



NEWS RELEASE

# Inspire Medical Systems, Inc. Announces Second Quarter 2022 Financial Results and Updates 2022 Outlook

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Inspire Reports Year-over-Year Revenue Growth of 73% in the Second Quarter

MINNEAPOLIS, Aug. 02, 2022 (GLOBE NEWSWIRE) -- Inspire Medical Systems, Inc. (NYSE: INSP) (Inspire), a medical technology company focused on the development and commercialization of innovative, minimally invasive solutions for patients with obstructive sleep apnea, today reported financial results for the quarter ended June 30, 2022.

## Recent Business Highlights

- Generated revenue of \$91.4 million in the second quarter of 2022, a 73% increase over the same quarter last year
- Achieved gross margin of 84.5% in the second quarter of 2022
- Activated 52 new centers in the U.S. in the second quarter of 2022, bringing the total to 785 U.S. medical centers providing Inspire therapy
- Created 17 new U.S. sales territories in the second quarter of 2022, bringing the total to 191 U.S. sales territories
- Received U.S. Food and Drug Administration (FDA) approval of expanded full-body MRI compatibility for Inspire therapy
- Introduced Inspire SleepSync™ Digital Health enabled by a new Bluetooth® Patient Remote at SLEEP 2022, the 36<sup>th</sup> annual meeting of the Associated Professional Sleep Societies
- Received FDA Breakthrough Device Designation for application to increase upper limit of Apnea Hypopnea

Index (AHI) to up to 100 events per hour from the original 65 events per hour, and to raise the Body Mass Index (BMI) warning for patients with a BMI of up to 40 from the previous limit of 32

"The Inspire team executed extremely well during the second quarter, continuing the rebound from the first quarter that was challenged by both COVID and our normal seasonality. Moreover, our strong second quarter performance overcame several challenges common across the medical technology sector, including supply chain issues, staffing shortages and economic concerns, further highlighting the team's resiliency and commitment to the patient," said Tim Herbert, President and Chief Executive Officer of Inspire Medical Systems. "Importantly, we continue to improve the performance of our Advisor Care Program (ACP), which over 85% of U.S. centers are leveraging, and continues to be the primary method for patients to obtain information about Inspire therapy and connect with a qualified physician. Looking ahead, based on this beneficial trend, as well as our ongoing technology and digital development activities and the positive reimbursement tailwinds, we are raising our full year 2022 revenue guidance to between \$354 million to \$362 million, an increase from our prior guidance of \$336 million to \$344 million."

"We also recently received two important regulatory approvals," continued Mr. Herbert. "The first, for expanded, full-body MRI compatibility, removes a barrier for some patients considering Inspire therapy. The second approval is for new stimulation and sensing silicone leads, which provides improved manufacturability, easier system implantation, increased long-term performance, and enhanced reliability. We are targeting the U.S. launch of the new leads for later in 2022. We also intend to execute the full U.S. launch of the Bluetooth®-enabled patient remote, which is a very important aspect of the SleepSync™ program. Additionally, we plan to submit to the FDA our request to increase Inspire therapy's indication by expanding the upper limit of AHI to 100 events per hour from 65, as well as raising the BMI warning in our indication to 40 from 32. Our application for this expanded indication recently received Breakthrough Device Designation from the FDA, thereby reducing the review time."

"Our international business also continues to gain momentum. In Europe, Germany benefited from a strong rebound in procedure growth in the second quarter, and we expect to maintain this progress throughout the second half of the year. Therapy adoption growth also continues in the Netherlands and in the United Kingdom, and we have made significant reimbursement advancements in France, Belgium, and Austria. In Asia, additional centers in Japan have conducted their first Inspire procedures, and initial Inspire cases have been performed at two separate centers in Singapore," concluded Mr. Herbert.

## Second Quarter 2022 Financial Results

Revenue was \$91.4 million for the three months ended June 30, 2022, a 73% increase from \$53.0 million in the corresponding period in the prior year. U.S. revenue for the quarter was \$87.9 million, an increase of 78% as compared to the prior year quarter. Second quarter revenue outside the U.S. was \$3.5 million, a decrease of 3% as

compared to the second quarter of 2021. While the volume of procedures increased in Europe in the second quarter, revenue was negatively impacted by unfavorable exchange rates.

Gross margin was 84.5% for the three months ended June 30, 2022, compared to 85.8% for the corresponding prior year period, with the reduction primarily due to higher component costs.

Operating expense increased to \$91.2 million for the second quarter of 2022, as compared to \$58.0 million in the corresponding prior year period, an increase of 57%. This planned increase primarily reflected ongoing investments in the expansion of the U.S. and European sales organizations, direct-to-patient marketing programs, continued product development efforts, as well as increased general corporate costs.

