

EDAP TMS SA  
Form 6-K  
September 27, 2016

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

EDAP TMS S.A. Files on

September 27, 2016

EDAP TMS S.A.

Parc d'activités la Poudrette - Lamartine

4/6 Rue du Dauphine

69120 Vaulx-en-Velin - France

Commission File Number: 0-29374

Edgar Filing: EDAP TMS SA - Form 6-K

Indicate by check mark whether the registrant files or will file annual reports under cover 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): .....

THIS REPORT ON FORM 6-K SHALL BE DEEMED TO BE INCORPORATED BY REFERENCE IN THE REGISTRATION STATEMENTS ON FORM F-3 (NOS. 333-195435 and 333-136811) OF EDAP TMS S.A. AND TO BE PART THEREOF FROM THE DATE ON WHICH THIS REPORT IS FURNISHED, TO THE EXTENT NOT SUPERSEDED BY DOCUMENTS OR REPORTS SUBSEQUENTLY FILED OR FURNISHED.

**Explanatory Note**

**Operating and Financial Review and Prospects and Unaudited Consolidated Interim Financial Statements for the six months ended and as of June 30, 2016**

The following discussion of our results of operations and liquidity and capital resources for the six months ended June 30, 2016 is based on, and should be read in conjunction with, the unaudited consolidated interim financial statements and the notes thereto included in this report on Form 6-K. The unaudited consolidated interim financial statements have been prepared in accordance with U.S. GAAP and refer to the new topic-based FASB Accounting Standards Codification (“ASC”).

The financial data included in this report has been prepared by, and is the responsibility of, EDAP TMS’s management. PricewaterhouseCoopers Audit has not audited, reviewed, compiled or performed any procedures with respect to the accompanying financial data. Accordingly, PricewaterhouseCoopers Audit does not express an opinion or any other form of assurance with respect thereto.

The unaudited consolidated interim financial statements filed in this report on Form 6-K supplements the unaudited financial information furnished on Form 6-K on August 25, 2016.

**Operating and Financial Review and Prospects for the six months ended and as of June 30, 2016**

Operating Results

Six Months Ended June 30, 2016 Compared to Six Months Ended June 30, 2015

(in millions of euros)	Six months ended June 30, 2016	<b>Six months ended June 30, 2015</b>
Total revenues	16.9	14.1
Total net sales	16.9	14.1

Edgar Filing: EDAP TMS SA - Form 6-K

Of which HIFU	6.7		3.9	
Of which UDS	10.2		10.1	
Total cost of sales	(9.2	)	(8.1	)
Gross profit	7.8		5.9	
Gross profit as a percentage of total net sales	45.8	%	42.1	%
Total operating expenses	(7.4	)	(6.8	)
Income (loss) from operations	0.4		(0.8	)
Net income (loss)	3.9		(2.0	)

Total revenues.

Our total revenues increased 20.4% from €14.1 million in the first half of 2015 to €16.9 million in the first half of 2016.

*UDS division.* The UDS division's total revenues increased 1.4% from €10.1 million in the first half of 2015 to €10.2 million in the first half of 2016, principally due to the revenue contribution from our product distribution activity.

The UDS division's net sales of medical devices decreased 0.8% from €5.6 million in the first half of 2015 to €5.5 million in the first half of 2016 with 16 lithotripsy devices sold in the first half of 2016 compared to 18 lithotripsy devices sold in the first half of 2015.

Net sales of UDS-related consumables, spare parts, supplies, leasing and services increased 4.0% from €4.5 million in the first half of 2015 to €4.7 million in the first half of 2016.

*HIFU division.* The HIFU division's total revenues increased 69.1% to €6.7 million in the first half of 2016 as compared to €4.0 million in the first half of 2015. This growth is based on the growth of both sales of equipment and treatment driven revenues.

The HIFU division's net sales of medical devices increased 114.8% to €3.7 million in the first half of 2016, as compared to €1.7 million in the first half of 2015. We sold six Ablatherm units and two Focal One units in the first half of 2016, as compared with three Focal One units in the first half of 2015.

Net sales of HIFU-related consumables, spare parts, supplies, leasing and services increased 33.2% to €2.9 million in the first half of 2016 as compared to €2.2 million in the first half of 2015.

Cost of sales.

Cost of sales increased 12.6% from €8.1 million in the first half of 2015 to €9.2 million in the first half of 2016, and represented 54.2% of net sales in the first half of 2016, down from 57.9% of net sales in the first half of 2015.

Operating expenses.

Operating expenses increased 9.1%, or €615 thousand, from €6.8 million in the first half of 2015 to €7.4 million in the first half of 2016, reflecting the sales and marketing efforts on expanding our HIFU business in the U.S.

Research and Development expenses, excluding expenses related to the FDA PMA trials, increased €501 thousand, or 41.8% and expenses related to the FDA PMA trials decreased €312 thousand, or 100.0% following the FDA clearance for Ablatherm end of 2015.

Marketing and Sales expenses increased €658 thousand, or 19.3%.

General and Administrative expenses decreased €232 thousand, or 12.7%.

Operating income (loss).

As a result of the factors discussed above, we recorded a consolidated operating income of €0.4 million in the first half of 2016 as compared to a consolidated operating loss of €0.8 million in the first half of 2015.

We realized an operating profit in the UDS division of €0.02 million in the first half of 2016, as compared to an operating profit of €0.3 million in the first half of 2015, and an operating profit in the HIFU division of €1.1 million in the first half of 2016, as compared to an operating loss of €0.1 million in the first half of 2015.

*Financial (expense) income, net.*

Financial (expense) income net was an income of €2.9 million in the first half of 2016, which was mostly comprised of a €2.9 million expense generated by the fair value adjustments of the outstanding warrants, compared with an expense of €1.3 million in the first half of 2015, reflecting the €1.3 million expense due to the adjustment of the warrants to fair value.

*Foreign currency exchange gains (loss), net.*

In the first half of 2016, we recorded a net foreign currency exchange gain of €0.7 million, compared to a gain of €0.3 million in the first half of 2015.

*Income taxes.*

Income tax was an expense of €91 thousand in the first half of 2016, compared to an expense of €69 thousand in the first half of 2015.

Net income (loss).

As a result of the above, we realized a consolidated net income of €3.9 million in the first half of 2016 compared with a consolidated net loss of €2.0 million in the first half of 2015.



**Liquidity and Capital Resources**

(in thousands of euros)	Six months ended June 30, 2016	Six months ended June 30, 2015
Net cash generated by (used in) operating activities	1,454	(836 )
Net cash used in investing activities	(934 )	(306 )
Net cash generated by (used in) financing activities	7,393	875
Net effect of exchange rate changes	(552 )	(25 )
Net increase/(decrease) in cash and cash equivalents	7,362	(292 )
Cash and cash equivalents at the beginning of the period	13,578	11,142
Cash and cash equivalents at the end of the period	20,940	10,851
Total cash and cash equivalents, and short-term investments as of June 30	21,940	11,851

Our cash position as of June 30, 2016 was €21.9 million (including €1.0 million of short-term treasury investments), compared to €11.9 million (including €1.0 million of short-term treasury investments), as of June 30, 2015. We experienced positive cash flows of €7.4 million in the first half of 2016 and negative cash flows of €0.3 million in the first half of 2015.

In 2016, net cash generated by operating activities was €1.5 million compared with net cash used in operating activities of €0.8 million in the first half of 2015.

In the first half of 2016, net cash used in operating activities reflected principally:

- a net income of €3.9 million;  
the elimination of €2.1 million of net income without an effect on cash, including €0.5 million of depreciation and amortization, €0.1 million loss for change in long-term provisions and non-cash compensation, €0.2 million of net capital loss on disposals of assets and €2.9 million income due to variation of the fair value of outstanding warrants;
- a decrease in trade accounts and other receivables of €2.2 million;
- an increase in inventories of €1.7 million;
- an increase in other assets of €0.2 million;
- an increase in payables of €0.2 million;
- a decrease in other current liabilities of €0.7 million.



