

EDAP TMS SA

Form 20-F

April 26, 2012

As filed with the Securities and Exchange Commission on April 26, 2012

UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 20-F

ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF
THE SECURITIES EXCHANGE ACT OF 1934

REGISTRATION STATEMENT PURSUANT TO SECTION 12(B) OR (G) OF THE SECURITIES
EXCHANGE ACT OF 1934,

OR

ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(D) OF THE SECURITIES EXCHANGE ACT OF
1934

for the Fiscal Year Ended December 31, 2011

OR

TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(D) OF THE SECURITIES EXCHANGE ACT
OF 1934

OR

SHELL COMPANY REPORT PURSUANT TO SECTION 13 OR 15(D) OF THE SECURITIES EXCHANGE
ACT OF 1934

000-29374

(Commission file number)

EDAP TMS S.A.

(Exact name of registrant as specified in its charter)

France

(Jurisdiction of incorporation or organization)

Parc d'Activites la Poudrette-Lamartine

4/6, rue du Dauphiné

69120 Vaulx-en-Velin, France

(Address of principal executive offices)

Mrs. Blandine Confort

Tel. +33 4 72 15 31 50, E-mail: bconfort@edap-tms.com

Parc d'Activites la Poudrette-Lamartine, 4/6, rue du Dauphiné, 69120 Vaulx-en-Velin, France

(Name, Telephone, E-mail and Address of Company Contact Person)

Securities registered or to be registered pursuant to Section 12(b) of the Act:

Title of each class	Name of each exchange on which registered
American Depositary Shares, each representing One Ordinary Share	NASDAQ Global Market
Ordinary Shares, nominal value €0.13 per share	NASDAQ Global Market

Securities registered or to be registered pursuant to Section 12(g) of the Act: None

Securities for which there is a reporting obligation pursuant to Section 15(d) of the Act: None

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Outstanding shares of each of the issuer's classes of capital or common stock as of December 31, 2011: 13,345,004 Ordinary Shares

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act.

Yes _____ No X

If this report is an annual or transition report, indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934. Yes _____ No X

Indicate by check mark whether the registrant: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports) and (2) has been subject to such filing requirements for the past 90 days. Yes X
No _____

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Website, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes _____ No X

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, or a non-accelerated filer. See definition of "accelerated filer and large accelerated filer" in Rule 12b-2 of the Exchange Act. (Check one):
Large accelerated filer _____ Accelerated filer _____ Non-accelerated filer X

Indicate by check mark which basis of accounting the registrant has used to prepare the financial statements included in this filing:

U.S. GAAP X International Financial Reporting Standards as issued by the International Accounting Standards Board _____ Other _____

If "Other" has been checked in response to the previous question indicate by check mark which financial statement item the registrant has elected to follow. Item 17 _____ Item 18 _____

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PRESENTATION OF FINANCIAL AND OTHER INFORMATION

Unless the context otherwise requires, references herein to “we,” “us” or “our” are to EDAP TMS S.A. and its consolidated subsidiaries and references herein to the “Company,” “EDAP” or “EDAP TMS” are to EDAP TMS S.A.

We prepare our consolidated financial statements in conformity with United States generally accepted accounting principles (“U.S. GAAP”). In this annual report, references to “euro” or “€” are to the legal currency of the countries of European Monetary Union, including the Republic of France, and references to “dollars,” “U.S. dollars” or “\$” are to the legal currency of the United States of America. Solely for the convenience of the reader, this annual report contains translations of certain euro amounts into dollars at specified rates. These translations should not be construed as representations that the euro amounts actually represent such dollar amounts or could be converted into dollars at those rates. See Item 3, “Key Information—Exchange Rates” for information regarding certain currency exchange rates and Item 11, “Quantitative and Qualitative Disclosures about Market Risk” for a discussion of the effects of fluctuations in currency exchange rates on the Company.

The following are registered trademarks of the Company in the United States: EDAP TMS® & associated logo, EDAP®, Technomed®, Ablatherm®, Ablasonic®, Ablapak®, Praktis®, Sonolith®, Sonolith i-sys®, Sonolith i-move®, @-REGISTRY®. This annual report also makes references to trade names and trademarks of companies other than the Company.

