InspireMD Reports Third Quarter 2024 Financial Results and Provides Business Update

November 12, 2024

– Submitted a Premarket Approval (PMA) application to the FDA seeking marketing approval of the CGuard Prime carotid stent system in the U.S. –

– Announced approval of an IDE application to initiate the CGUARDIANS II pivotal study of the CGuard Prime carotid stent system for use during TCAR procedures –

– Established its Headquarters in Miami, Florida, to optimally support the anticipated U.S. commercial launch of CGuard Prime in H1 2025, if approved –

Achieved another record high revenue and unit quarter of $1.81M and 3,121 respectively in served markets

—

Management to host investor conference call today, November 12th, at 8:30am ET

—

Miami, FL — November 12, 2024– InspireMD, Inc. (Nasdaq: NSPR), developer of the CGuard™ Prime carotid stent system for the treatment of carotid artery disease (CAD) and prevention of stroke, today announced financial and operating results for the third quarter ended September 30, 2024.

Third Quarter 2024 and Recent Developments:

- Announced that it has submitted a Premarket Approval (PMA) application to the U.S. Food and Drug Administration (FDA) seeking marketing approval for the CGuard Prime carotid stent system in the U.S.
- Announced approval of its Investigational Device Exemption (IDE) application to initiate the CGUARDIANS II pivotal study of the CGuard Prime carotid stent system for use during TCAR procedures.
- Established its Headquarters in Miami, Florida, to optimally support the anticipated U.S. commercial launch of CGuard Prime in the first half of 2025, if approved.
- Announced completion of enrollment in the groundbreaking CREST-2 clinical trial, with 23 patients in the stenting arm treated with CGuard, the only investigational device allowed by FDA for inclusion in the trial.
- Generated record quarterly revenue of $1.81 million, an increase of 16.3% over the third quarter of 2023, on 3,129 CGuard stents sold, up nearly 14.4% over the third quarter of 2023.

Marvin Slosman, CEO of InspireMD, commented: “Since our last quarterly update, we have made significant progress advancing our best-in-class carotid implant, CGuard Prime, towards potential U.S. approval while also moving toward the initiation of a pivotal study of CGuard Prime for a TCAR indication, which represents a key component of our commercial strategy.”

“The submission of our PMA application to FDA seeking U.S. approval of CGuard Prime is the result of years of tireless work by the entire InspireMD team and gives us line of sight to entry into the U.S. market in the first half of 2025, if approved. To support a robust launch, we’ve announced the opening of our new headquarters in Miami, Florida, that ideally positions us to support the world class commercial and operational infrastructure that we are assembling. South Florida has a rich history of medical device innovation, and we are pleased to be able to continue in that tradition.”

“We also announced that the FDA has approved our IDE application allowing us to move forward with the initiation of a pivotal trial of CGuard Prime for use in TCAR procedures. This represents an important step in the advancement of our development pipeline and demonstrates our commitment to addressing the broadest set of physician and patient needs with tools for both CAS and TCAR procedures. I look forward to additional clinical and regulatory milestones in the months ahead, highlighted by the potential U.S. approval and commercial launch of CGuard Prime in the first half of next year,” Mr. Slosman concluded.

Financial Results for the Third Quarter Ended September 30, 2024

For the three months ended September 30, 2024, revenue increased by $254,000, or 16.3%, to $1,810,000, from $1,556,000 during the three months ended September 30, 2023. This increase was driven by growth in existing and new markets.

For the three months ended September 30, 2024, gross profit (revenue less cost of revenues) decreased by $24,000, or 5.6%, to $414,000, from $438,000 during the three months ended September 30, 2023. This decrease in gross profit resulted from a

$24,000 increase in miscellaneous expense. Gross margin (gross profits as a percentage of revenue) decreased to 22.9% during the three months ended September 30, 2024, from 28.1% during the three months ended September 30, 2023, driven by the factor mentioned above.

Total operating expenses for the third quarter of 2024 were $8,876,000, an increase of $2,799,000, or 46.1%, compared to $6,077,000 for the third quarter of 2023. This increase was primarily due to an increase in compensation, clinical and development expenses in preparation for U.S. approval and launch.

Financial Income for the third quarter of 2024 was $572,000, an increase of $111,000, or 24.1%, compared to $461,000 for the third quarter of 2023. The increase in financial income primarily resulted from an increase in interest income from investments in marketable securities, money market funds and short-term bank deposits.

Net loss for the third quarter of 2024 totaled $7,890,000, or $0.16 per basic and diluted share, compared to a net loss of $5,178,000, or $0.15 per basic and diluted share, for the same period in 2023.

As of September 30, 2024, cash, cash equivalents and marketable securities were $40.4 million, compared to $39.0 million as of December 31, 2023.