In the first half of 2015, net cash used in operating activities reflected principally:

- a net loss of €2.0 million;
  - the elimination of €1.9 million of net expenses without an effect on cash, including €0.4 million of depreciation and amortization, €0.1 million of change in long-term provisions and non-cash compensation and €1.3 million due to variation of the fair value of outstanding warrants;
- an increase in trade accounts and other receivables of €0.8 million;
- an increase in inventories of €0.1 million;
- a decrease in payables of €0.6 million;
- an increase in other current liabilities of €0.8 million.

In the first half of 2016, net cash used in investing activities was €0.9 million compared with net cash used of €0.3 million in investing activities in the first half of 2015.

Net cash used in investing activities of €0.9 million in the first half of 2016 reflected mainly acquisitions of equipment of €0.2 million and investments of €0.7 million in capitalized assets produced by the Company, mostly for commercial demonstrations, training and RPP activity.

Net cash used in investing activities of €0.3 million in the first half of 2015 reflected mainly acquisitions of equipment of €0.2 million and investments of €0.1 million in capitalized assets produced by the Company.

In the first half of 2016, net cash provided in financing activities was €7.4 million compared with net cash used by financing activities of €0.9 million in the first half of 2015.

In the first half of 2016, net cash generated in financing activities reflected principally the €9.2 million net proceeds from the April 2016 Placement and the €0.1 million net proceeds from exercise of warrants, repayment of capital lease obligations totaling €0.1 million and of long term borrowings totaling €0.1 million, the reimbursement of €1.0 million of short term borrowing and the decrease of €0.7 million in bank overdrafts.

In the first half of 2015, these activities reflected principally the €0.2 million net proceeds from the exercise of warrants, repayment of capital lease obligations totaling €0.1 million and of long term borrowings totaling €0.1 million, and an increase of €0.9 million in bank overdrafts.

**Interim Unaudited Financial Statements for the six months ended and as of June 30, 2016**

Index

<u>Consolidated Balance Sheets (Unaudited) as of June 30, 2016 and December 31, 2015</u>	<u>7</u>
<u>Consolidated Statement of Income (Unaudited) for the periods ended June 30, 2016 and 2015</u>	<u>8</u>
<u>Consolidated Statement of Shareholders' Equity (Unaudited) for the period ended June 30, 2016</u>	<u>9</u>
<u>Consolidated Statements of Cash Flows (Unaudited) for the periods ended June 30, 2016 and 2015</u>	<u>10</u>
<u>Notes to Consolidated Interim Financial Statements</u>	<u>11</u>

**EDAP TMS S.A. AND SUBSIDIARIES****CONSOLIDATED BALANCE SHEETS****As of June 30, 2016 (unaudited) and December 31, 2015****(in thousands of euros unless otherwise noted)**

ASSETS	Notes	06-30-2016	12-31-2015
Current assets			
Cash and cash equivalents	2	20,940	13,578
Current portion of net trade accounts and notes receivable		9,292	10,744
Other receivables		1,281	1,018
Inventories	3	7,932	6,151
Deferred tax assets		43	47
Other assets, current portion		475	500
Short-term investment		1,000	1,000
Total current assets		40,963	33,039
Property and equipment, net		2,445	2,123
Intangible assets, net		59	39
Goodwill		2,412	2,412
Deposits and other non-current assets		451	376
Net trade accounts and notes receivable, non-current		365	593
Total assets		46,694	38,581
LIABILITIES AND SHAREHOLDERS' EQUITY			
Current liabilities			
Trade accounts and notes payable		6,317	6,098
Deferred revenues, current portion		2,363	1,597
Social security and other payroll withholdings taxes		987	1,211
Employee absences compensation		600	539
Income taxes payable		24	624
Other accrued liabilities		2,165	2,768
Short-term borrowings	4	1,096	2,814
Current portion of capital lease obligations	5	210	238
Current portion of financial instruments carried at fair value	6	835	172
Current portion of long-term debt	6	220	209
Total current liabilities		14,817	16,271
Deferred revenues, non-current		710	504
Capital lease obligations, non-current	5	227	294
Financial instruments carried at fair value, non-current	6	3,774	4,205
Long-term debt, non-current	6	492	592
Other long-term liabilities		2,317	2,285
Total liabilities		22,336	24,151
Shareholders' equity			

Edgar Filing: EDAP TMS SA - Form 6-K

Common stock, €0.13 par value; 29,098,144 shares issued and 28,727,616 shares outstanding; 25,753,989 shares issued and 25,383,461 shares outstanding; at June 30, 2016 and at December 31, 2015, respectively		3,783	3,348
Additional paid-in capital		64,421	58,560
Retained earnings		(38,910 )	(42,769 )
Cumulative other comprehensive loss		(3,794 )	(3,567 )
Treasury stock, at cost; 370,528 shares at June 30, 2016 & at Dec. 31, 2015	7	(1,142 )	(1,142 )
Total shareholders' equity	7	24,358	14,430
Total liabilities and shareholders' equity		46,694	38,581

7

## EDAP TMS S.A. AND SUBSIDIARIES

## CONSOLIDATED STATEMENTS OF INCOME (UNAUDITED)

For the periods ended June 30, 2016 and 2015

(in thousands of euros unless otherwise noted)

	Notes	6 months ended June 30, 2016	6 months ended June 30, 2015
Sales of goods		11,261	9,103
Sales of RPPs & leases		2,578	2,119
Sales of spare parts and services		3,078	2,830
Total sales		16,917	14,052
Other revenues		8	2
Total revenues		16,925	14,054
Cost of goods		(5,561)	(5,042)
Cost of RPPs & leases		(1,513)	(1,292)
Cost of spare parts and services		(2,097)	(1,809)
Total cost of sales		(9,171)	(8,143)
Gross profit		7,753	5,911
Research and development expenses		(1,701)	(1,512)
Selling and marketing expenses		(4,066)	(3,408)
General and administrative expenses		(1,598)	(1,830)
Income (loss) from operations		388	(839)
Financial (expense) income, net		2,891	(1,344)
Foreign currency exchange gain (loss), net		671	303
Other income (expense), net		-	(3)
Income (loss) before taxes		3,950	(1,884)
Income tax (expense) benefit		(91)	(69)
Net income (loss)		3,859	(1,953)
Basic net earnings (loss) per share		0.14	(0.08)
Shares outstanding		26,844,696	24,926,627
Diluted net earnings (loss) per share <sup>(1)</sup>		0.13	(0.08)
Diluted shares outstanding <sup>(1)</sup>		28,615,172	24,926,627

<sup>(1)</sup> Due to the net losses in the first six months of 2015, the assumed net exercise of stock options/warrants and stock relating to the convertible bonds in this year was excluded, as the effect would have been anti-dilutive.



