FocalTherics™ Reports Third Quarter 2026 Financial Results

Nov 05, 2026

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AUSTIN, Texas, Nov. 05, 2026 (GLOBE NEWSWIRE) -- FocalTherics™ (Nasdaq: FOCL) (the "Company"), a global leader in robotic focal therapy, today announced financial results for the third quarter of 2026.

Third Quarter 2026 Results and Recent Highlights

- Increased Revenue to $9.8 million, a 26% Increase Compared to the Prior Year Period
- 32% Increase in U.S. Procedure Volume over the Prior Year Period
- Recorded Seven Focal One® Capital System Sales compared to Six in the Prior Year Period,
- Expanded Focal One System Installed Base to 192, including 98 in the U.S. and 94 Internationally
- Increased Gross Margin to 51.4%, Compared to 46.6% in the Prior Year Period
- Expanded Commercial Focal One Endometriosis Programs to Three Centers in Europe
- Positive Coverage Policies Published by Major Commercial Payers for HIFU in Radiorecurrent Prostate Cancer

"We demonstrated steady commercial momentum in the third quarter, highlighted by expanding adoption across multiple new regions and additional system sales in the United States, Turkey, Mexico, and France," said Ryan Rhodes, CEO of FocalTherics. "U.S. procedure volumes accelerated year-over-year to 32% for the third quarter of 2026, compared to 15% in 2025. Driven by our sustained commercial traction, accelerating technology adoption, and our focus on our HIFU opportunity, we remain highly confident in our growth strategy and on the opportunity ahead as we close out the year."

Third Quarter 2026 Financial Results
Total revenue for the third quarter of 2026 was $9.8 million, compared to $7.8 million for the same period in 2025, representing an increase of 26% year-over-year. The Company sold seven Focal One systems during the quarter, versus six systems in the same period in 2025, representing a year-over-year growth of 17%. The Company's U.S. Focal One procedures grew 32% year-over-year.

Gross margin for the third quarter of 2026 was 51.4%, compared to 46.6% in the prior year period. The increase in gross margin was primarily attributable to improvement on standard cost of the Focal One and higher average selling price of our Focal One systems and Focalpaks.

Operating expenses were $12.8 million for the third quarter of 2026, compared to $10.3 million in the prior year period. The increase was due to incremental headcount-related compensation costs including higher stock-based compensation, and additional sales and marketing expenses related to various Urology meetings and events.

Operating loss was $7.8 million for the third quarter of 2026, compared to $6.7 million in the prior year period. Net loss was $4.5 million for the third quarter of 2026, or ($0.10) per share, compared to a net loss of $5.9 million, or ($0.16) per share in the prior year period. The decrease in net loss was primarily attributable to favorable non-cash impact of $2.6 million related to change in fair value of the European Investment Bank warrants and $0.5 million foreign currency exchange gain, partially offset by the higher operating loss of $1.1 million and $0.4 million of interest expense on the Tranche A and Tranche B drawdown.

Cash and cash equivalents as of September 30, 2026 totaled $56.3 million.

Narrowing 2026 Guidance
We are narrowing our full-year 2026 revenue guidance to be in the range of $50.0 to $52.0 million, representing 34% to 39% growth over 2025, from the prior range of $50.0 to $54.0 million.
We have included standalone historical financials for the HIFU business at the end of the document
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, November 5, 2026, at 4:30 p.m. Eastern Time
Domestic:	1-833-419-0865
International:	1-785-838-9333
Passcode:	FOCAL
Webcast:	https://viavid.webcasts.com/starthere.jsp?ei=1776674&tp_key=37ee4700b1

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 and our narrowed 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 our ability to successfully discontinue and wind down 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 Reports 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.

