

EDAP TMS SA
Form FWP
May 28, 2014

Filed pursuant to Rule 433
Registration Statement No. 333-195435
May 28, 2014

EDAP TMS S.A.

RECENT DEVELOPMENTS AS OF MAY 27, 2014

Note to potential investors. This consolidated summary of certain recent developments (this “Summary”) includes information that originally appeared in four separate press releases published by EDAP TMS S.A. (the “Company”) on, respectively, May 27, May 22, May 15 and April 21, 2014, each of which was furnished to the U.S. Securities and Exchange Commission (the “SEC”) on a Form 6-K on the date it was published as a press release.

Certain additional important information is included at the end of this Summary under the captions “Forward-looking Statements” and “Additional Information”. Potential investors are encouraged to read these sections carefully for information concerning forward-looking statements, as well as for details on how to obtain additional information in regards to a registration statement filed by the Company with the SEC.

1. Press Release dated May 27, 2014

EDAP Outlines Key Events Scheduled in the Ablatherm-HIFU PMA Process

EDAP TMS SA provided additional details on key events scheduled as part of the U.S. Food and Drug Administration (FDA) Pre-Market Approval (“PMA”) process for its Ablatherm-HIFU device for the treatment of localized prostate cancer.

In addition to the previously announced panel of experts that is scheduled to review the Ablatherm-HIFU device and provide a recommendation based on the clinical data submitted to the FDA, the Company has additional milestones to achieve as part of the PMA application process. The first relates to an engineering, manufacturing and quality assessment of EDAP’s factory, which consists of a routine inspection by the FDA. This has now been confirmed and scheduled to take place June 23 to June 26, 2014. In parallel there is a clinical data validation process, which includes an FDA audit of the investigation sites. The Company has received confirmation and scheduling of the “foreign” site’s audit which will be conducted in the course of July 2014.

2. Press Release dated May 22, 2014

EDAP's Ablatherm-HIFU FDA Panel Meeting Confirmed for July 30, 2014

The U.S. Food and Drug Administration (FDA) Gastroenterology and Urology Devices Panel of the Medical Devices Advisory Committee will review the Pre-Market Approval (“PMA”) application for EDAP's Ablatherm-HIFU device for the treatment of localized prostate cancer on July 30, 2014.

3. Press Release dated May 15, 2014

EDAP Reports First Quarter 2014 Results

- Record revenue of EUR 7.8 million for the first quarter 2014, a 31% year-over-year increase
 - First quarter 2014 gross margin up nine points to 46%
 - Second sequential quarter with positive operating income
 - Ablatherm HIFU PMA moves to panel preparation phase with FDA
 - Reimbursement of HIFU for prostate cancer granted in France
- HIFU officially recommended for prostate cancer by European Association of Urology

First Quarter 2014 Results

- Total revenue for the first quarter 2014 was EUR 7.8 million (USD 10.6 million), a 31% year-over-year increase compared to EUR 5.9 million (USD 7.8 million) for the first quarter 2013.
 - Total revenue for the HIFU division was EUR 3.3 million (USD 4.5 million) for the first quarter 2014, compared to EUR 1.4 million (USD 1.8 million) for the same period last year. Results for the first quarter 2014 included the sale of three Ablatherm and two Focal One devices.
- For the three months ended March 31, 2014, total revenue for the lithotripsy division was EUR 4.5 million (USD 6.1 million), in line with EUR 4.5 million (USD 6.0 million), during the year ago period. During the first quarter 2014, the Company recorded sales of nine lithotripsy machines, comprised of seven Sonolith i-move devices, one Sonolith i-sys device, and one Sonolith Praktis, compared to a total of ten devices sold in the first quarter of 2013.
- Gross profit for the first quarter 2014 was EUR 3.6 million (USD 4.9 million), compared to EUR 2.2 million (USD 2.9 million) for the year ago period. Gross profit margin was 45.9% in the first quarter 2014, compared to 37.1% in the year ago period. The change in the gross profit margin was mostly attributable to the increase in HIFU equipment sales.
- Operating expenses were EUR 3.0 million (USD 4.1 million) for the first quarter 2014, compared to EUR 3.4 million (USD 4.5 million) for the same period of 2013. As a result of our increased device sales during the quarter, operating profit was EUR 558,000 (USD 765,000) for the first quarter of 2014, compared to an operating loss of EUR 1.2 million (USD 1.6 million) in the first quarter of 2013. Most noticeably, this is the first time the Company reported two sequential quarters with positive operating income.
- Net income for the first quarter of 2014 was EUR 840,000 (USD 1.2 million), or EUR 0.04 per diluted share, as compared to net loss for the first quarter of 2013 of EUR 3.9 million (USD 5.1 million), or EUR 0.21 per diluted share.
- At March 31, 2014, cash and cash equivalents, including short-term treasury investments, were EUR 6.4 million (USD 8.9 million). The EUR 1.2 million cash utilization in the first quarter was attributed to increased receivables related to increased sales in the first quarter to be collected over the second and third quarters.