**EDAP TMS S.A. AND SUBSIDIARIES****CONSOLIDATED STATEMENTS OF SHAREHOLDERS' EQUITY****For the period ended June 30, 2016 (unaudited)****(in thousands of euros unless otherwise noted)**

	Number of Shares outstanding	Common Stock	Additional paid-in Capital	Retained Earnings	Cumulative Other Comprehensive Income (loss)	Treasury Stock	Total
Balance as of December 31, 2015	25,383,461	3,348	58,560	(42,769)	(3,567 )	(1,142 )	14,430
Net income				3,859			3,859
Translation adjustment					(227 )		(227 )
Warrants and stock options granted			100				100
Capital increase	3,344,155	435	5,762				6,197
Balance as of June 30, 2016	28,727,616	3,783	64,421	(38,910)	(3,794 )	(1,142 )	24,358



**EDAP TMS S.A. AND SUBSIDIARIES****CONSOLIDATED STATEMENTS OF CASH FLOWS (UNAUDITED)****For the periods ended June 30, 2016 and June 30, 2015****(in thousands of euros unless otherwise noted).**

	6 months ended June 30, 2016	6 months ended June 30, 2015
Cash flows from operating activities:		
Net income (loss)	3,859	(1,953 )
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	481	356
Change in warrants fair value	(2,907 )	1,319
Other Non-cash compensation	100	27
Change in allowances for doubtful accounts & slow-moving inventories	(7 )	105
Change in long-term provisions	(51 )	12
Net capital loss on disposals of assets	213	39
Deferred tax expense/(benefit)	49	22
Operating cash flow	1,737	(71 )
Increase/Decrease in operating assets and liabilities:		
Decrease/(Increase) in trade accounts and notes and other receivables	2,187	(818 )
Decrease/(Increase) in inventories	(1,728 )	(134 )
Decrease/(Increase) in other assets	(240 )	8
(Decrease)/Increase in trade accounts and notes payable	173	(587 )
(Decrease)/Increase in accrued expenses, other current liabilities	(674 )	766
Net increase/decrease in operating assets and liabilities	(282 )	(764 )
Net cash generated by (used in) operating activities	1,454	(836 )
Cash flows from investing activities:		
Additions to capitalized assets produced by the Company	(669 )	(101 )
Net proceeds from sale of leased back assets		
Acquisitions of property and equipment	(209 )	(207 )
Acquisitions of intangible assets	(24 )	(1 )
Acquisitions of short term investments		
Net proceeds from sale of assets		
Decrease/(Increase) in deposits and guarantees	(32 )	4
Net cash used in investing activities	(934 )	(306 )
Cash flow from financing activities:		
Proceeds from capital increase	6,197	208
Proceeds from long term borrowings, net of financing costs	3,168	
Repayment of long term borrowings	(113 )	(69 )

Edgar Filing: EDAP TMS SA - Form 6-K

Repayment of obligations under capital leases	(140 )	(120 )
Increase/(decrease) in bank overdrafts and short-term borrowings	(1,718 )	856
Net cash generated by (used in) financing activities	7,393	875
Net effect of exchange rate changes on cash and cash equivalents	(552 )	(25 )
Net increase (decrease) in cash and cash equivalents	7,362	(292 )
Cash and cash equivalents at beginning of year	13,578	11,142
Cash and cash equivalents at end of period	20,940	10,851

## **EDAP TMS S.A. AND SUBSIDIARIES**

### **NOTES TO CONSOLIDATED INTERIM UNAUDITED FINANCIAL STATEMENTS**

**(in thousands of euros unless otherwise noted, except per share data)**

#### **1—SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES**

##### *1-1 Nature of operations*

EDAP TMS S.A. and its subsidiaries (“the Company”) are engaged in the development, production, marketing, distribution and maintenance of a portfolio of minimally-invasive medical devices for the treatment of urological diseases. Moreover, the Company develops a novel HIFU treatment for liver cancer in cooperation with its long-term academic partner INSERM and leading cancer centers (the “HECAM” project). The Company currently produces devices for treating stones of the urinary tract and localized prostate cancer. Net sales consist primarily of direct sales to hospitals and clinics in France and Europe, export sales to third-party distributors and agents, and export sales through subsidiaries based in Germany, Italy, the United States and Asia.

The Company purchases the majority of the components used in its products from a number of suppliers but for some components, relies on a single source. Delay would be caused if the supply of these components or other components was interrupted and these delays could be extended in certain situations where a component substitution may require regulatory approval. Failure to obtain adequate supplies of these components in a timely manner could have a material adverse effect on the Company’s business, financial position and results of operation.

##### *1-2 Management estimates*

The preparation of financial statements in conformity with U.S. generally accepted accounting principles (“U.S. GAAP”) requires management to make estimates and assumptions, such as business plans, stock price volatility, duration of standard warranty per market and cost of maintenance contract used to determine the amount of revenue to differ. These estimates and assumptions affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. Actual results could differ from those estimates.

##### *1-3 Consolidation*

The accompanying consolidated financial statements include the accounts of EDAP TMS S.A. and all its domestic and foreign owned subsidiaries, which include EDAP TMS France SAS, EDAP Technomed Inc. (USA), Edap Technomed Sdn Bhd (Malaysia), Edap Technomed Italia S.R.L, EDAP Technomed Co. Ltd. (Japan) and EDAP TMS Gmbh (Germany). Edap Technomed Sdn Bhd was incorporated in early 1997. Edap Technomed Co. Ltd. was created in late 1996. EDAP TMS Gmbh was created in July 2006. EDAP SA, a subsidiary incorporating HIFU activities merged all of its activity into EDAP TMS France SAS in 2008. All intercompany transactions and balances are eliminated in consolidation.

#### ***1-4 Revenue recognition***

##### Sales of goods:

For medical device sales with no significant remaining vendor obligation, payments contingent upon customer financing, acceptance criteria that can be subjectively interpreted by the customer, or tied to the use of the device, revenue is recognized when evidence of an arrangement exists, title to the device passes (depending on terms, either upon shipment or delivery), and the customer has the intent and ability to pay in accordance with contract payment terms that are fixed or determinable. For sales in which payment is contingent upon customer financing, acceptance criteria can be subjectively interpreted by the customer, or payment depends on use of the device, revenue is recognized when the contingency is resolved. The Company provides training and provides a minimum of one-year warranty upon installation. The Company accrues for the estimated training and warranty costs at the time of sale. Revenues related to disposables are recognized when goods are delivered.

**EDAP TMS S.A. AND SUBSIDIARIES**

NOTES TO CONSOLIDATED INTERIM UNAUDITED FINANCIAL STATEMENTS

**(in thousands of euros unless otherwise noted, except per share data)**

Sales of RPPs and leases:

Revenues related to the sale of HIFU treatments invoiced on a “Revenue-Per-Procedure” (“RPP”) basis are recognized when the treatment procedure has been completed. Revenues from devices leased to customers under operating leases are recognized on a straight-line basis.

Sales of spare parts and services:

Revenues related to spare parts are recognized when goods are delivered. Maintenance contracts rarely exceed one year and are recognized on a straight line basis. Billings or cash receipts in advance of services due under maintenance contracts are recorded as deferred revenue.

***1-5 Shipping and handling costs***

The Company recognizes revenue from the shipping and handling of its products as a component of revenue. Shipping and handling costs are recorded as a component of cost of sales.

***1-6 Cash equivalents and short term investments***

Cash equivalents are cash investments which are highly liquid and have initial maturities of 90 days or less.

Cash investments with a maturity higher than 90 days are considered as short-term investments.

***1-7 Accounts Receivables***

Accounts receivables are stated at cost net of allowances for doubtful accounts. The Company makes judgments as to its ability to collect outstanding receivables and provides allowances for the portion of receivables when collection becomes doubtful. Provision is made based upon a specific review of all significant outstanding invoices. These estimates are based on our bad debt write-off experience, analysis of credit information, specific identification of probable bad debt based on our collection efforts, aging of accounts receivables and other known factors. Accounts receivables also include receivables factored for which the Company is supporting the collection risk.

***1-8 Inventories***

Inventories are valued at the lower of manufacturing cost, which is principally comprised of components and labor costs, or market (net realizable value). Cost is determined on a first-in, first-out basis for components and spare parts and by specific identification for finished goods (medical devices). The Company establishes reserves for inventory estimated to be obsolete, unmarketable or slow moving, first based on a detailed comparison between quantity in inventory and historical consumption and then based on case-by-case analysis of the difference between the cost of inventory and the related estimated market value.

