

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-Q

(Mark One)

☒ **QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the quarterly period ended June 30, 2022 or

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the transition period from to

Commission File Number: 001-38468



Inspire Medical Systems, Inc.

(Exact name of registrant as specified in its charter)

Delaware

(State or other jurisdiction of incorporation or organization)

**5500 Wayzata Blvd., Suite 1600
Golden Valley, MN**

(Address of principal executive offices)

26-1377674

(I.R.S. Employer Identification No.)

55416

(Zip Code)

(844) 672-4357

(Registrant's telephone number, including area code)

N/A

(Former name, former address and former fiscal year, if changed since last report)

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, \$0.001 par value per share	INSP	New York Stock Exchange

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes ☒ No ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer ☒ Accelerated filer ☐ Non-accelerated filer ☐ Smaller reporting company ☐ Emerging growth company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ☐ No ☒

As of July 26, 2022, the registrant had 27,638,570 shares of common stock, \$0.001 par value per share, outstanding.

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FORWARD-LOOKING STATEMENTS

This Quarterly Report on Form 10-Q contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. We intend such forward-looking statements to be covered by the safe harbor provisions for forward-looking statements contained in Section 27A of the Securities Act of 1933, as amended (the "Securities Act") and Section 21E of the Securities Exchange Act of 1934, as amended (the "Exchange Act"). All statements other than statements of historical facts contained in this Quarterly Report are forward-looking statements, including statements regarding our future results of operations and financial position, business strategy, the impact of the ongoing and global COVID-19 pandemic on our business, financial results and financial position, prospective products, international product approvals and commercializations, our expectations regarding the final reimbursement levels for Inspire therapy procedures, research and development costs, timing and likelihood of success, other insurance providers' plans to begin approving our Inspire therapy, and the plans and objectives of management for future operations.

In some cases, you can identify forward-looking statements by terms such as "may," "will," "should," "expect," "plan," "anticipate," "could," "intend," "target," "project," "contemplate," "believe," "estimate," "predict," "potential" or "continue" or the negative of these terms or other similar expressions, although not all forward-looking statements contain these words. The forward-looking statements in this Quarterly Report are only predictions and are based largely on our current expectations and projections about future events and financial trends that we believe may affect our business, financial condition, and results of operations. These forward-looking statements speak only as of the date of this Quarterly Report and are subject to a number of known and unknown risks, uncertainties, and assumptions, including, but not limited to:

- our history of operating losses and dependency on our Inspire system for revenues;
- commercial success and market acceptance of our Inspire therapy;
- 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;
- the impact on our business, financial condition, and results of operation from the ongoing and global COVID-19 pandemic, or any other pandemic, epidemic or outbreak of an infectious disease;
- our ability to expand our indications and develop and commercialize additional products and enhancements to our Inspire system;
- future results of operations, financial position, research and development costs, capital requirements, and our needs for additional financing;
- our ability to forecast customer demand for our Inspire system and manage our inventory;
- our dependence on third-party suppliers and contract manufacturers;
- risks related to 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 United States;
- our ability to manage our growth;
- our ability to hire and retain our senior management and other highly qualified personnel;
- risks related to product liability claims and warranty claims;
- our ability to address quality issues that may arise with our Inspire system;

- our ability to successfully integrate any acquired business, products or technologies;
- changes in global macroeconomic conditions;
- any failure of key information technology systems, processes or sites or damage to or inability to access our physical facilities;
- our ability to commercialize or obtain regulatory approvals or certifications for our Inspire therapy and system, or the effect of delays in commercializing or obtaining regulatory approvals or certifications;
- any violations of anti-bribery, anti-corruption, and anti-money laundering laws;
- risks related to our indebtedness;
- our ability to use our net operating losses and research and development carryforwards;
- the risk that we may be deemed to be an investment company under the Investment Company Act of 1940;
- United States Food and Drug Administration or other United States or foreign regulatory actions affecting us or the healthcare industry generally, including healthcare reform measures in the United States and international markets;
- our ability to establish and maintain intellectual property protection for our Inspire therapy and system or avoid claims of infringement;
- risks related to our common stock; and
- other important factors that could cause actual results, performance or achievements to differ materially from those contemplated that are found in "Part I, Item 1. Business," "Part I, Item 1A. Risk Factors," and "Part I, Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations" of our Annual Report on Form 10-K for the fiscal year ended December 31, 2021, as updated by "Part I, Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations" in this Quarterly Report on Form 10-Q.

Moreover, we operate in an evolving environment. New risk factors and uncertainties may emerge from time to time, and it is not possible for management to predict all risk factors and uncertainties.

You should read this Quarterly Report and the documents that we reference in this Quarterly Report completely and with the understanding that our actual future results may be materially different from what we expect. We qualify all of our forward-looking statements by these cautionary statements. Except as required by applicable law, we do not plan to publicly update or revise any forward-looking statements contained herein, whether as a result of any new information, future events, changed circumstances or otherwise.

Unless the context requires otherwise, references to "Inspire," the "Company," "we," "us," and "our," refer to Inspire Medical Systems, Inc.

PART I—FINANCIAL INFORMATION

Item 1. Consolidated Financial Statements.

Inspire Medical Systems, Inc.

Consolidated Balance Sheets

(in thousands, except share and per share amounts)

	June 30, 2022 (unaudited)	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	263,133	268,537
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	\$ 292,002	\$ 295,084
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	46,853	41,307
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	65,018	66,036
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	(310,573)	(279,389)
Total stockholders' equity	226,984	229,048
Total liabilities and stockholders' equity	\$ 292,002	\$ 295,084

The accompanying notes are an integral part of these unaudited consolidated financial statements.

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

The accompanying notes are an integral part of these unaudited consolidated financial statements.

Inspire Medical Systems, Inc.
Consolidated Statements of Stockholders' Equity (unaudited)
(in thousands, except share amounts)

Six Months Ended June 30, 2022						
	<u>Common Stock</u>		Additional Paid-In Capital	Accumulated Other Comprehensive Loss	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount				
Balance at December 31, 2021	27,416,106	\$ 27	\$ 508,465	\$ (55)	\$ (279,389)	\$ 229,048
Stock options exercised	151,186	1	3,086	—	—	3,087
Vesting of restricted stock units	569	—	—	—	—	—
Withholding taxes on net share settlement of restricted stock units	(205)	—	(43)	—	—	(43)
Issuance of common stock	348	—	79	—	—	79
Stock-based compensation expense	—	—	9,721	—	—	9,721
Other comprehensive loss	—	—	—	(143)	—	(143)
Net loss	—	—	—	—	(16,694)	(16,694)
Balance at March 31, 2022	27,568,004	28	521,308	(198)	(296,083)	225,055
Stock options exercised	52,383	—	1,549	—	—	1,549
Issuance of common stock	314	—	80	—	—	80
Issuance of common stock for employee stock purchase plan	13,743	—	2,134	—	—	2,134
Stock-based compensation expense	—	—	12,659	—	—	12,659
Other comprehensive loss	—	—	—	(3)	—	(3)
Net loss	—	—	—	—	(14,490)	(14,490)
Balance at June 30, 2022	27,634,444	\$ 28	\$ 537,730	\$ (201)	\$ (310,573)	\$ 226,984

The accompanying notes are an integral part of these unaudited consolidated financial statements.

Inspire Medical Systems, Inc.
Consolidated Statements of Stockholders' Equity (unaudited)
(in thousands, except share amounts)

Six Months Ended June 30, 2021						
	<u>Common Stock</u>		Additional Paid-In Capital	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount				
Balance at December 31, 2020	27,069,276	\$ 27	\$ 467,038	\$ 29	\$ (237,347)	\$ 229,747
Stock options exercised	133,421	—	3,550	—	—	3,550
Issuance of common stock	376	—	73	—	—	73
Stock-based compensation expense	—	—	5,997	—	—	5,997
Other comprehensive loss	—	—	—	(20)	—	(20)
Net loss	—	—	—	—	(16,216)	(16,216)
Balance at March 31, 2021	27,203,073	27	476,658	9	(253,563)	223,131
Stock options exercised	49,318	—	1,719	—	—	1,719
Issuance of common stock	329	—	72	—	—	72
Issuance of common stock for employee stock purchase plan	11,351	—	1,760	—	—	1,760
Stock-based compensation expense	—	—	6,341	—	—	6,341
Other comprehensive loss	—	—	—	(21)	—	(21)
Net loss	—	—	—	—	(13,088)	(13,088)
Balance at June 30, 2021	27,264,071	\$ 27	\$ 486,550	\$ (12)	\$ (266,651)	\$ 219,914

The accompanying notes are an integral part of these unaudited consolidated financial statements.

Inspire Medical Systems, Inc.
Consolidated Statements of Cash Flows (unaudited)
(in thousands)

	Six Months Ended June 30,	
	2022	2021
Operating activities		
Net loss	\$ (31,184)	\$ (29,304)
Adjustments to reconcile net loss:		
Depreciation and amortization	776	538
Non-cash lease expense	519	340
Stock-based compensation expense	22,380	12,338
Non-cash stock issuance for services rendered	159	145
Other, net	53	129
Changes in operating assets and liabilities:		
Accounts receivable	(6,207)	126
Inventories	(4,625)	(4,816)
Prepaid expenses and other current assets	(1,917)	(1,483)
Accounts payable	3,755	2,189
Accrued expenses and other liabilities	(2,411)	(717)
Net cash used in operating activities	(18,702)	(20,515)
Investing activities		
Purchases of property and equipment	(2,634)	(2,984)
Purchases of investments	—	(9,993)
Proceeds from sales or maturities of investments	—	12,500
Purchases of strategic investments	(10,250)	—
Net cash used in investing activities	(12,884)	(477)
Financing activities		
Payments on long-term debt obligation	(3,063)	—
Proceeds from the exercise of stock options	4,635	5,269
Taxes paid on net share settlement of restricted stock units	(43)	—
Proceeds from issuance of common stock from employee stock purchase plan	2,134	1,760
Net cash provided by financing activities	3,663	7,029
Effect of exchange rate on cash	26	(14)
Decrease in cash and cash equivalents	(27,897)	(13,977)
Cash and cash equivalents at beginning of period	214,467	190,518
Cash and cash equivalents at end of period	<u>\$ 186,570</u>	<u>\$ 176,541</u>
Supplemental cash flow information		
Cash paid for interest	\$ 922	\$ 941
Property and equipment included in accounts payable	1,212	125

The accompanying notes are an integral part of these unaudited consolidated financial statements.

