



FocalTherics™ Reports Second Quarter 2026 Financial Results

Aug 13, 2026

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AUSTIN, Texas, Aug. 13, 2026 (GLOBE NEWSWIRE) -- FocalTherics™ (Nasdaq: FOCL) (the "Company"), a global leader in robotic focal therapy, today announced financial results for the second quarter of 2026. This marks the Company's first reporting period presenting its HIFU business as continuing operations and its ESWL and Distribution businesses as discontinued operations.

Second Quarter 2026 Results and Recent Highlights of Continuing Operations (HIFU Segment)

- Increased Revenue to \$13.2 million, a 39% Increase Compared to the Prior Year Period
- Delivered 47% U.S. Procedure Volume Growth over the Prior Year Period
- Recorded 13 Focal One® Capital System Sales compared to 9 in the Prior Year Period, including 2 Conversions from Operating Leases
- Expanded Focal One System Installed Base to 184, including 96 in the U.S. and 88 Internationally
- Achieved 55.6% Gross Margin, Compared to 51.1% in the Prior Year Period
- Completed Corporate Name Change to FocalTherics™
- Launched First Commercial Focal One Endometriosis Program in Europe
- Announced Underwritten Public Offering for \$40 million of Gross Proceeds Expected to Close August 14, 2026

"We continue to demonstrate commercial success with our strongest second quarter ever, reflecting the growing strength of our core business and further supporting the strategic shift to Focal Therapy with our corporate rebranding to FocalTherics," said Ryan Rhodes, CEO of FocalTherics. "Along with strong commercial momentum, we are also pleased with the developing progress of the endometriosis commercial launch in Europe and look forward to establishing additional Focal One programs to increase access to an important, non-surgical option for women with this highly debilitating condition. In addition, with expected proceeds from our ongoing capital raise, we will continue to accelerate commercial adoption in the global prostate cancer market while leveraging our multi-indication Focal One platform to grow market opportunities in treating endometriosis and expanding into benign prostatic hyperplasia or BPH. We will also continue to invest in our innovation and product development initiatives driving advances in AI-assisted treatments, FocalConnect™ telecollaboration technology, and integrating histotripsy together with HIFU on our Focal One platform."

Second Quarter 2026 Financial Results for Continuing Operations (HIFU Segment)

Total revenue for the second quarter of 2026 was \$13.2 million, compared to \$9.5 million for the same period in 2025, representing an increase of 39% year-over-year. The Company sold thirteen Focal One systems during the quarter, versus nine systems in the same period in 2025, representing a year-over-year growth of 44%. The Company's U.S. Focal One procedures grew 47% year-over-year.

Gross margin for the second quarter of 2026 was 55.6%, compared to 51.1% in the prior year period. The increase in gross margin was primarily attributable to improvement of the standard cost of the Focal One system and favorable absorption due to higher production volumes.

Operating expenses were \$15.4 million for the second quarter of 2026, compared to \$11.5 million in the prior year period. These expenses included approximately \$0.8 million in one-time costs primarily attributable to corporate initiatives regarding rebranding, domestic filer transition and discontinued operations classification.

Operating loss was \$8.0 million for the second quarter of 2026, compared to \$6.6 million in the prior year period. Net loss was \$14.4 million for the second quarter of 2026, or (\$0.38) per share, compared to a net loss of \$6.4 million, or (\$0.17) per share in the prior year period. The increase in net loss was primarily attributable to the European Investment Bank warrant valuation impact of \$5.5 million during the quarter.

Cash and cash equivalents as of June 30, 2026 totaled \$21.5 million.

Reiterating 2026 Guidance for Continuing Operations (HIFU Segment)

- Total revenue of \$50.0 - \$54.0 million, representing 34% - 45% year-over-year growth

Discontinued Operations

During the second quarter of 2026, the ESWL and Distribution segments met the criteria to be classified as held for sale under ASC 205-20, Presentation of Financial Statements — Discontinued Operations, and ASC 360-10, Property, Plant, and Equipment, and the Company determined that the planned exit represents a strategic shift that will have a significant effect on the Company's operations and financial results. Accordingly, the Company's unaudited financial results as of and for the three and six months ended June 30, 2026 reflect the Company's ESWL and Distribution operating segments as discontinued operations.

