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# EDAP Reports Record HIFU Fourth Quarter and Full-Year 2024 Results

- Record full-year 2024 HIFU revenue of USD 25.7 million, an increase of 15.3% over full-year 2023
- Record Q4 2024 HIFU revenue of USD 9.3 million, an increase of 15.0% over Q4 2023
- U.S. Focal One HIFU procedures grew 51% on a year-over-year basis in 2024
- Focal One receives CE Mark for the treatment of deep infiltrating endometriosis
- Recent landmark HIFI study publication demonstrates positive outcomes with Focal One<sup>®</sup> Robotic HIFU versus surgery in the management of prostate cancer
- First patients treated in Phase I/II study evaluating Focal One Robotic HIFU for the treatment of Benign Prostatic Hyperplasia (BPH)
- Company to host conference call and webcast today, March 27th, at 8:30 a.m. EDT

AUSTIN, Texas, March 27, 2025 - EDAP TMS SA (Nasdaq: EDAP), the global leader in robotic energy-based therapies, reported today unaudited consolidated financial results for the fourth quarter and full-year 2024.

"Our strong fourth quarter performance reflects our continued progress in establishing Focal One Robotic HIFU as a mainstream treatment option for the management of prostate cancer," said Ryan Rhodes, Chief Executive Officer of EDAP TMS. "We achieved a quarterly record number of sales for Focal One systems, both in the U.S. and globally, and the number of Focal One procedures continues to grow at a solid pace. In December, we announced the publication of the HIFI Study in the prestigious medical journal, *European Urology*. We believe the positive results from this landmark clinical trial have the ability to reshape the treatment paradigm for prostate cancer and ultimately help drive further adoption of the Focal One platform.

"As we build momentum in our core Focal One business, we remain focused on expanding into multiple high growth opportunities for therapeutic HIFU, while also reducing investments in non-core products. Given Focal One's market leading technology, I believe we are uniquely positioned to create significant value for patients, physicians and our shareholders as we continue expanding into the prostate cancer market, while also advancing our clinical development programs in endometriosis, benign prostatic hyperplasia (BPH), and pancreatic cancer."

# **Business Update**

- On March 26, 2025, the Company's Focal One Robotic HIFU System received CE Mark certification from GMED, EDAP's notified body, for the treatment of posterior deep endometriosis infiltrating the rectum and surrounding structures.
- The Company recently attended the European Association of Urology Meeting, which took place in Madrid, Spain from March 21-24, 2025. During the conference, the Company offered numerous hands-on simulations with Focal One while also discussing the treatment implications from the recently published landmark HIFI Study.
- On March 3, 2025, the Company announced the appointment of Glen French to its Board of Directors. Mr. French is a highly accomplished executive with extensive business and clinical expertise in the development of innovative new medical devices and technology. For nearly a decade, Glen was the President and CEO of Pulmonx Corporation, which develops minimally invasive technologies for the diagnosis and treatment for patients with severe emphysema. Under his leadership, Pulmonx experienced more than 20% annual

compound revenue growth rate. Over the course of his career, he has co-founded, built and sold three medical device companies and took a fourth company public.

- On February 6, 2025, the Company announced the successful completion of the world's first OnQ Prostateassisted Focal One Robotic HIFU procedure at the University of California, San Francisco (UCSF) Prostate Center. This milestone marks the first clinical application of OnQ Prostate's patented Restriction Spectrum Imaging (RSI) technology to guide focal therapy, demonstrating how advanced MR-imaging can improve lesion localization and targeting for urologists performing focal therapy.
- On January 10, 2025, the Company announced the appointment of Joshua H. Levine to its Board of Directors. Mr. Levine is a strategic business leader with decades of diverse global board and executive management experience within the medical technology industry. He possesses a deep expertise in portfolio transformation, strategic business development and driving shareholder value. From 2012 to 2022, Mr. Levine served as President, Chief Executive Officer, and Director of Accuray Incorporated, where he led a transformative turnaround that involved all strategic, operational, and financial activities that restored the business to consistent top line growth, positive operating profit, free cash flow (EBITDA), and expanded the company's global footprint.
- On December 4, 2024, the Company announced the publication of the full results from the HIFI study in the
  prestigious, peer-reviewed journal, *European Urology*, which has the highest impact factor amongst scientific
  journals focused in urology. The study evaluated HIFU versus radical prostatectomy (RP) as a first line
  treatment of localized prostate cancer. The paper is entitled "Whole-gland or Subtotal High-intensity Focused
  Ultrasound Versus Radical Prostatectomy: The Prospective, Noninferiority, Nonrandomized, HIFI Trial" and is
  authored by Dr. Guillaume Ploussard from Department of Urology, UROSUD, Clinique La Croix du
  Sud, France. A link to the publication can be found here.