Inspire Medical Systems, Inc.
Notes to Consolidated Financial Statements (Unaudited)
(Table amounts in thousands, except share and per share amounts)

1. Organization

Description of Business

Inspire Medical Systems, Inc. is a medical technology company focused on the development and commercialization of innovative, minimally invasive solutions for patients with obstructive sleep apnea ("OSA"). Our proprietary Inspire system is the first and only United States ("U.S.") Food and Drug Administration ("FDA") approved neurostimulation technology that provides a safe and effective treatment for moderate to severe OSA. Inspire therapy received premarket approval ("PMA") from the FDA in 2014 and has been commercially available in certain European markets since 2011. Japan's Ministry of Health, Labour and Welfare ("MLHW") approved Inspire therapy to treat moderate to severe OSA in 2018 and was formally added to the Japan National Health Insurance Payment Listing in 2021. In 2020, the Australian Therapeutic Goods Administration approved Inspire therapy to treat moderate to severe OSA, and we are currently seeking reimbursement coverage in Australia.

2. Summary of Significant Accounting Policies

Basis of Presentation

The accompanying consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the U.S. ("GAAP") for interim financial reporting and as required by the rules and regulations of the Securities and Exchange Commission ("SEC"). Accordingly, they do not include all of the information and footnotes required by GAAP for complete financial statements. In the opinion of management, all adjustments (including those which are normal and recurring) considered necessary for a fair presentation of the interim financial information have been included. When preparing financial statements in conformity with GAAP, we must make estimates and assumptions that affect the reported amounts of assets, liabilities, revenues, expenses, and related disclosures at the date of the financial statements. Actual results could differ from those estimates. Additionally, the results of operations for the interim periods are not necessarily indicative of the operating results for the full fiscal year or any future periods. Certain prior period amounts have been reclassified to conform to the current presentation. These reclassifications had no material effect on the reported results of operations. All intercompany accounts and transactions have been eliminated in consolidation.

For a complete discussion of our significant accounting policies and other information, the unaudited consolidated financial statements and notes thereto should be read in conjunction with the audited financial statements included in our Annual Report on Form 10-K for the fiscal year ended December 31, 2021.

Cash and Cash Equivalents

We consider all highly liquid securities, readily convertible to cash, that have original maturities of 90 days or less from the date of purchase to be cash equivalents. The carrying amount reported in the consolidated balance sheets for cash is cost, which approximates fair value.

Foreign Currency

Sales and expenses denominated in foreign currencies are translated at average exchange rates in effect throughout the year. Foreign currency transaction gains and losses are included in other expense, net, in the consolidated statements of operations and comprehensive loss. Assets and liabilities of foreign operations are remeasured at period-end exchange rates with the impacts of foreign currency remeasurement recognized in other expense, net in the consolidated statements of operations and comprehensive loss. Any unrealized gains and losses due to translation adjustments are included in other accumulated other comprehensive loss within stockholders' equity.

Inspire Medical Systems, Inc.
Notes to Consolidated Financial Statements (unaudited)
(Table amounts in thousands, except share and per share amounts)

Investments

At both June 30, 2022 and December 31, 2021, our investments consisted of U.S. government securities. Investments are reported at their estimated fair market values which are based on quoted, active or inactive market prices when available. Any unrealized gains and losses due to interest rate fluctuations and other external factors are included in other accumulated other comprehensive loss within stockholders' equity. Any realized gains and losses are calculated on the specific identification method and reported net in other expense, net in the consolidated statements of operations and comprehensive loss. For both of the six months ended June 30, 2022 and 2021, we recognized \$0 of realized gains, net.

We reassess our estimated credit losses on investments each reporting period. U.S. government securities and cash equivalents are under a "zero-loss exception" for credit losses, meaning no credit loss risk calculation is necessary on those instruments due to the exceptionally low rate of default, which continues to decrease as the securities approach maturity, which for us is no longer than two years. We record changes in the allowance for credit losses for available-for-sale debt securities with a corresponding adjustment in credit loss expense on the consolidated statement of operations and comprehensive loss. No reversal of a previously recorded allowance for credit losses may be made to an amount below zero. The total allowance for credit losses was \$0 at both June 30, 2022 and December 31, 2021.

Fair Value of Financial Instruments

We measure certain financial assets and liabilities at fair value on a recurring basis, including cash equivalents and investments. Fair value is an exit price, representing the amount that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants. As such, fair value is a market-based measurement that should be determined based on assumptions that market participants would use in pricing an asset or a liability. A three-tier fair value hierarchy is established as a basis for considering such assumptions and for inputs used in the valuation methodologies in measuring fair value:

Level 1: Observable inputs, such as quoted prices (unadjusted) for identical assets or liabilities in active markets.

Level 2: Inputs other than quoted prices in active markets for identical assets and liabilities that are observable either directly or indirectly for substantially the full term of the asset or liability.

Level 3: Unobservable inputs that are supported by little or no market activities, which would require us to develop our own assumptions.

We use the methods and assumptions described below in determining the fair value of our financial instruments.

Money market funds: Fair values of money market funds are based on quoted market prices in active markets. These are included as Level 1 measurements in the tables below.

U.S. government securities: Consists of U.S. government Treasury bills with original maturities of less than two years. These are included as a Level 1 measurement in the tables below.

The following tables set forth by level within the fair value hierarchy our assets that are measured on a recurring basis and reported at fair value as of June 30, 2022 and December 31, 2021. Assets are classified in their entirety based on the lowest level of input that is significant to the fair value measurement.

Inspire Medical Systems, Inc.
Notes to Consolidated Financial Statements (unaudited)
(Table amounts in thousands, except share and per share amounts)

Fair Value Measurements as of June 30, 2022				
	Estimated Fair Value	Level 1	Level 2	Level 3
Cash equivalents:				
Money market funds	\$ 166,190	\$ 166,190	\$ —	\$ —
Total cash equivalents	166,190	166,190	—	—
Investments:				
U.S. government securities	9,752	9,752	—	—
Total investments	9,752	9,752	—	—
Total cash equivalents and investments	\$ 175,942	\$ 175,942	\$ —	\$ —

Fair Value Measurements as of December 31, 2021				
	Estimated Fair Value	Level 1	Level 2	Level 3
Cash equivalents:				
Money market funds	\$ 189,369	\$ 189,369	\$ —	\$ —
Total cash equivalents	189,369	189,369	—	—
Investments:				
U.S. government securities	9,938	9,938	—	—
Total investments	9,938	9,938	—	—
Total cash equivalents and investments	\$ 199,307	\$ 199,307	\$ —	\$ —

There were no transfers between levels during the periods ended June 30, 2022 and December 31, 2021.

Concentration of Credit Risk

Financial instruments, which potentially subject us to concentrations of credit risk, consist principally of cash equivalents, investments, and accounts receivable.

Our investment policy limits investments to certain types of debt securities issued by the U.S. government and its agencies, corporations with investment-grade credit ratings, or commercial paper and money market funds issued by the highest quality financial and non-financial companies. We place restrictions on maturities and concentration by type and issuer. We are exposed to credit risk in the event of a default by the issuers of these securities to the extent recorded on the consolidated balance sheets. However, as of June 30, 2022 and December 31, 2021, we limited our credit risk associated with cash equivalents by placing investments with banks we believe are highly creditworthy.

We believe that the credit risk in our accounts receivable is mitigated by our credit evaluation process, relatively short collection terms, and dispersion of our customer base. We generally do not require collateral, and losses on accounts receivable have historically not been significant.

Accounts Receivable and Allowance for Expected Credit Losses

Trade accounts receivable are recorded at the invoiced amount and do not bear interest. Customer credit terms are established prior to shipment with the general standard being net 30 days. Collateral or any other security to support payment of these receivables generally is not required.

Inspire Medical Systems, Inc.
Notes to Consolidated Financial Statements (unaudited)
(Table amounts in thousands, except share and per share amounts)

Each reporting period, we estimate the credit loss related to accounts receivable based on a migration analysis of accounts grouped by individual receivables delinquency status, and apply our historic loss rate adjusted for management's assumption of future market conditions. Any change in the allowance from new receivables acquired, or changes due to credit deterioration on previously existing receivables, is recorded in selling, general and administrative expenses. Write-offs of receivables considered uncollectible are deducted from the allowance. Specific accounts receivable are written-off once a determination is made that the amount is uncollectible. The write-off is recorded in the period in which the account receivable is deemed uncollectible. Recoveries are recognized when received and as a direct credit to earnings or as a reduction to the allowance for credit losses (which would indirectly reduce the loss by decreasing bad debt expense).

Inventories

Inventories are valued at the lower of cost or net realizable value, computed on a first-in, first-out basis and consisted of the following:

	June 30, 2022	December 31, 2021
Raw materials	\$ 6,427	\$ 3,119
Finished goods	15,430	14,112
Total inventories, net of reserves	<u>\$ 21,857</u>	<u>\$ 17,231</u>

We regularly review inventory quantities on-hand for excess and obsolete inventory and, when circumstances indicate, incur charges to write down inventories to their net realizable value. The determination of a reserve for excess and obsolete inventory involves management exercising judgment to determine the required reserve, considering future demand, product life cycles, introduction of new products and current market conditions. The reserve for excess and obsolete inventory was \$0.4 million and \$0.3 million as of June 30, 2022 and December 31, 2021, respectively.

Property and Equipment

Property and equipment are stated at cost, less accumulated depreciation and amortization and consisted of the following:

	June 30, 2022	December 31, 2021
Computer equipment and software	\$ 1,500	\$ 1,397
Manufacturing equipment	5,608	4,436
Other equipment	329	249
Leasehold improvements	1,397	281
Construction in process	6,009	5,175
Property and equipment, cost	<u>14,843</u>	<u>11,538</u>
Less: accumulated depreciation and amortization	<u>(3,828)</u>	<u>(3,052)</u>
Property and equipment, net	<u>\$ 11,015</u>	<u>\$ 8,486</u>

Depreciation is determined using the straight-line method over the estimated useful lives of the respective assets, generally three to five years. Leasehold improvements are amortized on a straight-line basis over the shorter of their estimated useful lives or the term of the lease. Depreciation and amortization expense was \$0.4 million and \$0.3 million for the three months ended June 30, 2022 and 2021, respectively, and \$0.8 million and \$0.5 million for the six months ended June 30, 2022 and 2021, respectively.

Inspire Medical Systems, Inc.
Notes to Consolidated Financial Statements (unaudited)
(Table amounts in thousands, except share and per share amounts)

Strategic Investments

For equity securities without readily determinable fair values, we have elected the measurement alternative under which we measure these investments at cost minus impairment, if any, plus or minus changes resulting from observable price changes in orderly transactions for the identical or a similar investment of the same issuer. These securities are presented within other non-current assets on the consolidated balance sheets. The balance of equity securities without readily determinable fair values was \$10.3 million and \$0 as of June 30, 2022 and December 31, 2021, respectively. There were no adjustments to the carrying amount during the six months ended June 30, 2022.

