

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: September 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: 001-37599

LivaNova

LivaNova PLC

(Exact name of registrant as specified in its charter)

England and Wales

98-1268150

(State or other jurisdiction of
incorporation or organization)

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

20 Eastbourne Terrace, London, United Kingdom, W2 6LG

(Address of principal executive offices)

(Zip Code)

Registrant's telephone number, including area code: **(44) (0) 203 325-0660**

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

<u>Title of each class</u>	<u>Trading Symbol(s)</u>	<u>Name of each exchange on which registered</u>
Ordinary Shares - £1.00 par value per share	LIVN	The NASDAQ Stock Market LLC

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	<input checked="" type="checkbox"/>	Accelerated filer	<input type="checkbox"/>
Non-accelerated filer	<input type="checkbox"/>	Smaller reporting company	<input type="checkbox"/>
Emerging growth company	<input type="checkbox"/>		

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 Act). Yes ☐ No ☒

<u>Class</u>	<u>Outstanding at October 26, 2022</u>
Ordinary Shares - £1.00 par value per share	53,522,703

LIVANOVA PLC
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In this Quarterly Report on Form 10-Q, “LivaNova,” “the Company,” “we,” “us” and “our” refer to LivaNova PLC and its consolidated subsidiaries.

This report may contain references to our proprietary intellectual property, including among others:

- Trademarks for our Neuromodulation systems, the VNS Therapy™ System, the VITARIA™ System and our proprietary pulse generator products: Model 102 (Pulse™), Model 102R (Pulse Duo™), Model 103 (Demipulse™), Model 104 (Demipulse Duo™), Model 106 (AspireSR™), Model 1000 (SenTiva™), Model 1000-D (SenTiva™ Duo), Model 7103 (VITARIA™ and TitrationAssist™) and Model 8103 (Symmetry™).
- Trademarks for our Cardiopulmonary products and systems: Essenz™, S5™, S3™, S5 Pro™, B-Capta™, Inspire™, Heartlink™, XTRA™, 3T Heater-Cooler™, Connect™ and Revolution™.
- Trademarks for our advanced circulatory support systems: TandemLife™, TandemHeart™, TandemLung™, ProtekDuo™, LifeSPARC™, ALung™, Hemolung™, Respiratory Dialysis™ and ActivMix™.
- Trademarks for our obstructive sleep apnea system: ImThera™ and aura6000™.

These trademarks and trade names are the property of LivaNova or the property of our consolidated subsidiaries and are protected under applicable intellectual property laws. Solely for convenience, our trademarks and trade names referred to in this Quarterly Report on Form 10-Q may appear without the ™ symbol, but such references are not intended to indicate in any way that we will not assert, to the fullest extent under applicable law, our rights to these trademarks and trade names.

NOTE ABOUT FORWARD-LOOKING STATEMENTS

Certain statements in this Quarterly Report on Form 10-Q, other than purely historical information, are “forward-looking statements” within the meaning of the Private Securities Litigation Reform Act of 1995, Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934, as amended (the “Exchange Act”). These statements include, but are not limited to, LivaNova’s plans, objectives, strategies, financial performance and outlook, trends, the amount and timing of future cash distributions, prospects or future events and involve known and unknown risks that are difficult to predict. As a result, our actual financial results, performance, achievements or prospects may differ materially from those expressed or implied by these forward-looking statements. In some cases, you can identify forward-looking statements by the use of words such as “may,” “could,” “seek,” “guidance,” “predict,” “potential,” “likely,” “believe,” “will,” “should,” “expect,” “anticipate,” “estimate,” “plan,” “intend,” “forecast,” “foresee” or variations of these terms and similar expressions, or the negative of these terms or similar expressions. Such forward-looking statements are necessarily based on estimates and assumptions that, while considered reasonable by LivaNova and its management based on their knowledge and understanding of the business and industry, are inherently uncertain. These statements are not guarantees of future performance, and stockholders should not place undue reliance on forward-looking statements. There are a number of risks, uncertainties and other important factors, many of which are beyond our control, that could cause our actual results to differ materially from the forward-looking statements contained in this Quarterly Report on Form 10-Q, and include but are not limited to the risks and uncertainties summarized below:

- risks related to reductions, interruptions or increasing costs related to the supply of raw materials and components and the distribution of finished products, including as a result of inflation and war;
- volatility in the global market and worldwide economic conditions, including volatility caused by the invasion of Ukraine, inflation, changes to existing trade agreements and relationships between the U.S. and other countries including the implementation of sanctions;
- non-U.S. operational and economic risks and concerns including the effect of changes in foreign exchange rates on quarterly operating results;
- failure to retain key personnel, prevent labor shortages, or manage labor costs;
- risks associated with the impairment of goodwill and other assets resulting from acquisitions;
- risks relating to the effects of interest rate fluctuations on our operating results;
- risks relating to the outbreak and spread of COVID-19 and its variants around the world, including market volatility, reductions in business operations and reduction in medical procedures;
- changes in technology, including the development of superior or alternative technology or devices by competitors and/or competition from providers of alternative medical therapies;
- losses or costs from pending, or future lawsuits and governmental investigations, including any amount of liability or damages imposed by the Appeals Court or the Supreme Court of Italy with respect to SNIA S.p.A.;
- failure to develop and commercialize new products and the rate and degree of market acceptance of such products;
- failure to obtain approvals or maintain the current regulatory approvals for our products’ approved indications;
- failure to comply with, or changes in, laws, regulations or administrative practices affecting government regulation of our products, including, but not limited to, U.S. Food and Drug Administration (“FDA”) laws and regulations;
- changes in customer spending patterns;
- failure to establish, expand or maintain market acceptance of our products for the treatment of our approved indications;
- any legislative or administrative reform to the healthcare system, including the U.S. Medicare or Medicaid systems or international reimbursement systems, that significantly reduces reimbursement for our products or procedures or denies coverage for such products or procedures or enhances coverage for competitive products or procedures, as well as adverse decisions by administrators of such systems on coverage or reimbursement issues relating to our products;
- failure to obtain or maintain coverage and reimbursement for our products’ approved indications and risks related to cost containment efforts of healthcare purchasing organizations;
- unfavorable results from clinical studies or failure to meet milestones;
- risks relating to our indebtedness under the exchangeable senior notes, our revolving credit facility and our 2022 Term Facilities, as defined herein;

- effectiveness of our internal controls over financial reporting;
- changes in our profitability and/or failure to manage costs and expenses;
- fluctuations in future quarterly operating results and/or variations in revenue and operating expenses relative to estimates;
- cyber-attacks or other disruptions to our information technology systems;
- product liability, intellectual property, shareholder-related, environmental-related, income tax and other litigation, disputes, losses and costs;
- protection, expiration and validity of our intellectual property;
- failure to comply with applicable U.S. laws and regulations, including federal and state privacy and security laws and regulations, and applicable non-U.S. laws and regulations;
- harsh weather or natural disasters, including as a result of climate change, that interrupt our business operations or the business operations of our hospital-customers or failure to comply with evolving environmental laws;
- failure of new acquisitions to further our strategic objectives or strengthen our existing businesses;
- changes in tax laws and regulations, including exposure to additional income tax liabilities;
- changes in our common stock price; and
- activist investors causing disruptions to the business.

Other factors that could cause our actual results to differ from our projected results are described in (1) “Part II, Item 1A. Risk Factors” and elsewhere in this and our other Quarterly Reports on Form 10-Q, (2) our Annual Report on Form 10-K for the fiscal year ended December 31, 2021 (“2021 Form 10-K”), (3) our reports and registration statements filed and furnished from time to time with the Securities and Exchange Commission (“SEC”) and (4) other announcements we make from time to time.

Readers are cautioned not to place undue reliance on our forward-looking statements, which speak only as of the date hereof. We undertake no obligation to update or revise any forward-looking statements after the date they are made, whether as a result of new information, future events or otherwise. You should read the following discussion and analysis in conjunction with our unaudited condensed consolidated financial statements and related notes included elsewhere in this report. Operating results for the nine months ended September 30, 2022 are not necessarily indicative of future results, including the full fiscal year. You should also refer to our “Annual Consolidated Financial Statements,” “Notes” thereto, “Management’s Discussion and Analysis of Financial Condition and Results of Operations” and “Risk Factors” contained in our 2021 Form 10-K and in our Quarterly Reports on Form 10-Q.

Financial Information and Currency of Financial Statements

All of the financial information included in this quarterly report has been prepared in accordance with generally accepted accounting principles in the United States of America (“U.S.” and such principles, “U.S. GAAP”). The reporting currency of our condensed consolidated financial statements is U.S. dollars (“USD”).

PART I. FINANCIAL INFORMATION

Item 1. Financial Statements

LIVANOVA PLC AND SUBSIDIARIES
CONDENSED CONSOLIDATED STATEMENTS OF INCOME (LOSS)
(UNAUDITED)

(In thousands, except per share amounts)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2022	2021 ⁽¹⁾	2022	2021 ⁽¹⁾
Net revenue	\$ 252,605	\$ 253,215	\$ 746,931	\$ 765,301
Cost of sales	81,687	84,551	223,220	260,950
Gross profit	170,918	168,664	523,711	504,351
Operating expenses:				
Selling, general and administrative	114,630	109,042	349,637	347,471
Research and development	35,725	42,133	110,872	139,315
Impairment of goodwill	129,396	—	129,396	—
Other operating expenses	23,140	1,067	24,518	43,103
Operating (loss) income	(131,973)	16,422	(90,712)	(25,538)
Interest expense	(12,661)	(11,355)	(34,889)	(43,806)
Loss on debt extinguishment	—	(60,238)	—	(60,238)
Foreign exchange and other income/(expense)	38,528	13,614	44,065	7,410
Loss before tax	(106,106)	(41,557)	(81,536)	(122,172)
Income tax expense	1,295	1,858	6,347	8,410
Income (loss) from equity method investments	57	(28)	(24)	(109)
Net loss	<u>\$ (107,344)</u>	<u>\$ (43,443)</u>	<u>\$ (87,907)</u>	<u>\$ (130,691)</u>
Basic loss per share	\$ (2.01)	\$ (0.84)	\$ (1.64)	\$ (2.63)
Diluted loss per share	\$ (2.01)	\$ (0.84)	\$ (1.64)	\$ (2.63)
Shares used in computing basic loss per share	53,534	51,582	53,474	49,748
Shares used in computing diluted loss per share	53,534	51,582	53,474	49,748

(1) The condensed consolidated statements of income (loss) for the three and nine months ended September 30, 2021 have been revised. For further details refer to “Note 1. Unaudited Condensed Consolidated Financial Statements.”

See accompanying notes to the condensed consolidated financial statements

LIVANOVA PLC AND SUBSIDIARIES
CONDENSED CONSOLIDATED STATEMENTS OF COMPREHENSIVE INCOME (LOSS)
(UNAUDITED)
(In thousands)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2022	2021 ⁽¹⁾	2022	2021 ⁽¹⁾
Net loss	\$ (107,344)	\$ (43,443)	\$ (87,907)	\$ (130,691)
Other comprehensive income (loss):				
Net change in unrealized loss on derivatives	1,653	(1,197)	(274)	(2,782)
Tax effect	—	287	—	668
Net of tax	1,653	(910)	(274)	(2,114)
Foreign currency translation adjustment	(39,887)	(18,986)	(85,653)	(22,516)
Total other comprehensive loss	(38,234)	(19,896)	(85,927)	(24,630)
Total comprehensive loss	<u>\$ (145,578)</u>	<u>\$ (63,339)</u>	<u>\$ (173,834)</u>	<u>\$ (155,321)</u>

(1) The condensed consolidated statements of comprehensive income (loss) for the three and nine months ended September 30, 2021 have been revised. For further details refer to “Note 1. Unaudited Condensed Consolidated Financial Statements.”

See accompanying notes to the condensed consolidated financial statements

LIVANOVA PLC AND SUBSIDIARIES
CONDENSED CONSOLIDATED BALANCE SHEETS
(UNAUDITED)
(In thousands, except share amounts)

	September 30, 2022	December 31, 2021
ASSETS		
<i>Current Assets:</i>		
Cash and cash equivalents	\$ 231,114	\$ 207,992
Restricted cash	275,165	—
Accounts receivable, net of allowance of \$11,351 at September 30, 2022 and \$13,512 at December 31, 2021	172,093	185,354
Inventories	122,041	105,840
Prepaid and refundable taxes	26,456	37,621
Current derivative assets	760	106,629
Prepaid expenses and other current assets	23,593	35,745
Total Current Assets	851,222	679,181
Property, plant and equipment, net	139,162	150,066
Goodwill	742,370	899,525
Intangible assets, net	365,026	399,682
Operating lease assets	34,976	40,600
Investments	13,941	16,598
Deferred tax assets	1,415	2,197
Long-term derivative assets	48,223	—
Other assets	16,543	13,102
Total Assets	\$ 2,212,878	\$ 2,200,951
LIABILITIES AND STOCKHOLDERS' EQUITY		
<i>Current Liabilities:</i>		
Current debt obligations	\$ 21,695	\$ 229,673
Accounts payable	69,616	68,000
Accrued liabilities and other	79,008	88,937
Current derivative liabilities	3,572	183,109
Current litigation provision liability	43,989	32,845
Taxes payable	12,398	15,140
Accrued employee compensation and related benefits	57,738	79,266
Total Current Liabilities	288,016	696,970
Long-term debt obligations	518,249	9,849
Contingent consideration	81,850	86,830
Deferred tax liabilities	6,525	7,728
Long-term operating lease liabilities	28,236	35,919
Long-term employee compensation and related benefits	17,509	19,105
Long-term derivative liabilities	83,145	—
Other long-term liabilities	42,385	49,905
Total Liabilities	1,065,915	906,306
<i>Commitments and contingencies (Note 10)</i>		
<i>Stockholders' Equity:</i>		
Ordinary Shares, £1.00 par value; unlimited shares authorized; 53,814,279 shares issued and 53,522,857 shares outstanding at September 30, 2022; 53,761,510 shares issued and 53,263,297 shares outstanding at December 31, 2021	82,376	82,295
Additional paid-in capital	2,143,762	2,117,961
Accumulated other comprehensive loss	(93,104)	(7,177)
Accumulated deficit	(985,691)	(897,784)
Treasury stock at cost, 291,422 ordinary shares at September 30, 2022; 498,213 ordinary shares at December 31, 2021	(380)	(650)
Total Stockholders' Equity	1,146,963	1,294,645
Total Liabilities and Stockholders' Equity	\$ 2,212,878	\$ 2,200,951

See accompanying notes to the condensed consolidated financial statements

LIVANOVA PLC AND SUBSIDIARIES
CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS
(UNAUDITED)
(In thousands)