HIFI is the first prospective, multi-center, non-inferiority comparative study evaluating HIFU and RP in the management of localized prostate cancer. This seven-year study (April 2015 - March 2022) enrolled a total of 3,328 patients from 46 treatment centers: 1,967 consecutive patients were treated with EDAP's robotic HIFU technologies, where Focal One was used for 90% of the patients, and 1,361 patients underwent radical prostatectomy. All patients were followed for 30 months. A summary of the HIFI results can be found at https://hifistudy.com/.

- On November 22, 2024, the Company announced a scientific presentation which demonstrated the technical feasibility of performing non-thermal histotripsy energy delivery and generating histotripsy lesions in biological tissues *ex vivo* using the Company's Focal One Robotic HIFU technology. The results from the study were presented on November 19<sup>th</sup> at the 187<sup>th</sup> Acoustical Society of America meeting, which is took place virtually from November 18 - 22, 2024.
- On November 2, 2024, the Center for Medicare and Medicaid Services, CMS, released the final payment rules for 2025. The HIFU procedure continues to be supported with favorable reimbursement with CMS finalizing a Medicare Hospital payment rate of \$9,247 as a national average, adjusted locally with the corresponding local wage index factor. The rate will become effective on January 1, 2025, and represents a 5.4% increase over the 2024 payment. This continues to support the favorable strategic business case for hospitals to both invest and integrate Focal One HIFU while providing greater access to this valuable, non-invasive treatment option.

CMS also released the physician fee schedule for 2025 which continues to provide strong physician reimbursement for HIFU with 17.73 work relative value units, or work RVUs, and 29.41 Total RVUs. These figures are significantly higher than any other prostate ablation procedure. Additionally, it provides physicians with a level of reimbursement that is more than 80% of the payment for performing surgery, including Robotic Radical Prostatectomy. The Company believes that this continued support of the defined reimbursement levels for the use of HIFU provides a financially sound and sustainable economic offering for both the hospital and the physician.

# **Clinical Pipeline Update**

### Pancreatic Cancer Program

On January 8, 2025, the Company announced that the first patient was treated in the phase I/II PULS Trial sponsored by the Centre Léon Bérard, Lyon, France, evaluating proprietary High Intensity Focused Ultrasound (HIFU) technology for the treatment of pancreatic tumors. The PULS Trial is a phase I/II, multicenter study for patients with locally advanced and unresectable pancreatic tumors. The phase I trial aims at evaluating the tolerance of intraoperative HIFU intervention on the pancreatic lesion. The phase II trial aims at evaluating the preliminary efficacy of the HIFU intervention.

### Benign Prostate Hyperplasia (BPH) Program

On October 1, 2024, the Company announced that the first patients were treated in Phase I/II study evaluating Focal One Robotic HIFU for the treatment of benign prostatic hyperplasia (BPH). The Phase I/II study is a company-sponsored, prospective, multicenter clinical trial designed as a two-part study. Part 1 of the Phase I/II study will take place at three leading academic prostate treatment centers in France with a recognized expertise in the treatment of BPH as well as in the use of Focal One HIFU technology. Part 1 is designed to define the optimal treatment parameters to effectively treat BPH and its related symptoms with minimal side effects. Part 2 of the study will expand patient enrollment across a larger number of treatment centers in order to validate the safety and efficacy of the parameters as defined in Part 1 of the study. In July, the Company received approval from the French National Agency for Medicines and Health Products Safety (ANSM) to initiate a Phase I/II clinical trial investigating Focal One Robotic HIFU in BPH.