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

	Three Months Ended:	
	September 30, 2026 $US	**September 30, 2025 $US**
Sales of goods	6,489	4,895
Sales of RPP and leases	2,367	2,216
Sales of spare parts and services	972	717
TOTAL NET SALES	**9,828**	**7,828**
Other revenues	—	(0)
TOTAL REVENUES	**9,828**	**7,828**
Cost of sales	(4,776)	(4,181)
GROSS PROFIT	**5,053**	**3,647**
Research & development expenses	(2,458)	(2,303)
Selling, general & administrative expenses	(10,371)	(8,014)
Total operating expenses	(12,829)	(10,316)
LOSS FROM OPERATIONS	**(7,777)**	**(6,669)**
Interest (expense) income, net	(559)	(60)
Gain (loss) from change in fair value of warrants liability	2,596	—
Currency exchange gains (loss), net	467	85
LOSS BEFORE TAXES FROM CONTINUING OPERATIONS	**(5,272)**	**(6,645)**
Income tax (expense) credit, net from continuing operations	(15)	(16)
LOSS FROM CONTINUING OPERATIONS	**(5,287)**	**(6,661)**
Income(loss) from discontinued operations, net of tax	825	721
NET LOSS	**(4,462)**	**(5,940)**
Loss per share – Basic and diluted	(0.10)	(0.16)
Average number of shares used in computation of EPS - basic and dilutive	42,625,694	37,438,630

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

	Nine Months Ended:	
	September 30, 2026 $US	**September 30, 2025 $US**
Sales of goods	24,272	15,081
Sales of RPP and leases	7,617	6,315

Sales of spare parts and services	2,736	2,441
TOTAL REVENUES	**34,624**	**23,838**
Cost of sales	(16,271)	(12,170)
GROSS PROFIT	**18,353**	**11,667**
Research & development expenses	(7,242)	(6,951)
Selling, general & administrative expenses	(34,945)	(24,753)
Total operating expenses	(42,186)	(31,704)
LOSS FROM OPERATIONS	**(23,834)**	**(20,037)**
Interest (expense) income, net	(1,710)	(142)
Gain (loss) from change in fair value of warrants liability	(4,254)	—
Currency exchange gains (loss), net	544	(579)
LOSS BEFORE TAXES FROM CONTINUING OPERATIONS	**(29,254)**	**(20,757)**
Income tax (expense) credit, net from continuing operations	(40)	(39)
LOSS FROM CONTINUING OPERATIONS	**(29,294)**	**(20,796)**
Income(loss) from discontinued operations, net of tax	**1,263**	**1,006**
NET LOSS	**(28,032)**	**(19,790)**
Loss per share – Basic and diluted	(0.71)	(0.53)
Average number of shares used in computation of EPS - basic and dilutive	39,227,611	37,417,439

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

	September 30, 2026 $US	December 31, 2025 $US
Cash, cash equivalents and short-term investments	56,269	20,452
Accounts receivable, net	10,177	14,948
Inventory	8,329	7,770
Other current assets	2,681	2,439
Total current assets of discontinued operations	17,328	11,555
TOTAL CURRENT ASSETS	**94,784**	**57,164**
Property, plant and equipment, net	9,052	8,789
Goodwill	732	757
Other non-current assets	6,149	6,181
Total non-current assets of discontinued operations	—	6,106
TOTAL ASSETS	**110,717**	**78,997**
Accounts payable & other accrued liabilities	17,857	17,436
Deferred revenues, current portion	7,326	6,452
Short term borrowing	426	4,386
Other current liabilities	1,318	3,005
Total current liabilities of discontinued operations	9,143	5,862
TOTAL CURRENT LIABILITIES	**36,070**	**37,141**
Obligations under operating and finance leases non-current	615	1,183
Long-term debt, non-current	35,233	15,903
Deferred revenues, non-current	898	768
Other long-term liabilities	1,963	1,632
Total non-current liabilities of discontinued operations	—	2,957
TOTAL LIABILITIES	**74,779**	**59,584**
TOTAL SHAREHOLDERS'EQUITY	**35,938**	**19,413**
TOTAL LIABILITIES & SHAREHOLDERS' EQUITY	**110,717**	**78,997**

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

	Nine Months Ended September 30, 2026 ($US)	Nine Months Ended September 30, 2025 ($US)
NET INCOME (LOSS)	**(28,032)**	**(19,790)**

Adjustments to reconcile net income (loss) to net cash generated by (used in) operating activities[1]	12,450	5,136
OPERATING CASH FLOW	**(15,582)**	**(14,654)**
Increase/Decrease in operating assets and liabilities	4,895	699
NET CASH GENERATED BY (USED IN) OPERATING ACTIVITIES	**(10,687)**	**(13,955)**
Additions to capitalized assets produced by the company and other capital expenditures	(3,361)	(4,002)
NET CASH GENERATED BY (USED IN) INVESTING ACTIVITIES	**(3,361)**	**(4,002)**
NET CASH GENERATED BY (USED IN) FINANCING ACTIVITIES	**50,707**	**(2,847)**
NET EFFECT OF EXCHANGE RATE CHANGES ON CASH AND CASH EQUIVALENTS	**(842)**	**2,217**
NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS	**35,817**	**(18,587)**