Impairment of Long-lived Assets

Long-lived assets consist primarily of property and equipment and operating lease right-of-use asset and are reviewed for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. If circumstances require that an asset be tested for possible impairment, we compare the undiscounted cash flows expected to be generated by the asset to the carrying amount of the asset. If the carrying amount of the asset is not recoverable on an undiscounted cash flow basis, we determine the fair value of the asset and recognize an impairment loss to the extent the carrying amount of the asset exceeds its fair value. We determine fair value using the income approach based on the present value of expected future cash flows or other appropriate measures of estimated fair value. Our cash flow assumptions consider historical and forecasted revenue and operating costs and other relevant factors. We did not record any impairment charges on long-lived assets during either of the six months ended June 30, 2022 or 2021.

Accrued Expenses

Accrued expenses consisted of the following:

	June 30, 2022	December 31, 2021
Payroll related	\$ 14,935	\$ 17,655
Interest	136	160
Product warranty liability	488	468
Operating lease liabilities, current portion	1,072	312
Other accrued expenses	1,939	1,859
Total accrued expenses	<u>\$ 18,570</u>	<u>\$ 20,454</u>

The following table shows the changes in our estimated product warranty liability accrual, included in accrued liabilities:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2022	2021	2022	2021
Balance at beginning of period	\$ 438	\$ 266	\$ 468	\$ 159
Accruals of warranties issued	110	70	121	248
Settlements of warranty claims	(60)	(53)	(101)	(124)
Balance at the end of the period	<u>\$ 488</u>	<u>\$ 283</u>	<u>\$ 488</u>	<u>\$ 283</u>

Revenue Recognition

We derive our revenue from sales of our products in the U.S. and internationally. Customers are primarily comprised of hospitals and ambulatory surgery centers, with distributors being used in certain international locations where we do not have a direct commercial presence.

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Revenues from product sales are recognized when the customer obtains control of the product, which occurs at a point in time, either upon shipment of the product or receipt of the product, depending on shipment terms. Our standard shipping terms are free on board shipping point, unless the customer requests that control and title to the inventory transfer upon delivery. In those cases where shipping and handling costs are billed to customers, we classify the amounts billed as a component of cost of goods sold.

Revenue is measured as the amount of consideration we expect to receive, adjusted for any applicable estimates of variable consideration and other factors affecting the transaction price, which is based on the invoiced price, in exchange for transferring products. All revenue is recognized when we satisfy our performance obligations under the contract. The majority of our contracts have a single performance obligation and are short term in nature.

Sales taxes and value added taxes in foreign jurisdictions that are collected from customers and remitted to governmental authorities are accounted for on a net basis and therefore are excluded from net sales. Shipping and handling costs associated with outbound freight after control over a product has transferred to a customer are accounted for as a fulfillment cost and are included in cost of goods sold.

Variable consideration related to certain customer sales incentives is estimated based on the amounts expected to be paid based on the agreement with the customer using probability assessments.

We offer customers a limited right of return for our product in case of non-conformity or performance issues. We estimate the amount of our product sales that may be returned by our customers based on historical sales and returns. As our historical product returns to date have been immaterial, we have not recorded a reduction in revenue related to variable consideration for product returns.

See Note 9 for disaggregated revenue by geographic area.

Cost of Goods Sold

Cost of goods sold consists primarily of acquisition costs for the components of the Inspire system, overhead costs, scrap and inventory obsolescence, warranty replacement costs, as well as distribution-related expenses such as logistics and shipping costs, net of shipping costs charged to customers. The overhead costs include the cost of material procurement, depreciation expense for production equipment, and operations supervision and management personnel, including employee compensation, stock-based compensation, supplies, and travel.

Research and Development

Research and development expenses consist primarily of product development, clinical and regulatory affairs, quality assurance, consulting services, and other costs associated with products and technologies in development. These expenses include employee compensation, including stock-based compensation, supplies, materials, consulting, and travel expenses related to research and development programs. Clinical expenses include clinical trial design, clinical site reimbursement, data management, travel expenses, and the cost of manufacturing products for clinical trials.

Stock-Based Compensation

We maintain an equity incentive plan to provide long-term incentives for eligible employees, consultants, and members of the board of directors. The plan allows for the issuance of restricted stock units ("RSUs"), performance stock units ("PSUs"), and non-statutory and incentive stock options to employees, and RSUs, PSUs, and non-statutory stock options to consultants and directors. We also offer an employee stock purchase plan ("ESPP") which allows participating employees to purchase shares of our common stock at a discount through payroll deductions.

We recognize equity-based compensation expense for awards of equity instruments based on the grant date fair value of those awards as expense in the consolidated statements of operations and comprehensive loss. We estimate the fair value of stock options using the Black-Scholes option pricing model and the fair value of RSUs and

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PSUs is equal to the closing price of our common stock on the grant date. The fair value of each purchase under the employee stock purchase plan is estimated at the beginning of the offering period using the Black-Scholes option pricing model.

Stock-based compensation expense is recognized on a straight-line basis over the vesting term for stock options and RSUs, and over the vesting and performance period based on the probability of achieving the performance objectives for PSUs. We account for award forfeitures as they occur.

Advertising Expenses

We expense the costs of advertising, including promotional expenses, as incurred. Advertising expenses were \$18.0 million and \$11.5 million during the three months ended June 30, 2022 and 2021, respectively, and \$33.5 million and \$20.6 million for the six months ended June 30, 2022 and 2021, respectively.

Leases

Operating leases are included in operating lease right-of-use ("ROU") asset, accrued expenses, and operating lease liability – non-current portion in our consolidated balance sheets. ROU assets represent our right to use an underlying asset for the lease term and lease liabilities represent our obligation to make lease payments arising from the lease. Operating lease ROU assets and liabilities are recognized at the lease commencement date based on the present value of lease payments over the lease term. In determining the present value of lease payments, we use our incremental borrowing rate based on the information available at the lease commencement date as the rate implicit in the lease is not readily determinable. The determination of our incremental borrowing rate requires management judgment based on information available at lease commencement. The operating lease ROU assets also include adjustments for prepayments, accrued lease payments, and exclude lease incentives. Our lease terms may include options to extend or terminate the lease when it is reasonably certain that we will exercise such options. Operating lease cost is recognized on a straight-line basis over the expected lease term. Lease agreements that include lease and non-lease components are accounted for as a single lease component. Lease agreements with a noncancelable term of less than 12 months are not recorded on our consolidated balance sheets.

Income Taxes

We account for income taxes using the liability method. Under this method, deferred tax assets and liabilities are determined based on the differences between the financial reporting and tax bases of assets and liabilities and are measured using the enacted tax rates that will be in effect when the differences are expected to reverse. Valuation allowances against deferred tax assets are established, when necessary, to reduce deferred tax assets to the amounts expected to be realized. As we have historically incurred operating losses, we have recorded a full valuation allowance against our net deferred tax assets, and there is no provision for income taxes other than minimal state taxes and an accrual for uncertain tax benefits. Our policy is to record interest and penalties expense related to uncertain tax positions as other expense in the consolidated statements of operations and comprehensive loss.

Comprehensive Loss

Comprehensive loss consists of net loss and changes in unrealized gains and losses due to interest rate fluctuations and other external factors on investments classified as available-for-sale, and foreign currency translation adjustments. Accumulated other comprehensive loss is presented in the accompanying consolidated balance sheets as a component of stockholders' equity.

Loss Per Share

Basic net loss per share is computed by dividing the net loss by the weighted average number of shares of common stock outstanding during the period. Diluted net loss per share is computed by dividing the net loss by the weighted

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average number of shares of common stock and dilutive potential shares of common stock outstanding during the period. Because we have reported a net loss for all periods presented, diluted net loss per share is the same as basic net loss per share as all potentially dilutive shares consisting of outstanding stock options, unvested RSUs and PSUs, and shares issuable under our employee stock purchase plan were antidilutive in those periods.

Recent Accounting Pronouncements

We have reviewed and considered all recent accounting pronouncements that have not yet been adopted and believe there are none that could potentially have a material impact on our business practices, financial condition, results of operations, or disclosures.

3. Investments

Our investments are classified as available-for-sale and consist of the following:

	June 30, 2022			
	Amortized Cost	Unrealized Gross		Aggregate Fair Value
		Gains	Losses	
Short-Term:				
U.S. government securities	\$ 9,995	\$ —	\$ (243)	\$ 9,752
Short-term investments	\$ 9,995	\$ —	\$ (243)	\$ 9,752
	December 31, 2021			
	Amortized Cost	Unrealized Gross		Aggregate Fair Value
		Gains	Losses	
Long-Term:				
U.S. government securities	\$ 9,993	\$ —	\$ (55)	\$ 9,938
Long-term investments	\$ 9,993	\$ —	\$ (55)	\$ 9,938

As of June 30, 2022 and December 31, 2021, we had no investments with a contractual maturity of greater than two years. Currently, we do not intend to sell the investments and it is not more likely than not that we will be required to sell the investments before recovery of their amortized cost bases, which may be maturity. We do not consider those investments to be other-than-temporarily impaired as of June 30, 2022. At the end of each reporting period, we evaluate potential credit impairment on available-for-sale securities in an unrealized loss position, based on the expected cash flows to be collected and the yield-to-maturity on those securities. Securities with a valuation allowance for expected credit losses and deemed uncollectible are permanently written-down, and a reversal out of the valuation allowance occurs.

4. Leases

We lease approximately 70,000 square feet of office space for our corporate headquarters under non-cancelable operating leases. The leases expire May 31, 2028 with options to renew for one additional period of five years at the then-prevailing market rate. The exercises of the lease renewal options are at our sole discretion and were not included in the lease term for the calculation of the ROU assets and lease liabilities when the leases commenced as they were not reasonably certain of exercise.

In addition to base rent, we also pay our proportionate share of the operating expenses, as defined in the leases. These payments are made monthly and adjusted annually to reflect actual charges incurred for operating expenses,

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such as common area maintenance, taxes, and insurance. In conjunction with the leases, the landlord agreed to provide total rent abatement of \$2.3 million.

The following table presents the lease balances within the consolidated balance sheets:

	June 30, 2022	December 31, 2021
Right-of-use assets:		
Operating lease right-of-use assets	\$ 7,400	\$ 7,919
Operating lease liabilities:		
Accrued expenses	1,072	312
Operating lease liabilities, non-current portion	8,224	8,796
Total operating lease liabilities	<u>\$ 9,296</u>	<u>\$ 9,108</u>

As of June 30, 2022, the remaining lease term was 5.9 years and the weighted average discount rate was 5.3%. The operating cash outflows from our operating leases were \$0.1 million for both of the three-month periods ended June 30, 2022 and 2021 and \$0.1 million for both of the six-month periods ended June 30, 2022 and 2021.