Net loss was \$14.5 million for the second quarter of 2022, as compared to \$13.1 million in the corresponding prior year period. The diluted net loss per share for the second quarter of 2022 was \$0.53 per share, as compared to \$0.48 in the prior year period.

As of June 30, 2022, cash, cash equivalents and investments were \$196.3 million, compared to \$224.4 million at December 31, 2021. During the second quarter of 2022, Inspire completed a minority investment in EnsoData, Inc. of \$10 million.

#### Full Year 2022 Guidance

Given the positive trends during the second quarter, Inspire is increasing its full year 2022 revenue guidance to between \$354 million to \$362 million, which would represent growth of 52% to 55% over full year 2021 revenue of \$233.4 million. This compares to the prior revenue guidance of \$336 million to \$344 million.

The Company is adjusting its full year 2022 gross margin guidance to 83% to 85% from the previous guidance of 85% to 86%. The reduction is primarily due to higher costs of certain component parts and potential inventory obsolescence charges associated with product transitions expected to occur during the remainder of fiscal 2022, including the introduction of new silicone leads and the Bluetooth®-enabled patient remote. The amount of the charges, if any, will depend on the timing of the introduction of these products both in the U.S. and outside of the U.S., which is uncertain at this time. Longer term, the Company expects gross margins to return to the prior guidance levels.

Inspire is maintaining its guidance relating to the opening of new U.S. medical centers of 52 to 56 per quarter for the remainder of the year, as well as its guidance of 11 to 12 new territories per quarter for the remainder of the year.

## Webcast and Conference Call

Inspire's management will host a conference call after market close today, Tuesday, August 2, 2022, at 5:00 p.m. Eastern Time to discuss these results and answer questions.

To access the conference call, please preregister on

<https://register.vevent.com/register/BI4058d3e176814a968254dc928152a629>. Registrants will receive confirmation with dial-in details.

A live webcast of the event can be accessed on <https://edge.media-server.com/mmc/p/6ngur2bu>. A replay of the webcast will be available on <https://investors.inspiresleep.com> starting approximately two hours after the event and archived on the site for two weeks

## About Inspire Medical Systems

Inspire is a medical technology company focused on the development and commercialization of innovative, minimally invasive solutions for patients with obstructive sleep apnea. Inspire's proprietary Inspire therapy is the first and only FDA-approved neurostimulation technology that provides a safe and effective treatment for moderate to severe obstructive sleep apnea.

For additional information about Inspire, please visit [www.inspiresleep.com](http://www.inspiresleep.com).

## Forward Looking Statements

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. All statements other than statements of historical facts are forward-looking statements, including, without limitation, statements regarding full year 2022 financial outlook, our expectations to activate new U.S. medical centers and add new territories per quarter in 2022 and the impact of such additions, and our strategy and investments to grow and scale our business. In some cases, you can identify forward-looking statements by terms such as "may," "will," "should," "expect," "plan," "anticipate," "could," "future," "outlook," "guidance," "intend," "target," "project," "contemplate," "believe," "estimate," "predict," "potential," "continue," or the negative of these terms or other similar expressions, although not all forward-looking statements contain these words.

These forward-looking statements are based on management's current expectations and involve known and unknown risks and uncertainties that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements. Such risks and uncertainties include, among others, estimates regarding the annual total addressable

market for our Inspire therapy in the U.S. and our market opportunity outside the U.S.; future results of operations, financial position, research and development costs, capital requirements and our needs for additional financing; commercial success and market acceptance of our Inspire therapy; the impact of the ongoing and global COVID-19 pandemic; general and international economic, political, and other risks, including currency and stock market fluctuations and the uncertain economic environment; our ability to achieve and maintain adequate levels of coverage or reimbursement for our Inspire system or any future products we may seek to commercialize; competitive companies and technologies in our industry; our ability to enhance our Inspire system, expand our indications and develop and commercialize additional products; our business model and strategic plans for our products, technologies and business, including our implementation thereof; our ability to accurately forecast customer demand for our Inspire system and manage our inventory; our dependence on third-party suppliers, contract manufacturers and shipping carriers; consolidation in the healthcare industry; our ability to expand, manage and maintain our direct sales and marketing organization, and to market and sell our Inspire system in markets outside of the U.S.; risks associated with international operations; our ability to manage our growth; our ability to increase the number of active medical centers implanting Inspire therapy; our ability to hire and retain our senior management and other highly qualified personnel; risk of product liability claims; risks related to information technology and cybersecurity; risk of damage to or interruptions at our facilities; our ability to commercialize or obtain regulatory approvals for our Inspire therapy and system, or the effect of delays in commercializing or obtaining regulatory approvals; FDA or other U.S. or foreign regulatory actions affecting us or the healthcare industry generally, including healthcare reform measures in the U.S. and international markets; and the timing or likelihood of regulatory filings and approvals. Other important factors that could cause actual results, performance or achievements to differ materially from those contemplated in this press release can be found under the captions "Risk Factors" and "Management's Discussion and Analysis of Financial Condition and Results of Operations" in our Annual Report on Form 10-K for the fiscal year ended December 31, 2021, as updated in our Quarterly Report on Form 10-Q for the quarter ended June 30, 2022 to be filed with the SEC, and as such factors may be updated from time to time in our other filings with the SEC, which are accessible on the SEC's website at [www.sec.gov](http://www.sec.gov) and the Investors page of our website at [www.inspiresleep.com](http://www.inspiresleep.com). These and other important factors could cause actual results to differ materially from those indicated by the forward-looking statements made in this press release. Any such forward-looking statements represent management's estimates as of the date of this press release. While we may elect to update such forward-looking statements at some point in the future, unless required by applicable law, we disclaim any obligation to do so, even if subsequent events cause our views to change. Thus, one should not assume that our silence over time means that actual events are bearing out as expressed or implied in such forward-looking statements. These forward-looking statements should not be relied upon as representing our views as of any date subsequent to the date of this press release.

