

EDAP Reports Second Quarter 2020 Results and Provides Operational Update

Aug 26, 2020

- 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 27th, 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 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:	
	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
TOTAL NET SALES	9,233	12,485	10,242	14,035
Other revenues	23	-	25	-
TOTAL REVENUES	9,255	12,485	10,267	14,035
Cost of sales	(4,931)	(6,154)	(5,470)	(6,918)
GROSS PROFIT	4,324	6,331	4,797	7,117
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)
OPERATING PROFIT (LOSS)	303	1,654	336	1,860
Interest (expense) income, net	(19)	(32)	(21)	(36)
Currency exchange gains (loss), net	(346)	(161)	(384)	(181)
Other income, net	(1)	0	(1)	0
INCOME (LOSS) BEFORE TAXES AND MINORITY INTEREST	(63)	1,462	(70)	1,643
Income tax (expense) credit	(112)	(82)	(124)	(92)
NET INCOME (LOSS)	(175)	1,379	(194)	1,551
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
TOTAL NET SALES	16,841	22,617	18,631	25,550
Other revenues	24	-	27	-
TOTAL REVENUES	16,865	22,617	18,658	25,550
Cost of sales	(9,479)	(11,420)	(10,487)	(12,901)
GROSS PROFIT	7,386	11,196	8,171	12,648
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)
OPERATING PROFIT (LOSS)	(1,157)	1,862	(1,280)	2,104
Interest (expense) income, net	(39)	(63)	(43)	(71)
Currency exchange gains (loss), net	(57)	104	(63)	118
Other income, net	0	0	(1)	-
INCOME (LOSS) BEFORE TAXES AND MINORITY INTEREST	(1,254)	1,904	(1,388)	2,151
Income tax (expense) credit	(228)	(197)	(252)	(223)
NET INCOME (LOSS)	(1,483)	1,707	(1,640)	1,928
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
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
TOTAL NET SALES	4,450	5,865	6,525		16,841
Other revenues	24	0	0		24
TOTAL REVENUES	4,474	5,865	6,525		16,865
GROSS PROFIT (% of Total Revenues)	2,384 53.3%	2,481 42.3%	2,521 38.6%		7,386 43.8%
Research & Development	(1,155)	(639)	(175)		(1,968)
Total SG&A plus depreciation	(1,905)	(1,440)	(2,450)	(780)	(6,575)
OPERATING PROFIT (LOSS)	(676)	402	(104)	(780)	(1,157)

Attachment

- [2020-08-26 -- EDAP 2Q 2020 Press Release FINAL](#)



Source: EDAP TMS S.A.