5. Long-Term Debt

In March 2019 we amended our \$24.5 million term loan and security agreement, which we refer to as our credit facility. The debt was interest only until April 1, 2022 and matures on March 1, 2024. The basic interest rate is the 30-day U.S. LIBOR rate, subject to a floor of 7.60%. The agreement provides a mechanism for determining an alternative interest rate to replace the U.S. LIBOR rate upon the occurrence of certain circumstances. In addition to the principal and interest payments, we are required to pay a final payment fee of 3.50% on all amounts outstanding, which is being accreted using the effective interest rate method over the term of the credit facility and shall be due at the earlier of maturity or prepayment. Borrowings are prepayable at our option in whole, subject to a prepayment fee of 1.00%. As of June 30, 2022, we had \$21.4 million outstanding under our credit facility.

The credit facility includes affirmative and restrictive covenants and events of default, including the following events of default: payment defaults, breaches of covenants, judgment defaults, cross defaults to certain other contracts, certain events with respect to governmental approvals if such events could cause a material adverse change, a material impairment in the perfection or priority of the lender's security interest or in the value of the collateral, a material adverse change in the business, operations, or condition of us or any of our subsidiaries, and a material impairment of the prospect of repayment of the loans. Upon the occurrence of an event of default, a default increase in the interest rate of an additional 5.00% could be applied to the outstanding loan balance and the lender could declare all outstanding obligations immediately due and payable and take such other actions as set forth in the loan and security agreement.

Our obligations under the credit facility are secured by a first priority security interest in substantially all of our assets, other than our intellectual property. There are no financial covenants contained in the loan and security agreement. We were in compliance with the affirmative and restrictive covenants as of June 30, 2022.

6. Employee Retirement Plan

We sponsor a defined contribution employee retirement plan covering all of our full-time employees. The plan allows for eligible employees to defer a portion of their eligible compensation up to the maximum allowed by IRS Regulations. Beginning January 1, 2022, we elected to begin making voluntary matching contributions to the plan. We match 50% of the first 6% of each participating employee's contribution, up to 3% of eligible earnings. Our match contributions are made to funds designated by the participant, none of which are based on Inspire common stock. Discretionary contributions to the plan totaled \$0.6 million and \$1.3 million for the three and six months ended June 30, 2022, respectively.

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7. Stock-Based Compensation

As of June 30, 2022, there were 3,927,924 shares reserved for issuance under our equity incentive plan, of which 1,536,745 shares were available for issuance.

Stock-based compensation expense is recognized on a straight-line basis over the vesting term for stock options and RSUs, and over the performance period based on the probability of achieving the performance objectives for PSUs, and is reduced by actual forfeitures as they occur. If there are any modifications or cancellations of the underlying unvested securities, we may be required to accelerate, increase, or cancel any remaining unearned stock compensation expense. Future stock-based compensation expense and unearned stock-based compensation will increase to the extent that we grant additional stock-based awards.

Stock Options

Options are granted at the exercise price, which is equal to the closing price of our stock on the date of grant. The stock options granted to employees include a four-year service period and 25% vest after the first year of service and the remainder vest in equal installments over the next 36 months of service. The stock options granted to the board of directors vest in one or three equal annual installments, in each case, subject to the director's continuous service through the applicable vesting date. The stock options have a contractual life of ten years.

A summary of stock option activity and related information is as follows:

	Options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (years)	Aggregate Intrinsic Value (in thousands)
Outstanding at December 31, 2021	2,646,235	\$ 80.41	7.1	\$397,015
Granted	354,625	\$ 220.52		
Exercised	(203,569)	\$ 22.83		\$39,304
Forfeited/expired	(45,466)	\$ 152.07		
Outstanding at June 30, 2022	<u>2,751,825</u>	\$ 101.54	7.2	\$248,352
Exercisable at June 30, 2022	<u>1,604,150</u>	\$ 56.26	6.2	\$205,953

The aggregate intrinsic value of options exercised is the difference between the estimated fair market value of our common stock at the date of exercise and the exercise price for those options. The aggregate intrinsic value of outstanding options is the difference between the closing price as of the date outstanding and the exercise price of the underlying stock options.

As of June 30, 2022, the amount of unearned stock-based compensation to be expensed from now through the year 2026 related to unvested employee and non-employee director stock options is \$90.7 million, which we expect to recognize over a weighted average period of 2.5 years.

The fair value of options was estimated as of the grant date using the Black-Scholes option pricing model using the following assumptions:

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	Six Months Ended June 30,	
	2022	2021
Expected term (years)	5.50 - 6.25	5.50 - 6.25
Expected volatility	56.2 - 56.9%	55.0 - 55.9%
Risk-free interest rate	1.75 - 3.04%	0.79 - 1.4%
Expected dividend yield	0.0%	0.0%
Weighted average fair value	\$121.74	\$108.41

Expected Term — Due to our limited amount of historical exercise, forfeiture, and expiration activity, we have opted to use the "simplified method" for estimating the expected term of options, whereby the expected term equals the arithmetic average of the vesting terms and the original contractual term of the option. We will continue to analyze our expected term assumption as more historical data becomes available.

Expected Volatility — Due to our limited operating history and a lack of company specific historical and implied volatility data, we have incorporated our historical stock trading volatility with those of a group of similar companies that are publicly traded for the calculation of volatility. When selecting this peer group of public companies on which we have based our expected stock price volatility, we generally selected companies with comparable characteristics to it, including enterprise value, stages of clinical development, risk profiles, position within the industry, and with historical share price information sufficient to meet the expected life of the stock-based awards. We will continue to analyze the historical stock price volatility assumption as more historical data for our common stock becomes available.

Risk-Free Interest Rate — The risk-free rate assumption is based on the U.S. government Treasury instruments with maturities similar to the expected term of our stock options.

Expected Dividend Yield — The expected dividend assumption is based on our history of not paying dividends and our expectation that we will not declare dividends for the foreseeable future.

Restricted Stock Units

RSUs are share awards that entitle the holder to receive freely tradable shares of our common stock upon vesting. The RSUs cannot be transferred and the awards are subject to forfeiture if the holder's employment terminates prior to the release of the vesting restrictions. The RSUs generally include a three-year service period and vest in equal installments on each anniversary of the date of grant, provided the employee remains continuously employed with the Company.

A summary of RSUs and related information is as follows:

	Restricted Stock Units	Weighted Average Grant Date Fair Value	Aggregate Intrinsic Value (in thousands)
Unvested at December 31, 2021	2,275	\$ 201.51	\$ 524
Granted	88,304	\$ 216.15	
Vested	(569)	\$ 201.51	
Forfeited	(2,501)	\$ 225.70	
Unvested at June 30, 2022	<u>87,509</u>	\$ 215.59	\$ 15,985

The fair value of the RSUs is equal to the closing price of our common stock on the grant date. The aggregate intrinsic value of RSUs outstanding was based on our closing stock price on the last trading day of the period. As of

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June 30, 2022, there was \$17.1 million of unrecognized stock-based compensation expense related to RSUs that is expected to be recognized over a weighted average period of 2.7 years.

Performance Stock Units

During the quarter ended March 31, 2022, the Company granted PSUs to officers and key employees. The number of PSUs that will ultimately be earned is based on our performance relative to a pre-established goal for the three-year period ending December 31, 2024. The expense is recorded on a straight-line basis over the requisite service period based on an estimate of the number of PSUs expected to vest. Management expectations related to the achievement of the performance goal associated with PSU grants is assessed each reporting period. The number of shares earned at the end of the three-year period will vary based on actual performance, from 0% to 200% of the number of PSUs granted. If the performance condition is not met or not expected to be met, any compensation expense recognized associated with the grant will be reversed.

A summary of PSUs and related information is as follows:

	Performance Stock Units	Weighted Average Grant Date Fair Value	Aggregate Intrinsic Value (in thousands)
Unvested at December 31, 2021	—	\$ —	\$ —
Granted	78,351	\$ 227.53	
Forfeited	(879)	\$ 227.53	
Unvested at June 30, 2022	<u>77,472</u>	\$ 227.53	\$ 14,152

There were no PSUs granted prior to 2022. The fair value of the PSUs is equal to the closing price of our common stock on the grant date. As of June 30, 2022, there was \$23.4 million of unrecognized stock-based compensation expense related to outstanding PSUs that is expected to be recognized over a period of approximately 2.8 years.

Employee Stock Purchase Plan

Employees may participate in our ESPP provided they meet certain eligibility requirements. The purchase price for our common stock under the terms of the ESPP is defined as 85% of the lower of the closing market price per share of our common stock on the first or last trading day of each stock purchase period. On June 30, 2022, 13,743 shares were purchased under the ESPP using employee contributions.

8. Income Taxes

At both June 30, 2022 and December 31, 2021, a valuation allowance was recorded against all deferred tax assets due to our cumulative net loss position. We recorded income tax expense of \$0.1 million and \$0.0 million in the three months ended June 30, 2022 and 2021, respectively, and \$0.2 million and \$0.0 million in the six months ended June 30, 2022 and 2021, respectively. The nominal income tax expense in those periods reflects minimal state income tax expense and an accrual for uncertain tax benefits.

As of December 31, 2021, our gross federal net operating loss carryforward was \$286.6 million, which will expire at various dates beginning in 2028. In addition, net operating loss carryforwards for state income tax purposes of \$198.2 million that include net operating losses will begin to expire in 2023. We also have gross research and development credit carryforwards of \$7.0 million as of December 31, 2021, which will expire at various dates beginning in 2033.

Utilization of the net operating loss carryforwards may be subject to an annual limitation due to the ownership change limitations provided by Section 382 of the Internal Revenue Code of 1986 and similar state provisions. We have not performed a detailed analysis to determine whether an ownership change has occurred. Such a change of

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ownership would limit our utilization of the net operating losses and could be triggered by subsequent sales of securities by us or our stockholders.

Realization of the deferred tax assets is dependent upon the generation of future taxable income, if any, the amount and timing of which are uncertain. Based on available objective evidence and cumulative losses, we believe it is more likely than not that the deferred tax assets are not recognizable and will not be recognizable until we have sufficient taxable income. Accordingly, the net deferred tax assets have been fully offset by a valuation allowance.

We had \$0.1 million of gross unrecognized tax benefits as of each of June 30, 2022 and December 31, 2021.

We file income tax returns in the applicable jurisdictions. The 2018 to 2021 tax years remain open to examination by the IRS, while the 2018 to 2020 tax years remain open to examination by all other major taxing authorities to which we are subject. We do not expect a significant change to our unrecognized tax benefits over the next 12 months.