Investor & Media Contact:

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Inspire Medical Systems, Inc.

Consolidated Statements of Operations and Comprehensive Loss (unaudited)

(in thousands, except share and per share amounts)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2022	2021	2022	2021
Revenue	\$ 91,386	\$ 52,959	\$ 160,768	\$ 93,311
Cost of goods sold	14,173	7,518	24,177	13,499
Gross profit	77,213	45,441	136,591	79,812
Operating expenses:				
Research and development	14,534	9,288	26,404	17,442
Selling, general and administrative	76,686	48,697	140,250	90,603
Total operating expenses	91,220	57,985	166,654	108,045
Operating loss	(14,007)	(12,544)	(30,063)	(28,233)
Other expense (income):				
Interest and dividend income	(297)	(31)	(331)	(88)
Interest expense	494	530	1,021	1,053
Other expense, net	144	19	189	57
Total other expense	341	518	879	1,022
Loss before income taxes	(14,348)	(13,062)	(30,942)	(29,255)
Income taxes	142	26	242	49
Net loss	(14,490)	(13,088)	(31,184)	(29,304)
Other comprehensive loss:				
Foreign currency translation gain	42	—	42	—
Unrealized loss on investments	(45)	(21)	(188)	(41)
Total comprehensive loss	\$ (14,493)	\$ (13,109)	\$ (31,330)	\$ (29,345)
Net loss per share, basic and diluted	\$ (0.53)	\$ (0.48)	\$ (1.13)	\$ (1.08)
Weighted average common shares used to compute net loss per share, basic and diluted	27,594,874	27,230,044	27,556,286	27,187,438

Inspire Medical Systems, Inc.

Consolidated Balance Sheets (unaudited)

(in thousands, except share and per share amounts)

	June 30, 2022	December 31, 2021
Assets		

Current assets:		
Cash and cash equivalents	\$ 186,570	\$ 214,467
Investments, short-term	9,752	—
Accounts receivable, net of allowance for credit losses of \$32 and \$99, respectively	40,380	34,179
Inventories	21,857	17,231
Prepaid expenses and other current assets	4,574	2,660
Total current assets	<u>263,133</u>	<u>268,537</u>
Investments, long-term	—	9,938
Property and equipment, net	11,015	8,486
Operating lease right-of-use assets	7,400	7,919
Other non-current assets	10,454	204
Total assets	<u>\$ 292,002</u>	<u>\$ 295,084</u>
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	\$ 16,033	\$ 11,665
Accrued expenses	18,570	20,454
Notes payable, current portion	12,250	9,188
Total current liabilities	<u>46,853</u>	<u>41,307</u>
Notes payable, non-current portion	9,795	15,799
Operating lease liabilities, non-current portion	8,224	8,796
Other non-current liabilities	146	134
Total liabilities	<u>65,018</u>	<u>66,036</u>
Stockholders' equity:		
Preferred Stock, \$0.001 par value, 10,000,000 shares authorized; no shares issued and outstanding	—	—
Common Stock, \$0.001 par value per share; 200,000,000 shares authorized; 27,634,444 and 27,416,106 issued and outstanding at June 30, 2022 and December 31, 2021, respectively	28	27
Additional paid-in capital	537,730	508,465
Accumulated other comprehensive loss	(201)	(55)
Accumulated deficit	<u>(310,573)</u>	<u>(279,389)</u>
Total stockholders' equity	<u>226,984</u>	<u>229,048</u>
Total liabilities and stockholders' equity	<u>\$ 292,002</u>	<u>\$ 295,084</u>

Source: Inspire Medical Systems, Inc.