***1-9 Property and equipment***

Property and equipment is stated at historical cost. Depreciation and amortization of property and equipment are calculated using the straight-line method over the estimated useful life of the related assets, as follows:

Leasehold improvements	10 years or lease term if shorter
Equipment	3-10 years
Furniture, fixtures, fittings and other	2-10 years

Equipment includes industrial equipment and research equipment that has alternative future uses. Equipment also includes devices that are manufactured by the Company and leased to customers through operating leases related to Revenue-Per-Procedure transactions and devices subject to sale and leaseback transactions. This equipment is depreciated over a period of seven years.

## **EDAP TMS S.A. AND SUBSIDIARIES**

### **NOTES TO CONSOLIDATED INTERIM UNAUDITED FINANCIAL STATEMENTS**

**(in thousands of euros unless otherwise noted, except per share data)**

#### ***1-10 Long-lived assets***

The Company reviews the carrying value of its long-lived assets, including fixed assets and intangible assets, for impairment whenever events or changes in circumstances indicate that the carrying amount of such assets may not be fully recoverable. Recoverability of long-lived assets is assessed by a comparison of the carrying amount of the assets (or the Group of assets, including the asset in question, that represents the lowest level of separately-identifiable cash flows) to the total estimated undiscounted cash flows expected to be generated by the asset or group of assets. If the future net undiscounted cash flows is less than the carrying amount of the asset or group of assets, the asset or group of assets is considered impaired and an expense is recognized equal to the amount required to reduce the carrying amount of the asset or group of assets to its then fair value. Fair value is determined by discounting the cash flows expected to be generated by the assets, when the quoted market prices are not available for the long-lived assets. Estimated future cash flows are based on assumptions and are subject to risk and uncertainty.

#### ***1-11 Goodwill and intangible assets***

Goodwill represents the excess of purchase price over the fair value of identifiable net assets of businesses acquired. Goodwill is not amortized but instead tested annually for impairment or more frequently when events or change in circumstances indicate that the assets might be impaired by comparing the carrying value to the fair value of the reporting units to which it is assigned. Under ASC 350, "Goodwill and other intangible assets", the impairment test is performed in two steps. The first step compares the fair value of the reporting unit with its carrying amount, including goodwill. If the fair value of the reporting unit is less than its carrying amount, a second step is performed to measure the amount of impairment loss. The second step allocates the fair value of the reporting unit to the Company's tangible and intangible assets and liabilities. This derives an implied fair value for the reporting unit's goodwill. If the carrying amount of the reporting units goodwill exceeds the implied fair value of that goodwill, an impairment loss is recognized equal to that excess. For the purpose of any impairment test, the Company relies upon projections of future undiscounted cash flows and takes into account assumptions regarding the evolution of the market and its ability to successfully develop and commercialize its products.

Changes in market conditions could have a major impact on the valuation of these assets and could result in additional impairment losses.

Intangible assets consist primarily of purchased patents relating to lithotripters, purchased licenses, a purchased trade name and a purchased trademark. The basis for valuation of these assets is their historical acquisition cost. Amortization of intangible assets is calculated by the straight-line method over the shorter of the contractual or estimated useful life of the assets, as follows:

Patents	5 years
Licenses	5 years
Trade name and trademark	7 years

***1-12 Treasury Stocks***

Treasury stock purchases are accounted for at cost. The sale of treasury stocks is accounted for using the first in first out method. Gains on the sale or retirement of treasury stocks are accounted for as additional paid-in capital whereas losses on the sale or retirement of treasury stock are recorded as additional paid-in capital to the extent that previous net gains from sale or retirement of treasury stocks are included therein; otherwise the losses shall be recorded to accumulated benefit (deficit) account. Gains or losses from the sale or retirement of treasury stock do not affect reported results of operations.



## **EDAP TMS S.A. AND SUBSIDIARIES**

### NOTES TO CONSOLIDATED INTERIM UNAUDITED FINANCIAL STATEMENTS

**(in thousands of euros unless otherwise noted, except per share data)**

#### ***1-13 Warranty expenses***

The Company provides customers with a warranty for each product sold and accrues warranty expense at time of sale based upon historical claims experience. Standard warranty period may vary from 1 year to 2 years depending on the market. Actual warranty costs incurred are charged against the accrual when paid and are classified in cost of sales in the statement of income.

#### ***1-14 Income taxes***

The Company accounts for income taxes in accordance with ASC 740, "Accounting for Income Taxes". Under ASC 740, deferred tax assets and liabilities are determined based on differences between the financial reporting and tax basis of assets and liabilities and are measured by applying enacted tax rates and laws to taxable years in which such differences are expected to reverse. A valuation allowance is established if, based on the weight of available evidence, it is more likely than not that some portion, or all of the deferred tax assets, will not be realized. In accordance with ASC 740, no provision has been made for income or withholding taxes on undistributed earnings of foreign subsidiaries, such undistributed earnings being permanently reinvested.

As of January 1, 2007, the Company adopted FIN 48 (now ASC 740) "Accounting for uncertainty in income tax". Under ASC 740, the measurement of a tax position that meets the more-likely-than-not recognition threshold must take into consideration the amounts and probabilities of the outcomes that could be realized upon ultimate settlement using the facts, circumstances and information available at the reporting date.

#### ***1-15 Research and development costs***

Research and development costs are recorded as an expense in the period in which they are incurred. The French government provides tax credits to companies for innovative research and development. This tax credit is calculated based on a percentage of eligible research and development costs and it can be refundable in cash and is not

contingent on future taxable income. As such, the Company considers the research tax credits as a grant, offsetting operating expenses.

### ***1-16 Advertising costs***

Advertising costs are recorded as an expense in the period in which they are incurred.

### ***1-17 Foreign currency translation and transactions***

#### *Translation of the financial statements of consolidated companies*

The reporting currency of EDAP TMS S.A. for all years presented is the euro (€). The functional currency of each subsidiary is its local currency. In accordance with ASC 830, all accounts in the financial statements are translated into euro from the functional currency at exchange rate as follows:

- assets and liabilities are translated at year-end exchange rates;
- shareholders' equity is translated at historical exchange rates (as of the date of contribution);
- statement of income items are translated at average exchange rates for the year; and
- translation gains and losses are recorded in a separate component of shareholders' equity.

#### *Foreign currencies transactions*

Transactions involving foreign currencies are translated into the functional currency using the exchange rate prevailing at the time of the transactions. Receivables and payables denominated in foreign currencies are translated at year-end exchange rates. The resulting unrealized exchange gains and losses are carried to the statement of income.

## **EDAP TMS S.A. AND SUBSIDIARIES**

### **NOTES TO CONSOLIDATED INTERIM UNAUDITED FINANCIAL STATEMENTS**

**(in thousands of euros unless otherwise noted, except per share data)**

#### ***1-18 Earnings per share***

Basic earnings per share is computed by dividing income available to common shareholders by the weighted average number of shares of common stock outstanding for the period. Diluted earnings per share reflects potential dilution that could occur if securities or other contracts to issue common stock were exercised or converted into common stock or resulted in the issuance of common stock that then shared in the earnings of the Company. The dilutive effects of the Company's common stock options and warrants is determined using the treasury stock method to measure the number of shares that are assumed to have been repurchased using the average market price during the period, which is converted from U.S. dollars at the average exchange rate for the period.

#### ***1-19 Derivative instruments***

ASC 815 requires the Company to recognize all of its derivative instruments as either assets or liabilities in the statement of financial position at fair value. The accounting for changes in the fair value (i.e., gains or losses) of a derivative instrument depends on whether it has been designated and qualifies as part of a hedging relationship and further, on the type of hedging relationship. For those derivative instruments that are designated and qualify as hedging instruments, the Company must classify the hedging instrument, based upon the exposure being hedged, as fair value hedge, cash flow hedge or a hedge of a net investment in a foreign operation.