9. Segment Reporting and Revenue Disaggregation

We operate our business as one reporting segment. An operating segment is defined as a component of an enterprise for which separate discrete financial information is available and evaluated regularly by the chief operating decision maker, or decision-making group, in deciding how to allocate resources and in assessing performance. Segment information is consistent with how management reviews the business, makes investing and resource allocation decisions and assesses operating performance.

We sell our Inspire system to hospitals and ambulatory surgery centers in the U.S. and in select countries in Europe through a direct sales organization, and in Japan and Singapore through distributors. Revenue by geographic region is as follows:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2022	2021	2022	2021
United States	\$ 87,876	\$ 49,353	\$ 154,302	\$ 87,122
All other countries	3,510	3,606	6,466	6,189
Total revenue	<u>\$ 91,386</u>	<u>\$ 52,959</u>	<u>\$ 160,768</u>	<u>\$ 93,311</u>

All of our long-lived assets are located in the U.S.

10. Loss Per Share

Basic net loss per share is computed by dividing the net loss by the weighted average number of shares of common stock outstanding during the period. Diluted net loss per share is computed by dividing the net loss by the weighted average number of shares of common stock and dilutive potential shares of common stock outstanding during the period. Because we have reported a net loss for all periods presented, diluted net loss per share is the same as basic net loss per share as all of the following potentially dilutive shares were antidilutive in those periods.

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The following common stock-based awards were excluded from the computation of diluted net loss per common share for the periods presented because including them would have been anti-dilutive:

	June 30,	
	2022	2021
Common stock options outstanding	2,751,825	2,746,103
Unvested restricted stock units	87,509	2,275
Unvested performance stock units	77,472	—
Total	2,916,806	2,748,378

Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations.

The following discussion and analysis of our financial condition and results of operations should be read in conjunction with our consolidated financial statements and the related notes to those statements included elsewhere in this Quarterly Report on Form 10-Q, as well as the audited financial statements and the related notes thereto, and the discussion under "Management's Discussion and Analysis of Financial Condition and Results of Operations" and "Business" included in our Annual Report on Form 10-K for the fiscal year ended December 31, 2021. Some of the information contained in this discussion and analysis or set forth elsewhere in this Quarterly Report on Form 10-Q, such as information with respect to our plans and strategy for our business and the impact of the ongoing and global COVID-19 pandemic on our business, financial results and financial condition on our business, financial results and financial condition includes forward-looking statements that involve risks and uncertainties. As a result of many important factors, including those set forth in the "Risk Factors" section of our Annual Report on Form 10-K for the fiscal year ended December 31, 2021, our actual results could differ materially from the results described in, or implied by, these forward-looking statements.

Overview

We are a medical technology company focused on the development and commercialization of innovative, minimally invasive solutions for patients with OSA. Our proprietary Inspire system is the first and only FDA-approved neurostimulation technology that provides a safe and effective treatment for moderate to severe OSA. We have developed a novel, closed-loop solution that continuously monitors a patient's breathing and delivers mild hypoglossal nerve stimulation to maintain an open airway. Inspire therapy is indicated for patients with moderate to severe OSA who do not have significant central sleep apnea and do not have a complete concentric collapse of the airway at the soft palate level. In addition, patients in the U.S., Japan, and Singapore must have been confirmed to fail or be unable to tolerate positive airway pressure treatments, such as CPAP, and be 18 years of age or older, though there are no similar requirements for patients in Europe.

We sell our Inspire system to hospitals and ambulatory surgery centers ("ASCs") in the U.S. and in select countries in Europe through a direct sales organization and we sell our Inspire system in Japan and Singapore through distributors. Our direct sales force engages in sales efforts and promotional activities focused on ENT physicians and sleep centers. In addition, we highlight our compelling clinical data and value proposition to increase awareness and adoption amongst referring physicians. We build upon this top-down approach with strong direct-to-consumer marketing initiatives to create awareness of the benefits of our Inspire system and drive interest through patient empowerment. This outreach helps to educate thousands of patients on our Inspire therapy.

Although our sales and marketing efforts are directed at patients and physicians because they are the primary users of our technology, we consider the hospitals and ASCs where the procedure is performed to be our customers, as they are the purchasing agents of our Inspire system. Our customers are reimbursed the cost required to treat each patient through various third-party payors, such as commercial payors and government agencies. Our Inspire system is currently reimbursed primarily on a per-patient prior authorization basis for patients covered by commercial payors, under Local Coverage Determinations for patients covered by Medicare, and under U.S. government contract for patients who are treated by the Veterans Health Administration. As of August 2, 2022, we have secured positive coverage policies with many U.S. commercial payors, including virtually all large national commercial insurers, covering approximately 260 million lives in the U.S. In addition, all seven Medicare Administrative Contractors published final policies in 2020 that provide coverage of Inspire therapy when certain coverage criteria are met.

The procedure performed to implant our device was previously described for billing purposes using a Category I Current Procedural Terminology ("CPT") code (64568), which was used in conjunction with a temporary Category III CPT code (+0466T). At the October 2020 American Medical Association ("AMA") CPT Editorial Panel meeting, the AMA approved the creation of new Category I CPT codes (64582, 64583, and 64584) to separately identify hypoglossal nerve stimulator services. A new Category I code (42975) was also approved for Drug-Induced Sleep Endoscopy ("DISE"), which is the final procedure to determine which patients are appropriate for Inspire therapy. These new codes went into effect on January 1, 2022. With these approvals, a formal survey was conducted to

determine the Medicare reimbursement levels assigned to each code and in November 2021 the final 2022 reimbursement rates were announced by the Centers for Medicare and Medicaid Services ("CMS"). The 2022 national average physician payments are approximately \$888 for implantation of a hypoglossal nerve stimulator and approximately \$115 for the DISE procedure. The 2022 rates of Medicare reimbursement to our hospital customers is approximately \$30,063, an increase of 2% over the 2021 rate. The ASC reimbursement rate for 2022 is approximately \$24,828, an increase of 2% over the 2021 rate.

In July 2022, the 2023 proposed Medicare reimbursement payments were announced. The 2023 proposed rate to our hospital customers is \$29,932, a decrease of less than 1% from the 2022 rate. The proposed ASC reimbursement for 2023 is \$25,744, an increase of 4% over the 2022 rate. The 2023 national average physician payments are proposed to be \$858 for implantation of a hypoglossal nerve stimulator, a 3% decrease over the 2022 payment, and \$95 for the DISE procedure, a 17% decrease from the 2022 amount. These reimbursement decisions will be reviewed by the CMS in conjunction with the annual Medicare Physician Fee Schedule rulemaking cycle with final decisions expected in November 2022.

Japan's Ministry of Health, Labour and Welfare ("MLHW") approved Inspire therapy to treat moderate to severe OSA in 2018 and was formally added to the Japan National Health Insurance Payment Listing in 2021. The first implant of Inspire therapy in Japan occurred in February 2022. Reimbursement in Singapore is handled through hospital innovation budgets or private health insurance sources. The first implants of Inspire therapy in Singapore occurred in May 2022. In 2020, the Australian Therapeutic Goods Administration approved Inspire therapy to treat moderate to severe OSA, and we are currently seeking reimbursement in Australia.

For the six months ended June 30, 2022, 96.0% of our revenue was derived in the U.S. and 4.0% was derived outside of the U.S. No single customer accounted for more than 10% of our revenue during the six months ended June 30, 2022.

We rely on third-party suppliers to manufacture our Inspire system and its components. Many of these suppliers are currently single source suppliers. We have experienced and continue to experience minor supply disruptions during the COVID pandemic, but have managed to avoid any significant supply and inventory issues. We seek to maintain higher levels of inventory to protect ourselves from supply interruptions, and, as a result, we are subject to the risk of inventory obsolescence and expiration, which could lead to inventory impairment charges. In the U.S. and Singapore, our products are shipped directly to our customers on a purchase order basis, primarily by a third-party vendor with a facility in Tennessee, although we do ship some products from our facility in Minnesota. Warehousing and shipping operations for our European customers are handled by a third-party vendor with a facility located in the Netherlands. Shipments of products to our Japanese distributor are handled from our facility in Minnesota. Customers do not have the right to return non-defective product, nor do we place product on consignment. Our sales representatives do not maintain trunk stock.

Since our inception in 2007, we have financed our operations primarily through sales of our Inspire system, private placements of our convertible preferred securities, amounts borrowed under our credit facility, and equity offerings of our common stock. We have devoted significant resources to research and development activities related to our Inspire system, including clinical and regulatory initiatives to obtain marketing approval, and sales and marketing activities. For the three months ended June 30, 2022, we generated revenue of \$91.4 million with a gross margin of 84.5% and had a net loss of \$14.5 million compared to revenue of \$53.0 million with a gross margin of 85.8% and a net loss of \$13.1 million for the three months ended June 30, 2021. For the six months ended June 30, 2022, we generated revenue of \$160.8 million with a gross margin of 85.0% and had a net loss of \$31.2 million compared to revenue of \$93.3 million with a gross margin of 85.5% and a net loss of \$29.3 million for the six months ended June 30, 2021. Our accumulated deficit as of June 30, 2022 was \$310.6 million.

We have invested heavily in product development. Our research and development activities have been centered on driving continuous improvements to our Inspire therapy. We have also made significant investments in clinical studies to demonstrate the safety and efficacy of our Inspire therapy and to support regulatory submissions. We continue to make investments in research and development efforts to develop our next generation Inspire systems and support our future regulatory submissions for expanded indications and for new markets such as additional European countries and the Asia Pacific region. For example, in July 2022, we received FDA approval for additional

magnetic resonance imaging ("MRI") scan conditions for use with Inspire therapy. This full-body MRI approval expands the Inspire use labeling that previously allowed only head, neck, and extremity MRI scans. In December 2021, we received FDA approval for our Bluetooth-enabled patient remote control. In the first quarter of 2021, we received FDA approvals for both a new Inspire physician programmer platform and an improved two-incision surgical implant procedure that eliminates one incision with a revised placement of the pressure sensing lead. In May 2021, we received CE Mark approval in Europe for the two-incision implant procedure. Japan's MLHW approved Inspire therapy to treat moderate to severe OSA in 2018 and was formally added to the Japan National Health Insurance Payment Listing in 2021.

Our direct-to-consumer marketing includes the use of social media platforms such as Facebook, Google ad placements, and radio and television commercials. In January 2021, we began airing television commercials and in January 2022, we purchased our first national television advertising spots and began airing new TV commercials. The objective of this outreach is to bring patients to our website, where they can find educational materials and videos on sleep apnea and the use and benefits of our Inspire therapy, contact information for physicians and clinical sites, and information regarding community awareness events. Further, our team leverages the Inspire Sleep app for patient education. We expect to continue to increase our direct-to-consumer activities.