	Nine Months Ended September 30,	
	2022	2021 ⁽¹⁾
Operating Activities:		
Net loss	\$ (87,907)	\$ (130,691)
Non-cash items included in net loss:		
Impairment of goodwill	129,396	—
Remeasurement of derivative instruments	(38,825)	(2,211)
Stock-based compensation	32,492	30,574
Remeasurement of contingent consideration to fair value	(33,323)	17,755
Amortization	18,970	20,005
Depreciation	16,593	18,493
Amortization of debt issuance costs	16,394	13,087
Amortization of operating lease assets	7,100	12,133
Deferred tax expense (benefit)	977	(1,026)
Loss on debt extinguishment	—	60,238
Remeasurement of Respicardia investment and loan	—	(4,642)
Other	392	1,944
Changes in operating assets and liabilities:		
Accounts receivable, net	(1,665)	(7,851)
Inventories	(22,571)	8,778
Other current and non-current assets	12,191	20,532
Accounts payable and accrued current and non-current liabilities	(5,395)	2,999
Taxes payable	(1,772)	4,996
Litigation provision liability	8,171	3,951
Net cash provided by operating activities	51,218	69,064
Investing Activities:		
Purchases of property, plant and equipment	(17,383)	(17,893)
Acquisition, net of cash acquired	(8,857)	—
Purchase of investments	(928)	(3,520)
Proceeds from sale of Heart Valves, net of cash disposed	—	40,244
Proceeds from sale of Respicardia investment and loan	—	23,057
Other	(293)	(1,353)
Net cash (used in) provided by investing activities	(27,461)	40,535
Financing Activities:		
Proceeds from long-term debt obligations	507,547	—
Repayment of long-term debt obligations	(220,784)	(451,396)
Shares repurchased from employees for minimum tax withholding	(8,550)	(12,246)
Proceeds from deferred consideration from sale of Heart Valves, net of working capital adjustments	4,597	—
Payment of debt issuance costs	(3,292)	(1,875)
Proceeds from share issuances under ESPP	1,788	1,750
Proceeds from issuance of ordinary shares, net	—	324,180
Payment of make-whole premium on long-term debt obligations	—	(35,594)
Payment of contingent consideration	—	(5,249)
Other	481	2,247
Net cash provided by (used in) financing activities	281,787	(178,183)
Effect of exchange rate changes on cash, cash equivalents and restricted cash	(7,257)	(2,402)
Net increase (decrease) in cash, cash equivalents and restricted cash	298,287	(70,986)
Cash, cash equivalents and restricted cash at beginning of period	207,992	252,832
Cash, cash equivalents and restricted cash at end of period	\$ 506,279	\$ 181,846

(1) The condensed consolidated statement of cash flows for the three and nine months ended September 30, 2021 have been revised. For further details refer to “Note 1. Unaudited Condensed Consolidated Financial Statements.”

See accompanying notes to the condensed consolidated financial statements

LIVANOVA PLC AND SUBSIDIARIES
NOTES TO THE CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
(Unaudited)

Note 1. Unaudited Condensed Consolidated Financial Statements

Basis of Presentation

The accompanying condensed consolidated financial statements of LivaNova as of, and for the three and nine months ended September 30, 2022 and 2021, have been prepared in accordance with U.S. GAAP for interim financial information and the instructions to Form 10-Q and Article 10 of Regulation S-X. The accompanying condensed consolidated balance sheet of LivaNova at December 31, 2021 has been derived from audited financial statements contained in our 2021 Form 10-K, but does not include all of the information and footnotes required by U.S. GAAP for complete financial statements. In the opinion of management, the condensed consolidated financial statements reflect all adjustments considered necessary for a fair statement of the operating results of LivaNova and its subsidiaries, for the three and nine months ended September 30, 2022, and are not necessarily indicative of the results that may be expected for the year ending December 31, 2022. The financial information presented herein should be read in conjunction with the audited consolidated financial statements and notes thereto accompanying our 2021 Form 10-K.

Global Developments

COVID-19

The COVID-19 pandemic (“COVID-19”) and its effects on the economy, employment, patient behaviors and supply chain, among others, has caused and may continue to cause variable demand for our products. Our business continues to be affected by varying levels of government-imposed lockdowns in Asia, as well as global hospital-related challenges, which have led to a decrease in procedures. Notwithstanding improving market dynamics, our Neuromodulation business continues to experience ongoing COVID-19 related headwinds, as described above. Meanwhile, the recovery of global cardiopulmonary procedures has resulted in stronger demand for our Cardiopulmonary products. Our Advanced Circulatory Support (“ACS”) business has been negatively impacted by a reduction in patients treated with extracorporeal membrane oxygenation (“ECMO”) related to fewer severe COVID-19 cases and hospital-related challenges. We are monitoring the potential for various strains of the virus to cause a resumption of high levels of infection and hospitalization that, in turn, may affect the demand for our products, particularly as we move into the winter months.

Moreover, although our RECOVER study and ANTHEM-HFrEF and OSPREY clinical trials continue to progress, there may be delays or closures of sites in the future should COVID-19 or variants thereof strengthen or reemerge.

Our net revenue and profitability have been negatively affected by the unfavorable foreign currency exchange impact of the strengthened U.S. dollar against a number of currencies. Furthermore, we continue to experience supply chain delays and interruptions, labor shortages, inflationary pressures and logistical issues in the wake of COVID-19. Though, to date, our supply of raw materials and the production and distribution of finished products have not been materially affected, demand and low capacity worldwide have caused longer lead times and put price pressure on key raw materials. Moreover, freight and labor costs at our manufacturing facilities have increased substantially due to COVID-related disruptions and in the wake of inflation globally. The Company continues to respond to such challenges, and while we have business continuity plans in place, the impact of the ongoing challenges we are experiencing, along with their potential escalation, may adversely affect our business and the recoverability of our tangible and intangible assets. The future impact of pandemic-related developments remains uncertain.

Ukraine Invasion

In February 2022, Russia launched an invasion in Ukraine which caused us to assess our ability to sell in the market due to international sanctions, to consider the potential impact of raw material sourced from the region, and to determine whether we are able to transact in a compliant fashion. Although the region represented 1% of our total net revenue for 2021, the Russian invasion of Ukraine has increased economic uncertainties, and a significant escalation or continuation of the conflict could have a material, global impact on our operating results. In addition, our Russian employees and local subsidiary are subject to evolving laws and regulations imposed by the Russian authorities in response to international sanctions.

Revision of Previously Issued Financial Statements

During the fourth quarter of 2021, the Company identified and corrected an error related to foreign currency exchange rates utilized to calculate inventory and cost of sales for the years ended December 31, 2017 through 2020 and the nine months ended September 30, 2021. Using the guidance in ASC Topic 250, *Accounting Changes and Error Corrections*, ASC Topic 250-S99-1, *Assessing Materiality*, and ASC Topic 250-S99-2, *Considering the Effects of Prior Year Misstatements when Quantifying Misstatements in Current Year Financial Statements*, we evaluated whether our previously issued consolidated financial statements were materially misstated due to these errors. Based upon our evaluation of both quantitative and qualitative factors, we believe that the effects of these errors were not material individually or in the aggregate to any previously reported quarterly or annual period. Accordingly, we have revised our previously issued financial statements as shown below (in thousands):

Consolidated Statements of Income (Loss)

	Three Months Ended September 30, 2021			Nine Months Ended September 30, 2021		
	As Previously Reported	Adjustments	As Revised	As Previously Reported	Adjustments	As Revised
Cost of sales	\$ 83,105	\$ 1,446	\$ 84,551	\$ 256,828	\$ 4,122	\$ 260,950
Operating income (loss)	17,868	(1,446)	16,422	(21,416)	(4,122)	(25,538)
Loss before tax	(40,111)	(1,446)	(41,557)	(118,050)	(4,122)	(122,172)
Income tax expense (benefit)	2,098	(240)	1,858	9,094	(684)	8,410
Net loss	(42,237)	(1,206)	(43,443)	(127,253)	(3,438)	(130,691)
Basic and diluted loss per share	\$ (0.82)	\$ (0.02)	\$ (0.84)	\$ (2.56)	\$ (0.07)	\$ (2.63)

Consolidated Statements of Comprehensive Income (Loss)

	Three Months Ended September 30, 2021			Nine Months Ended September 30, 2021		
	As Previously Reported	Adjustments	As Revised	As Previously Reported	Adjustments	As Revised
Net loss	\$ (42,237)	\$ (1,206)	\$ (43,443)	\$ (127,253)	\$ (3,438)	\$ (130,691)
Total comprehensive loss	(62,133)	(1,206)	(63,339)	(151,883)	(3,438)	(155,321)

Consolidated Statements of Stockholders' Equity

	As Previously Reported		Adjustments		As Revised	
	Accumulated Deficit	Total Stockholders' Equity	Accumulated Deficit	Total Stockholders' Equity	Accumulated Deficit	Total Stockholders' Equity
September 30, 2021	\$ (879,655)	\$ 1,312,498	\$ (13,002)	\$ (13,002)	\$ (892,657)	\$ 1,299,496

Consolidated Statements of Cash Flows

	Nine Months Ended September 30, 2021		
	As Previously Reported	Adjustments	As Revised
Net loss	\$ (127,253)	\$ (3,438)	\$ (130,691)
Deferred tax benefit	(342)	(684)	(1,026)
Changes in operating assets and liabilities:			
Inventories	4,656	4,122	8,778
Net cash provided by operating activities	69,064	—	69,064

Reclassifications

We have reclassified certain prior period amounts on the condensed consolidated statements of income (loss), the condensed consolidated balance sheets and the condensed consolidated statements of cash flows for comparative purposes. These reclassifications did not have a material effect on our financial condition, results of operations or cash flows.

Significant Accounting Policies

Our significant accounting policies are detailed below and in “Note 2. Basis of Presentation, Use of Accounting Estimates and Significant Accounting Policies” and “Note 3. Revenue Recognition” of our 2021 Form 10-K.

Restricted Cash

The Company classifies cash that is not available for use in its operations as restricted cash within current assets on the condensed consolidated balance sheet. As of September 30, 2022, our restricted cash balance totaled \$275.2 million and was comprised of cash deposits with Barclays held as collateral for a first demand bank guarantee of €270.0 million (approximately \$263.9 million as of September 30, 2022) to obtain the suspension of the Court of Appeal of Milan judgment for the payment of damages in connection with the SNIA litigation until review of such judgment by the Italian Supreme Court (the “SNIA Litigation Guarantee”). As security for the SNIA Litigation Guarantee, LivaNova is required to grant cash collateral to Barclays in USD in an amount equal to the USD equivalent of 105% of the amount of the SNIA Litigation Guarantee calibrated on a biweekly basis. For additional information regarding the SNIA litigation, please refer to “Note 10. Commitments and Contingencies.”

Note 2. Business Combinations

As of December 31, 2021, LivaNova owned a 3% investment in ALung Technologies, Inc. (“ALung”), a privately held medical device company focused on creating advanced medical devices for treating respiratory failure. On May 2, 2022, we acquired the remaining 97% of equity interests in ALung for a purchase price of up to \$110.0 million, consisting of \$10.0 million paid at closing, subject to customary adjustments, and contingent consideration of up to \$100.0 million payable upon achievement of certain sales-based milestones beginning in 2023 and ending in 2027. Total consideration included approximately \$5.5 million of non-cash consideration.

The following table presents the acquisition date fair value of the consideration transferred and the fair value of our interest in ALung prior to the acquisition, including certain measurement period adjustments (in thousands):

	Initial Fair Value of Consideration	Measurement Period Adjustments ⁽¹⁾	Adjusted Fair Value of Consideration
Cash and other considerations	\$ 15,586	\$ —	\$ 15,586
Contingent consideration	26,369	(9,578)	16,791
Fair value of consideration transferred	<u>\$ 41,955</u>	<u>\$ (9,578)</u>	<u>\$ 32,377</u>

(1) During the third quarter of 2022, measurement period adjustments were recorded based on information obtained about facts and circumstances that existed as of the acquisition date.

The following table presents the preliminary purchase price allocation at fair value for the ALung acquisition, including certain measurement period adjustments (in thousands):

	Initial Purchase Price Allocation	Measurement Period Adjustments ⁽¹⁾	Adjusted Purchase Price Allocation
Developed technology - 15-year life	\$ 13,950	\$ (11,050)	\$ 2,900
Goodwill	25,893	977	26,870
Other assets and liabilities, net	2,112	495	2,607
Net assets acquired	<u>\$ 41,955</u>	<u>\$ (9,578)</u>	<u>\$ 32,377</u>

(1) During the third quarter of 2022, measurement period adjustments were recorded based on information obtained about facts and circumstances that existed as of the acquisition date.

Goodwill arising from the ALung acquisition, which is not deductible for tax purposes, primarily represents the synergies anticipated between ALung and our ACS business. The assets acquired, including goodwill, are recognized in our ACS segment. The goodwill for the ACS reporting unit was fully impaired during the third quarter of 2022. Please refer to “Note 5. Goodwill and Intangible Assets” for further details.

We recognized ALung acquisition-related expenses of approximately \$0.5 million and \$4.9 million during the three and nine months ended September 30, 2022, respectively, within “Selling, general and administrative” expenses on our consolidated statement of income (loss).

The Company's consolidated financial statements include the operating results of ALung from the acquisition date. Separate post-acquisition operating results and pro forma financial information for this acquisition have not been presented as the effect was not material for disclosure purposes.

The contingent consideration payments are triggered upon the achievement of thresholds associated with sales of products covered by the purchase agreement and are estimated to occur during the years reflected in the table below. The sales-based earnout was valued using projected sales from our internal strategic plan and is a Level 3 fair value measurement, which includes the following significant unobservable inputs (in thousands):

ALung Acquisition	Fair value at May 2, 2022	Valuation Technique	Unobservable Input	Ranges
Sales-based earnout	\$ 16,791	Monte Carlo simulation	Risk-adjusted discount rate	7.0% - 8.4%
			Credit risk discount rate	6.4% - 8.0%
			Revenue volatility	25.7%
			Projected years of earnout	2023 - 2027

For a reconciliation of the beginning and ending balance of contingent consideration liabilities refer to "Note 7. Fair Value Measurements."

Note 3. Divestiture of Heart Valve Business

On December 2, 2020, LivaNova entered into a Purchase Agreement with Mitral Holdco S.à r.l. ("Mitral"), a company incorporated under the laws of Luxembourg and wholly-owned and controlled by funds advised by Gyrus Capital S.A., a Swiss private equity firm. The Purchase Agreement provides for the divestiture of certain of LivaNova's subsidiaries as well as certain other assets and liabilities relating to the Company's Heart Valve business and site management operations conducted by the Company's subsidiary LivaNova Site Management ("LSM") at the Company's Saluggia campus for €60.0 million. On April 9, 2021, LivaNova and the Purchaser entered into an A&R Purchase Agreement which amends and restates the original Purchase Agreement to, among other things, defer the closing of the sale and purchase of LSM by up to two years and include or amend certain additional terms relating to such deferral, including certain amendments relating to the potential hazardous substances liabilities of LSM and the related expense reimbursement provisions.