Gains and losses from derivative instruments are recorded in the income statement.

#### ***1-20 Employee stock option plans***

At June 30, 2016, the Company had four stock-based employee compensation plans. The Company adopted ASC 718, "Share-Based Payment", effective January 1, 2006. ASC 718 requires the recognition of fair value of stock compensation as an expense in the calculation of net income (loss).

The Company did not make any stock option grant during the year ended December 31, 2015 but did grant 575,000 stock options to subscribe to new shares to certain employees of the Company in April 2016.

The fair value of each stock option granted during the year is estimated on the date of grant using the Black-Scholes option pricing model with the following assumptions:

	06-30-2016	12-31-2015 <sup>(1)</sup>
Weighted-average expected life (years)	6.25	—
Expected volatility rates	60.6 %	—
Expected dividend yield	—	—
Risk-free interest rate	0.01 %	—
Weighted-average exercise price (€)	3.22	—
Weighted-average fair value of options granted during the year (€)	1.67	—

(1) The Company did not make any grants during the years ended December 31, 2015.

### ***1-21 Warrants***

On March 28, 2012, pursuant to a securities purchase agreement dated March 22, 2012, as amended, the Company issued new ordinary shares in the form of ADSs to selected institutional investors in a registered direct placement (the “March 2012 Placement”) with warrants attached (the “March 2012 Investor Warrants”). The Company also issued warrants to the placement agent, Rodman & Renshaw LLC (the “March 2012 Placement Agent Warrants” and together with the March 2012 Investor Warrants, the “March 2012 Warrants”). The Company has accounted for the March 2012 Warrants as a liability and reflected this analysis in the Company’s financial statements filed for the year 2012.

## **EDAP TMS S.A. AND SUBSIDIARIES**

### NOTES TO CONSOLIDATED INTERIM UNAUDITED FINANCIAL STATEMENTS

**(in thousands of euros unless otherwise noted, except per share data)**

The Company used the Black-Scholes pricing model to value the March 2012 Warrants at inception, with changes in fair value recorded as a financial expense or income.

On May 28, 2013, pursuant to a securities purchase agreement dated May 20, 2013, as amended, the Company issued new ordinary shares in the form of ADSs to selected institutional investors in a registered direct placement (the “May 2013 Placement”) with warrants attached (the “May 2013 Investor Warrants”). The Company also issued warrants to the placement agent, H.C. Wainwright & Co., LLC (the “May 2013 Placement Agent Warrants” and together with the May 2013 Investor Warrants, the “May 2013 Warrants”). As the May 2013 Warrants comprised the same structure and provisions than the March 2012 Warrants, including an exercise price determined in U.S. dollars while the functional currency of the Company is the Euro, the Company determined that the May 2013 Warrants should be accounted for as a liability.

The Company used the Black-Scholes pricing model to value the May 2013 Warrants at inception, with changes in fair value recorded as a financial expense or income.

On April 14, 2016, pursuant to a securities purchase agreement dated April 7, 2016, as amended, the Company issued new ordinary shares in the form of ADSs to selected institutional investors in a registered direct placement (the “April 2016 Placement”) with warrants attached (the “April 2016 Investor Warrants”). As the April 2016 Warrants comprised the same structure and provisions than the March 2012 and May 2013 Warrants, including an exercise price determined in U.S. dollars while the functional currency of the Company is the Euro, the Company determined that the April 2016 Warrants should be accounted for as a liability.

The Company used the Black-Scholes pricing model to value the April 2016 Warrants at inception, with changes in fair value recorded as a financial expense or income.

#### ***1-22 Leases and Sales and leaseback transactions***

In accordance with ASC 840, Accounting for Leases, the Company classifies all leases at the inception date as either a capital lease or an operating lease. A lease is a capital lease if it meets any one of the following criteria; otherwise, it is an operating lease:

- Ownership is transferred to the lessee by the end of the lease term;
  - The lease contains a bargain purchase option;
  - The lease term is at least 75% of the property's estimated remaining economic life;
- The present value of the minimum lease payments at the beginning of the lease term is 90% or more of the fair value of the leased property to the lessor at the inception date.

For sales type leases, the following two additional criteria are applied:

- Collectability of the minimum lease payment is reasonably predictable;
- No important uncertainties surround the amount of un-reimbursable costs yet to be incurred by the lessor under the lease.

The Company enters into sale and leaseback transactions from time to time. In accordance with ASC 840, any profit or loss on the sale is deferred and amortized prospectively over the term of the lease, in proportion to the leased asset if a capital lease, or in proportion to the related gross rental charged to expense over the lease term, if an operating lease.

**EDAP TMS S.A. AND SUBSIDIARIES****NOTES TO CONSOLIDATED INTERIM UNAUDITED FINANCIAL STATEMENTS****(in thousands of euros unless otherwise noted, except per share data)****2—CASH, CASH EQUIVALENTS AND SHORT TERM INVESTMENTS**

Cash and cash equivalents and short terms investments are comprised of the following:

	06-30-2016	12-31-2015
Total cash and cash equivalents	20,940	13,578
Short term investments	1,000	1,000
Total cash and cash equivalent and short term investments	21,940	14,578

Short term investments are comprised of money market funds. The aggregate fair value of the short term investments is consistent with their book value.

**3—INVENTORIES**

Inventories consist of the following:

	06-30-2016	12-31-2015
Components, spare parts	4,345	4,085
Work-in-progress	1,706	676
Finished goods	2,653	2,118
Total gross inventories	8,704	6,879
Less: provision for slow-moving inventory	(773 )	(728 )
Total	7,932	6,151

#### **4—SHORT-TERM BORROWINGS**

As of June 30, 2016, short-term borrowings consist mainly of €1,096 thousand of account receivables factored and for which the Company is supporting the risk of non-collection.

As of June 30, 2015, short-term borrowings consist mainly of €1,980 thousand of account receivables factored and for which the Company is supporting the risk of non-collection and loans in euros amounting to €1,000 thousand with the following conditions:

'000 Euros	Amount	Maturation	Interest rate
EDAP-TMS France SAS	1,000	November 19, 2015	Euribor + 0,7%

#### **5—CAPITAL LEASE OBLIGATIONS**

The Company leases certain of its equipment under capital leases. At June 30, 2016, this equipment consists mainly of medical devices for an amount of €193 thousand and vehicles for an amount of €244 thousand.



**EDAP TMS S.A. AND SUBSIDIARIES**

## NOTES TO CONSOLIDATED INTERIM UNAUDITED FINANCIAL STATEMENTS

(in thousands of euros unless otherwise noted, except per share data)

**6— LONG TERM DEBT, AND FINANCIAL INSTRUMENTS CARRIED AT FAIR VALUE****6-1 Long-term debt:**

	06-30-2016	12-31-2015
Japanese yen term loan	163	183
Germany term loan	398	443
Italy term loan	152	175
Malaysia term loan	-	1
Total long term debt	712	802
Less current portion	(220 )	(209 )
Total long-term portion	492	592

As of June 30, 2016, long-term debt in Japan consists of 2 loans in Yen with the following conditions:

	Initial Amount	Maturation	Interest rate
EDAP Technomed Co. Ltd	55,000,000	June 30, 2018	1.80%
	10,000,000	June 30, 2018	2.10%

As of December 31, 2015, long-term debt in Japan consists of 2 loans in Yen with the following conditions:

	Amount	Maturation	Interest rate
EDAP Technomed Co. Ltd	55,000,000	June 30, 2018	1.80%
	10,000,000	June 30, 2018	0.10%

## Edgar Filing: EDAP TMS SA - Form 6-K

As of June 30, 2016, long-term debt in Germany consists of a loan in euro of an initial amount of €450 thousand with an interest rate at 2.49% due to mature on November 30, 2020. This loan is pledged by an HIFU equipment with a purchase value of €450 thousand and receivables amounting €391 thousand.