Financial Results for the Nine Months Ended September 30, 2024

For the nine months ended September 30, 2024, revenue increased by $616,000, or 13.9%, to $5,060,000 from $4,444,000 during the nine months ended September 30, 2023. This sales increase was due to growth in existing and new markets, partially offset by a reduction in clinical trial revenue driven by the conclusion of C-GUARDIANS enrollment in June 2023.

For the nine months ended September 30, 2024, gross profit (revenue less cost of revenues) decreased by 20.4%, or $265,000, to $1,037,000, compared to $1,302,000 for the same period in 2023. This decrease in gross profit resulted from an increase in material and labor costs mainly due to compensation expense for new and current employees, higher sales volume, additional space to build capacity for anticipated increased volume requirements and additional training expenses. There were also additional costs related to facility downtime for maintenance and higher scrap due to increases in production levels. This decrease was offset by an increase in revenue.

Total operating expenses for the nine months ended September 30, 2024, were $25,173,000, an increase of $8,536,000, or 51.3%, compared to $16,637,000 for the nine months ended September 30, 2023. This increase was primarily due to an increase in compensation and development expenses.

Financial Income for the nine months ended September 30, 2024 was $1,305,000, an increase of $481,000, or 58.4%, compared to $824,000 for the nine months ended September 30, 2023. The increase in financial income was driven primarily from a $478,000 increase in interest income from investments in marketable securities, money market funds and short-term bank deposits.

Net loss for the nine months ended September 30, 2024 totaled $22,831,000, or $0.58 per basic and diluted share, compared to a net loss of $14,511,000, or $0.69 per basic and diluted share, for the nine months ended September 30, 2023.

Conference Call and Webcast Details

Management will host a conference call at 8:30 am ET today, November 12th, to review financial results and provide an update on corporate developments. Following management's formal remarks, there will be a question-and-answer session.

Tuesday, November 12th at 8:30 a.m. ET

Domestic:	1-800-225-9448
International:	1-203-518-9708
Conference ID:	IMD3Q24
Webcast:	Webcast Link – Click Here

About InspireMD, Inc.

InspireMD seeks to utilize its proprietary MicroNet® technology to make its products the industry standard for carotid stenting by providing outstanding acute results and durable, stroke-free, long-term outcomes. InspireMD's common stock is quoted on the Nasdaq under the ticker symbol NSPR.

We routinely post information that may be important to investors on our website. For more information, please visit inspiremd.com.

Forward-looking Statements

This press release contains "forward-looking statements." Forward-looking statements include, but are not limited to, statements regarding InspireMD or its management team's expectations, hopes, beliefs, intentions or strategies regarding future events, future financial performance, strategies, expectations, competitive environment and regulation, including potential U.S. commercial launch. Such statements may be preceded by the words "intends," "may," "will," "plans," "expects," "anticipates," "projects," "predicts," "estimates," "aims," "believes," "hopes," "potential", "scheduled" or similar words. Forward-looking statements are not guarantees of future performance, are based on certain assumptions and are subject to various known and unknown risks and uncertainties, many of which are beyond the company's control, and cannot be predicted or quantified and consequently, actual results may differ materially from those expressed or implied by such forward-looking statements. Such risks and uncertainties include, without limitation, risks and uncertainties associated with our history of recurring losses and negative cash flows from operating activities; substantial doubt about our ability to continue as a going concern; significant future commitments and the uncertainty regarding the adequacy of our liquidity to pursue our complete business objectives; our need to raise additional capital to meet our business requirements in the future and such capital raising may be costly or difficult to obtain and could dilute out stockholders' ownership interests; market acceptance of our products; an inability to secure and maintain regulatory approvals for the sale of our products; negative clinical trial results or lengthy product delays in key markets; our ability to maintain compliance with the Nasdaq listing standards; our ability to generate revenues from our products and obtain and maintain regulatory approvals for our products; our ability to adequately protect our intellectual property; our dependence on a single manufacturing facility and our ability to comply with stringent manufacturing quality standards and to increase production as necessary; the risk that the data collected from our current and planned clinical trials may not be sufficient to demonstrate that our technology is an attractive alternative to other procedures and products; intense competition in our industry, with competitors having substantially greater financial, technological, research and development, regulatory and clinical, manufacturing, marketing and sales, distribution and personnel resources than we do; entry of new competitors and products and potential technological obsolescence of our products; inability to carry out research, development and commercialization plans; loss of a key customer or supplier; technical problems with our research and products and potential product liability claims; product malfunctions; price increases for supplies and components; insufficient or inadequate reimbursement by governmental and other third-party payers for our products; our efforts to successfully obtain and maintain intellectual property protection covering our products, which may not be successful; adverse federal, state and local government regulation, in the United States, Europe or Israel and other foreign jurisdictions; the fact that we conduct business in multiple foreign jurisdictions, exposing us to foreign currency exchange rate fluctuations, logistical and communications challenges, burdens and costs of compliance with foreign laws and political and economic instability in each jurisdiction; the escalation of hostilities in Israel, which could impair our ability to manufacture our products; and current or future unfavorable economic and market conditions and adverse developments with respect to financial institutions and associated liquidity risk. More detailed information about the Company and the risk factors that may affect the realization of forward-looking statements is set forth in the Company's filings with the Securities and Exchange Commission (SEC), including the Company's Annual Report on Form 10-K and its Quarterly Reports on Form 10-Q. Investors and security holders are urged to read these documents free of charge on the SEC's web site at https://www.sec.gov. The Company assumes no obligation to publicly update or revise its forward-looking statements as a result of new information, future events or otherwise.