#### **Upcoming Meetings and Events**

In the second quarter of 2025, EDAP expects to have its largest presence at this year's the American Urology Association (AUA) Meeting, which will place from April 26-29, 2025, in Las Vegas, Nevada. The AUA meeting is the most widely attended urology-focused conference in the world and is considered the most highly influential, global medical meeting focused on urology.

#### Fourth Quarter 2024 Results

Total worldwide revenue for the fourth quarter of 2024 was EUR 20.3 million (USD 21.5 million), an increase of 3.6% as compared to worldwide revenue of EUR 19.6 million (USD 21.3 million) for the same period in 2023.

Total revenue in the HIFU business for the fourth quarter of 2024 was EUR 8.8 million (USD 9.3 million), as compared to EUR 7.5 million (USD 8.1 million) for the fourth quarter of 2023. The Company sold 11 Focal One systems during the fourth quarter of 2024 versus 10 systems sold in the fourth quarter of 2023. Worldwide disposables revenue grew 28.5% in the fourth quarter of 2024 over the prior year period, driven by 31% growth in Focal One procedures in the US.

Total revenue in the Distribution business for the fourth quarter of 2024 was EUR 9.1 million (USD 9.6 million), as compared to EUR 9.9 million (USD 10.7 million) for the fourth quarter of 2023. The decrease in Distribution revenue was driven primarily by product mix.

Total revenue in the LITHO business for the fourth quarter of 2024 was EUR 2.4 million (USD 2.6 million), as compared to EUR 2.3 million (USD 2.5 million) for the fourth quarter of 2023. The increase in LITHO revenue was driven by 5 lithotripsy units sold in the fourth quarter of 2024 as compared to 3 units sold in the fourth quarter of 2023.

Gross profit for the fourth quarter of 2024 was EUR 9.1 million (USD 9.6 million), compared to EUR 8.6 million (USD 9.3 million) for the same period in 2023. Gross profit margin on net sales was 44.8% in the fourth quarter of 2024, compared to 43.7% for the comparable period in Q4 2023. The increase in gross profit margin year-over-year was

primarily due to a higher number of Focal One system sales in the U.S., including the conversion of two operating leases to capital sales.

Operating expenses were 12.8 million euros (USD 13.6 million) for the fourth quarter, compared to 12.0 million euros (USD 13.1 million) for the same period in 2023. The modest increase in operating expenses was primarily due to focused investments in our HIFU business segment, as well as variable compensation.

Operating loss for the fourth quarter of 2024 was EUR 3.7 million (USD 4.0 million), compared to an operating loss of EUR 3.5 million (USD 3.8 million) in the fourth quarter of 2023.

Net loss for the fourth quarter of 2024 was EUR 1.9 million (USD 2.1 million), or EUR (0.05) per share, as compared to net loss of EUR 5.0 million (USD 5.5 million), or EUR (0.14) per share in the fourth quarter of 2023.

#### Full-Year 2024 Results

Total worldwide revenue for the twelve months ended December 31, 2024, was EUR 64.1 million (USD 69.2 million), an increase of 6.1% from total worldwide revenue of EUR 60.4 million (USD 65.4 million) for the same period in 2023.

Total revenue in the HIFU business for the twelve months ended December 31, 2024, was EUR 23.8 million (USD 25.7 million), an increase of 15.7% as compared to EUR 20.6 million (USD 22.3 million) for the twelve months ended December 31, 2023.

Total revenue in the Distribution business for the twelve months ended December 31, 2024, was EUR 31.3 million (USD 33.8 million), an increase of 4.6% compared to EUR 29.9 million (USD 32.4 million) for the twelve months ended December 31, 2023.

Total revenue in the LITHO business for the twelve months ended December 31, 2024, was EUR 9.0 million (USD 9.7 million), a decrease of 9.3% from EUR 9.9 million (USD 10.7 million) for the twelve months ended December 31, 2023.