As of December 31, 2015, long-term debt in Germany consists of a loan in euro of an initial amount of €450 thousand with an interest rate at 2.49% due to mature on November 30, 2020. This loan is pledged by an HIFU equipment with a purchase value of €450 thousand and receivables amounting €391 thousand.

As of June 30, 2016, long-term debt in Italy consists of a loan in euro of an initial amount of €242 thousand with an interest rate at Euribor 1 month + 4.5% due to mature on June 6, 2019.

As of December 31, 2015, long-term debt in Italy consists of a loan in euro of an initial amount of €242 thousand with an interest rate at Euribor 1 month + 4.5% due to mature on June 6, 2019.

### ***6-2 Financial instruments carried at fair value:***

	06-30-2016	12-31-2015
Investor Warrants	4,608	4,205
Placement Agent Warrants	-	172
Total	4,608	4,377
Less current portion	(835 )	(172 )
Total long-term portion	3,774	4,205

## EDAP TMS S.A. AND SUBSIDIARIES

### NOTES TO CONSOLIDATED INTERIM UNAUDITED FINANCIAL STATEMENTS

**(in thousands of euros unless otherwise noted, except per share data)**

On March 28, 2012, pursuant to a securities purchase agreement dated March 22, 2012, as amended, the Company issued 2,812,500 ordinary shares in the form of ADSs to selected institutional investors in a registered direct placement (the “March 2012 Placement”), at a price of \$2.00 per share, with warrants attached (the “March 2012 Investor Warrants”). The March 2012 Investor Warrants allow investors to purchase up to 1,406,250 shares in the form of ADSs at an exercise price of \$2.75. The March 2012 Investor Warrants are exercisable immediately and expire on March 28, 2017. The Company also issued warrants to purchase up to 168,750 shares in the form of ADSs to the placement agent, Rodman & Renshaw LLC, with an exercise price of \$2.50 (the “March 2012 Placement Agent Warrants” and together with the Investor Warrants, the “March 2012 Warrants”). The March 2012 Placement Agent Warrants are exercisable from September 24, 2012 and expire on October 21, 2016. Total gross proceeds for the placement amounted to \$5.625 million (€ 4.214 million) out of which \$2.429 million (€1.821 million) allocated to the Investor and Placement Agent Warrants based on their fair value and accounted for as liability, and the remaining \$3.196 million (€2.393 million) allocated to the share capital increase.

The form of the securities purchase agreement and the form of Investor Warrant were furnished to the SEC on our report on Form 6-K dated March 28, 2012.

The Company determined that the March 2012 Warrants to purchase up to 1,575,000 new ordinary shares of the Company (1,406,250 shares underlying the March 2012 Investor Warrants and 168,750 shares underlying the March 2012 Placement Agent Warrants) should be accounted for as a liability.

On May 28, 2013, pursuant to a securities purchase agreement dated May 20, 2013, as amended, the Company issued 3,000,000 ordinary shares in the form of ADSs to selected institutional investors in a registered direct placement (the “May 2013 Placement”), at a price of \$4.00 per share, with warrants attached (the “May 2013 Investor Warrants”). The May 2013 Investor Warrants allow investors to purchase up to 1,500,000 shares in the form of ADSs at an exercise price of \$4.25. The May 2013 Investor Warrants are exercisable from November 29, 2013 and expire on November 29, 2018. The Company also issued warrants to purchase up to 180,000 shares in the form of ADSs to the placement agent, H.C. Wainwright & Co., LLC, with an exercise price of \$5.00 per share (the “May 2013 Placement Agent Warrants” and together with the Investor Warrants, the “May 2013 Warrants”). The May 2013 Placement Agent Warrants are exercisable from November 29, 2013 and expire on May 28, 2016. As the May 2013 Warrants comprised the same structure and provisions than the March 2012 Warrants, including an exercise price determined in U.S. dollars while the functional currency of the Company is the Euro, the Company determined that the May 2013 Warrants should be accounted for as a liability. Total gross proceeds for the placement amounted to \$12.0 million (€ 9.270 million), out of which \$3.817 million (€2.950 million) allocated to the Investor and Placement Agent Warrants based on their fair value

and accounted for as liability, and the remaining \$8.183 million (€6.320 million) allocated to the share capital increase. The form of the securities purchase agreement and the form of Investor Warrant were furnished to the SEC on our report on Form 6-K dated May 28, 2013.

The Company used the Black-Scholes pricing model to value the May 2013 Warrants at inception, with changes in fair value recorded as a financial expense or income.

**EDAP TMS S.A. AND SUBSIDIARIES**

NOTES TO CONSOLIDATED INTERIM UNAUDITED FINANCIAL STATEMENTS

**(in thousands of euros unless otherwise noted, except per share data)**

On April 14, 2016, pursuant to a securities purchase agreement dated April 7, 2016, the Company issued 3,283,284 ordinary shares in the form of ADSs to selected institutional investors in a registered direct placement (the “April 2016 Placement”), at a price of \$3.50 per share, with warrants attached (the “April 2016 Investor Warrants”). The April 2016 Investor Warrants allow investors to purchase up to 3,283,284 shares in the form of ADSs at an exercise price of \$4.50. The April 2016 Investor Warrants are exercisable from October 14, 2016 and expire on October 14, 2018. As the April 2016 Warrants comprised the same structure and provisions than the March 2012 and May 2013 Warrants, including an exercise price determined in U.S. dollars while the functional currency of the Company is the Euro, the Company determined that the April 2016 Warrants should be accounted for as a liability. Total gross proceeds for the placement amounted to \$11.5 million (€ 10.2 million), out of which \$3.578 million (€3.168 million) allocated to the Investor Warrants based on their fair value and accounted for as liability, and the remaining \$7.913 million (€7.006 million) allocated to the share capital increase. The form of the securities purchase agreement and the form of Investor Warrant were furnished to the SEC on our report on Form 6-K dated April 14, 2016.

The Company used the Black-Scholes pricing model to value the April 2016 Warrants at inception, with changes in fair value recorded as a financial expense or income.

Fair Value of the March 2012 Investor Warrants:

The valuation model of the Investor Warrants uses a Black-Scholes model.

At inception date, the Black-Scholes valuation model used the following main assumptions and parameters:

-	Share price at closing date: \$1.95
-	Strike price of warrants: \$2.75
-	Risk free interest rate at 5 years: 1.05%
-	Share price volatility: 120%
-	Dividend rates: 0%

Edgar Filing: EDAP TMS SA - Form 6-K

As of December 31, 2015, the Black-Scholes valuation model used the following main assumptions and parameters:

- Warrants' maturity is assumed to be their legal duration as per Warrant contract
- Share price at closing date: \$4.13
- Strike price of warrants: \$2.75
- Risk free interest rate at 5 years: 0%
- Share price volatility: 70%
- Dividend rates: 0%

As of June 30, 2016, the Black-Scholes valuation model used the following main assumptions and parameters:

- Share price at closing date: \$3.31
- Strike price of warrants: \$2.75
- Risk free interest rate at 5 years: 0.00%
- Share price volatility: 60%
- Dividend rates: 0%

On that basis, the unit fair value of the Investor Warrants was \$1.55 per warrant at inception date, \$1.86 per warrant as of December 31, 2015, and \$0.94 per warrant as of June 30, 2016. The total fair value for the issued Investor warrants was \$2.173 million at inception date, \$1.840 million as of December 31, 2015 and \$0.927 million as of June 30, 2016.