In early 2020, we started a call center concept, the Inspire Advisor Care Program ("ACP"). The primary purpose of this program is to assist patients with making a connection with a qualified healthcare provider based on their specific needs. As of June 30, 2022, over 85% of our U.S. centers utilize the ACP. We plan to continue to increase the number of our U.S. centers using the ACP.

One of the many benefits of the ACP is the anecdotal feedback we are able to collect from patients during conversations with the ACP representatives. An example of this is the intelligence we have gathered that leads us to believe that we are beginning to see increased patient inquiries about Inspire as a result of the Philips Respironics CPAP recall. Following the recall announcement in July 2021, it took time for patients to learn about the recall, become educated about treatment alternatives and ultimately schedule an appointment with a healthcare provider to determine eligibility for an Inspire procedure. While we cannot quantify the impact from the recall, the feedback from the ACP, as well as prior authorizations data and the Inspire Sleep app, all indicate increased patient flow as a result of the Philips recall. Long term, we believe that there could be a sustained benefit to our business as a result of the recall.

We also continue to make significant investments to build our sales and marketing organization by increasing the number of U.S. and European sales representatives and continuing our direct-to-consumer marketing efforts in existing and new markets throughout the U.S. and in Europe. During the three months ended June 30, 2022, we created 17 new U.S. sales territories, bringing the total to 191 U.S. territories as of June 30, 2022. During that same period, we activated 52 new centers, bringing the total to 785 U.S. medical centers implanting Inspire therapy as of June 30, 2022. At June 30, 2022, ASCs made up 23% of our total U.S. implanting centers, up from 22% at December 31, 2021.

Because of these and other factors, we may continue to incur net losses for the next several years, and we may require substantial additional funding, which may include future equity and debt financings.

COVID-19 Pandemic Update

Our business, operations, and financial condition and results have been and may continue to be impacted by the COVID-19 pandemic. In 2020, we experienced significant reduction in revenue and product sales, as our customers were negatively impacted by the decline in the volume of elective procedures that resulted from the global healthcare system's response to COVID-19. During the quarter ended March 31, 2021, resurgences of COVID-19 in various U.S. and European regions disrupted our ability to access our clinician customers and their patients, although surgical volumes generally returned to pre-pandemic levels by the end of the quarter. As 2021 progressed, we observed a diminishing degree of COVID-related impacts to our reported revenue. During the six months ended June 30, 2022, resurgences of COVID-19 in various U.S. and international regions again impacted our revenue, although surgical volumes had generally returned to pre-pandemic levels by the end of the first quarter, and therefore the impact on the quarter ended June 30, 2022 was less significant. We believe there continues to be

some adverse impact on our revenues. However, the extent to which the COVID-19 pandemic continues to impact our results of operations and financial condition will depend on future developments that are highly uncertain and cannot be predicted, including new information that may emerge concerning the severity and longevity of COVID-19 and its variants, the resurgence of COVID-19 in regions that have begun to recover from the initial impact of the pandemic, the impact of COVID-19 on economic activity, and the actions to contain its impact on public health and the global economy.

To date, we have not experienced significant disruptions to our supply chain network as a result of the COVID-19 pandemic. We have also not reduced our capital expenditures and are continuing to invest in research and development, however, we may determine to allocate resources differently due to impacts of the COVID-19 pandemic.

Components of Our Results of Operations

Revenue

We derive primarily all of our revenue from the sale of our Inspire system to hospitals and ASCs in the U.S., select countries in Europe, Japan, and Singapore. We recognize revenues from sales of our Inspire system when the customer obtains control of the product, which occurs at a point in time, either upon shipment of the product or receipt of the product, depending on shipment terms.

Our revenue has fluctuated, and may continue to fluctuate, from quarter to quarter due to a variety of factors. For example, we have historically experienced seasonality in our first and fourth quarters and have experienced adverse impacts on our revenue due to the COVID-19 pandemic and foreign currency exchange rates.

Cost of Goods Sold and Gross Margin

Cost of goods sold consists primarily of acquisition costs for the components of the Inspire system, overhead costs, scrap, and inventory obsolescence, warranty replacement costs, as well as distribution-related expenses such as logistics and shipping costs, net of shipping costs charged to customers. The overhead costs include the cost of material procurement, depreciation expense for production equipment, and operations supervision and management personnel, including employee compensation, stock-based compensation, supplies, and travel. We expect cost of goods sold to increase or decrease in absolute dollars primarily as, and to the extent, our revenue grows or declines, respectively.

We calculate gross margin as gross profit divided by revenue. Our gross margin has been and we expect it will continue to be affected by a variety of factors, including manufacturing costs, the average selling price of our Inspire system, the implementation of cost-reduction strategies, inventory obsolescence costs, which generally occur when new generations of our Inspire system are introduced, and to a lesser extent the sales mix between the U.S. and countries outside of the U.S., as our average selling price in the U.S. tends to be higher than in other countries. Our gross margin may increase slightly to the extent our production volumes increase and we receive discounts on the costs charged by our contract manufacturers, thereby reducing our per unit costs, and when we implement price increases on our products, thereby increasing our revenue. On the other hand, our gross margin may decrease slightly to the extent our materials and labor prices increase due to supply chain issues and inflation, thereby increasing our per unit costs. However, our gross margin may also fluctuate from quarter to quarter due to seasonality and foreign currency exchange rates.

Our gross margin for the remainder of 2022 may be lower than in previous periods 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, we expect gross margins to return to previous levels.

Research and Development Expenses

Research and development expenses consist primarily of product development, engineering, clinical studies to develop and support our products, regulatory expenses, quality assurance, testing, consulting services and other costs associated with the next generation versions of the Inspire system. These expenses include employee compensation, including stock-based compensation, supplies, materials, consulting, and travel expenses related to research and development programs. Additionally, these expenses include clinical trial management, payments to clinical investigators, data management and travel expenses for our various clinical trials.

We expect research and development expenses to increase in the future as we develop next generation versions of our Inspire system and continue to expand our clinical studies to further expand positive coverage policies from private commercial payors in the U.S. and enter into new markets including additional European countries and the Asia Pacific region. We expect research and development expenses as a percentage of revenue to vary over time depending on the level and timing of initiating new product development efforts and new clinical development activities.

Selling, General and Administrative Expenses

Selling, general and administrative ("SG&A") expenses consist primarily of compensation for personnel, including base salaries, stock-based compensation expense and commissions related to our sales organization, finance, information technology, and human resource functions, as well as spending related to marketing, sales operations, and training and reimbursement personnel. Other SG&A expenses include training physicians, travel expenses, advertising, direct-to-consumer promotional programs, conferences, trade shows and consulting services, professional services fees, audit fees, insurance costs and general corporate expenses, including facilities-related expenses.

We expect SG&A expenses to continue to increase as we expand our commercial infrastructure to both drive and support our planned growth in revenue and as we increase our headcount and expand administrative personnel to support our growth and operations as a public company including finance personnel and information technology services. Additionally, we anticipate an increase in our stock-based compensation expense with grants of stock options, restricted stock units, performance stock units, and shares of our common stock purchased pursuant to our employee stock purchase plan.

Other Expense

Other expense consists primarily of interest expense payable under our credit facility, realized losses on foreign currency, and interest and dividend income.

Seasonality

Historically, we have experienced seasonality in our first and fourth quarters, and we expect this trend to continue. In the U.S., we have experienced, and may in the future experience, higher sales in the fourth quarter as a result of patients having paid their annual insurance deductibles in full, thereby reducing their out-of-pocket costs. Alternatively, in the first quarter, many U.S. patients' insurance deductibles reset, requiring more out-of-pocket costs, which negatively impacts our sales during this period. In Germany, we have experienced reduced demand for our Inspire therapy in the first quarter of each year as Neue Untersuchungs-und-Behandlungsmethoden ("NUB") coverage status is being determined and as hospitals are establishing their budgets pertaining to allocation of funds to purchase our Inspire therapy. Beginning January 1, 2021, Inspire therapy is fully integrated into the German hospital reimbursement system ("G-DRG"), and we therefore may experience less seasonal fluctuations in Germany although it may not eliminate them.

Results of Operations

	Three Months Ended June 30,				Six Months Ended June 30,			
	2022	2021	\$ Change	% Change	2022	2021	\$ Change	% Change
(in thousands, except percentages)								
Revenue	\$ 91,386	\$ 52,959	\$ 38,427	72.6 %	\$ 160,768	\$ 93,311	\$ 67,457	72.3 %
Cost of goods sold	14,173	7,518	6,655	88.5 %	24,177	13,499	10,678	79.1 %
Gross profit	77,213	45,441	31,772	69.9 %	136,591	79,812	56,779	71.1 %
Gross margin	84.5%	85.8%			85.0%	85.5%		
Operating expenses:								
Research and development	14,534	9,288	5,246	56.5 %	26,404	17,442	8,962	51.4 %
Selling, general and administrative	76,686	48,697	27,989	57.5 %	140,250	90,603	49,647	54.8 %
Total operating expenses	91,220	57,985	33,235	57.3 %	166,654	108,045	58,609	54.2 %
Operating loss	(14,007)	(12,544)	(1,463)	11.7 %	(30,063)	(28,233)	(1,830)	6.5 %
Other expense, net	341	518	(177)	(34.2)%	879	1,022	(143)	(14.0)%
Loss before income taxes	(14,348)	(13,062)	(1,286)	9.8 %	(30,942)	(29,255)	(1,687)	5.8 %
Income taxes	142	26	116	446.2 %	242	49	193	393.9 %
Net loss	\$ (14,490)	\$ (13,088)	\$ (1,402)	10.7 %	\$ (31,184)	\$ (29,304)	\$ (1,880)	6.4 %

Comparison of the Three Months Ended June 30, 2022 and 2021

Revenue

Revenue increased \$38.4 million, or 72.6%, to \$91.4 million for the three months ended June 30, 2022 compared to \$53.0 million for the three months ended June 30, 2021. These results reflect an increase in sales of our Inspire system of \$38.5 million in the U.S. and a decrease of \$0.1 million outside of the U.S. Revenue growth was primarily due to increased market penetration in existing territories, expansion into new territories, and increased physician and patient awareness of our Inspire system.