Prior-period results presented in this release have been recast to reflect this classification on a consistent basis. As a result, all continuing operations figures and growth rates presented herein reflect the Company's HIFU business only.

Conference Call Information

A conference call and webcast to discuss the second quarter 2026 financial results will be hosted by Ryan Rhodes, Chief Executive Officer and Ken Mobeck, Chief Financial Officer. Please refer to the information below for conference call dial-in information and webcast registration.

Date: Thursday, August 13, 2026, at 4:30 p.m. Eastern Time
Domestic: 1-800-245-3047
International: 1-203-518-9765
Passcode: FOCAL
Webcast: https://viaid.webcasts.com/starthere.jsp?ei=1767672&tp_key=2d69d92ca7

About FocalTherics

A recognized global leader in robotic focal therapy, FocalTherics develops, manufactures, and markets minimally invasive medical devices worldwide to treat various conditions using proprietary focused ultrasound technology. The Company's flagship platform, Focal One Robotic HIFU, combines advanced imaging, real-time treatment planning, robotic precision, and HIFU technology to deliver personalized focal therapy designed to optimize clinical outcomes while preserving quality of life.

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, and include statements such as quote from our Chief Executive Officer, the expected closing and proceeds from our offering, and our financial performance guidance. 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, 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 10-K and Quarterly Report on Form 10-Q.

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.

Investor Contact

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

	Three Months Ended:	
	June 30, 2026 \$US	June 30, 2025 \$US
Sales of goods	9,527	6,385
Sales of RPPs & leases	2,758	2,155
Sales of spare parts and services	918	969
TOTAL NET SALES	13,203	9,509
Other revenues	(0)	—
TOTAL REVENUES	13,203	9,509
Cost of sales	(5,865)	(4,646)
GROSS PROFIT	7,338	4,863
Research & development expenses	(2,317)	(2,291)
Selling, general & administrative expenses	(13,054)	(9,194)
Total operating expenses	(15,371)	(11,485)
LOSS FROM OPERATIONS	(8,033)	(6,623)
Interest (expense) income, net	(748)	(79)
		•
Loss from change in fair value of warrant liability	(5,547)	
Currency exchange gains (loss), net	(76)	362
LOSS BEFORE TAXES FROM CONTINUING OPERATIONS	(14,404)	(6,340)
Income tax (expense) credit, net from continuing operations	(8)	(14)
LOSS FROM CONTINUING OPERATIONS	(14,412)	(6,354)
Income(loss) from discontinued operations, net of tax	(75)	(51)

NET LOSS	(14,487)	(6,406)
Loss per share – Basic and diluted	(0.39)	(0.17)
Average number of shares used in computation of EPS - basic and dilutive	37,527,950	37,420,318

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

	Six Months Ended:	
	June 30, 2026 \$US	June 30, 2025 \$US
Sales of goods	17,782	10,185
Sales of RPPs & leases	5,250	4,100
Sales of spare parts and services	1,764	1,724
TOTAL REVENUES	24,796	16,009
Cost of sales	(11,496)	(7,989)
GROSS PROFIT	13,300	8,020
Research & development expenses	(4,784)	(4,648)
Selling, general & administrative expenses	(24,574)	(16,739)
Total operating expenses	(29,357)	(21,388)
LOSS FROM OPERATIONS	(16,057)	(13,368)
Interest (expense) income, net	(1,151)	(81)
Loss from change in fair value of warrant liability	(6,851)	—
Currency exchange gains (loss), net	77	(664)
LOSS BEFORE TAXES FROM CONTINUING OPERATIONS	(23,982)	(14,113)
Income tax (expense) credit, net from continuing operations	(25)	(23)
LOSS FROM CONTINUING OPERATIONS	(24,007)	(14,135)
Income(loss) from discontinued operations, net of tax	437	285
NET LOSS	(23,570)	(13,850)
Loss per share – Basic and diluted	(0.63)	(0.37)
Average number of shares used in computation of EPS - basic and dilutive	37,481,986	37,406,202