CAUTIONARY STATEMENT ON FORWARD-LOOKING INFORMATION

This annual report includes certain forward-looking statements within the meaning of Section 27A of the U.S. Securities Act of 1933 (the “Securities Act”) or Section 21E of the U.S. Securities Exchange Act of 1934 (the “Exchange Act”), usually containing words such as “believe,” “plan,” “intend,” “estimate,” “expect” and “anticipate” or similar which reflect our views about future events and financial performance. Actual events or results may differ materially from those projected in such forward-looking statements as a result of various factors that may be beyond our control. These factors include, without limitation:

- the effects of intense competition in the markets in which we operate;
- the uncertainty of market acceptance for our HIFU devices;
- the clinical status of our HIFU devices;
- the uncertainty of reimbursement status of procedures performed with our products;
- the market potential for our Sonolith i-move
- the impact of government regulation, particularly relating to public healthcare systems and the commercial distribution of medical devices;
 - the uncertainty in the U.S. FDA approval process, mostly changes in FDA recommendations and guidance;
 - dependence on our strategic suppliers;
 - any event or other occurrence that would interrupt operations at our primary production facility;
 - reliance on patents, licenses and key proprietary technologies;
 - product liability risk;
- risk of exchange rate fluctuations, particularly between the euro and the U.S. dollar and between the euro and the Japanese yen;
 - fluctuations in results of operations due to the seasonal nature of demand for medical devices;
 - risks associated to the current uncertain worldwide economic and financial environment;
 - risks associated with the March 2012 Warrants, New Debentures and January 2012 Warrants;
 - risks relating to ownership of our securities.

You should also consider the information contained in Item 3, “Key Information—Risk Factors” and Item 5, “Operating and Financial Review and Prospects,” as well as the information contained in our periodic filings with the Securities and

Exchange Commission (the “SEC”) (including our reports on Form 6-K) for further discussion of the risks and uncertainties that may cause such differences to occur. Forward-looking statements speak only as of the date they are made. Other than required by law, we do not undertake any obligation to update them in light of new information or future developments.

PART I

Item 1. Identity of Directors, Senior Management and Advisors

Not applicable.

Item 2. Offer Statistics and Expected Timetable

Not applicable.

Item 3. Key Information

Selected Financial Data

The following table sets forth selected consolidated financial data for the periods indicated. This information is qualified by and should be read in conjunction with the consolidated financial statements and the Notes thereto included in Part III of this annual report, as well as Item 5, "Operating and Financial Review and Prospects." The selected balance sheet data as of December 31, 2009, 2010 and 2011 and the selected income statement data for the years ended December 31, 2009, 2010 and 2011 set forth below have been derived from our consolidated financial statements included in this annual report. These financial statements, together with our consolidated financial statements have been prepared in accordance with U.S. GAAP. To date, we have not been required, and presently are not required under French law, to prepare consolidated financial statements under French GAAP or IFRS, nor have we done so.

In thousands of euro, except per share data in euro	Year Ended and at December 31,				
	2007	2008	2009	2010	2011
INCOME STATEMENT DATA					
Total revenues	22,327	23,053	24,885	23,708	22,292
Total net sales	22,213	22,856	24,839	23,202	22,272
Gross profit	9,179	9,099	10,672	9,455	8,857
Operating expenses	(13,158)	(13,258)	(13,874)	(13,272)	11,353
Loss from operations	(3,979)	(4,159)	(3,202)	(3,818)	(2,497)
Income (loss) before income taxes	(5,461)	1,648	(7,694)	(11,778)	(543)
Income tax (expense) benefit	30	(51)	(72)	(939)	(395)
Net income (loss)	(5,430)	1,597	(7,766)	(12,717)	(938)
Basic earnings (loss) per share	(0.59)	0.17	(0.74)	(0.98)	(0.07)
Diluted earnings (loss) per share	(0.59)	0.17	(0.74)	(0.98)	(0.07)
	—	—	—	—	

Dividends per
share(1)

Basic weighted average shares outstanding	9,200,757	9,582,593	10,510,305	13,008,401	13,345,004
Diluted weighted average shares outstanding	9,200,757	9,658,295	10,567,563	13,094,235	13,353,985

BALANCE SHEET DATA

Total current
assets

36,124	35,786	&#
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