Gross profit for the twelve months ended December 31, 2024, was EUR 26.6 million (USD 28.7 million), compared to EUR 24.4 million (USD 26.4 million), for the twelve months ended December 31, 2023. Gross profit margin on net sales was 41.4% for the twelve months ended December 31, 2024, compared to 40.4% for the comparable period in 2023.

Operating expenses were EUR 47.1 million (USD 50.8 million) for the twelve months ended December 31, 2024, compared to EUR 44.2 million (USD 47.9 million) for the same period in 2023.

Operating loss for the twelve months ended December 31, 2024, was EUR 20.5 million (USD 22.2 million), compared to an operating loss of EUR 19.8 million (USD 21.5 million) for the twelve months ended December 31, 2023.

Net loss for the twelve months ended December 31, 2024, was EUR 19.0 million (USD 20.5 million), or EUR (0.51) per share, as compared to a net loss of EUR 21.2 million (USD 22.9 million), or EUR (0.57) per share for the twelve months ended December 31, 2023.

As of December 31, 2024, the Company held cash and cash equivalents of EUR 29.8 million (USD 30.9 million) as compared to EUR 43.5 million (USD 48.1 million) as of December 31, 2023.

#### **Conference Call Information**

A conference call and webcast to discuss the fourth quarter and full year 2024 financial results will be hosted by Ryan Rhodes, Chief Executive Officer, Ken Mobeck, Chief Financial Officer, and François Dietsch, Chief Accounting Officer. Please refer to the information below for conference call dial-in information and webcast registration.

Date:Thursday, March 27th @ 8:30am Eastern TimeDomestic:1-800-225-9448International:1-203-518-9708Passcode (Conf ID):EDAP

Webcast:

https://viavid.webcasts.com/starthere.jsp?ei=1706804&tp\_key=5b71915afc

#### About EDAP TMS SA

A recognized leader in robotic energy-based therapies, EDAP TMS develops, manufactures, promotes and distributes worldwide minimally invasive medical devices for various conditions using ultrasound technology. By combining the latest technologies in imaging, robotics and precise non-invasive energy delivery, EDAP TMS introduced the Focal One<sup>®</sup> in Europe and in the U.S. as the leading prostate focal therapy controlled by urologists with the potential to expand to multiple indications beyond prostate cancer. For more information on the Company, please visit https://focalone.com.

#### **Forward-Looking Statements**

In addition to historical information, this press release contains forward-looking statements within the meaning of applicable federal securities laws, including 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, which may be identified by words such as "believe," "can," "contemplate," "could," "plan," "intend," "is designed to," "may," "might," "potential," "objective," "target," "project," "predict," "forecast," "ambition," "guideline," "should," "will," "estimate," "expect" and "anticipate," or the negative of these and similar expressions, which reflect our views about future events and financial performance. 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 and distribution divisions, as well as risks associated with the current worldwide inflationary environment, the uncertain worldwide economic, political and financial environment, geopolitical instability, climate change and pandemics like the COVID 19 pandemic, or other public health crises, and their related impact on our business operations, including their impacts across our businesses or demand for our devices and services.

Other 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.

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. These forward-looking statements are based upon information, assumptions and estimates available to us as of the date of this press release, and while we believe such information forms a reasonable basis for such statements, such information may be limited or incomplete.

#### **Company Contact**

Blandine Confort Investor Relations / Legal Affairs EDAP TMS SA +33 4 72 15 31 50 bconfort@edap-tms.com