Investor Contacts:

Craig Shore

Chief Financial Officer

InspireMD, Inc.

888-776-6804

craigs@inspiremd.com

Chuck Padala, Managing Director

LifeSci Advisors

646-627-8390

chuck@lifesciadvisors.com

investor-relations@inspiremd.com

CONSOLIDATED BALANCE SHEETS [(2)]

(U.S. dollars in thousands)

ASSETS	**September 30,**	**December 31,**

	2024	2023
Current Assets:		
Cash and cash equivalents	$15,818	$9,640
Marketable securities	24,584	29,383
Accounts receivable:		
Trade, net	1,530	1,804
Other	741	648
Prepaid expenses	1,276	578
Inventory	2,445	2,106
Total current assets	46,394	44,159
Non-current assets:		
Property, plant and equipment, net	1,946	1,060
Operating lease right of use assets	1,145	1,473
Funds in respect of employee rights upon retirement	996	951
Total non-current assets	4,087	3,484
Total assets	$50,481	$47,643

LIABILITIES AND EQUITY	**September 30, 2024**	**December 31, 2023**
Current liabilities:		
Accounts payable and accruals:		
Trade	1,305	939
Other	5,960	5,081
Total current liabilities	7,265	6,020
Long-term liabilities:		
Operating lease liabilities	682	1,038
Liability for employees rights upon retirement	1,183	1,084
Total long-term liabilities	1,865	2,122
Total liabilities	9,130	8,142
Equity:		
Common stock, par value $0.0001 per share; 150,000,000 shares authorized at September 30, 2024 and December 31, 2023; 25,719,632 and 21,841,215 shares issued and outstanding at September 30, 2024 and December 31, 2023, respectively	3	2
Preferred C shares, par value $0.0001 per share;		
1,172,000 shares authorized at September 30, 2024 and December 31, 2023; 1,718 shares issued and outstanding at September 30, 2024 and December 31, 2023, respectively	*	*

Additional paid-in capital	285,680	261,000
Accumulated deficit	(244,332)	(221,501)
Total equity	41,351	39,501
Total liabilities and equity	$50,481	$47,643

(1) All 2024 financial information is derived from the Company's 2024 unaudited financial statements, as disclosed in the Company's Quarterly Report on Form 10-Q, filed with the Securities and Exchange Commission; all 2023 financial information is derived from the Company's 2023 unaudited financial statements, as disclosed in the Company's Quarterly Report on Form 10-Q, filed with the Securities and Exchange Commission.

(2) All September 30, 2024, financial information is derived from the Company's 2024 unaudited financial statements, as disclosed in the Company's Quarterly Report on Form 10-Q, filed with the Securities and Exchange Commission. All December 31, 2023 financial information is derived from the Company's 2023 audited financial statements as disclosed in the Company's Annual Report on Form 10-K, for the twelve months ended December 31, 2023 filed with the Securities

CONSOLIDATED STATEMENTS OF OPERATIONS [(1)]

(U.S. dollars in thousands, except per share data)

	Three months ended September 30,		**Nine months ended September 30,**	
	2024	**2023**	**2024**	**2023**
Revenues	$1,810	$1,556	$5,060	$4,444
Cost of revenues	1,396	1,118	4,023	3,142
Gross Profit	414	438	1,037	1,302
Operating Expenses:				
Research and development	3,915	2,110	9,941	5,946
Selling and marketing	1,472	876	4,154	2,556
General and administrative	3,489	3,091	11,078	8,135
Total operating expenses	8,876	6,077	25,173	16,637
Loss from operations	(8,462)	(5,639)	(24,136)	(15,335)
Financial income	572	461	1,305	824
Net Loss	$(7,890)	$(5,178)	$(22,831)	$(14,511)

Net loss per share – basic and diluted	$(0.16)	$(0.15)	$(0.58)	$(0.69)
Weighted average number of shares of common stock used in computing net loss per share – basic and diluted	48,369,412	33,984,953	39,413,004	21,148,538