<b>1,462</b>	<b>(70)</b>	<b>1,643</b>
Income tax (expense) credit	(112)	(82)	(124)	(92)
<b>NET INCOME (LOSS)</b>	<b>(175)</b>	<b>1,379</b>	<b>(194)</b>	<b>1,551</b>
Earning per share – Basic	(0.01)	0.05	(0.01)	0.05
Average number of shares used in computation of EPS	29,141,566	28,997,886	29,141,566	28,997,886
Earning per share – Diluted	(0.01)	0.05	(0.01)	0.05
Average number of shares used in computation of EPS for positive net income	29,141,566	29,604,779	29,141,566	29,604,779

**NOTE:** Translated for convenience of the reader to U.S. dollars at the 2020 average three months' noon buying rate of 1 Euro = 1.093 USD, and 2019 average three months noon buying rate of 1 Euro = 1.1241 USD

**EDAP TMS S.A.**  
**UNAUDITED CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS**  
(Amounts in thousands of Euros and U.S. Dollars, except per share data)

	Six Months Ended:		Six Months Ended:	
	June 30, 2020 Euros	June 30, 2019 Euros	June 30, 2020 \$US	June 30, 2019 \$US
Sales of medical equipment	10,099	15,262	11,173	17,241
Net Sales of RPP and Leases	2,202	2,799	2,436	3,163
Sales of spare parts, supplies and Services	4,539	4,555	5,022	5,146
<b>TOTAL NET SALES</b>	<b>16,841</b>	<b>22,617</b>	<b>18,631</b>	<b>25,550</b>
Other revenues	24	-	27	-
<b>TOTAL REVENUES</b>	<b>16,865</b>	<b>22,617</b>	<b>18,658</b>	<b>25,550</b>
Cost of sales	(9,479)	(11,420)	(10,487)	(12,901)
<b>GROSS PROFIT</b>	<b>7,386</b>	<b>11,196</b>	<b>8,171</b>	<b>12,648</b>
Research & development expenses	(1,968)	(1,999)	(2,177)	(2,258)
S, G & A expenses	(6,575)	(7,335)	(7,274)	(8,286)
Total operating expenses	(8,543)	(9,334)	(9,452)	(10,544)
<b>OPERATING PROFIT (LOSS)</b>	<b>(1,157)</b>	<b>1,862</b>	<b>(1,280)</b>	<b>2,104</b>
Interest (expense) income, net	(39)	(63)	(43)	(71)
Currency exchange gains (loss), net	(57)	104	(63)	118
Other income, net	0	0	(1)	-
<b>INCOME (LOSS) BEFORE TAXES AND MINORITY INTEREST</b>	<b>(1,254)</b>	<b>1,904</b>	<b>(1,388)</b>	<b>2,151</b>
Income tax (expense) credit	(228)	(197)	(252)	(223)
<b>NET INCOME (LOSS)</b>	<b>(1,483)</b>	<b>1,707</b>	<b>(1,640)</b>	<b>1,928</b>
Earning per share – Basic	(0.05)	0.06	(0.06)	0.07
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	(0.05)	0.06	(0.06)	0.07
Average number of shares used in computation of EPS for positive net income	29,141,566	29,630,567	29,141,566	29,630,567

**NOTE:** Translated for convenience of the reader to U.S. dollars at the 2020 average six months' noon buying rate of 1 Euro = 1.1063 USD, and 2019 average six months noon buying rate of 1 Euro = 1.1297 USD.

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

	June 30, 2020 Euros	Mar. 31, 2020 Euros	June 30, 2020 \$US	Mar. 31, 2020 \$US
Cash, cash equivalents and short-term investments	15,704	18,450	17,647	20,323
Total current assets	38,307	39,188	43,046	43,168
Total current liabilities	14,845	16,664	16,681	18,356
Shareholders' Equity	25,867	25,896	29,068	28,526

NOTE: Translated for convenience of the reader to U.S. dollars at the noon buying rate of 1 Euro = 1.1237 USD, on June 30, 2020 and at the noon buying rate of 1 Euro = 1.1016 USD, on March 31, 2020

**EDAP TMS S.A.**  
**UNAUDITED CONDENSED STATEMENTS OF OPERATIONS BY DIVISION**  
**SIX MONTHS ENDED JUNE 30, 2020**  
(Amounts in thousands of Euros)

	HIFU Division		ESWL Division		Distribution Division		Reconciling Items	Total After Consolidation	
Sales of goods	1,836		2,624		5,640			10,099	
Sales of RPPs & Leases	1,699		405		97			2,202	
Sales of spare parts & services	915		2,836		788			4,539	
<b>TOTAL NET SALES</b>	<b>4,450</b>		<b>5,865</b>		<b>6,525</b>			<b>16,841</b>	
Other revenues	24		0		0			24	
<b>TOTAL REVENUES</b>	<b>4,474</b>		<b>5,865</b>		<b>6,525</b>			<b>16,865</b>	
<b>GROSS PROFIT (% of Total Revenues)</b>	<b>2,384</b>	<b>53.3 %</b>	<b>2,481</b>	<b>42.3%</b>	<b>2,521</b>	<b>38.6%</b>		<b>7,386</b>	<b>43.8%</b>
Research & Development	(1,155)		(639)		(175)			(1,968)	
Total SG&A plus depreciation	(1,905)		(1,440)		(2,450)		(780)	(6,575)	
<b>OPERATING PROFIT (LOSS)</b>	<b>(676)</b>		<b>402</b>		<b>(104)</b>		<b>(780)</b>	<b>(1,157)</b>	