The closing of the sale of the Heart Valve business occurred on June 1, 2021, and we received €34.8 million (approximately \$42.5 million as of June 1, 2021), subject to customary trade working capital and net indebtedness adjustments, as set forth in the Purchase Agreement. We also received \$3.0 million in December 2021 and the remaining deferred purchase price of €9.3 million in July 2022. In July 2022, we also made a €4.8 million payment to Mitral upon finalizing the trade working capital and net indebtedness adjustments. During the three and nine months ended September 30, 2021, we recognized a (loss) gain from the sale of the Heart Valve business of \$(0.1) million and \$0.7 million, respectively, which is included within other operating expenses on the condensed consolidated statements of income (loss).

On July 29, 2022, we received a demand letter from Mitral for approximately €20.8 million (\$21.2 million as of July 29, 2022) for breach of warranty claims under the A&R Purchase Agreement. Specifically, the claims allege failure to disclose certain information relating to a supplier, thereby allegedly impacting the profitability of Mitral's business in China and Japan. We responded via letter on October 14, 2022, that we do not believe Mitral's claims will be sustained and that LivaNova is not responsible for any alleged breach of warranty. We also noted that warranty claims of this type, subject to certain exceptions, are capped at €8 million, and the amount of any such loss. The Company has not recognized a liability related to this matter because any potential loss is not currently probable.

Note 4. Restructuring

We initiate restructuring plans to leverage economies of scale, streamline distribution and logistics, and strengthen operational and administrative effectiveness in order to reduce overall costs.

During the second quarter of 2022, management committed to implement a cost-optimization and cost reduction program to adapt to current economic conditions, which includes a workforce reduction to be completed by mid-2023. We recognized a charge of \$4.1 million and \$4.6 million during the three and nine months ended September 30, 2022, respectively. The total estimated restructuring costs associated with the plan are approximately \$10.0 million including employee termination benefits, consulting fees and contract termination costs.

The following table provides a reconciliation of the beginning and ending balance of the accruals and other reserves recorded in connection with our restructuring plans included within accrued liabilities and other and other long-term liabilities on the condensed consolidated balance sheet (in thousands):

Balance at December 31, 2021 ⁽¹⁾	\$	836
Charges		4,608
Cash payments		(1,831)
Balance at September 30, 2022	\$	3,613

(1) Represents restructuring plans initiated prior to 2022.

The following table presents restructuring expense by reportable segment (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2022	2021	2022	2021
Cardiopulmonary	\$ 371	\$ 53	\$ 390	\$ 2,882
Neuromodulation	2,328	(28)	2,278	1,493
Advanced Circulatory Support	739	—	739	—
Other	669	63	1,201	5,406
Total ⁽¹⁾	\$ 4,107	\$ 88	\$ 4,608	\$ 9,781

(1) Restructuring expense is included within other operating expenses on the condensed consolidated statements of income (loss).

Note 5. Goodwill and Intangible Assets

We test goodwill and indefinite-lived intangible assets for impairment on an annual basis on October 1 or when events or changes in circumstances indicate that a potential impairment exists.

As part of our assessment as of September 30, 2022, we considered that revenue for our ACS reporting unit during the nine months ended September 30, 2022, had declined by approximately 29% compared to the prior year period, primarily as a result of a reduction in severe COVID-19 cases, hospital-related challenges and product mix. Furthermore, future revenue projections were reduced. Based on these circumstances, we concluded it was more likely than not that the goodwill of our ACS reporting unit was impaired, and we performed a quantitative assessment of the goodwill as of September 30, 2022, using management's current estimate of future cash flows. Based on the valuation performed, we determined that the fair value of the ACS reporting unit was less than the carrying value and recognized a goodwill impairment of \$129.4 million, in our condensed consolidated statements of income (loss) for the three and nine months ended September 30, 2022. Cumulative goodwill impairments from continuing operations since the merger of Cyberonics, Inc. and Sorin S.p.A. in October 2015 through September 30, 2022 totaled \$193.1 million.

We also performed an interim impairment analysis related to the ImThera IPR&D intangible asset. As a result, we determined that the fair value of the asset exceeded the carrying value by 11% and the IPR&D intangible asset was not impaired.

Note 6. Investments

Investments on the condensed consolidated balance sheets represent the carrying value of our investments in equity securities of non-consolidated affiliates without readily determinable fair values and an investment accounted for under the equity method. As of September 30, 2022 and December 31, 2021, the carrying value of our investments was \$13.9 million and \$16.6 million, respectively.

As of December 31, 2021, LivaNova owned a 3% investment in ALung with a carrying value of \$3.0 million, as well as held a note receivable due from ALung with a carrying value of \$2.5 million. On May 2, 2022, we acquired the remaining 97% of equity interests in ALung. Please refer to “Note 2. Business Combinations” for further details.

In April 2021, Zoll Medical Corporation acquired Respicardia Inc., a privately funded U.S. company in which we had an equity investment and also to which we had a loan outstanding. As a result of the acquisition, we received proceeds of \$23.1 million for both our investment and loan receivable, which had carrying values of \$17.7 million and \$0.8 million as of December 31, 2020, respectively. The Company recorded a gain of \$4.6 million during the first quarter of 2021 to adjust the investment and loans receivable to fair value, which is included in “Foreign exchange and other income/(expense)” on the condensed consolidated statement of income (loss).

During the second quarter of 2021, the Company received a cash dividend from its investment in MD Start II of \$3.1 million, which is included in “Foreign exchange and other income/(expense)” on the condensed consolidated statements of income (loss) for the nine months ended September 30, 2021.

Note 7. Fair Value Measurements

We review the fair value hierarchy classification on a quarterly basis. Changes in the ability to observe valuation inputs may result in a reclassification of levels for certain securities within the fair value hierarchy. There were no transfers between Level 1, Level 2, or Level 3 during the nine months ended September 30, 2022 and 2021.

Assets and Liabilities Measured at Fair Value on a Recurring Basis

The following tables provide information by level for assets and liabilities that are measured at fair value on a recurring basis (in thousands):

	Fair Value as of September 30, 2022	Fair Value Measurements Using Inputs Considered as:		
		Level 1	Level 2	Level 3
Assets:				
Derivative assets - designated as cash flow hedges (foreign currency exchange rate “FX”)	\$ 377	\$ —	\$ 377	\$ —
Derivative assets - designated as cash flow hedges (interest rate swaps)	760	—	760	—
Derivative assets - freestanding instruments (FX)	47	—	47	—
Derivative assets - capped call derivatives	48,223	—	—	48,223
Convertible notes receivable	282	—	—	282
	<u>\$ 49,689</u>	<u>\$ —</u>	<u>\$ 1,184</u>	<u>\$ 48,505</u>
Liabilities:				
Derivative liabilities - designated as cash flow hedges (FX)	\$ 2,764	\$ —	\$ 2,764	\$ —
Derivative liabilities - freestanding instruments (FX)	1,232	—	1,232	—
Derivative liabilities - embedded exchange feature	83,145	—	—	83,145
Contingent consideration arrangements	81,850	—	—	81,850
	<u>\$ 168,991</u>	<u>\$ —</u>	<u>\$ 3,996</u>	<u>\$ 164,995</u>

	Fair Value as of December 31, 2021	Fair Value Measurements Using Inputs Considered as:		
		Level 1	Level 2	Level 3
Assets:				
Derivative assets - designated as cash flow hedges (FX)	\$ 243	\$ —	\$ 243	\$ —
Derivative assets - freestanding instruments (FX)	61	—	61	—
Derivative assets - capped call derivatives	106,629	—	—	106,629
Convertible notes receivable	2,767	—	—	2,767
	<u>\$ 109,700</u>	<u>\$ —</u>	<u>\$ 304</u>	<u>\$ 109,396</u>
Liabilities:				
Derivative liabilities - designated as cash flow hedges (FX)	\$ 1,286	\$ —	\$ 1,286	\$ —
Derivative liabilities - freestanding instruments (FX)	427	—	427	—
Derivative liabilities - embedded exchange feature	181,700	—	—	181,700
Contingent consideration arrangements	98,382	—	—	98,382
	<u>\$ 281,795</u>	<u>\$ —</u>	<u>\$ 1,713</u>	<u>\$ 280,082</u>

The following table provides a reconciliation of the beginning and ending balances of our recurring fair value measurements, using significant unobservable inputs (Level 3) (in thousands):

	Capped Call Derivative Asset	Convertible Notes Receivable	Embedded Exchange Feature Derivative Liability	Contingent Consideration Liability Arrangements
As of December 31, 2021	\$ 106,629	\$ 2,767	\$ 181,700	\$ 98,382
Additions	—	—	—	26,369
Utilized as business combination consideration	—	(2,485)	—	—
Measurement period adjustments ⁽¹⁾	—	—	—	(9,578)
Changes in fair value ⁽²⁾	(58,406)	—	(98,555)	(33,323)
Total at September 30, 2022 - long-term	<u>\$ 48,223</u>	<u>\$ 282</u>	<u>\$ 83,145</u>	<u>\$ 81,850</u>

(1) For further details refer to “Note 2. Business Combinations.”

(2) The decrease in fair value associated with contingent consideration arrangements during the nine months ended September 30, 2022 was primarily related to the change in (i) the discount rates due to increasing interest rates, (ii) the probability of the regulatory milestone-based payment associated with the acquisition of TandemLife and (iii) the timing of projected achievement of a certain regulatory milestone and timing of sales-based earnout payments associated with the acquisition of ImThera.

Embedded Exchange Feature and Capped Call Derivatives

In June 2020, the Company issued \$287.5 million in cash exchangeable senior notes and entered into related capped call transactions. The cash exchangeable senior notes include an embedded exchange feature that is bifurcated from the cash exchangeable senior notes. Please refer to “Note 8. Financing Arrangements” for further details. The embedded exchange feature derivative is measured at fair value using a binomial lattice model and discounted cash flows that utilize observable and unobservable market data. The capped call derivative is measured at fair value using the Black-Scholes model utilizing observable and unobservable market data, including stock price, remaining contractual term, expected volatility, risk-free interest rate and expected dividend yield, as applicable.

The embedded exchange feature and capped call derivatives are classified as Level 3 as the Company uses historical volatility and implied volatility from options traded to determine expected stock price volatility, an unobservable input that is significant to the valuation. In general, an increase in our stock price or stock price volatility would increase the fair value of the embedded exchange feature and capped call derivatives which would result in an increase in expense. As time to the expiration of the derivatives decreases, the fair value of the derivatives would decrease. The future impact on net income depends on how significant inputs such as stock price, stock price volatility and time to the expiration of the derivatives change in relation to

other inputs. Changes in the fair value of the embedded exchange feature derivative and capped call derivatives are recognized in “Foreign exchange and other income/(expense)” in the condensed consolidated statements of income (loss).

The fair value of the embedded exchange feature derivative liability and the capped call derivative assets were \$83.1 million and \$48.2 million, respectively, as of September 30, 2022 and the stock price volatility was 49%. As of September 30, 2022, a 10% lower volatility, holding other inputs constant, would result in approximate fair value for the embedded exchange feature derivative of \$68.8 million and a 10% higher volatility, holding other inputs constant, would result in approximate fair value of \$96.9 million. As of September 30, 2022, a 10% lower volatility, holding other inputs constant, would result in approximate fair value for the capped call derivatives of \$46.8 million and a 10% higher volatility, holding other inputs constant, would result in approximate fair value of \$47.3 million.

Contingent Consideration Arrangements

The following table provides the fair value of our Level 3 contingent consideration arrangements by acquisition (in thousands):

	September 30, 2022	December 31, 2021
ImThera	\$ 66,678	\$ 86,830
ALung	15,172	—
TandemLife	—	11,552
	<u>\$ 81,850</u>	<u>\$ 98,382</u>

The ImThera business combination involved contingent consideration arrangements composed of potential cash payments upon the achievement of a certain regulatory milestone and a sales-based earnout associated with sales of products. The sales-based earnouts are valued using projected sales from our internal strategic plan. These arrangements are Level 3 fair value measurements and include the following significant unobservable inputs as of September 30, 2022:

ImThera Acquisition	Valuation Technique	Unobservable Input	Inputs
Regulatory milestone-based payment	Discounted cash flow	Discount rate	10.8%
		Probability of payment	85%
		Projected payment year	2025
Sales-based earnout	Monte Carlo simulation	Risk-adjusted discount rate	14.8% - 15.0%
		Credit risk discount rate	11.1% - 11.6%
		Revenue volatility	32.5%
		Probability of payment	85%
		Projected years of earnout	2026 - 2029

The ALung business combination involved a contingent consideration arrangement composed of potential cash payments upon the achievement of certain sales-based thresholds associated with sales of products. The arrangement is a Level 3 fair value measurement and includes the following significant unobservable inputs as of September 30, 2022:

ALung Acquisition	Valuation Technique	Unobservable Input	Inputs
Sales-based earnout	Monte Carlo simulation	Risk-adjusted discount rate	8.5% - 9.6%
		Credit risk discount rate	9.6% - 11.4%
		Revenue volatility	26.8%
		Projected years of earnout	2023 - 2027

The TandemLife business combination involved a contingent consideration arrangement composed of potential cash payments upon the achievement of certain regulatory milestones. The probability of payment for the final regulatory milestone was reduced to 0% during the three months ended September 30, 2022.

Note 8. Financing Arrangements

The outstanding principal amount of our long-term debt as of September 30, 2022 and December 31, 2021 was as follows (in thousands, except interest rates):

	September 30, 2022	December 31, 2021	Maturity	Interest Rate
Term Facilities	\$ 290,689	\$ —	July 2027	5.71%
2020 Cash Exchangeable Senior Notes	235,776	225,140	December 2025	3.00%
Bank of America Merrill Lynch Banco Múltiplo S.A.	6,323	6,113	July 2023	13.76%
Mediocredito Italiano	2,196	3,379	December 2023	0.50% - 2.74%
Bank of America, U.S.	1,500	1,500	January 2023	5.45%
Other	515	663		
Total long-term facilities	536,999	236,795		
Less current portion of long-term debt	18,750	226,946		
Total long-term debt obligations	\$ 518,249	\$ 9,849		

Revolving Credit

The outstanding principal amount of our short-term unsecured revolving credit agreements and other agreements with various banks was \$2.9 million and \$2.7 million at September 30, 2022 and December 31, 2021, respectively, with interest rates ranging from 3.14% to 13.92% and loan terms ranging from overnight to 90 days, as of September 30, 2022.