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UNAUDITED CONDENSED CONSOLIDATED BALANCE SHEETS
(Amounts in thousands of U.S. Dollars)

	June 30, 2026 \$US	December 31, 2025 \$US
Cash, cash equivalents	21,542	20,452
Accounts receivable, net	10,060	14,948
Inventory	8,251	7,770
Other current assets	2,350	2,439
Total current assets of discontinued operations	16,812	11,555
TOTAL CURRENT ASSETS	59,015	57,164
Property, plant and equipment, net	8,635	8,789
Goodwill	735	757
Other non-current assets	6,164	6,181
Total non-current assets of discontinued operations	-	6,106
TOTAL ASSETS	74,548	78,997
Accounts payable & other accrued liabilities	17,830	17,436
Deferred revenues, current portion	6,395	6,452
Short term borrowing	1,860	4,386
Other current liabilities	1,786	3,005
Total current liabilities of discontinued operations	8,978	5,862
TOTAL CURRENT LIABILITIES	36,849	37,141
Obligations under operating and finance leases non-current	835	1,183
Long-term debt, non-current	37,197	15,903
Deferred revenues, non-current	923	768
Other long-term liabilities	1,970	1,632
Total non-current liabilities of discontinued operations	-	2,957
TOTAL LIABILITIES	77,773	59,584

TOTAL SHAREHOLDERS' EQUITY	(3,225)	19,413
TOTAL LIABILITIES & SHAREHOLDERS' EQUITY	74,548	78,997

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UNAUDITED CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS
(Amounts in thousands of U.S. Dollars)

	Six Months Ended June 30, 2026 (\$US)	Six Months Ended June 30, 2025 (\$US)
NET INCOME (LOSS)	(23,570)	(13,850)
Adjustments to reconcile net income (loss) to net cash generated by (used in) operating activities ⁽¹⁾	11,750	3,024
OPERATING CASH FLOW	(11,820)	(10,827)
Increase/Decrease in operating assets and liabilities	5,157	779
NET CASH GENERATED BY (USED IN) OPERATING ACTIVITIES	(6,663)	(10,047)
Short term investments	—	—
Additions to capitalized assets produced by the company and other capital expenditures	(2,017)	(2,917)
NET CASH GENERATED BY (USED IN) INVESTING ACTIVITIES	(2,017)	(2,917)
NET CASH GENERATED BY (USED IN) FINANCING ACTIVITIES	10,402	(1,198)
NET EFFECT OF EXCHANGE RATE CHANGES ON CASH AND CASH EQUIVALENTS	(632)	2,231
NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS	1,090	(11,931)

(1) including share-based compensation expenses for \$1,157,000 for the six months ended June 30, 2026 and \$847,000 for the six months ended June 30, 2025, as well as warrant fair value adjustment of \$4,847,000 related to Tranche A and \$1,597,000 related to Tranche B for the six months ended June 30, 2026

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UNAUDITED CONDENSED STATEMENTS OF OPERATIONS BY DIVISION
six months ended June 30, 2026
(Amounts in thousands of U.S. Dollars)

Six months ended June 30, 2026	HIFU Division		Reconciling Items	Total After Consolidation	
Sales of goods	17,782		—	17,782	
Sales of RPPs & leases	5,250		—	5,250	
Sales of spare parts and services	1,764		—	1,764	
TOTAL REVENUES	24,796		—	24,796	
GROSS PROFIT (% of Net Sales)	13,300	53.6 %	—	13,300	53.6 %
Research & development expenses	(4,784)		—	(4,784)	
Selling, general & administrative expenses	(20,309)		(4,265)	(24,574)	
OPERATING PROFIT (LOSS)	(11,792)		(4,265)	(16,057)	