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

| | Three Months Ended: | | Three Months Ended: | |
|---|----------------------------|----------------------------|---------------------------|---------------------------|
| | March 31, 2014 Euros | March 31, 2013 Euros | March 31, 2014 \$US | March 31, 2013 \$US |
| Sales of goods | 5,414 | 3,693 | 7,415 | 4,860 |
| Net Sales of RPP and Leases | 998 | 933 | 1,367 | 1,228 |
| Sales of spare parts and Services | 1,349 | 1,301 | 1,848 | 1,712 |
| TOTAL NET SALES | 7,762 | 5,927 | 10,630 | 7,800 |
| Other revenues | 3 | (0) | 4 | (0) |
| TOTAL REVENUES | 7,765 | 5,927 | 10,634 | 7,800 |
| Cost of goods | (2,815) | (2,243) | (3,855) | (2,951) |
| Cost of RPP and Leases | (505) | (523) | (692) | (688) |
| Cost of spare parts & services | (881) | (964) | (1,206) | (1,268) |
| Cost of sales | (4,201) | (3,729) | (5,753) | (4,908) |
| GROSS PROFIT | 3,564 | 2,198 | 4,881 | 2,892 |
| Research & development expenses | (686) | (932) | (939) | (1,227) |
| Marketing & Sales expenses | (1,441) | (1,534) | (1,973) | (2,019) |
| G & A expenses | (879) | (922) | (1,204) | (1,213) |
| Total operating expenses | (3,006) | (3,389) | (4,116) | (4,459) |
| OPERATING PROFIT (LOSS) | 558 | (1,191) | 765 | (1,567) |
| Interest (expense) income, net | 259 | (2,429) | 355 | (3,197) |
| Currency exchange gains (loss), net | 55 | (212) | 76 | (279) |
| Other income (loss), net | (3) | (2) | (4) | (2) |
| INCOME (LOSS) BEFORE TAXES AND MINORITY INTEREST | 870 | (3,833) | 1,192 | (5,045) |
| Income tax (expense) credit | (30) | (50) | (41) | (65) |
| NET INCOME (LOSS) | 840 | (3,883) | 1,151 | (5,110) |

Edgar Filing: EDAP TMS SA - Form FWP

| | | | | |
|---|------------|------------|------------|------------|
| Earning per share – Basic | 0.04 | (0.21) | 0.05 | (0.27) |
| Average number of shares used in computation of EPS | 21,789,670 | 18,716,013 | 21,789,670 | 18,716,013 |
| Earning per share – Diluted | 0.04 | (0.21) | 0.05 | (0.27) |
| Average number of shares used in computation of EPS for positive net income | 23,951,832 | 21,155,488 | 23,951,832 | 21,155,488 |

NOTE: Translated for convenience of the reader to U.S. dollars at the 2014 average three months noon buying rate of 1 Euro = 1.3695 USD, and 2013 average three months noon buying rate of 1 Euro = 1.3160 USD.

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

| | Mar. 31, 2014 Euros | Dec. 31, 2013 Euros | Mar. 31, 2014 \$US | Dec. 31, 2013 \$US |
|---|---------------------------|---------------------------|--------------------------|--------------------------|
| Cash, cash equivalents and short term investments | 6,443 | 7,681 | 8,877 | 10,584 |
| Total current assets | 22,951 | 22,171 | 31,622 | 30,551 |
| Total current liabilities | 12,117 | 11,589 | 16,695 | 15,969 |
| Shareholders' Equity | 10,160 | 9,284 | 13,999 | 12,794 |

NOTE: Translated for convenience of the reader to U.S. dollars at the noon buying rate of 1 Euro = 1.3778 USD, on March 31, 2014 and at the noon buying rate of 1 Euro = 1.3780 USD, on December 31, 2013.

EDAP TMS S.A.
 CONDENSED STATEMENTS OF OPERATIONS BY DIVISION
 THREE MONTHS ENDED MARCH 31, 2014
 (Amounts in thousands of Euros)

| | HIFU Division | | UDS Division | | FDA Trials | Corporate | Total After Consolidation | |
|------------------------------------|------------------|-------------|-----------------|-------------|---------------|--------------|---------------------------------|-------------|
| Sales of goods | 2,491 | | 2,923 | | | | 5,414 | |
| Sales of RPPs & Leases | 550 | | 448 | | | | 998 | |
| Sales of spare parts & services | 245 | | 1,104 | | | | 1,349 | |
| TOTAL NET SALES | 3,287 | | 4,475 | | | | 7,762 | |
| Other revenues | 3 | | -- | | | | 3 | |
| TOTAL REVENUES | 3,290 | | 4,475 | | | | 7,765 | |
| GROSS PROFIT | 1,948 | 59 % | 1,617 | 36 % | | | 3,564 | 46 % |
| Research & Development | (307) | | (222) | | (157) | | (686) | |
| Total SG&A plus depreciation | (582) | | (1,392) | | | (346) | (2,320) | |
| OPERATING PROFIT (LOSS) | 1,058 | | 3 | | (157) | (346) | 558 | |

4. Press Release dated April 21, 2014

EDAP Announces Reimbursement of HIFU Treatment for Prostate Cancer by France's Ministry of Health

EDAP TMS SA announced the reimbursement of prostate cancer treatment procedures using High Intensity Focused Ultrasound (“HIFU”) by the French health authorities. The French Minister of Social Affairs and Health outlined the acceptance of HIFU treatment for prostate cancer for reimbursement during a visit to the Company's headquarters on April 18, 2014. Such reimbursement is part of an innovative process to further validate breakthrough therapies and to accelerate reimbursement process based on clinical trials and data registries.

Forward-Looking Statements

In addition to historical information, press releases 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 uncertainties of the U.S. FDA approval process, the clinical status and market acceptance of our HIFU devices and the continued market potential for our lithotripsy device. 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. Ablatherm-HIFU treatment is in clinical trials, but not FDA-approved or marketed in the United States.

Additional Information

EDAP has filed a registration statement (including a prospectus) with the SEC for the offering to which this communication relates. Before you invest, you should read the prospectus in that registration statement and other documents EDAP has filed with the SEC for more complete information about it and this offering. You may get these documents for free by visiting EDGAR on the SEC Web site at www.sec.gov. Alternatively, EDAP will arrange to send you the prospectus after filing if you request it by calling +1-212-356-0500.