On August 13, 2021, LivaNova PLC and its wholly-owned subsidiary, LivaNova USA, Inc. (the “Borrower”) entered into a First Lien Credit Agreement with the lenders and issuing banks party thereto and Goldman Sachs Bank USA, as First Lien Administrative Agent and First Lien Collateral Agent, relating to a \$125 million senior secured multi-currency revolving credit facility to be made available to the Borrower (the “2021 First Lien Credit Agreement”). The 2021 First Lien Credit Agreement, as amended from time to time, expires on August 13, 2026 and bears interest at a rate equal to, for U.S. dollar-denominated loans, an adjusted Secured Overnight Financing Rate (“SOFR”) with a floor of 0.00%, or a Base Rate, plus, in each case, a variable margin based on the Company’s senior secured net leverage ratio. Interest is paid monthly or quarterly, as selected by the Borrower, with any outstanding principal due at maturity. The First Lien Credit Agreement also contemplates the payment of commitment fees on the unused portion of the commitments, at a variable percentage based on the Company’s senior secured net leverage ratio. The 2021 First Lien Credit Agreement is available for working capital and other general corporate purposes and, if drawn, can be repaid at any time without premium or penalty. As of September 30, 2022, we were in compliance with the financial covenants contained in our 2021 First Lien Credit Agreement.

There were no outstanding borrowings under the 2021 First Lien Credit Agreement as of September 30, 2022 and December 31, 2021.

Bridge Loan Facility

On February 24, 2022, LivaNova PLC and its wholly-owned subsidiary, LivaNova USA, Inc., entered into an Incremental Facility Amendment No. 1 to the 2021 First Lien Credit Agreement, relating to a €200 million bridge loan facility (the “Bridge Loan Facility”). On March 16, 2022, LivaNova entered into Amendment No. 2 to the 2021 First Lien Credit Agreement, which converted the available borrowings under the Bridge Loan Facility from €200 million to \$220.0 million and converted the EURIBOR rate in the 2021 First Lien Credit Agreement to SOFR. LivaNova delivered a borrowing notice for \$220.0 million in connection with the Bridge Loan Facility, which was funded on March 17, 2022.

On March 18, 2022, LivaNova PLC, acting through its Italian branch, entered into an Indemnity Letter and an Account Pledge Agreement with Barclays, further to which Barclays issued the SNIA Litigation Guarantee. As security for the SNIA Litigation Guarantee, LivaNova is required to grant cash collateral to Barclays in USD in an amount equal to the USD equivalent of 105% of the amount of the SNIA Litigation Guarantee calibrated on a biweekly basis. The proceeds of the Bridge Loan Facility were used by LivaNova to post a portion of the cash collateral supporting the SNIA Litigation Guarantee. The cash held as collateral supporting the SNIA Litigation Guarantee of \$275.2 million was classified as restricted cash on the condensed consolidated balance sheet as of September 30, 2022. For additional information regarding the SNIA litigation, please refer to “Note 10. Commitments and Contingencies.”

Debt discounts and issuance costs related to the Bridge Loan Facility were approximately \$4.5 million. Amortization of debt discount and issuance costs for the Bridge Loan Facility was \$4.5 million for the nine months ended September 30, 2022 and is included in interest expense on the consolidated statement of income (loss).

The Bridge Loan Facility was repaid in full on July 6, 2022.

Term Facilities

On July 6, 2022, LivaNova and its wholly-owned subsidiary, LivaNova USA, Inc. (“LivaNova USA”), entered into a new incremental facility amendment (the “Incremental Amendment No. 2”) to its 2021 First Lien Credit Agreement. The Incremental Amendment No. 2 provides for LivaNova USA to, among other things, obtain commitments for term loan facilities from a syndicate of lenders in an aggregate principal amount of \$350 million consisting of (i) an initial term loan facility in an aggregate principal amount of \$300 million (the “Initial Term Facility”) and (ii) a delayed draw term loan facility in an additional aggregate principal amount of \$50 million, which are available in one single drawing on or after July 6 until the date that is nine months after such date (the “Delayed Draw Term Facility” and, together with the Initial Term Facility, the “Term Facilities”). As of September 30, 2022, availability under the Delayed Draw Term Facility was \$50 million.

Proceeds of the Initial Term Facility were used to repay in full the Bridge Loan Facility on July 6, 2022, with the remainder used for general corporate purposes of the Company. The Term Facilities have a maturity of the earlier of (i) five years or (ii) 91 days prior to December 15, 2025, the maturity date of the 2020 Cash Exchangeable Senior Notes, unless by that date LivaNova USA will have either redeemed or refinanced the Notes, or set aside an amount of cash equal to the then-outstanding principal amount of the Notes. The Term Facilities bear interest at a rate equal to an adjusted term SOFR plus a variable margin based on the Company’s consolidated Total Net Leverage Ratio. As of September 30, 2022, the applicable margin over Adjusted SOFR was equal to 3.50% per annum. The Term Facilities are subject to an original issue discount of 1.5% of their principal amount. The Delayed Draw Term Facility also contemplates the payment of commitment fees at a variable percentage based on the Company’s Total Net Leverage Ratio. As of September 30, 2022, the applicable commitment fee percentage was equal to 0.50% per annum. The Term Facilities are subject to quarterly principal repayment, based on the following amortization schedule: (i) during the first year from the initial funding date: 1.9%; (ii) year two: 5.0%; (iii) year three: 5.0%; (iv) year four: 7.5%; and (v) year five: 10.0%, with the remainder to be paid at maturity. The effective interest rate of the Initial Term Facility at September 30, 2022 was 6.53%.

The 2021 First Lien Credit Agreement, as amended, contains customary representations, warranties and covenants, including the requirement to maintain a Senior Secured First Lien Net Leverage Ratio, calculated as the ratio of Consolidated Senior Secured First Lien Net Indebtedness to Consolidated EBITDA, as defined in the credit agreement, for the period of four consecutive fiscal quarters ended on the calculation date, of not more than 3.50 to 1.00 and an Interest Coverage Ratio, calculated as the ratio of Consolidated EBITDA to Consolidated Interest Expense, as defined in the credit agreement, for the period of four consecutive fiscal quarters ended on the calculation date, of not less than 3.00 to 1.00. As of September 30, 2022, we were in compliance with the financial covenants contained in our 2021 First Lien Credit Agreement.

Debt discounts and issuance costs related to the Initial Term Facility were approximately \$9.6 million. Amortization of debt discount and issuance costs for the Initial Term Facility was \$0.4 million for each of the three and nine months ended September 30, 2022, and is included in interest expense on the consolidated statement of income (loss). The unamortized discount and issuance costs related to the Initial Term Facility as of September 30, 2022 was \$9.2 million. Issuance costs related to the Delayed Draw Term Facility were approximately \$1.6 million. Amortization of issuance costs for the Delayed Draw Term Facility was \$0.5 million for each of the three and nine months ended September 30, 2022, and is included in interest expense on the consolidated statement of income (loss). The unamortized issuance cost related to the Delayed Draw Term Facility as of September 30, 2022 was \$1.1 million and is included within prepaid expenses and other current assets on the condensed consolidated balance sheet.

2020 Cash Exchangeable Senior Notes

On June 17, 2020, our wholly-owned subsidiary, LivaNova USA, Inc., issued \$287.5 million aggregate principal amount of 3.00% Notes (the “Notes”) by private placement to qualified institutional buyers pursuant to Rule 144A under the Securities Act of 1933, as amended. The sale of the Notes resulted in approximately \$278.0 million in net proceeds to the Company after deducting issuance costs. Interest is payable semiannually in arrears on June 15 and December 15 of each year. The effective interest rate of the Notes at September 30, 2022 was 9.95%. The Notes mature on December 15, 2025 unless earlier exchanged, repurchased, or redeemed.

Debt discounts and issuance costs related to the Notes were approximately \$82.0 million and included \$75.0 million of discount attributable to the embedded exchange feature, discussed below, and \$7.0 million of allocated issuance costs to the Notes related to legal, bank and accounting fees. Amortization of debt discount and issuance costs for the Notes was

\$3.7 million and \$10.6 million for the three and nine months ended September 30, 2022, respectively, and is included in interest expense on the consolidated statement of income (loss). The unamortized discount related to the Notes as of September 30, 2022 and December 31, 2021 was \$51.7 million and \$62.4 million, respectively.

Holders of the Notes are entitled to exchange the Notes at any time during specified periods, at their option. This includes the right to exchange the Notes during any calendar quarter, if the last reported sale price of LivaNova's ordinary shares, with a nominal value of £1.00 per share, is greater than or equal to 130% of the exchange price, or \$79.27 per share for at least 20 trading days (whether or not consecutive) during a period of 30 consecutive trading days ending on, and including, the last trading day of the immediately preceding calendar quarter. The exchange condition was not satisfied during the quarterly period ending September 30, 2022. As a result, we have included our obligations from the Notes and the associated embedded exchange feature derivative as a long-term liability on the consolidated balance sheet as of September 30, 2022. The Notes are exchangeable solely into cash and are not exchangeable into ordinary shares of LivaNova or any other security under any circumstances. The initial exchange rate for the Notes is 16.3980 ordinary shares per \$1,000 principal amount of Notes (equivalent to an initial exchange price of approximately \$60.98 per share). The exchange rate is subject to adjustment in certain circumstances, as set forth in the indenture governing the Notes.

The Company may redeem the Notes at its option, on or after June 20, 2023 and prior to the 51st scheduled trading day immediately preceding the maturity date, in whole or in part, if the last reported sale price per ordinary share has been at least 130% of the exchange price then in effect for at least 20 trading days (whether or not consecutive), including the trading day immediately preceding the date on which the Company provides notice of redemption, during any 30 consecutive trading day period ending on, and including, the trading day immediately preceding the date on which the Company provides notice of redemption, at a redemption price equal to 100% of the principal amount of the Notes to be redeemed, plus accrued and unpaid interest to, but excluding, the redemption date. Additionally, the Company may redeem the Notes at its option, prior to their stated maturity, in whole but not in part, in connection with certain tax-related events.

Embedded Exchange Feature

The embedded exchange feature of the Notes requires bifurcation from the Notes and is accounted for as a derivative liability. The fair value of the Notes' embedded exchange feature derivative at the time of issuance was \$75.0 million and was recorded as debt discount on the Notes. This discount is amortized as interest expense using the effective interest method over the term of the Notes. The Notes' embedded exchange feature derivative is carried on the condensed consolidated balance sheets at its estimated fair value and is adjusted at the end of each reporting period, with the unrealized gain or loss reflected within "Foreign exchange and other income/(expense)" in the condensed consolidated statements of income (loss). The fair value of the embedded exchange feature derivative liability was \$83.1 million as of September 30, 2022.

Capped Call Transactions

In connection with the pricing of the Notes, the Company entered into privately negotiated capped call transactions with certain of the initial purchasers of the Notes or their respective affiliates. The capped call transactions cover, subject to anti-dilution adjustments substantially similar to those applicable to the Notes, the number of LivaNova's ordinary shares underlying the Notes and are expected generally to offset any cash payments the Company is required to make upon exchange of the Notes in excess of the principal amount thereof in the event that the market value per ordinary share, as measured under the capped call transactions, is greater than the strike price of the capped call transactions, with such offset being subject to an initial cap price of \$100.00 per share. The capped call transactions expire on December 15, 2025 and must be settled in cash. If the capped call transactions are converted or redeemed early, settlement occurs at their termination value, which is equal to their fair value at the time of the redemption. The capped call transactions are carried on the condensed consolidated balance sheets as a derivative asset at their estimated fair value and are adjusted at the end of each reporting period, with unrealized gain or loss reflected within "Foreign exchange and other income/(expense)" in the condensed consolidated statements of income (loss). The fair value of the capped call derivative assets was \$48.2 million as of September 30, 2022. As of September 30, 2022, the capped call derivative assets are classified as long-term.

Note 9. Derivatives and Risk Management

Due to the global nature of our operations, we are exposed to foreign currency exchange rate fluctuations. We enter into FX derivative contracts and interest rate swap contracts to reduce the impact of foreign currency exchange rate and interest rate fluctuations, respectively, on earnings and cash flow. We are also exposed to equity price risk in connection with our Notes, including exchange and settlement provisions based on the price of our ordinary shares at exchange or maturity of the Notes. In addition, the capped call transactions associated with the Notes also include settlement provisions that are based on the price of our ordinary shares, subject to a capped price per share. We do not enter into derivative contracts for speculative purposes.

We measure all outstanding derivatives each period end at fair value and report the fair value as either financial assets or liabilities on the condensed consolidated balance sheets. At inception of the contract, the derivative is designated as either a freestanding derivative or a hedge. Derivatives that are not designated as hedging instruments are referred to as freestanding derivatives with changes in fair value included in earnings.

If the derivative qualifies for hedge accounting, changes in the fair value of the derivative will be recorded in accumulated other comprehensive income (“AOCI”) until the hedged item is recognized in earnings upon settlement/termination. FX derivative gains and losses in AOCI are reclassified to our condensed consolidated statements of income (loss) as shown in the tables below, and interest rate swap gains and losses in AOCI are reclassified to interest expense on our condensed consolidated statements of income (loss). We evaluate hedge effectiveness at inception. Cash flows from derivative contracts are reported as operating activities on our condensed consolidated statements of cash flows.

Freestanding FX Derivative Contracts

The gross notional amount of FX derivative contracts not designated as hedging instruments outstanding at September 30, 2022 and December 31, 2021 was \$149.5 million and \$136.7 million, respectively. These derivative contracts are designed to offset the FX effects in earnings of various intercompany loans and trade receivables. We recorded net gains for these freestanding derivatives of \$7.7 million and \$2.4 million for the three months ended September 30, 2022 and 2021, respectively, and \$12.7 million and \$8.4 million for the nine months ended September 30, 2022 and 2021, respectively. These gains are included in “Foreign exchange and other income/(expense)” in the condensed consolidated statements of income (loss).

Counterparty Credit Risk

We are exposed to credit risk in the event of non-performance by the counterparties to our derivatives.

The two counterparties to the capped call transactions are financial institutions. To limit our credit risk, we selected financial institutions with a minimum long-term investment grade credit rating. Our exposure to the credit risk of the counterparties is not secured by any collateral. If a counterparty becomes subject to insolvency proceedings, we will become an unsecured creditor in those proceedings, with a claim equal to our exposure at that time under the capped call transactions with that counterparty.

To manage credit risk with respect to our other derivatives, the Company selects and periodically reviews counterparties based on credit ratings, limits its exposure with respect to each counterparty, and monitors the market positions. However, if one or more of these counterparties were in a liability position to the Company and were unable to meet their obligations, any transactions with the counterparty could be subject to early termination, which could result in substantial losses for the Company.