(1) *including share-based compensation expenses for $2,359 thousand for the nine months ended September 30, 2026 and $1,746 thousand for the nine months ended September 30, 2025, as well as warrant fair value adjustment of $3,036 thousand related to Tranche A and $839 thousand related to Tranche B for the nine months ended September 30, 2026*

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

Nine months ended September 30, 2026	**HIFU Division**		**Reconciling Items**	**Total After Consolidation**	
Sales of goods	24,272		—	24,272	
Sales of RPP and leases	7,617		—	7,617	
Sales of spare parts and services	2,736		—	2,736	
TOTAL REVENUES	**34,624**		**—**	**34,624**	
GROSS PROFIT (% of Net Sales)	**18,353**	**53.0 %**	**—**	**18,353**	**53.0 %**
Research & development expenses	(7,242)		—	(7,242)	
Selling, general & administrative expenses	(29,046)		(5,899)	(34,945)	
OPERATING PROFIT (LOSS)	**(17,935)**		**(5,899)**	**(23,834)**	

EDAP TMS S.A.
UNAUDITED CONDENSED STATEMENTS OF OPERATIONS BY DIVISION
three months ended September 30, 2026
(Amounts in thousands of U.S. Dollars)

Three months ended September 30, 2026	**HIFU Division**		**Reconciling Items**	**Total After Consolidation**	
Sales of goods	6,489		—	6,489	
Sales of RPP and leases	2,367		—	2,367	
Sales of spare parts and services	972		—	972	
TOTAL REVENUES	**9,828**		**(0)**	**9,828**	
GROSS PROFIT (% of Net Sales)	**5,053**	**51.4 %**	**(0)**	**5,053**	**51.4 %**
Research & development expenses	(2,458)		—	(2,458)	
Selling, general & administrative expenses	(8,737)		(1,634)	(10,371)	
OPERATING PROFIT (LOSS)	**(6,142)**		**(1,634)**	**(7,777)**	

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

Three months ended June 30, 2026	**HIFU Division**		**Reconciling Items**	**Total After Consolidation**	
Sales of goods	9,527		—	9,527	
Sales of RPP and leases	2,758		—	2,758	
Sales of spare parts and services	918		—	918	
TOTAL REVENUES	**13,202**		**—**	**13,202**	
GROSS PROFIT (% of Net Sales)	**7,338**	**55.6 %**	**—**	**7,338**	**55.6 %**
Research & development expenses	(2,317)		—	(2,317)	
Selling, general & administrative expenses	(10,869)		(2,185)	(13,054)	
OPERATING PROFIT (LOSS)	**(5,848)**		**(2,185)**	**(8,033)**	

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UNAUDITED CONDENSED STATEMENTS OF OPERATIONS BY DIVISION
three months ended March 31, 2026
(Amounts in thousands of U.S. Dollars)

Three months ended March 31, 2026	HIFU Division		Reconciling Items	Total After Consolidation	
Sales of goods	8,256		—	8,256	
Sales of RPP and leases	2,492		—	2,492	
Sales of spare parts and services	845		—	845	
TOTAL REVENUES	**11,593**		**—**	**11,593**	
GROSS PROFIT (% of Net Sales)	**5,962**	**51.4 %**	**—**	**5,962**	**51.4 %**
Research & development expenses	(2,467)		—	(2,467)	
Selling, general & administrative expenses	(9,439)		(2,080)	(11,520)	
OPERATING PROFIT (LOSS)	**(5,944)**		**(2,080)**	**(8,024)**	

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UNAUDITED CONDENSED STATEMENTS OF OPERATIONS BY DIVISION
twelve months ended December 31, 2025
(Amounts in thousands of U.S. Dollars)

Twelve months ended December 31, 2025	HIFU Division		Reconciling Items	Total After Consolidation	
Sales of goods	24,857		—	24,857	
Sales of RPP and leases	8,791		—	8,791	
Sales of spare parts and services	3,703		—	3,703	
TOTAL REVENUES	**37,351**		**—**	**37,351**	
GROSS PROFIT (% of Net Sales)	**17,978**	**48.1 %**	**—**	**17,978**	**48.1 %**
Research & development expenses	(8,909)		—	(8,909)	
Selling, general & administrative expenses	(29,748)		(5,843)	(35,591)	
OPERATING PROFIT (LOSS)	**(20,679)**		**(5,843)**	**(26,522)**	