**EDAP TMS S.A. AND SUBSIDIARIES**

NOTES TO CONSOLIDATED INTERIM UNAUDITED FINANCIAL STATEMENTS

(in thousands of euros unless otherwise noted, except per share data)

Fair Value of the March 2012 Placement Agent Warrants:

The valuation model of the Placement Agent Warrants uses a Black-Scholes model.

At inception date, the Black-Scholes valuation model used the following main assumptions and parameters:

-	Share price at closing date: \$1.95
-	Strike price of warrants: \$2.5
-	Risk free interest rate at 4.5 years: 0.92%
-	Share price volatility: 120%
-	Dividend rates: 0%

As of December 31, 2015, the Black-Scholes valuation model used the following main assumptions and parameters:

-	Warrants' maturity is assumed to be their legal duration as per Warrant contract
-	Share price at closing date: \$4.13
-	Strike price of warrants: \$2.5
-	Risk free interest rate at 4.5 years: 0%
-	Share price volatility: 70%
-	Dividend rates: 0%

As of June 30, 2016, all the March 2012 Placement Agent Warrants were exercised.

On that basis, the unit fair value of the Placement Agent Warrants was \$1.52 per warrant at inception date, and \$1.87 per warrant as of December 31, 2015. The total fair value for the issued Placement Agent warrants was \$0.256 million at inception date, \$0.107 million as of December 31, 2015, and \$0.000 million as of June 30, 2016.

Fair Value of the May 2013 Investor Warrants:

The valuation model of the Investor Warrants uses a Black-Scholes model.

At inception date, the Black-Scholes valuation model used the following main assumptions and parameters:

-	Share price at closing date: \$3.96
-	Strike price of warrants: \$4.25
-	Risk free interest rate at 5.5 years: 1.07%
-	Share price volatility: 71%
-	Dividend rates: 0%

As of December 31, 2015, the Black-Scholes valuation model used the following main assumptions and parameters:

-	Warrants' maturity is assumed to be their legal duration as per Warrant contract
-	Share price at closing date: \$4.13
-	Strike price of warrants: \$4.25
-	Risk free interest rate at 5.5 years: 0%
-	Share price volatility: 70%
-	Dividend rates: 0%



**EDAP TMS S.A. AND SUBSIDIARIES**

NOTES TO CONSOLIDATED INTERIM UNAUDITED FINANCIAL STATEMENTS

**(in thousands of euros unless otherwise noted, except per share data)**

As of June 30, 2016, the Black-Scholes valuation model used the following main assumptions and parameters:

-	Warrants' maturity is assumed to be their legal duration as per Warrant contract
-	Share price at closing date: \$3.31
-	Strike price of warrants: \$4.25
-	Risk free interest rate at 5.5 years: 0.00%
-	Share price volatility: 60.2%
-	Dividend rates: 0%

On that basis, the unit fair value of the Investor Warrants was \$2.35 per warrant at inception date, \$1.82 per warrant as of December 31, 2015 and \$0.94 per warrant as of June 30, 2016. The total fair value for the issued Investor warrants was \$3.525 million at inception date, \$2.737 million as of December 31, 2015 and \$1.404 million as of June 30, 2016.

Fair Value of the May 2013 Placement Agent Warrants:

The valuation model of the Placement Agent Warrants uses a Black-Scholes model.

At inception date, the Black-Scholes valuation model used the following main assumptions and parameters:

-	Share price at closing date: \$3.96
-	Strike price of warrants: \$5.00
-	Risk free interest rate at 3 years: 0.36%
-	Share price volatility: 72%
-	Dividend rates: 0%

As of December 31, 2015, the Black-Scholes valuation model used the following main assumptions and parameters:

- Warrants' maturity is assumed to be their legal duration as per Warrant contract
  - Share price at closing date: \$4.13
  - Strike price of warrants: \$5.00
  - Risk free interest rate at 3 years: 0%
  - Share price volatility: 70%
  - Dividend rates: 0%

As of June 30, 2016, all the March 2013 Placement Agent Warrants were exercised or forfeited.

On that basis, the unit fair value of the Placement Agent Warrants was \$1.62 per warrant at inception date and \$0.44 per warrant as of December 31, 2015. The total fair value for the issued Placement Agent warrants was \$0.292 million at inception date, \$0.080 million as of December 31, 2015 and \$0.000 million as of June 30, 2016.

Fair Value of the April 2016 Investor Warrants:

The valuation model of the Investor Warrants uses a Black-Scholes model.

**EDAP TMS S.A. AND SUBSIDIARIES**

NOTES TO CONSOLIDATED INTERIM UNAUDITED FINANCIAL STATEMENTS

**(in thousands of euros unless otherwise noted, except per share data)**

At inception date, the Black-Scholes valuation model used the following main assumptions and parameters:

-	Share price at closing date: \$3.64
-	Strike price of warrants: \$4.50
-	Risk free interest rate at 2.5 years: 0.00%
-	Share price volatility: 60.20%
-	Dividend rates: 0%

As of June 30, 2016, the Black-Scholes valuation model used the following main assumptions and parameters:

-	Warrants' maturity is assumed to be their legal duration as per Warrant contract
-	Share price at closing date: \$3.31
-	Strike price of warrants: \$4.50
-	Risk free interest rate at 2.5 years: 0.00%
-	Share price volatility: 60.20%
-	Dividend rates: 0%

On that basis, the unit fair value of the Investor Warrants was \$1.09 per warrant at inception date and \$0.85 per warrant as of June 30, 2016. The total fair value for the issued Investor warrants was \$3.579 million at inception date, \$2.785 million as of June 30, 2016.

Long-term debt and financial instruments carried at fair value at June 30, 2016 mature as follows:

2016	103
2017	1,056
2018	3,963
2019	117

2020 83  
Total 5,320

## **7—SHAREHOLDERS' EQUITY**

### ***7-1 Common stock***

As of June 30, 2016, EDAP TMS S.A.'s common stock consisted of 29,098,144 issued shares, fully paid, and with a par value of €0.13 each. 28,727,616 of the shares were outstanding.

### ***7-2 Pre-emptive subscription rights***

Shareholders have preemptive rights to subscribe on a *pro rata* basis for additional shares issued by the Company for cash. Shareholders may waive such preemptive subscription rights at an extraordinary general meeting of shareholders under certain circumstances. Preemptive subscription rights, if not previously waived, are transferable during the subscription period relating to a particular offer of shares.

### ***7-3 Dividend rights***

Dividends may be distributed from the statutory retained earnings, subject to the requirements of French law and the Company's by-laws. The Company has not distributed any dividends since its inception.

## **EDAP TMS S.A. AND SUBSIDIARIES**

### NOTES TO CONSOLIDATED INTERIM UNAUDITED FINANCIAL STATEMENTS

**(in thousands of euros unless otherwise noted, except per share data)**

#### *7-4 Treasury stock*

As of June 30, 2016, the 370,528 shares of treasury stock consisted of (i) 190,238 shares acquired between August and December 1998 for €649 thousand, and (ii) 180,290 shares acquired in June and July 2001 for €493 thousand. All 370,528 shares of treasury stock have been acquired to cover outstanding stock options (see Note 7-5).

#### *7-5 Stock-option plans*

As of June 30, 2016, the 370,528 ordinary shares held as treasury stock were dedicated to serve stock purchase option plans as follows: 127,100 shares which may be purchased at a price of €2.38 per share pursuant to the exercise of options that were granted on June 25, 2010.