Cash Flow Hedges

Foreign Currency Risk

We utilize FX derivative contracts, designed as cash flow hedges, to hedge the variability of cash flows associated with our 12-month U.S. dollar forecasts of revenues and costs denominated in British Pound, Japanese Yen and the Euro. We transfer to earnings from AOCI the gain or loss realized on the FX derivative contracts at the time of invoicing.

Interest Rate Risk

We entered into interest rate swaps, which qualify for and are designated as cash flow hedges, for a notional amount covering a portion of the Initial Term Facility's outstanding principal through July 2023, in order to minimize the impact of changes in interest rates by swapping a portion of the Initial Term Facility's floating-rate interest payments for fixed-rate interest payments. The Initial Term Facility matures in July 2027.

The gross notional amounts of open derivative contracts designated as cash flow hedges at September 30, 2022 and December 31, 2021 were as follows (in thousands):

Description of Derivative Contract	September 30, 2022	December 31, 2021
FX derivative contracts to be exchanged for British Pounds	\$ 2,708	\$ 11,160
FX derivative contracts to be exchanged for Japanese Yen	1,668	6,648
FX derivative contracts to be exchanged for Euro	14,572	58,224
Interest rate swap contracts	210,000	—
	<u>\$ 228,948</u>	<u>\$ 76,032</u>

After-tax net (loss) gain associated with derivatives designated as cash flow hedges recorded in the ending balance of AOCI and the amount expected to be reclassified to earnings in the next 12 months are as follows (in thousands):

Description of Derivative Contract	After-Tax Net (Loss) Gain in AOCI as of September 30, 2022	After-Tax Net (Loss) Gain in AOCI as of September 30, 2022 Expected to be Reclassified to Earnings in Next 12 Months
FX derivative contracts	\$ (2,367)	\$ (2,367)
Interest rate swap contracts	\$ 1,151	\$ 1,151

Pre-tax gains (losses) for derivative contracts designated as cash flow hedges recognized in other comprehensive income (loss) ("OCI") and the amount reclassified to earnings from AOCI were as follows (in thousands):

		Three Months Ended September 30,			
		2022		2021	
Description of Derivative Contract	Location in Earnings of Reclassified Gain or Loss	Gains Recognized in OCI	Gains (Losses) Reclassified from AOCI to Earnings	Losses Recognized in OCI	Gains Reclassified from AOCI to Earnings
FX derivative contracts	Foreign exchange and other income/(expense)	\$ 413	\$ 1,838	\$ (491)	\$ 133
FX derivative contracts	SG&A	—	(1,927)	—	573
Interest rate swap contracts	Interest expense	1,151	—	—	—
		<u>\$ 1,564</u>	<u>\$ (89)</u>	<u>\$ (491)</u>	<u>\$ 706</u>

		Nine Months Ended September 30,			
		2022		2021	
Description of Derivative Contract	Location in Earnings of Reclassified Gain or Loss	(Losses) Gains Recognized in OCI	Gains (Losses) Reclassified from AOCI to Earnings	Losses Recognized in OCI	(Losses) Gains Reclassified from AOCI to Earnings
FX derivative contracts	Foreign exchange and other gains (losses)	\$ (1,345)	\$ 3,517	\$ (3,335)	\$ (2,669)
FX derivative contracts	SG&A	—	(3,437)	—	2,116
Interest rate swap contracts	Interest expense	1,151	—	—	—
		<u>\$ (194)</u>	<u>\$ 80</u>	<u>\$ (3,335)</u>	<u>\$ (553)</u>

We offset fair value amounts associated with our derivative instruments on our condensed consolidated balance sheets that are executed with the same counterparty under master netting arrangements. Our netting arrangements include a right to set off or net together purchases and sales of similar products in the settlement process.

The following tables present the fair value and the location of derivative contracts reported on the condensed consolidated balance sheets (in thousands):

September 30, 2022	Asset Derivatives		Liability Derivatives	
Derivatives Designated as Hedging Instruments	Balance Sheet Location	Fair Value ⁽¹⁾	Balance Sheet Location	Fair Value ⁽¹⁾
FX derivative contracts	Current derivative liabilities	\$ 377	Current derivative liabilities	\$ 2,764
Interest rate swap contracts	Current derivative assets	760		
Total derivatives designated as hedging instruments		1,137		2,764
Derivatives Not Designated as Hedging Instruments				
FX derivative contracts	Current derivative liabilities	47	Current derivative liabilities	1,232
Capped call derivatives	Long-term derivative assets	48,223		
Embedded exchange feature			Long-term derivative liabilities	83,145
Total derivatives not designated as hedging instruments		48,270		84,377
Total derivatives		<u>\$ 49,407</u>		<u>\$ 87,141</u>
December 31, 2021	Asset Derivatives		Liability Derivatives	
Derivatives Designated as Hedging Instruments	Balance Sheet Location	Fair Value ⁽¹⁾	Balance Sheet Location	Fair Value ⁽¹⁾
FX derivative contracts	Current derivative liabilities	\$ 243	Current derivative liabilities	\$ 1,286
Total derivatives designated as hedging instruments		243		1,286
Derivatives Not Designated as Hedging Instruments				
FX derivative contracts	Current derivative liabilities	61	Current derivative liabilities	427
Capped call derivatives	Current derivative assets	106,629		
Embedded exchange feature			Current derivative liabilities	181,700
Total derivatives not designated as hedging instruments		106,690		182,127
Total derivatives		<u>\$ 106,933</u>		<u>\$ 183,413</u>

(1) For the classification of inputs used to evaluate the fair value of our derivatives, refer to “Note 7. Fair Value Measurements.”

Note 10. Commitments and Contingencies

FDA Warning Letter

On December 29, 2015, the FDA issued a Warning Letter alleging certain violations of FDA regulations applicable to medical device manufacturers at our Munich, Germany and Arvada, Colorado facilities.

The FDA inspected the Munich facility from August 24, 2015 to August 27, 2015 and the Arvada facility from August 24, 2015 to September 1, 2015. On August 27, 2015, the FDA issued a Form 483 identifying two observed non-conformities with certain regulatory requirements at the Munich facility. We did not receive a Form 483 in connection with the FDA's inspection of the Arvada facility. Following receipt of the Form 483, we provided written responses to the FDA describing corrective and preventive actions that were underway or to be taken to address the FDA's observations at the Munich facility. The Warning Letter responded in part to our responses and identified other alleged violations related to the manufacture of our 3T Heater-Cooler device that were not previously included in the Form 483.

The Warning Letter further stated that our 3T devices and other devices we manufactured at our Munich facility were subject to refusal of admission into the U.S. until resolution of the issues set forth by the FDA in the Warning Letter. The FDA had informed us that the import alert was limited to the 3T devices, but that the agency reserved the right to expand the scope of the import alert if future circumstances warranted such action. The Warning Letter did not request that existing users cease using the 3T device, and manufacturing and shipment of all of our products other than the 3T device were unaffected by the import limitation. To help clarify these issues for current customers, we issued an informational Customer Letter in January 2016 and that same month agreed with the FDA on a process for shipping 3T devices to existing U.S. users pursuant to a certificate of medical necessity program.

Finally, the Warning Letter stated that premarket approval applications for Class III devices to which certain Quality System regulation deviations identified in the Warning Letter were reasonably related would not be approved until the violations had been corrected; however, this restriction applied only to the Munich and Arvada facilities, which do not manufacture or design devices subject to Class III premarket approval.

On February 25, 2020, LivaNova received clearance for K191402, a 510(k) for the 3T devices that addressed issues contained in the 2015 Warning Letter along with design changes that further mitigate the potential risk of aerosolization. Concurrent with this clearance, (1) 3T devices manufactured in accordance with K191402 will not be subjected to the import alert and (2) LivaNova initiated a correction to distribute the updated Operating Instructions cleared under K191402. With this 510(k) clearance, all actions to remediate the FDA's inspectional observations in the Warning Letter were complete, and LivaNova awaited the FDA's close-out inspection.

On April 28, 2022, the FDA completed its close-out inspection of the Munich, Germany facility and, at the conclusion of the inspection, issued a Form 483 which contained three inspectional observations in the areas of design validation, process validation and complaint investigations. We submitted a detailed response including our proposed corrective and preventative actions to address the FDA's observations. On August 10, 2022, LivaNova received the Establishment Inspection Report, indicating that the FDA considers the inspection closed. We await the FDA's determination regarding closure of the Warning Letter, the timing of which is uncertain. See "Item 1A. Risk Factors" in this Form 10-Q for additional information.

CDC and FDA Safety Communications and Company Field Safety Notice

On October 13, 2016, the Center for Disease Control (the "CDC") and the FDA separately released safety notifications regarding the 3T devices. The CDC's Morbidity and Mortality Weekly Report ("MMWR") and Health Advisory Notice ("HAN") reported that tests conducted by the CDC and its affiliates indicate that there appears to be genetic similarity between both patient and 3T device strains of the non-tuberculous mycobacterium ("NTM") bacteria *M. chimaera* isolated in hospitals in Iowa and Pennsylvania. Citing the geographic separation between the two hospitals referenced in the investigation, the report asserts that 3T devices manufactured prior to August 18, 2014 could have been contaminated during the manufacturing process. The CDC's HAN and FDA's Safety Communication, issued contemporaneously with the MMWR report, each assess certain risks associated with 3T devices and provide guidance for providers and patients. The CDC notification states that the decision to use the 3T device during a surgical operation is to be taken by the surgeon based on a risk approach and on patient need. Both the CDC's and FDA's communications confirm that 3T devices are critical medical devices and enable doctors to perform life-saving cardiac surgery procedures.

Also on October 13, 2016, concurrent with the CDC's HAN and FDA's Safety Communication, we issued a Field Safety Notice Update for U.S. users of 3T devices to proactively and voluntarily contact facilities to aid in implementation of the CDC and FDA recommendations. In the fourth quarter of 2016, we initiated a program to provide existing 3T device users with a new loaner 3T device at no charge pending regulatory approval and implementation of additional risk mitigation strategies

worldwide, including a vacuum canister and internal sealing upgrade program and a deep disinfection service. In April 2017, we obtained CE Mark in Europe for the design change of the 3T device, and in October 2018, the FDA concluded that we could commence the vacuum canister and internal sealing upgrade program in the U.S. On February 25, 2020, LivaNova received clearance for K191402, a 510(k) for the 3T devices that addressed issues contained in the 2015 Warning Letter along with design changes that further mitigate the potential risk of aerosolization. We are in the process of completing and closing out all recall activities with the FDA. While our vacuum canister and internal sealing upgrade program and deep cleaning service in the U.S. are complete, these services will continue as a servicing option outside of the U.S.

On December 31, 2016, we recognized a liability for our product remediation plan related to our 3T device. We concluded that it was probable that a liability had been incurred upon management's approval of the plan and the commitments made by management to various regulatory authorities globally during the fourth quarter of 2016, and furthermore, the cost associated with the plan was reasonably estimable. At September 30, 2022, the product remediation liability was \$0.7 million.

Saluggia Site Hazardous Substances

LSM, formerly a subsidiary of Sorin, one of the companies that merged into LivaNova PLC in 2015, manages site services for the campus in Saluggia, Italy. In addition to a LivaNova manufacturing facility, the Saluggia campus is also the location of manufacturing facilities of third parties, a cafeteria for workers, and storage facilities for hazardous substances and equipment previously used in a nuclear research center, later turned nuclear medicine business, between the 1960s and the late 1990s. Pursuant to authorization from the Italian government, LSM has, and continues to, perform ordinary maintenance, secure the facilities, monitor air and water quality and file applicable reports with the competent environmental authorities.

During 2020, LSM received correspondence from ISIN (a sub-body of the Italian Ministry of Economic Development) requesting that within five years, LSM demonstrate the financial capacity to meet its obligations under Italian law to clean and dismantle any contaminated buildings and equipment as well as to deliver hazardous substances to a national repository. This repository will be built by the Italian government at a location and time yet to be determined. ISIN subsequently published Technical Guide n. 30, which identifies the technical criteria, and general safety and protection requirements for the design, construction, operation and dismantling of temporary storage facilities for the hazardous substances. In January 2021, a list of 67 potential sites for the national repository was published.

Although there is no legal obligation to begin any work or deliver the hazardous substances, as the performance of these obligations is contingent on the construction of the as-yet unbuilt national repository, based on the aforementioned factors, the Company concluded its obligation to clean, dismantle, and deliver any hazardous substances to a national repository is probable and reasonably estimable. The estimated liability as of September 30, 2022 was \$33.6 million, which represented the low end of the estimated range of loss of \$33.6 million to \$42.7 million. The estimated liability as of December 31, 2021 was \$39.3 million. The decrease in the liability from December 31, 2021 was primarily due to the effects of foreign currency changes during the nine months ended September 30, 2022.

Litigation

Product Liability

The Company is currently involved in litigation involving our 3T device. The litigation includes federal multi-district litigation in the U.S. District Court for the Middle District of Pennsylvania, various U.S. state court cases and cases in jurisdictions outside the U.S. A class action, filed in February 2016 in the U.S. District Court for the Middle District of Pennsylvania, consisting of all Pennsylvania residents who underwent open heart surgery at WellSpan York Hospital and Penn State Milton S. Hershey Medical Center between 2011 and 2015 and who currently are asymptomatic for NTM infection, was dismissed on July 16, 2021.

On March 29, 2019, we announced a settlement framework that provides for a comprehensive resolution of the personal injury cases pending in the multi-district litigation in U.S. federal court, the related class action in federal court, as well as certain cases in state courts across the United States. The agreement, which makes no admission of liability, is subject to certain conditions, including acceptance of the settlement by individual claimants and provides for a total payment of up to \$225 million to resolve the claims covered by the settlement. Per the agreed-upon terms, the first payment of \$135 million was paid into a qualified settlement fund in July 2019 and the second payment of \$90 million was paid in January 2020. Cases covered by the settlement are being dismissed as amounts are disbursed to individual plaintiffs from the qualified settlement fund.

Cases in state courts in the U.S. and in jurisdictions outside the U.S. continue to progress. As of November 2, 2022, including the cases encompassed in the settlement framework described above that have not yet been dismissed, we were aware of approximately 90 filed and unfiled claims worldwide, with the majority of the claims in various federal or state courts throughout the United States. This number includes seven cases that have settled but have not yet been dismissed. The

complaints generally seek damages and other relief based on theories of strict liability, negligence, breach of express and implied warranties, failure to warn, design and manufacturing defect, fraudulent and negligent misrepresentation or concealment, unjust enrichment, and violations of various state consumer protection statutes.

During the third quarter of 2022, we recorded an additional liability of \$18.6 million due to new information received about the nature of certain claims. At September 30, 2022, the provision for these matters was \$46.8 million. While the amount accrued represents our best estimate for those filed and unfilled claims that we believe are both probable and estimable at this time, and which are a subset of the filed and unfilled claims worldwide of which we are currently aware, the actual liability for resolution of these matters may vary from our estimate. The remaining claims for which a provision has not been recorded are remote or the potential loss is not estimable at this time.