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UNAUDITED CONDENSED STATEMENTS OF OPERATIONS BY DIVISION
three months ended December 31, 2025
(Amounts in thousands of U.S. Dollars)

Three months ended December 31, 2025	HIFU Division		Reconciling Items	Total After Consolidation	
Sales of goods	9,776		—	9,776	
Sales of RPP and leases	2,476		—	2,476	
Sales of spare parts and services	1,262		—	1,262	
TOTAL REVENUES	**13,513**		**(0)**	**13,513**	
GROSS PROFIT (% of Net Sales)	**6,311**	**46.7 %**	**(0)**	**6,311**	**46.7 %**
Research & development expenses	(1,958)		—	(1,958)	
Selling, general & administrative expenses	(8,514)		(2,324)	(10,838)	
OPERATING PROFIT (LOSS)	**(4,161)**		**(2,324)**	**(6,485)**	

EDAP TMS S.A.
UNAUDITED CONDENSED STATEMENTS OF OPERATIONS BY DIVISION
three months ended September 30, 2025
(Amounts in thousands of U.S. Dollars)

Three months ended September 30, 2025	HIFU Division		Reconciling Items	Total After Consolidation	
Sales of goods	4,895		—	4,895	
Sales of RPP and leases	2,216		—	2,216	
Sales of spare parts and services	717		—	717	
TOTAL REVENUES	**7,828**		**—**	**7,828**	
GROSS PROFIT (% of Net Sales)	**3,647**	**46.6 %**	**—**	**3,647**	**46.6 %**
Research & development expenses	(2,303)		—	(2,303)	
Selling, general & administrative expenses	(6,756)		(1,258)	(8,014)	
OPERATING PROFIT (LOSS)	**(5,412)**		**(1,258)**	**(6,669)**	

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UNAUDITED CONDENSED STATEMENTS OF OPERATIONS BY DIVISION
three months ended June 30, 2025
(Amounts in thousands of U.S. Dollars)

Three months ended June 30, 2025	HIFU Division		Reconciling Items	Total After Consolidation	
Sales of goods	6,385		—	6,385	
Sales of RPP and leases	2,155		—	2,155	
Sales of spare parts and services	969		—	969	
TOTAL REVENUES	**9,509**		**—**	**9,509**	
GROSS PROFIT (% of Net Sales)	**4,863**	**51.1 %**	**—**	**4,863**	**51.1 %**
Research & development expenses	(2,291)		—	(2,291)	
Selling, general & administrative expenses	(8,036)		(1,158)	(9,194)	
OPERATING PROFIT (LOSS)	**(5,465)**		**(1,158)**	**(6,623)**	

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UNAUDITED CONDENSED STATEMENTS OF OPERATIONS BY DIVISION
three months ended March 31, 2025
(Amounts in thousands of U.S. Dollars)

Three months ended March 31, 2025	HIFU Division		Reconciling Items	Total After Consolidation	
Sales of goods	3,800		—	3,800	
Sales of RPP and leases	1,945		—	1,945	
Sales of spare parts and services	755		—	755	
TOTAL REVENUES	**6,500**		**—**	**6,500**	
GROSS PROFIT (% of Net Sales)	**3,158**	**48.6 %**	**—**	**3,158**	**48.6 %**
Research & development expenses	(2,358)		—	(2,358)	
Selling, general & administrative expenses	(6,441)		(1,104)	(7,545)	
OPERATING PROFIT (LOSS)	**(5,641)**		**(1,104)**	**(6,745)**	

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

Twelve months ended December 31, 2024	HIFU Division		Reconciling Items	Total After Consolidation	
Sales of goods	16,046		—	16,046	
Sales of RPP and leases	6,789		—	6,789	
Sales of spare parts and services	2,967		—	2,967	
TOTAL REVENUES	**25,803**		**—**	**25,803**	
GROSS PROFIT (% of Net Sales)	**13,283**	**51.5 %**	**—**	**13,283**	**51.5 %**
Research & development expenses	(7,245)		—	(7,245)	
Selling, general & administrative expenses	(24,936)		(4,585)	(29,520)	
OPERATING PROFIT (LOSS)	**(18,897)**		**(4,585)**	**(23,482)**	