# **Investor Contact**

John Fraunces LifeSci Advisors, LLC (917) 355-2395 jfraunces@lifesciadvisors.com

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

	Three Mon	ths Ended:	Three Months Ended:		
	December 31, 2024 Euros	December 31, 2023 Euros	December 31, 2024 \$US	December 31, 2023 \$US	
Sales of goods	14,559	15,021	15,410	16,292	
Net sales of RPP and leases	2,363	1,611	2,501	1,747	
Sales of spare parts, supplies and services	3,395	2,981	3,594	3,233	
TOTAL REVENUES	20,318	19,613	21,505	21,272	
Cost of sales	(11,220)	(11,051)	(11,875)	(11,986)	
GROSS PROFIT	9,098	8,562	9,629	9,286	
Research & development expenses	(1,865)	(2,201)	(1,974)	(2,387)	
Selling, general & administrative expenses	(10,971)	(9,842)	(11,612)	(10,674)	
Total operating expenses	(12,836)	(12,042)	(13,586)	(13,061)	
OPERATING LOSS	(3,738)	(3,481)	(3,957)	(3,775)	
Interest (expense) income, net	122	220	130	239	
Currency exchange gains (loss), net	1,664	(1,450)	1,761	(1,573)	
LOSS BEFORE INCOME TAXES	(1,952)	(4,710)	(2,066)	(5,109)	
Income tax (expense) credit, net	11	(332)	12	(361)	
NET LOSS	(1,940)	(5,043)	(2,054)	(5,469)	
Loss per share – Basic and diluted	(0.05)	(0.14)	(0.05)	(0.15)	
Average number of shares used in computation of basic and diluted EPS	37,371,992	37,066,627	37,371,992	37,066,627	

NOTE: Translated for convenience of the reader to U.S. dollars at the 2024 average three months' exchange rate of 1 Euro = 1.0584 USD, and 2023 average three months' exchange rate of 1 Euro = 1.0846 USD

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

	Year I	Ended:	Year Ended:		
	December 31, 2024 Euros	December 31, 2023 Euros	December 31, 2024 \$US	December 31, 2023 \$US	
Sales of goods	44,037	42,333	47,515	45,835	
Net sales of RPP and leases	7,610	6,176	8,211	6,687	
Sales of spare parts, supplies and services	12,468	11,914	13,452	12,899	
TOTAL REVENUES	64,114	60,423	69,178	65,421	
Cost of sales	(37,558)	(36,012)	(40,524)	(38,991)	
GROSS PROFIT	26,556	24,411	28,654	26,430	
Research & development expenses	(7,726)	(6,963)	(8,337)	(7,539)	
Selling, general & administrative expenses	(39,364)	(37,261)	(42,473)	(40,343)	
Total operating expenses	(47,090)	(44,224)	(50,809)	(47,882)	
OPERATING LOSS	(20,534)	(19,813)	(22,156)	(21,452)	
Interest (expense) income, net	560	1,079	604	1,168	
Currency exchange gains (loss), net	1,245	(1,799)	1,344	(1,948)	
LOSS BEFORE INCOME TAXES	(18,729)	(20,533)	(20,208)	(22,232)	
Income tax (expense) credit, net	(289)	(644)	(312)	(698)	
NET LOSS	(19,018)	(21,178)	(20,520)	(22,930)	
Loss per share – Basic and diluted	(0.51)	(0.57)	(0.55)	(0.62)	
Average number of shares used in computation of basic and diluted EPS	37,286,446	36,996,722	37,286,446	36,996,722	

NOTE: Translated for convenience of the reader to U.S. dollars at the 2024 average twelve months' exchange rate of 1 Euro = 1.0790 USD, and 2023 average twelve months' exchange rate of 1 Euro = 1.0827 USD

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

	December 31, 2024 Euros	December 31, 2023 Euros	December 31, 2024 \$US	December 31, 2023 \$US
Cash, cash equivalents and short-term investments	29,836	43,471	30,883	48,087
Accounts receivable, net	20,288	19,238	21,000	21,281
Inventory	18,495	15,112	19,143	16,717
Other current assets	1,258	659	1,302	729
TOTAL CURRENT ASSETS	69,876	78,480	72,328	86,814
Property, plant and equipment, net	10,336	8,193	10,699	9,063
Goodwill	2,412	2,412	2,496	2,668
Other non-current assets	3,439	2,464	3,560	2,725
TOTAL ASSETS	86,063	91,548	89,083	101,270
Accounts payable & other accrued liabilities	21,350	18,435	22,099	20,392
Deferred revenues, current portion	6,641	4,049	6,874	4,479
Short term borrowing	6,243	2,466	6,462	2,728
Other current liabilities	3,577	2,646	3,702	2,927
TOTAL CURRENT LIABILITIES	37,811	27,596	39,138	30,526
Obligations under operating and finance leases non-current	1,939	1,315	2,007	1,454
Long-term debt, non-current	2,162	1,997	2,238	2,209
Deferred revenues, non-current	358	643	370	712
Other long-term liabilities	2,897	3,075	2,999	3,402
TOTAL LIABILITIES	45,167	34,626	46,752	38,304
TOTAL SHAREHOLDERS'EQUITY	40,896	56,922	42,331	62,966
TOTAL LIABILITIES & SHAREHOLDERS' EQUITY	86,063	91,548	89,083	101,270