Changes in the carrying amount of the litigation provision liability are as follows (in thousands):

Total litigation provision liability at December 31, 2021	\$	39,470
Payments		(11,148)
Adjustments ⁽¹⁾		19,319
FX and other		(884)
Total litigation provision liability at September 30, 2022		46,757
Less current portion of litigation provision liability at September 30, 2022		43,989
Long-term portion of litigation provision liability at September 30, 2022 ⁽²⁾	\$	2,768

(1) Adjustments to the litigation provision are included within other operating expenses on the condensed consolidated statements of income (loss) and were \$18.6 million and \$19.3 million for the three and nine months ended September 30, 2022, respectively.

(2) Included within other long-term liabilities on the condensed consolidated balance sheet.

Environmental Liability

Sorin was created as a result of a spin-off (the “Sorin spin-off”) from SNIA in January 2004, and in October 2015, Sorin was merged into LivaNova. SNIA subsequently became insolvent, and the Italian Ministry of the Environment and the Protection of Land and Sea (the “Italian Ministry of the Environment”), sought compensation from SNIA in an aggregate amount of approximately \$3.4 billion for remediation costs relating to the environmental damage at chemical sites previously operated by SNIA’s other subsidiaries.

There are proceedings relating to the SNIA bankruptcy to which we are not a party in the Bankruptcy Court of Udine and the Bankruptcy Court of Milan. In September 2011, the Bankruptcy Court of Udine held that the Italian Ministry of the Environment and other Italian government agencies (the “Public Administrations”) were not creditors of either SNIA or its subsidiaries in connection with their claims in the Italian insolvency proceedings. The Public Administrations appealed. In January 2016, the Court of Udine rejected the appeal, and the Public Administrations appealed to the Supreme Court. Similarly, in July 2014, the Bankruptcy Court of Milan held that the Public Administrations were not creditors of either SNIA or its subsidiaries. The Public Administrations appealed. In April 2022, Bankruptcy Court of Milan declared the Public Administrations to be a non-privileged creditor of SNIA for up to €454 million, and the Public Administrations appealed to the Supreme Court.

In January 2012, SNIA filed a civil action against Sorin in the Civil Court of Milan asserting joint liability of a parent and a spun-off company; the Public Administrations entered voluntarily into the proceeding, asking Sorin, as jointly liable with SNIA, to pay compensation for SNIA’s environmental damages. On April 1, 2016, the Court of Milan dismissed all legal actions of SNIA and of the Public Administrations further requiring the Public Administrations to pay Sorin approximately €292,000 (approximately \$285,371 as of September 30, 2022) for legal fees. The Public Administrations appealed the 2016 decision to the Court of Appeal of Milan (“Court of Appeal”). On March 5, 2019, the Court of Appeal issued a partial decision on the merits declaring Sorin/LivaNova jointly liable with SNIA for SNIA’s environmental liabilities in an amount up to the fair value of the net worth received by Sorin because of the Sorin spin-off, an estimated €572.1 million (approximately \$559.1 million as of September 30, 2022). We appealed the partial decision on liability to the Italian Supreme Court in August 2019.

In November 2021, the Court of Appeal delivered the remainder of its decision, ordering LivaNova to pay damages of approximately €453.6 million (approximately \$443.3 million as of September 30, 2022). We appealed the decision on damages in December 2021. The Italian Supreme Court held a hearing on October 5, 2022 to address the appeals of liability and damages. We expect a decision in the first half of 2023.

On February 21, 2022, the Court of Appeal notified the Company that it granted the Company a suspension with respect to the payment of damages until a decision has been reached on the appeal to the Italian Supreme Court. This suspension was subject to our providing a first demand bank guarantee of €270.0 million (approximately \$263.9 million as of September 30, 2022) within 30 calendar days, and on March 21, 2022, LivaNova delivered the guarantee, thereby satisfying the condition. Refer to “Note 8. Financing Arrangements” for information on the financing of the guarantee.

In 2011, Caffaro, a SNIA subsidiary, sold its Brescia chemical business to Caffaro Brescia, a third party belonging to the Todisco group, and as part of the acquisition, Caffaro Brescia agreed to secure hydraulic barriers at the site and maintain existing environmental security measures. In September 2020, Caffaro Brescia declared it was withdrawing from its agreement to maintain the environmental measures. In January 2021, we (in addition to Caffaro Brescia, and other non-LivaNova entities) received an administrative order (“Order”) from the Italian Ministry of the Environment requiring us to ensure the maintenance of the environmental measures and to guarantee that such works remain fully operational, the annual management and maintenance for which is estimated at approximately €1 million per year. LivaNova’s receipt of the Order appears to be based on the aforementioned Court of Appeal decision regarding our alleged joint liability with SNIA for SNIA’s environmental liabilities. Our response, dated February 16, 2021, disputes the grounds upon which the Order is based. We also appealed the Order in the Administrative Court in Brescia.

We have not recognized a liability in connection with these related matters because any potential loss is not currently probable.

Contract Litigation / Claims

On November 25, 2019, LivaNova received notice of a lawsuit initiated by former members of Caisson Interventional, LLC (“Caisson”), a subsidiary of the Company acquired in 2017. The lawsuit, Todd J. Mortier, as Member Representative of the former Members of Caisson Interventional, LLC v. LivaNova USA, Inc., was filed in the United States District Court for the District of Minnesota. The complaint alleged (i) breach of contract, (ii) breach of the covenant of good faith and fair dealing and (iii) unjust enrichment in connection with the Company’s operation of Caisson’s Transcatheter Mitral Valve Replacement (“TMVR”) program and the Company’s November 20, 2019 announcement that it was ending the TMVR program at the end of 2019. The lawsuit sought damages arising out of the 2017 acquisition agreement, including various regulatory milestone payments. In May 2022, the District Court granted LivaNova’s motion for summary judgment; in response, Caisson filed a notice of appeal to the Eighth Circuit Court of Appeal. We intend to vigorously defend this claim. The Company has not recognized a liability related to this matter because any potential loss is not currently probable or reasonably estimable.

Please refer to “Note 3. Divestiture of Heart Valve Business” for information regarding a demand letter received by the Company from Mitral on July 29, 2022. The Company has not recognized a liability related to this matter because any potential loss is not currently probable.

Other Matters

Additionally, we are the subject of various pending or threatened legal actions and proceedings that arise in the ordinary course of our business. These matters are subject to many uncertainties and outcomes that are not predictable and that may not be known for extended periods of time. Since the outcome of these matters cannot be predicted with certainty, the costs associated with them could have a material adverse effect on our consolidated net income, financial position or liquidity.

Note 11. Stockholders' Equity

The tables below present the condensed consolidated statements of stockholders' equity as of and for the three and nine months ended September 30, 2022 and 2021 (in thousands):

	Ordinary Shares	Ordinary Shares - Amount	Additional Paid- In Capital	Treasury Stock	Accumulated Other Comprehensive (Loss) Income	Accumulated Deficit ⁽¹⁾	Total Stockholders' Equity ⁽¹⁾
June 30, 2022	53,810	\$ 82,359	\$ 2,133,258	\$ (397)	\$ (54,870)	\$ (878,347)	\$ 1,282,003
Stock-based compensation plans	4	17	10,504	17	—	—	10,538
Net loss	—	—	—	—	—	(107,344)	(107,344)
Other comprehensive loss	—	—	—	—	(38,234)	—	(38,234)
September 30, 2022	53,814	\$ 82,376	\$ 2,143,762	\$ (380)	\$ (93,104)	\$ (985,691)	\$ 1,146,963
June 30, 2021	49,523	\$ 76,405	\$ 1,779,113	\$ (705)	\$ 23,075	\$ (849,214)	\$ 1,028,674
Issuance of shares	4,182	5,808	316,798	—	—	—	322,606
Stock-based compensation plans	27	41	11,480	34	—	—	11,555
Net loss	—	—	—	—	—	(43,443)	(43,443)
Other comprehensive loss	—	—	—	—	(19,896)	—	(19,896)
September 30, 2021	53,732	\$ 82,254	\$ 2,107,391	\$ (671)	\$ 3,179	\$ (892,657)	\$ 1,299,496
December 31, 2021	53,762	\$ 82,295	\$ 2,117,961	\$ (650)	\$ (7,177)	\$ (897,784)	\$ 1,294,645
Stock-based compensation plans	52	81	25,801	270	—	—	26,152
Net loss	—	—	—	—	—	(87,907)	(87,907)
Other comprehensive loss	—	—	—	—	(85,927)	—	(85,927)
September 30, 2022	53,814	\$ 82,376	\$ 2,143,762	\$ (380)	\$ (93,104)	\$ (985,691)	\$ 1,146,963
December 30, 2020	49,447	\$ 76,300	\$ 1,768,156	\$ (1,034)	\$ 27,809	\$ (761,966)	\$ 1,109,265
Issuance of shares	4,182	5,808	316,798	—	—	—	322,606
Stock-based compensation plans	103	146	22,437	363	—	—	22,946
Net loss	—	—	—	—	—	(130,691)	(130,691)
Other comprehensive loss	—	—	—	—	(24,630)	—	(24,630)
September 30, 2021	53,732	\$ 82,254	\$ 2,107,391	\$ (671)	\$ 3,179	\$ (892,657)	\$ 1,299,496

(1) Accumulated deficit and total stockholders' equity as of September 30, 2021 and net loss for the three and nine months ended September 30, 2021 have been revised. For further details refer to "Note 1. Unaudited Condensed Consolidated Financial Statements."

The table below presents the change in each component of AOCI, net of tax, and the reclassifications out of AOCI into net income (loss) for the nine months ended September 30, 2022 and 2021 (in thousands):

	Change in Unrealized Gain (Loss) on Derivatives	Foreign Currency Translation Adjustments Gain (Loss) ⁽¹⁾	Total
December 31, 2021	\$ (945)	\$ (6,232)	\$ (7,177)
Other comprehensive loss before reclassifications, before tax	(194)	(85,653)	(85,847)
Tax benefit	—	—	—
Other comprehensive loss before reclassifications, net of tax	(194)	(85,653)	(85,847)
Reclassification of gain from accumulated other comprehensive loss, before tax	(80)	—	(80)
Reclassification of tax benefit	—	—	—
Reclassification of gain from accumulated other comprehensive loss, after tax	(80)	—	(80)
Net current-period other comprehensive loss, net of tax	(274)	(85,653)	(85,927)
September 30, 2022	\$ (1,219)	\$ (91,885)	\$ (93,104)
December 31, 2020	\$ 2,319	\$ 25,490	\$ 27,809
Other comprehensive loss before reclassifications, before tax	(3,335)	(22,516)	(25,851)
Tax benefit	801	—	801
Other comprehensive loss before reclassifications, net of tax	(2,534)	(22,516)	(25,050)
Reclassification of loss from accumulated other comprehensive income, before tax	553	—	553
Reclassification of tax benefit	(133)	—	(133)
Reclassification of loss from accumulated other comprehensive income, after tax	420	—	420
Net current-period other comprehensive loss, net of tax	(2,114)	(22,516)	(24,630)
September 30, 2021	\$ 205	\$ 2,974	\$ 3,179

(1) Taxes are not provided for foreign currency translation adjustments as translation adjustments are related to earnings that are intended to be reinvested in the countries where earned.

Note 12. Stock-Based Incentive Plans

Stock-based incentive plans compensation expense is as follows (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2022	2021	2022	2021
Service-based restricted stock units (“RSUs”)	\$ 5,484	\$ 4,757	\$ 16,710	\$ 14,804
Service-based stock appreciation rights (“SARs”)	3,069	3,053	9,727	9,439
Market performance-based restricted stock units	1,049	925	2,903	2,586
Operating performance-based restricted stock units	875	2,072	2,271	2,578
Employee share purchase plan	250	315	881	1,167
Total stock-based compensation expense	\$ 10,727	\$ 11,122	\$ 32,492	\$ 30,574

Stock-based awards may be granted under the 2015 Incentive Award Plan (the “2015 Plan”) and the 2022 Incentive Award Plan (the “2022 Plan”) in the form of stock options, SARs, RSUs and other stock-based and cash-based awards. As of September 30, 2022, there were 197,059 shares available for future grants to our Non-Executive Directors under the 2015 Plan and 1,900,000 shares pursuant to Options or Stock Appreciation Rights and 1,165,819 shares pursuant to other types of awards available for future grants to our employees under the 2022 Plan.

During the nine months ended September 30, 2022, we issued stock-based compensatory awards with terms approved by the Compensation Committee of our Board of Directors. The awards with service conditions generally vest ratably from two to four years and are subject to forfeiture unless service conditions are met. The market performance-based awards that were issued cliff vest after three years subject to the rank of our total shareholder return for the three-year period ending December 31, 2024 relative to the total shareholder returns for a peer group of companies. The adjusted free cash flow and return on invested capital operating performance-based awards that were issued cliff vest after three years subject to the achievement of certain thresholds of cumulative results for the three-year period ending December 31, 2024. Compensation expense related to awards granted during 2022 for the three and nine months ended September 30, 2022 was \$3.4 million and \$6.5 million, respectively.

Stock-based compensation agreements issued during the nine months ended September 30, 2022, representing potential shares and their weighted average grant date fair values by type follows (shares in thousands, fair value in dollars):

	Nine Months Ended September 30, 2022	
	Shares	Weighted Average Grant Date Fair Value
Service-based SARs	553,050	\$ 34.13
Service-based RSUs	300,588	\$ 78.32
Market performance-based RSUs	44,180	\$ 103.02
Operating performance-based RSUs	44,174	\$ 82.04

Note 13. Income Taxes

Our effective income tax rate for the three and nine months ended September 30, 2022 was (1.2)% and (7.8)%, respectively, compared with (4.5)% and (6.9)%, respectively, for the three and nine months ended September 30, 2021. Our effective income tax rate fluctuates based on, among other factors, changes in pretax income in countries with varying statutory tax rates, valuation allowances, tax credits and incentives, and unrecognized tax benefits associated with uncertain tax positions.

We continually assess the realizability of our worldwide deferred tax asset and valuation allowance positions, and when the need arises, we establish or release valuation allowances accordingly.

Compared with the three months ended September 30, 2021, the change in the effective tax rate for the three months ended September 30, 2022 was primarily attributable to discrete items and changes in income before tax in countries with varying statutory tax rates as compared to the discrete tax impact of debt extinguishment during the three months ended September 30, 2021.

Compared with the nine months ended September 30, 2021, the change in the effective tax rate for the nine months ended September 30, 2022 was primarily attributable to discrete items and changes in income before tax in countries with varying statutory tax rates as compared to discrete items and the discrete tax impact of the sale of the Heart Valve business and the debt extinguishment during the nine months ended September 30, 2021.