Revenue information by region is summarized as follows:

	Three Months Ended June 30,				Change	
	2022		2021			
	Amount	% of Revenue	Amount	% of Revenue	\$	%
(in thousands, except percentages)						
United States	\$ 87,876	96.2 %	\$ 49,353	93.2 %	\$ 38,523	78.1 %
All other countries	3,510	3.8 %	3,606	6.8 %	(96)	(2.7)%
Total revenue	\$ 91,386	100.0 %	\$ 52,959	100.0 %	\$ 38,427	72.6 %

Revenue generated in the U.S. was \$87.9 million for the three months ended June 30, 2022, an increase of \$38.5 million, or 78.1%, compared to the three months ended June 30, 2021. Revenue growth in the U.S. was primarily due to increased market penetration in existing territories, expansion into new territories, increased physician and patient awareness of our Inspire system, and to a lesser extent, a list price increase that began to impact some U.S. customers in May 2022. The list price increase will be phased in to all U.S. customers over the remainder of 2022 and into the beginning of 2023.

Revenue generated outside of the U.S. was \$3.5 million in the three months ended June 30, 2022, a decrease of \$0.1 million, or 2.7%, compared to the three months ended June 30, 2021. The decrease in revenue was primarily due to unfavorable exchange rates, which was somewhat offset by increased market penetration in existing territories, the expansion of our European sales representatives into new territories, increased physician and patient awareness of our Inspire system, and sales to our new Singapore distributor.

Cost of Goods Sold and Gross Margin

Cost of goods sold increased \$6.7 million, or 88.5%, to \$14.2 million for the three months ended June 30, 2022 compared to \$7.5 million for the three months ended June 30, 2021. The increase was primarily due to product costs associated with higher sales volume of our Inspire system, as well as higher costs of certain component parts which was impacted by inflation and COVID-related supply chain issues.

Gross margin decreased to 84.5% for the three months ended June 30, 2022 compared to 85.8% for the three months ended June 30, 2021. Gross margin for the three months ended June 30, 2022 was lower primarily due to higher costs of certain component parts, somewhat offset by increased sales volume and manufacturing efficiencies, as well as a price increase which began taking effect for some U.S. customers during the three months ended June 30, 2022.

Research and Development Expenses

Research and development expenses increased \$5.2 million, or 56.5%, to \$14.5 million for the three months ended June 30, 2022 compared to \$9.3 million for the three months ended June 30, 2021. This change was primarily due to an increase of \$2.8 million of compensation and employee-related expenses, mainly as a result of increased headcount and stock-based compensation expense, an increase of \$2.6 million for ongoing research and development costs, including ongoing development of the Inspire Cloud and the next generation Inspire system, and a \$0.2 million decrease in regulatory submissions and clinical studies expenses.

Selling, General and Administrative Expenses

SG&A expenses increased \$28.0 million, or 57.5%, to \$76.7 million for the three months ended June 30, 2022 compared to \$48.7 million for the three months ended June 30, 2021. The primary driver of this change was an increase of \$16.7 million in compensation, including salaries, commissions, stock-based compensation, and other employee-related expenses, mainly as a result of increased headcount. In addition, marketing expenses increased \$7.8 million, primarily consisting of direct-to-consumer initiatives, including new national TV advertisements, which began airing in January 2022, and the expansion of our Advisor Care Program call center. Other drivers of the change to SG&A expenses included an increase in travel expenses of \$2.0 million and an increase in general corporate costs of \$1.7 million primarily due to office rent expense, insurance costs, computer equipment and software, and consulting fees.

Other Expense

Other expense decreased \$0.2 million, or 34.2%, to \$0.3 million for the three months ended June 30, 2022 compared to \$0.5 million for the three months ended June 30, 2021. The change was primarily due to an increase of \$0.3 million in interest and dividend income due to higher interest rates, somewhat offset by an increase of \$0.1 million in foreign currency translation losses due to exchange rates.

Income Taxes

We recorded a provision for incomes taxes of approximately \$0.1 million for both of the three months ended June 30, 2022 and June 30, 2021.

Comparison of the Six Months Ended June 30, 2022 and 2021

Revenue

Revenue increased \$67.5 million, or 72.3%, to \$160.8 million for the six months ended June 30, 2022 compared to \$93.3 million for the six months ended June 30, 2021. The increase was attributable to a \$67.2 million increase in sales of our Inspire system in the U.S and an increase of \$0.3 million outside of the U.S. Revenue growth was primarily due to increased market penetration in existing territories, expansion into new territories, and increased physician and patient awareness of our Inspire system.

During both of the six-month periods ended June 30, 2022 and 2021, resurgences of COVID-19 in various U.S. and international regions disrupted our ability to access our clinician customers and their patients, although surgical volumes generally returned to pre-pandemic levels by the end of the first quarter of each respective year.

Revenue information by region is summarized as follows:

	Six Months Ended June 30,				Change	
	2022		2021			
	Amount	% of Revenue	Amount	% of Revenue	\$	%
	(in thousands, except percentages)					
United States	\$ 154,302	96.0 %	\$ 87,122	93.4 %	\$ 67,180	77.1 %
All other countries	6,466	4.0 %	6,189	6.6 %	277	4.5 %
Total revenue	\$ 160,768	100.0 %	\$ 93,311	100.0 %	\$ 67,457	72.3 %

Revenue generated in the U.S. was \$154.3 million for the six months ended June 30, 2022, an increase of \$67.2 million, or 77.1%, compared to the six months ended June 30, 2021. Revenue growth in the U.S. was primarily due to increased market penetration in existing territories, the expansion into new territories, increased physician and patient awareness of our Inspire system, and to a lesser extent, a list price increase that began to impact some U.S. customers in May 2022. The list price increase will be phased in to all U.S. customers over the remainder of 2022 and into the beginning of 2023. As noted above, U.S. revenue during both periods was negatively impacted by the COVID-19 pandemic.

Revenue generated outside of the U.S. was \$6.5 million in the six months ended June 30, 2022, an increase of \$0.3 million, or 4.5%, compared to the six months ended June 30, 2021. Revenue growth outside the U.S. was primarily due to increased market penetration in existing territories, the expansion of our European sales representatives into new territories, sales to our Japan and Singapore distributors, and increased physician and patient awareness of our Inspire system. The growth was somewhat offset by unfavorable exchange rates. As noted above, international revenue during both periods was negatively impacted by the COVID-19 pandemic.

Cost of Goods Sold and Gross Margin

Cost of goods sold increased \$10.7 million, or 79.1%, to \$24.2 million for the six months ended June 30, 2022 compared to \$13.5 million for the six months ended June 30, 2021. The increase was primarily due to product costs associated with higher sales volume of our Inspire system, as well as higher costs of certain component parts which was impacted by inflation and COVID-related supply chain issues.

Gross margin decreased to 85.0% for the six months ended June 30, 2022 compared to 85.5% for the six months ended June 30, 2021. Gross margin for the six months ended June 30, 2022 was lower primarily due to higher costs of certain component parts, somewhat offset by increased sales volume and manufacturing efficiencies, as well as a list price increase which began taking effect for some U.S. customers during the three months ended June 30, 2022.

Research and Development Expenses

Research and development expenses increased \$9.0 million, or 51.4%, to \$26.4 million for the six months ended June 30, 2022 compared to \$17.4 million for the six months ended June 30, 2021. This change was primarily due to an increase of \$4.7 million of compensation and employee-related expenses, mainly as a result of increased headcount and stock-based compensation expense, \$4.5 million for ongoing research and development costs, including ongoing development of the Inspire Cloud and the next generation Inspire system, somewhat offset by a \$0.2 million decrease in regulatory submissions and clinical studies expenses.

Selling, General and Administrative Expenses

SG&A expenses increased \$49.6 million, or 54.8%, to \$140.3 million for the six months ended June 30, 2022 compared to \$90.6 million for the six months ended June 30, 2021. The primary driver of this change was an increase of \$29.1 million in compensation, including salaries, commissions, stock-based compensation, and other employee-related expenses, mainly as a result of increased headcount. In addition, marketing expenses increased \$4.4 million, primarily consisting of direct-to-consumer initiatives, including new national TV advertisements, which began airing in January 2022, and the expansion of our Advisor Care Program call center. Other drivers of the change to SG&A expenses included an increase in travel expenses of \$3.3 million and an increase in general corporate costs of \$2.5 million primarily due to office rent expense, insurance costs, computer equipment and software, consulting fees, and bank fees.

Other Expense, Net

Other expense, net decreased by \$0.1 million, or 14.0%, to \$0.9 million of expense, net for the six months ended June 30, 2022 compared to \$1.0 million of expense for the six months ended June 30, 2021. This change was primarily due to an increase of \$0.2 million in interest and dividend income due to higher interest rates on our cash, cash equivalents and investments balances, somewhat offset by an increase of \$0.1 million in foreign currency translation losses due to exchange rates.

Income Taxes

We recorded a provision for income taxes of \$0.2 million for the six months ended June 30, 2022 and a provision of approximately \$0.1 million for the six months ended June 30, 2021.

Liquidity and Capital Resources

As of June 30, 2022, we had cash, cash equivalents and available-for-sale securities of \$196.3 million, a decrease of \$28.1 million from \$224.4 million as of December 31, 2021. Working capital totaled \$216.3 million as of June 30, 2022, a decrease of \$11.0 million from December 31, 2021. We define working capital as current assets less current liabilities. The decrease in working capital was primarily due to a \$27.9 million decrease in cash and cash equivalents which was used to support operations, make strategic investments totaling \$10.3 million, and payments on our long-term debt of \$3.1 million. Working capital also decreased with a \$4.4 million increase in accounts payable, generally due to our business volume and headcount growth from the prior year, and the movement of \$3.1 million of our long-term debt into current liabilities, as the first principal payments became due in April 2022. The decrease in working capital was partially offset by the movement of \$9.8 million of our long-term investments into the short-term investments category as the related maturity date is now within 12 months; an increase of \$6.2 million in accounts receivable due to higher sales; an increase of \$4.6 million in inventory balances which grew to meet higher sales and to establish safety stock to avoid inventory shortages in the event of COVID-related production or supply issues; a \$1.9 million increase prepaid expense and other current assets primarily due to prepaid insurance costs; and a decrease of \$1.9 million in accrued expenses primarily due to accrued compensation paid during the first quarter of 2022.

We proactively manage our access to capital to support liquidity and continued growth. Our sources of capital include sales of our Inspire system, borrowings under credit facilities and registered offerings of our common stock.

At June 30, 2022, we had \$21.4 million of outstanding borrowings under our credit facility and no borrowings remain available under this credit facility. We began paying principal payments on the borrowings in April 2022, and the scheduled maturity date of the facility is March 2024. We were in compliance with all covenants under the credit facility as of June 30, 2022.