NOTE: Translated for convenience of the reader to U.S. dollars at the exchange rate of 1 Euro = 1.0351 USD, on December 31, 2024 and at the exchange rate of 1 Euro = 1.1062 USD, on December 31, 2023.

#### EDAP TMS S.A. UNAUDITED CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS (Amounts in thousands of Euros and U.S. Dollars)

	Year Ended December 31, 2024 (Euros)	Twelve Months Ended December 31, 2023 (Euros)	Year Ended December 31, 2024 (\$US)	Twelve Months Ended December 31, 2023 (\$US)
NET INCOME (LOSS)	(19,018)	(21,178)	(20,520)	(22,930)
Adjustments to reconcile net income (loss) to net cash generated by (used in) operating activities <sup>(1)</sup>	7,395	9,403	7,979	10,181
OPERATING CASH FLOW	(11,623)	(11,775)	(12,541)	(12,749)
Increase/Decrease in operating assets and liabilities	(1,961)	(2,903)	(2,116)	(3,144)
NET CASH GENERATED BY (USED IN) OPERATING ACTIVITIES	(13,584)	(14,678)	(14,657)	(15,892)
Additions to capitalized assets produced by the company and other capital expenditures	(4,120)	(4,344)	(4,445)	(4,704)
NET CASH GENERATED BY (USED IN) INVESTING ACTIVITIES	(4,120)	(4,344)	(4,445)	(4,704)
NET CASH GENERATED BY (USED IN) FINANCING ACTIVITIES	4,635	(911)	5,001	(986)
NET EFFECT OF EXCHANGE RATE CHANGES ON CASH AND CASH EQUIVALENTS	(566)	268	(3,103)	2,130
NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS	(13,635)	(19,666)	(17,204)	(19,452)

<sup>(1)</sup> including share based compensation expenses for 3,283 thousand of Euros for the year ended December 31, 2024 and 6,865 thousand of Euros for the full year ended December 31, 2023.

NOTE: Translated for convenience of the reader to U.S. dollars at the 2024 average twelve months' exchange rate of 1 Euro = 1.0790 USD, and 2023 average twelve months exchange rate of 1 Euro = 1.0827 USD

#### EDAP TMS S.A. UNAUDITED CONDENSED STATEMENTS OF OPERATIONS BY DIVISION twelve months ended December 31, 2024 (Amounts in thousands of Euros)

	HIFU Division		ESWL Division		Distribution Division		Reconciling Items	Total After Consolidation	
Sales of goods	14,825		3,481		25,731			44,037	
Net sales of RPP and leases	6,273		1,033		304		—	7,610	
Sales of spare parts, supplies and services	2,741		4,468		5,258			12,468	
TOTAL REVENUES	23,839		8,982		31,293			64,114	
GROSS PROFIT (% of Net Sales)	12,272	51.5 %	3,486	38.8 %	10,798	34.5 %		26,556	41.4 %
Research & development expenses	(6,693)		(365)		(668)			(7,726)	
Selling, general & administrative expenses	(23,038)		(1,911)		(10,700)		(3,714)	(39,364)	
OPERATING PROFIT (LOSS)	(17,459)		1,210		(571)		(3,714)	(20,534)	

NOTE: Reconciling Items include headquarters costs.