We operate in multiple jurisdictions throughout the world, and our tax returns are periodically audited or subjected to review by tax authorities. As a result, there is an uncertainty in income taxes recognized in our financial statements. Tax benefits totaling \$1.5 million and \$1.7 million were unrecognized as of September 30, 2022 and December 31, 2021, respectively. It is reasonably possible that, within the next twelve months, due to the settlement of uncertain tax positions with various tax authorities and the expiration of statutes of limitations, unrecognized tax benefits could decrease by up to approximately \$0.9 million.

On August 16, 2022, the Inflation Reduction Act of 2022 (the “IRA”) was enacted in the U.S. The IRA is effective for tax years beginning after December 31, 2022 and introduces a 15% alternative minimum tax on corporations with an average annual adjusted financial statement income greater than \$1 billion and a 1% excise tax on the net fair market value of stock repurchases. While we do not anticipate a significant tax impact from the IRA, we will continue to evaluate as additional guidance becomes available.

Note 14. Earnings Per Share

Reconciliation of the shares used in the basic and diluted earnings per share computations for the three and nine months ended September 30, 2022 and 2021 are as follows (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2022	2021	2022	2021
Basic weighted average shares outstanding	53,534	51,582	53,474	49,748
Add effects of share-based compensation instruments ⁽¹⁾	—	—	—	—
Diluted weighted average shares outstanding	53,534	51,582	53,474	49,748

(1) Excluded from the computation of diluted earnings per share were stock options, SARs and restricted share units totaling 3.9 million and 3.7 million for the three months ended September 30, 2022 and 2021, respectively, and 4.0 million for both the nine months ended September 30, 2022 and 2021, because to include them would have been anti-dilutive under the treasury stock method.

Note 15. Geographic and Segment Information

We identify operating segments based on the way we manage, evaluate and internally report our business activities for purposes of allocating resources, developing and executing our strategy, and assessing performance. We have three reportable segments: Cardiopulmonary, Neuromodulation and ACS.

Our Cardiopulmonary segment is engaged in the development, production and sale of cardiopulmonary products, including oxygenators, heart-lung machines, autotransfusion systems, perfusion tubing systems, cannulae and other related accessories.

Our Neuromodulation segment is engaged in the design, development and marketing of devices that deliver neuromodulation therapy for treating drug-resistant epilepsy (“DRE”) and difficult-to-treat depression (“DTD”). Neuromodulation products include the VNS Therapy System, which consists of an implantable pulse generator, a lead that connects the generator to the vagus nerve, and other accessories. It also includes the development and management of clinical testing of our aura6000 System for treating obstructive sleep apnea (“OSA”). This device stimulates the hypoglossal nerve, which in turn, engages certain muscles in the tongue in order to open the airway while a patient is sleeping. Our Neuromodulation segment also includes the VITARIA System for treating heart failure by stimulating the right vagus nerve.

Our ACS segment is engaged in the development, production and sale of leading-edge temporary life support products. Our ACS products, which comprise the LifeSPARC platform, simplify temporary extracorporeal cardiopulmonary life support solutions for critically ill patients. The LifeSPARC platform includes a common compact console and pump that provides temporary support for emergent rescue patients in a variety of settings. Our ACS segment also includes the Hemolung Respiratory Assist System (“Hemolung RAS”), which was acquired in May 2022 as part of the acquisition of ALung.

“Other” includes corporate shared service expenses for finance, legal, human resources, information technology and corporate business development. For 2021, other also includes the results of our Heart Valves business, which was disposed of on June 1, 2021.

Net revenue of our reportable segments includes revenues from the sale of products that each reportable segment develops and manufactures or distributes. We define segment income as operating income before merger and integration, restructuring and amortization of intangibles.

We operate under three geographic regions: U.S., Europe, and Rest of World. The table below presents net revenue by operating segment and geographic region (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2022	2021	2022	2021
Cardiopulmonary				
United States	\$ 38,476	\$ 40,143	\$ 114,437	\$ 113,290
Europe	28,754	32,850	93,980	98,609
Rest of World	53,729	50,242	155,437	137,931
	120,959	123,235	363,854	349,830
Neuromodulation				
United States	96,504	88,724	275,145	262,803
Europe	11,130	12,516	37,296	38,799
Rest of World	14,201	12,047	37,416	33,020
	121,835	113,287	349,857	334,622
Advanced Circulatory Support				
United States	8,430	14,925	28,183	40,449
Europe	114	355	1,220	761
Rest of World	92	119	268	456
	8,636	15,399	29,671	41,666
Other ⁽¹⁾				
United States	—	—	—	4,929
Europe	—	—	—	14,407
Rest of World	1,175	1,294	3,549	19,847
	1,175	1,294	3,549	39,183
Totals				
United States	143,410	143,792	417,765	421,471
Europe ⁽²⁾	39,998	45,721	132,496	152,576
Rest of World	69,197	63,702	196,670	191,254
Total ⁽³⁾	\$ 252,605	\$ 253,215	\$ 746,931	\$ 765,301

(1) For the nine months ended September 30, 2021, other primarily includes the net revenue of the Company's Heart Valves business, which was disposed of on June 1, 2021.

(2) Europe includes those countries in which we have a direct sales presence, whereas European countries in which we sell through distributors are included in Rest of World.

(3) No single customer represented over 10% of our consolidated net revenue. No country's net revenue exceeded 10% of our consolidated revenue except for the U.S.

The table below presents a reconciliation of segment (loss) income to consolidated loss before tax (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2022	2021 ⁽¹⁾	2022	2021 ⁽¹⁾
Cardiopulmonary	\$ (10,324)	\$ 11,957	\$ 215	\$ (11,700)
Neuromodulation	43,281	36,183	132,119	108,422
Advanced Circulatory Support	(134,902)	2,387	(136,855)	3,469
Other ⁽²⁾	(19,627)	(27,348)	(62,159)	(95,177)
Total reportable segment (loss) income	(121,572)	23,179	(66,680)	5,014
Other expenses ⁽³⁾	10,401	6,757	24,032	30,552
Operating (loss) income	(131,973)	16,422	(90,712)	(25,538)
Interest expense	(12,661)	(11,355)	(34,889)	(43,806)
Loss on debt extinguishment	—	(60,238)	—	(60,238)
Foreign exchange and other income/(expense)	38,528	13,614	44,065	7,410
Loss before tax	<u>\$ (106,106)</u>	<u>\$ (41,557)</u>	<u>\$ (81,536)</u>	<u>\$ (122,172)</u>

(1) Segment income for the three and nine months ended September 30, 2021 has been revised. For further details refer to “Note 1. Unaudited Condensed Consolidated Financial Statements.”

(2) Other includes corporate shared service expenses for finance, legal, human resources, information technology and corporate business development. For 2021, other also includes the results of the Company’s Heart Valves business, which was disposed of on June 1, 2021.

(3) Other expenses primarily consist of amortization of intangible assets, merger and integration expense and restructuring expense.

Assets by segment are as follows (in thousands):

	September 30, 2022	December 31, 2021
Cardiopulmonary	\$ 810,983	\$ 921,481
Neuromodulation	642,701	646,394
Advanced Circulatory Support	123,681	231,846
Other	635,513	401,230
Total	<u>\$ 2,212,878</u>	<u>\$ 2,200,951</u>

Capital expenditures by segment are as follows (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2022	2021	2022	2021
Cardiopulmonary	\$ 2,295	\$ 3,464	\$ 7,337	\$ 9,184
Neuromodulation	192	45	322	136
Advanced Circulatory Support	589	—	1,273	1,084
Other	2,852	28	8,439	4,379
Total	<u>\$ 5,928</u>	<u>\$ 3,537</u>	<u>\$ 17,371</u>	<u>\$ 14,783</u>

The changes in the carrying amount of goodwill by segment for the nine months ended September 30, 2022 were as follows (in thousands):

	Cardiopulmonary	Neuromodulation	Advanced Circulatory Support	Total
December 31, 2021	\$ 398,245	\$ 398,754	\$ 102,526	\$ 899,525
Goodwill as a result of acquisition	—	—	25,893	25,893
Measurement period adjustments	—	—	977	977
Impairment ⁽¹⁾	—	—	(129,396)	(129,396)
Foreign currency adjustments	(54,629)	—	—	(54,629)
September 30, 2022	<u>\$ 343,616</u>	<u>\$ 398,754</u>	<u>\$ —</u>	<u>\$ 742,370</u>

(1) Refer to “Note 5. Goodwill and Intangible Assets”

Property, plant and equipment, net by geography are as follows (in thousands):

	September 30, 2022	December 31, 2021
United States	\$ 63,924	\$ 60,852
Europe	71,471	85,313
Rest of World	3,767	3,901
Total	<u>\$ 139,162</u>	<u>\$ 150,066</u>

Note 16. Supplemental Financial Information

Inventories consisted of the following (in thousands):

	September 30, 2022	December 31, 2021
Raw materials	\$ 60,445	\$ 43,958
Work-in-process	17,379	14,161
Finished goods	44,217	47,721
	<u>\$ 122,041</u>	<u>\$ 105,840</u>

As of September 30, 2022 and December 31, 2021, inventories included adjustments totaling \$7.2 million and \$8.9 million, respectively, to record balances at lower of cost or net realizable value.

Accrued liabilities and other consisted of the following (in thousands):

	September 30, 2022	December 31, 2021
Legal and other administrative costs	\$ 15,240	\$ 11,832
Contract liabilities	10,053	8,419
Operating lease liabilities	9,616	11,261
Research and development costs	6,613	5,329
Interest payable	6,608	359
Contingent consideration ⁽¹⁾	—	11,552
Restructuring liabilities	3,613	836
Provisions for agents, returns and other	1,556	2,535
Amount payable to Gyrus Capital S.A.	—	11,418
Other accrued expenses	25,709	25,396
	<u>\$ 79,008</u>	<u>\$ 88,937</u>

(1) Refer to “Note 7. Fair Value Measurements”

As of September 30, 2022 and December 31, 2021, contract liabilities totaling \$13.5 million and \$9.8 million, respectively, were included within accrued liabilities and other long-term liabilities on the condensed consolidated balance sheets.

The table below presents the items included within “Foreign exchange and other income/(expense)” on the condensed consolidated statements of income (loss) (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2022	2021	2022	2021
Exchangeable Notes fair value adjustment ⁽¹⁾	\$ 50,945	\$ 23,489	\$ 98,555	\$ (28,895)
Capped call fair value adjustment ⁽¹⁾	(13,385)	(9,741)	(58,406)	22,217
Investment revaluation ⁽²⁾	—	—	—	4,642
Dividend Income ⁽²⁾	305	287	305	3,420
Other derivative liabilities fair value adjustment	—	200	—	4,290
Foreign exchange rate fluctuations	575	(782)	3,707	352
Interest income	547	178	624	293
Other	(459)	(17)	(720)	1,091
Foreign exchange and other income/(expense)	<u>\$ 38,528</u>	<u>\$ 13,614</u>	<u>\$ 44,065</u>	<u>\$ 7,410</u>

(1) Refer to “Note 7. Fair Value Measurements”

(2) Refer to “Note 6. Investments”

The table below presents a reconciliation of cash, cash equivalents and restricted cash reported on the condensed consolidated balance sheets that sum to the total of the amounts shown on the condensed consolidated statement of cash flows (in thousands):

	September 30, 2022	December 31, 2021
Cash and cash equivalents	\$ 231,114	\$ 207,992
Restricted cash ⁽¹⁾	275,165	—
Cash, cash equivalents and restricted cash	<u>\$ 506,279</u>	<u>\$ 207,992</u>

(1) Restricted cash represents funds held as collateral for the SNIA Litigation Guarantee. Refer to “Note 10. Commitments and Contingencies.”

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

The following discussion and analysis should be read in conjunction with our condensed consolidated financial statements and related notes, which appear elsewhere in this document, and with our 2021 Form 10-K. Our discussion and analysis may contain forward-looking statements that involve risks and uncertainties. Our actual results may differ materially from those anticipated in these forward-looking statements as a result of certain factors, including those set forth under "Risk Factors" in Part I, Item 1A. of our 2021 Form 10-K, as updated and supplemented by our Quarterly Reports on Form 10-Q, including in Part II, Item 1A. and elsewhere in this Quarterly Report on Form 10-Q.

The capitalized terms used below have been defined in the notes to our condensed consolidated financial statements. In the following text, the terms "LivaNova," "the Company," "we," "us" and "our" refer to LivaNova PLC and its consolidated subsidiaries.

Global Developments

COVID-19

COVID-19 and its effects on the economy, employment, patient behaviors and supply chain, among others, has caused and may continue to cause variable demand for our products. Our business continues to be affected by varying levels of government-imposed lockdowns in Asia, as well as global hospital-related challenges, which have led to a decrease in procedures. Notwithstanding improving market dynamics, our Neuromodulation business continues to experience ongoing COVID-19 related headwinds, as described above. Meanwhile, the recovery of global cardiopulmonary procedures has resulted in stronger demand for our Cardiopulmonary products. Our ACS business has been negatively impacted by a reduction in patients treated with ECMO related to fewer severe COVID-19 cases and hospital-related challenges. We are monitoring the potential for various strains of the virus to cause a resumption of high levels of infection and hospitalization that, in turn, may affect the demand for our products, particularly as we move into the winter months.

Moreover, although our RECOVER study and ANTHEM-HFrEF and OSPREY clinical trials continue to progress, there may be delays or closures of sites in the future should COVID-19 or variants thereof strengthen or reemerge.

Our net revenue and profitability have been negatively affected by the unfavorable foreign currency exchange impact of the strengthened U.S. dollar against a number of currencies. Furthermore, we continue to experience supply chain delays and interruptions, labor shortages, inflationary pressures and logistical issues in the wake of COVID-19. Though, to date, our supply of raw materials and the production and distribution of finished products have not been materially affected, demand and low capacity worldwide have caused longer lead times and put price pressure on key raw materials. Moreover, freight and labor costs at our manufacturing facilities have increased substantially due to COVID-related disruptions and in the wake of inflation globally. The Company continues to respond to such challenges, and while we have business continuity plans in place, the impact of the ongoing challenges we are experiencing, along with their potential escalation, may adversely affect our business and the recoverability of our tangible and intangible assets. The future impact of pandemic-related developments remains uncertain.

Importantly, we continue to take actions in managing the health and safety of our employees throughout the pandemic. Though there has been no Company-wide mandate to return to the office, employees are encouraged to return for purposeful collaboration. We continue to maintain safety protocols and encourage our employees to seek vaccination. We have incurred additional expenses in connection with our response to COVID-19, including manufacturing inefficiencies and costs related to enabling our employees to support our customers while working remotely.