The primary objective of our investment activities is to preserve our capital for the purpose of funding operations while at the same time maximizing the income we receive from our investments without significantly increasing risk or decreasing availability. To achieve these objectives, our investment policy allows us to maintain a portfolio of certain types of debt securities issued by the U.S. government and its agencies, corporations with investment-grade credit ratings, or commercial paper and money market funds issued by the highest quality financial and non-financial companies. At June 30, 2022, we had \$166.2 million in money market funds and \$9.8 million of investments in U.S. government securities, and no investments with a contractual maturity over one year.

In the six months ended June 30, 2022, our SG&A expenditures increased significantly over the prior year period levels, and we anticipate further increases in the remainder of 2022. Our SG&A expenditures, primarily for increasing headcount and advertising, may exceed any associated increases in revenues, and therefore would reduce our cash flow from operations. We also anticipate R&D expenses will continue to be significant in the remainder of fiscal 2022, primarily related to the ongoing development of the Inspire Cloud and the next generation Inspire system.

We spent \$2.6 million on purchases of property and equipment in six months ended June 30, 2022, mainly on testing systems, production equipment, and leasehold improvements on our corporate office. We anticipate further capital expenditures in 2022, primarily for additional equipment.

As of June 30, 2022, we did not have any off-balance sheet arrangements that have, or are reasonably likely to have, a current or future material effect on our financial condition, results of operations, liquidity, capital expenditures or capital resources.

We believe that our existing cash and cash equivalents and investments, which totaled \$196.3 million as of June 30, 2022, together with cash flow from operations, will provide liquidity sufficient to meet our cash needs and fund our operations and planned capital expenditures for at least the next 12 months. There can be no assurance, however, that our business will continue to generate cash flows at historic levels.

Beyond the next 12 months, our cash requirements will depend extensively on the timing of market introduction, and extent of market acceptance of, our Inspire system. Our long-term cash requirements also will be significantly impacted by the level of our investment in commercialization, entry into new markets such as Singapore, Hong Kong, and Australia, whether we make strategic acquisitions, and competition. We cannot accurately predict our long-term cash requirements at this time. Additionally, the COVID-19 pandemic has negatively impacted the global economy, disrupted global supply chains and created significant volatility and disruption of financial markets. An extended period of global supply chain and economic disruption could materially affect our business, results of operations, access to sources of liquidity and financial condition. We may seek additional sources of liquidity and capital resources through additional securities offerings or through borrowings under a new credit facility. There can be no assurance that such transactions will be available to us on favorable terms, if at all.

Cash Flows

The following table presents a summary of our cash flow for the periods indicated:

	Six Months Ended June 30,	
	2022	2021
	(in thousands)	
Net cash provided by (used in):		
Operating activities	\$ (18,702)	\$ (20,515)
Investing activities	(12,884)	(477)
Financing activities	3,663	7,029
Effect of exchange rate on cash	26	(14)
Net decrease in cash and cash equivalents	<u>\$ (27,897)</u>	<u>\$ (13,977)</u>

Operating Activities

The net cash used in operating activities was \$18.7 million for the six months ended June 30, 2022 and consisted of a net loss of \$31.2 million, non-cash charges of \$23.9 million, and a decrease in net operating assets of \$11.4 million. The non-cash charges consisted primarily of stock-based compensation, which increased mainly as a result of granting more stock options and restricted stock to employees at a higher fair market value, as well as the introduction of performance stock unit grants. The remainder of the non-cash charges included depreciation and amortization, non-cash lease expense, stock issued for services rendered, accretion of the debt discount, and accretion of the investment discount. Operating assets includes inventories, which increased due to manufacturing of systems inventory to meet increased sales and to establish safety stock to avoid inventory shortages in the event of COVID-related production or supply issues. Operating assets also includes accounts receivable which increased due to higher sales, and prepaid expenses and other current assets which increased primarily due to prepaid insurance. Operating liabilities includes accrued expenses, which decreased primarily due to the payment of accrued compensation as annual bonuses were paid, and accounts payable, which increased generally due to our increased business volume year-over-year and the costs to support the growth of our operations, including compensation and personnel-related costs.

Investing Activities

Net cash used in investing activities for the six months ended June 30, 2022 was \$12.9 million and consisted of purchases of property and equipment of \$2.6 million and the purchase of strategic investments of \$10.3 million.

Financing Activities

Net cash provided by financing activities was \$3.7 million for the six months ended June 30, 2022 and consisted of proceeds from the exercise of stock options of \$4.6 million and \$2.1 million in proceeds from the issuance of common stock from our ESPP, partially offset \$3.1 million in payments on our long-term debt obligation and less than \$0.1 million of taxes paid to net share settlement of RSUs.

Contractual Obligations and Commitments

There have been no material changes to our contractual obligations and commitments from those described in our Annual Report on Form 10-K for the fiscal year ended December 31, 2021.

Critical Accounting Policies and Estimates

Our critical accounting policies and estimates are described in "Management's Discussion and Analysis of Financial Condition and Results of Operations—Critical Accounting Policies and Estimates" in our Annual Report on Form 10-K for the fiscal year ended December 31, 2021. We have reviewed and determined that those critical accounting policies and estimates remain our critical accounting policies and estimates as of and for the three and six months ended June 30, 2022.

Recent Accounting Pronouncements

We have reviewed all recently issued standards and have determined that such standards will not have a significant impact on our consolidated financial statements or do not otherwise apply to our operations.

Item 3. Quantitative and Qualitative Disclosures About Market Risk.

Interest Rate Risk

The risk associated with fluctuating interest rates is primarily limited to our cash equivalents which are carried at quoted market prices and our short-term investments. We do not currently use or plan to use financial derivatives in our investment portfolio. The interest rate for our outstanding debt is variable. A hypothetical 1% change in interest rates during any of the periods presented would not have had a material impact on our consolidated financial statements.

Credit Risk, Foreign Currency Risk, and Inflation Risk

For market risks related to changes in credit, foreign currency, and inflation, reference is made to Item 7A "Quantitative and Qualitative Disclosures About Market Risk" contained in Part II of our Annual Report on Form 10-K for the year ended December 31, 2021. Our exposure to these risks has not materially changed from those disclosed in our Annual Report on Form 10-K for the fiscal year ended December 31, 2021.

Item 4. Controls and Procedures.

Evaluation of disclosure controls and procedures

The term "disclosure controls and procedures," as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act, refers to controls and other procedures that are designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to the company's management, including its principal executive and principal financial officers, or persons performing similar functions, as appropriate to allow timely decisions regarding required disclosure. Our management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives, and our management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Our management, with the participation of our chief executive officer and our chief financial officer, evaluated the effectiveness of our disclosure controls and procedures as of the end of the period covered by this Quarterly Report on Form 10-Q. Based on that evaluation, our chief executive officer and our chief financial officer concluded that our disclosure controls and procedures were effective, at the reasonable assurance level, as of the end of the period covered by this Quarterly Report on Form 10-Q.

Changes in internal control over financial reporting.

There were no changes in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) that occurred during the quarter ended June 30, 2022 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II—OTHER INFORMATION

Item 1. Legal Proceedings.

From time to time we may be involved in claims and proceedings arising in the course of our business. The outcome of any such claims or proceedings, regardless of the merits, is inherently uncertain. We are not party to any material legal proceedings.

Item 1A. Risk Factors.

For a discussion of our potential risks and uncertainties, see the information in "Part I, Item 1A. Risk Factors" in our Annual Report on Form 10-K for the fiscal year ended December 31, 2021. There have been no material changes to the risk factors disclosed in our Annual Report on Form 10-K for the fiscal year ended December 31, 2021.

Item 2. Unregistered Sales of Equity Securities and Use of Proceeds.

None.

Item 3. Defaults Upon Senior Securities.

None.

Item 4. Mine Safety Disclosures.

Not applicable.

Item 5. Other Information.

None.

Item 6. Exhibits.

Exhibit Number	Description	Form	File No.	Exhibit	Filing Date	Filed/ Furnished Herewith
3.1	Seventh Amended and Restated Certificate of Incorporation of Inspire Medical Systems, Inc.	8-K	001-38468	3.1	5/7/2018	
3.2	Amended and Restated Bylaws of Inspire Medical Systems, Inc.	8-K	001-38468	3.2	5/7/2018	
10.1	Third Amendment to the Loan and Security Agreement, dated as of June 15, by and between Inspire Medical Systems, Inc. and Oxford Finance LLC.	8-K	001-38468	10.1	6/22/2022	
31.1	Certification of Principal Executive Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002					*
31.2	Certification of Principal Financial Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002					*
32.1	Certification of Principal Executive Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002					**
32.2	Certification of Principal Financial Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002					**
101.INS	Inline XBRL Instance Document - the instance document does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document					*
101.SCH	Inline XBRL Taxonomy Extension Schema Document					*
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document					*
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document					*
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document					*
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document					*
104	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101)					*

* Filed herewith.

** Furnished herewith.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

Inspire Medical Systems, Inc.

Date: August 2, 2022

By: /s/ TIMOTHY P. HERBERT
Timothy P. Herbert
President, Chief Executive Officer and Director
(principal executive officer)

Date: August 2, 2022

By: /s/ RICHARD J. BUCHHOLZ
Richard J. Buchholz
Chief Financial Officer
(principal financial officer and principal accounting officer)

CERTIFICATION

I, Timothy P. Herbert, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Inspire Medical Systems, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f) for the registrant and have:
 - a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - b. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - c. Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - d. Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: August 2, 2022

By: /s/ TIMOTHY P. HERBERT

Timothy P. Herbert
President, Chief Executive Officer and Director
(principal executive officer)

CERTIFICATION

I, Richard J. Buchholz, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Inspire Medical Systems, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f) for the registrant and have:
 - a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - b. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - c. Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - d. Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: August 2, 2022

By: /s/ RICHARD J. BUCHHOLZ

Richard J. Buchholz
Chief Financial Officer
(principal financial officer and principal
accounting officer)

1. The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and
2. The information contained in the Report fairly presents, in all material respects, the financial condition and result of operations of the Company.

By: /s/ TIMOTHY P. HERBERT
Timothy P. Herbert
President, Chief Executive Officer and Director
(principal executive officer)

The foregoing certification is being furnished solely to accompany the Report pursuant to 18 U.S.C. § 1350, and is not being filed for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, and is not to be incorporated by reference into any filing of the Company, whether made before or after the date hereof, regardless of any general incorporation language in such filing.

1. The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and
2. The information contained in the Report fairly presents, in all material respects, the financial condition and result of operations of the Company.

By: /s/ RICHARD J. BUCHHOLZ

The foregoing certification is being furnished solely to accompany the Report pursuant to 18 U.S.C. § 1350, and is not being filed for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, and is not to be incorporated by reference into any filing of the Company, whether made before or after the date hereof, regardless of any general incorporation language in such filing.