As of June 30 2016, the Company sponsored four stock purchase and subscription option plans:

On May 22, 2007, the shareholders of the Company authorized the Board of Directors to grant up to 600,000 options to subscribe to 600,000 new Shares. Conforming to this stock option plan, the Board of Directors granted 504,088 options to subscribe to new Shares to certain employees of EDAP TMS on October 29, 2007, and 95,912 options to subscribe to new Shares to certain employees of EDAP TMS on June 25, 2010. Under this plan, a total of 440,500 options to subscribe to new shares were still in force on June 30, 2015.

On June 24, 2010, the shareholders of the Company authorized the Board of Directors to grant up to 229,100 options to purchase up to 229,100 Shares. Conforming to this stock option plan, the Board of Directors granted 229,100 options to purchase Shares to certain employees of EDAP TMS on June 25, 2010. Under this plan, 149,100 options were still in force on June 30, 2015.

Edgar Filing: EDAP TMS SA - Form 6-K

On December 19, 2012, the shareholders authorized the Board of Directors to grant up to 500,000 options to subscribe to 500,000 new shares at a fixed price to be set by the Board of Directors. Conforming to this stock option plan, the Board of Directors granted 500,000 options to subscribe Shares to certain employees of EDAP TMS on January 18, 2013. Under this plan, 400,000 options were still in force on June 30, 2015.

On February 18, 2016, the shareholders authorized the Board of Directors to grant up to 1,000,000 options to subscribe to 1,000,000 new shares at a fixed price to be set by the Board of Directors. Conforming to this stock option plan, the Board of Directors granted 575,000 options to subscribe Shares to certain employees of EDAP TMS on April 26, 2016. Under this plan, 562,000 options were still in force on June 30, 2016.

**EDAP TMS S.A. AND SUBSIDIARIES**

## NOTES TO CONSOLIDATED INTERIM UNAUDITED FINANCIAL STATEMENTS

(in thousands of euros unless otherwise noted, except per share data)

As of June 30, 2016, a summary of stock option activity to purchase or to subscribe to Shares under these plans is as follows:

	June 30, 2016		December 31, 2015		December 31, 2014	
	Options	Weighted average exercise price (€)	Options	Weighted average exercise price (€)	Options	Weighted average exercise price (€)
Outstanding on January 1,	917,188	2.79	1,095,850	2.76	1,310,850	2.70
Granted	575,000	3.22	-	-	-	-
Exercised			(72,412 )	2.13	(750 )	3.99
Forfeited	(42,750 )	2.98	(106,250 )	2.88	(90,250 )	2.07
Expired			-	-	(124,000 )	2.60
Outstanding at the end of the period	1,449,438	2.96	917,188	2.79	1,095,850	2.76
Exercisable at the end of the period	702,438	3.02	724,688	3.03	784,600	3.09
Shares purchase options available for grant on at end of period	243,428		232,428		83,428	

The following table summarizes information about options to purchase Shares already held by the Company as treasury Shares, or to subscribe to new Shares, at June 30, 2016:

Exercise price (€)	Outstanding options			Fully vested options <sup>(1)</sup>		
	Options	Weighted average remaining contractual life	Weighted average exercise price (€)	Options	Weighted average exercise price (€)	Aggregate Intrinsic Value (2)
3.99	347,838	1.3	3.99	347,838	3.99	-
2.38	127,100	4.0	2.38	127,100	2.38	76,427
3.22	562,000	9.8	3.22	-	3.22	-
1.91	362,500	6.5	1.91	270,000	1.91	289,260
1.88	50,000	4.0	1.88	50,000	1.88	55,066
1.88 to 3.99	1,449,438	6.4	2.96	794,938	2.89	420,753

(1) Fully vested options are all exercisable options

(2) The aggregate intrinsic value represents the total pre-tax intrinsic value, based on the Company's closing stock price of \$3.31 at June 30, 2016, which would have been received by the option holders had all in-the-money option holders exercised their options as of that date.

The Company applies FAS 123R on Share Based Payments and its related interpretations in accounting for its employee stock options.



**EDAP TMS S.A. AND SUBSIDIARIES**

## NOTES TO CONSOLIDATED INTERIM UNAUDITED FINANCIAL STATEMENTS

(in thousands of euros unless otherwise noted, except per share data)

**8—FINANCIAL INCOME, NET**

Interest (expense) income, net consists of the following:

	6 months 2016	6 months 2015
Interest income	9	3
Interest expense	(27 )	(28 )
Warrants exercised or forfeited	174	66
Changes in fair value of the warrants	2,734	(1,385)
Total	2,891	(1,344)

**9—SEGMENT INFORMATION**

In July of fiscal year 2002, the Company announced an organizational realignment that created two operating divisions within the Company. For reporting purposes, this organizational realignment created three reporting segments: the holding company, EDAP TMS S.A. ('EDAP TMS Corporate'), the High Intensity Focused Ultrasound ('HIFU') Division and the Urological Devices and Services ('UDS') Division. Then, in 2007, the Company created a new reporting segment dedicated to the FDA approval for Ablatherm-HIFU activity. Segment operating profit or loss are determined in accordance with the same policies as those described in the summary of significant accounting policies except that interest income and expense, current and deferred income taxes, are not allocated to individual segments. A reconciliation of segment operating profit or loss to consolidated net loss is as follows:

	6 months 2016	6 months 2015
Segment operating loss	388	(839 )

Edgar Filing: EDAP TMS SA - Form 6-K

Interest income, net	2,891	(1,344)
Foreign Currency exchange (losses) gains, net	671	303
Other income, net	-	(3 )
Income tax (expense) credit net	(91 )	(69 )
Consolidated net loss net	3,859	(1,953)

**EDAP TMS S.A. AND SUBSIDIARIES**

## NOTES TO CONSOLIDATED INTERIM UNAUDITED FINANCIAL STATEMENTS

(in thousands of euros unless otherwise noted, except per share data)

A summary of the Company's operations by business unit is presented below for periods ending June 30, 2016 and 2015:

	HIFU Division	UDS Division	EDAP TMS Corporate	FDA	Total consolidated
<b><u>6 months 2016</u></b>					
Sales of Goods (incl. consumables)	4,536	6,725	-	-	11,261
Sales of RPPs & Leases,	1,811	766	-	-	2,578
Sales of Spare Parts & Services	328	2,750	-	-	3,078
Total Net Sales	6,676	10,241	-	-	16,917
Other Revenues	6	2	-	-	8
Total Revenues	6,682	10,243	-	-	16,925
Gross Profit	4,081	3,672	-	-	7,753
Research & Development	(1,048 )	(653 )	-	-	(1,701 )
SG&A + Depreciation	(1,979 )	(2,996 )	(689 )	-	(5,664 )
Operating income (loss)	1,054	23	(689 )	-	388

	HIFU Division	UDS Division	EDAP TMS Corporate	FDA	Total consolidated
<b><u>6 months 2015</u></b>					
Sales of Goods (incl. consumables)	2,318	6,785	-	-	9,103
Sales of RPPs & Leases,	1,297	822	-	-	2,119
Sales of Spare Parts & Services	333	2,497	-	-	2,830
Total Net Sales	3,948	10,104	-	-	14,052
Other Revenues	2	-	-	-	2
Total Revenues	3,950	10,104	-	-	14,054
Gross Profit	2,158	3,753	-	-	5,911
Research & Development	(745 )	(455 )	-	(312)	(1,512 )
SG&A + Depreciation	(1,504 )	(3,014 )	(721 )	-	(5,238 )
Operating income (loss)	(91 )	284	(721 )	(312)	(839 )



**10—SUBSEQUENT SIGNIFICANT EVENTS**

N/A

**SIGNATURES**

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

Date: September 27, 2016

EDAP TMS S.A.

/S/ FRANCOIS DIETSCH  
FRANCOIS DIETSCH  
CHIEF FINANCIAL OFFICER