Ukraine Invasion

In February 2022, Russia launched an invasion in Ukraine which caused us to assess our ability to sell in the market due to international sanctions, to consider the potential impact of raw material sourced from the region, and to determine whether we are able to transact in a compliant fashion. Although the region represented 1% of our total net revenue for 2021, the Russian invasion of Ukraine has increased economic uncertainties, and a significant escalation or continuation of the conflict could have a material, global impact on our operating results. In addition, our Russian employees and local subsidiary are subject to evolving laws and regulations imposed by the Russian authorities in response to international sanctions.

Business Overview

We are a public limited company organized under the laws of England and Wales and headquartered in London, England. We are a global medical device company focused on the development and delivery of important products and therapies for the benefit of patients, healthcare professionals and healthcare systems throughout the world. We design, develop, manufacture and sell innovative products and therapies that are consistent with our mission to provide hope to patients through innovative technologies, delivering life-changing improvements for both the Head and Heart.

LivaNova is comprised of three reportable segments: Cardiopulmonary, Neuromodulation and ACS, corresponding to our primary business units. Other includes corporate shared service expenses for finance, legal, human resources, information technology and corporate business development. For 2021, other also includes the results of our Heart Valves business, which was disposed of on June 1, 2021.

For further information regarding our business segments, historical financial information and our methodology for the presentation of financial results, please refer to the condensed consolidated financial statements and accompanying notes of this Quarterly Report on Form 10-Q.

Cardiopulmonary

Our Cardiopulmonary segment is engaged in the development, production and sale of cardiopulmonary products, including oxygenators, heart-lung machines, autotransfusion systems, perfusion tubing systems, cannulae and other related accessories.

Information on Cardiopulmonary that could potentially impact our condensed consolidated financial statements and related disclosures is incorporated by reference to Part I. Note 10. Commitments and Contingencies: FDA Warning Letter, and Part I. Note 10. Commitments and Contingencies: Product Liability.

Neuromodulation

Our Neuromodulation segment is engaged in the design, development and marketing of devices that deliver neuromodulation therapy for treating DRE and DTD. Neuromodulation products include the VNS Therapy System, which consists of an implantable pulse generator, a lead that connects the generator to the vagus nerve, and other accessories. It also includes the development and management of clinical testing of our aura6000 System for treating OSA. This device stimulates the hypoglossal nerve, which in turn, engages certain muscles in the tongue in order to open the airway while a patient is sleeping. Our Neuromodulation segment also includes the VITARIA System for treating heart failure by stimulating the right vagus nerve.

In March 2022, LivaNova announced the 250th unipolar depression patient was implanted in the DTD RECOVER study. This key milestone preceded conducting the first interim analysis. The study was designed with frequent interim analyses to be conducted by an independent Statistical Analysis Committee. The interim analyses will assess if predictive probability of success has been reached for the unipolar cohort of the study. If any analysis reveals that the predictive probability of success has been reached, the results will be shared with the U.S. Centers for Medicare & Medicaid Services (“CMS”) with the intent that randomized controlled trial enrollment for that patient population will cease and future patients will be enrolled into the prospective, open-label longitudinal study. The study is currently under way as part of a Coverage with Evidence Development framework per the CMS National Coverage Determination process. The trial, if successful, will be used to support a peer-reviewed article and reconsideration of reimbursement for VNS Therapy by CMS for the treatment of depression that is difficult to treat.

Advanced Circulatory Support

Our ACS segment is engaged in the development, production and sale of leading-edge temporary life support products. Our ACS products, which comprise the LifeSPARC platform, simplify temporary extracorporeal cardiopulmonary life support solutions for critically ill patients. The LifeSPARC platform includes a common compact console and pump that provides temporary support for emergent rescue patients in a variety of settings. Designed for ease of use, the system offers power and versatility for multi-disciplinary programs to support more patients in more places. The platform is accompanied by four specialized and ready-to-deploy kits, each designed to support diverse cannulation strategies. Our ACS segment also includes the Hemolung RAS. The Hemolung RAS is the only FDA-cleared platform designed specifically for low-flow extracorporeal carbon dioxide removal for acute respiratory failure. The Hemolung RAS was acquired in May 2022 as part of the acquisition of ALung. In August 2022, CMS approved a New Technology Add-on Payment (“NTAP”) for our Hemolung RAS for in-patient care. The NTAP designation is awarded to novel medical technologies and services supported by clinical evidence that are expected to substantially improve the diagnosis or treatment of Medicare beneficiaries and was received October 1, 2022.

On May 2, 2022, we acquired the remaining 97% of equity interests in ALung, a privately held medical device company focused on creating advanced medical devices for treating respiratory failure, for a purchase price of up to \$110.0 million, consisting of \$10.0 million paid at closing, subject to customary adjustments, and contingent considerations of up to \$100.0 million payable upon achievement of certain sales-based milestones beginning in 2023 and ending in 2027. Due to synergies anticipated between ALung and our existing ACS business, the assets acquired, including goodwill, are recognized in our ACS segment. The goodwill for the ACS reporting unit was fully impaired during the third quarter of 2022. The fair value of the contingent consideration liability as of May 2, 2022, the acquisition date, and September 30, 2022 was \$16.8 million and \$15.2 million, respectively. For additional information, please refer to “Note 2. Business Combinations” and “Note 5. Goodwill and Intangible Assets” in the condensed consolidated financial statements in this Quarterly Report on Form 10-Q.

Critical Accounting Estimates

For a discussion of our critical accounting estimates, see “Management’s Discussion and Analysis of Financial Condition and Results of Operations” that is included in the 2021 Form 10-K. As a result of certain events and contributing factors in the third quarter of 2022, the Company performed an interim impairment analysis related to its ACS reporting unit and ImThera IPR&D intangible asset. For additional information, please refer to “Note 5. Goodwill and Intangible Assets” in the condensed consolidated financial statements in this Quarterly Report on Form 10-Q.

The accompanying unaudited condensed consolidated financial statements of LivaNova and its consolidated subsidiaries have been prepared in accordance with U.S. GAAP on an interim basis.

Results of Operations

The following table summarizes our condensed consolidated results of operations (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2022	2021 ⁽¹⁾	2022	2021 ⁽¹⁾
Net revenue	\$ 252,605	\$ 253,215	\$ 746,931	\$ 765,301
Cost of sales	81,687	84,551	223,220	260,950
Gross profit	170,918	168,664	523,711	504,351
Operating expenses:				
Selling, general and administrative	114,630	109,042	349,637	347,471
Research and development	35,725	42,133	110,872	139,315
Impairment of goodwill	129,396	—	129,396	—
Other operating expenses	23,140	1,067	24,518	43,103
Operating (loss) income	(131,973)	16,422	(90,712)	(25,538)
Interest expense	(12,661)	(11,355)	(34,889)	(43,806)
Loss on debt extinguishment	—	(60,238)	—	(60,238)
Foreign exchange and other income/(expense)	38,528	13,614	44,065	7,410
Loss before tax	(106,106)	(41,557)	(81,536)	(122,172)
Income tax expense	1,295	1,858	6,347	8,410
Income (loss) from equity method investments	57	(28)	(24)	(109)
Net loss	\$ (107,344)	\$ (43,443)	\$ (87,907)	\$ (130,691)

- (1) The condensed consolidated results for the three and nine months ended September 30, 2021 have been revised. For further details refer to “Note 1. Unaudited Condensed Consolidated Financial Statements” in the condensed consolidated financial statements in this Quarterly Report on Form 10-Q.

Net Revenue

The table below presents net revenue by operating segment and geographic region (in thousands, except for percentages):

	Three Months Ended September 30,			Nine Months Ended September 30,		
	2022	2021	% Change	2022	2021	% Change
Cardiopulmonary						
United States	\$ 38,476	\$ 40,143	(4.2)%	\$ 114,437	\$ 113,290	1.0 %
Europe	28,754	32,850	(12.5)%	93,980	98,609	(4.7)%
Rest of World	53,729	50,242	6.9 %	155,437	137,931	12.7 %
	<u>120,959</u>	<u>123,235</u>	(1.8)%	<u>363,854</u>	<u>349,830</u>	4.0 %
Neuromodulation						
United States	96,504	88,724	8.8 %	275,145	262,803	4.7 %
Europe	11,130	12,516	(11.1)%	37,296	38,799	(3.9)%
Rest of World	14,201	12,047	17.9 %	37,416	33,020	13.3 %
	<u>121,835</u>	<u>113,287</u>	7.5 %	<u>349,857</u>	<u>334,622</u>	4.6 %
Advanced Circulatory Support						
United States	8,430	14,925	(43.5)%	28,183	40,449	(30.3)%
Europe	114	355	(67.9)%	1,220	761	60.3 %
Rest of World	92	119	(22.7)%	268	456	(41.2)%
	<u>8,636</u>	<u>15,399</u>	(43.9)%	<u>29,671</u>	<u>41,666</u>	(28.8)%
Other ⁽¹⁾						
United States	—	—	— %	—	4,929	(100.0)%
Europe	—	—	— %	—	14,407	(100.0)%
Rest of World	1,175	1,294	(9.2)%	3,549	19,847	(82.1)%
	<u>1,175</u>	<u>1,294</u>	(9.2)%	<u>3,549</u>	<u>39,183</u>	(90.9)%
Totals						
United States	143,410	143,792	(0.3)%	417,765	421,471	(0.9)%
Europe ⁽²⁾	39,998	45,721	(12.5)%	132,496	152,576	(13.2)%
Rest of World	69,197	63,702	8.6 %	196,670	191,254	2.8 %
Total	<u>\$ 252,605</u>	<u>\$ 253,215</u>	(0.2)%	<u>\$ 746,931</u>	<u>\$ 765,301</u>	(2.4)%

(1) For the nine months ended September 30, 2021, other primarily includes the net revenue of the Company's Heart Valves business, which was disposed of on June 1, 2021.

(2) Europe revenue include those countries in which we have a direct sales presence, whereas European countries in which we sell through distributors are included in "Rest of World."

The table below presents segment (loss) income (in thousands, except for percentages):

	Three Months Ended September 30,			Nine Months Ended September 30,		
	2022	2021 ⁽¹⁾	% Change	2022	2021 ⁽¹⁾	% Change
Cardiopulmonary	\$ (10,324)	\$ 11,957	(186.3)%	\$ 215	\$ (11,700)	(101.8)%
Neuromodulation	43,281	36,183	19.6 %	132,119	108,422	21.9 %
Advanced Circulatory Support	(134,902)	2,387	(5,751.5)%	(136,855)	3,469	(4,045.1)%
Other ⁽²⁾	(19,627)	(27,348)	(28.2)%	(62,159)	(95,177)	(34.7)%
Total reportable segment (loss) income ⁽³⁾	\$ (121,572)	\$ 23,179	(624.5)%	\$ (66,680)	\$ 5,014	(1,429.9)%

- (1) Segment income for the three and nine months ended September 30, 2021 has been revised. For further details refer to “Note 1. Unaudited Condensed Consolidated Financial Statements” in the condensed consolidated financial statements in this Quarterly Report on Form 10-Q.
- (2) Other includes corporate shared service expenses for finance, legal, human resources, information technology and corporate business development. For 2021, other also includes the results of the Company’s Heart Valves business, which was disposed of on June 1, 2021.
- (3) For a reconciliation of segment (loss) income to loss before tax refer to “Note 15. Geographic and Segment Information” in the condensed consolidated financial statements in this Quarterly Report on Form 10-Q.

Cardiopulmonary

Cardiopulmonary net revenue for the three months ended September 30, 2022 decreased 1.8% to \$121.0 million compared to the three months ended September 30, 2021 primarily due to unfavorable foreign currency fluctuations of approximately \$10.4 million. This decrease was partially offset by growth in the Rest of World and Europe regions. This growth was primarily driven by oxygenator revenue due to an increase in cardiac surgery procedures and strength in heart-lung machine placements in the Rest of World region.

Cardiopulmonary net revenue for the nine months ended September 30, 2022 increased 4.0% to \$363.9 million compared to the nine months ended September 30, 2021 primarily due to growth in the Europe and Rest of World regions. This growth was primarily driven by oxygenator revenue due to an increase in cardiac surgery procedures and strength in heart-lung machine placements in the Rest of World region. These increases were partially offset by unfavorable foreign currency fluctuations of approximately \$24.4 million.

Cardiopulmonary segment loss for the three months ended September 30, 2022 was \$10.3 million, as compared to segment income of \$12.0 million for the three months ended September 30, 2021. The decrease in segment income was primarily due to an increase in the litigation provision and legal costs related to our 3T Heater-Cooler device totaling \$20.1 million, as well as a decrease in net revenue, as discussed above.

Cardiopulmonary segment income for the nine months ended September 30, 2022 was \$0.2 million, as compared to segment loss of \$11.7 million for the nine months ended September 30, 2021. The increase in segment income was primarily due to a decrease in the litigation provision and legal costs related to our 3T Heater-Cooler device totaling \$13.9 million, as well as an increase in net revenue, as discussed above.

Neuromodulation

Neuromodulation net revenue for the three and nine months ended September 30, 2022 increased 7.5% to \$121.8 million and 4.6% to \$349.9 million, respectively, compared to the three and nine months ended September 30, 2021, respectively. These increases represented growth across all regions driven by replacement implants as well as improving market dynamics. Additionally, these increases in net revenue were adversely impacted by unfavorable foreign currency fluctuations of approximately \$3.3 million and \$7.1 million versus the three and nine-month comparative periods, respectively.

Neuromodulation segment income for the three and nine months ended September 30, 2022 was \$43.3 million and \$132.1 million, respectively, as compared to \$36.2 million and \$108.4 million for the three and nine months ended September 30, 2021, respectively. These increases in segment income were primarily due to the net impact of the change in fair value of the sales-based and milestone-based contingent consideration arrangement associated with the acquisition of ImThera of \$10.6 million and \$34.8 million for the three and nine-month comparative periods, respectively, as well as a increases in net revenue of \$8.5 million and \$15.2 million for the three and nine-month comparative periods, respectively, as discussed above. These increases were partially offset by increases in R&D expenses for the three and nine months ended September 30, 2022

compared to the three and nine months ended September 30, 2021 totaling \$2.7 million and \$9.4 million, respectively, associated with the Company's RECOVER study and ANTHEM-HFrEF and OSPREY clinical trials.

Advanced Circulatory Support

ACS net revenue for the three and nine months ended September 30, 2022 decreased 43.9% to \$8.6 million and 28.8% to \$29.7 million, respectively, compared to the three and nine months ended September 30, 2021, respectively, primarily due to a reduction in patients treated with ECMO related to fewer severe COVID-19 cases, hospital-related challenges and product mix, partially offset by growth in non-COVID-19 cases.

ACS segment loss for the three months ended September 30, 2022 was \$134.9 million as compared to segment income of \$2.4 million for the three months ended September 30, 2021. Segment loss for the nine months ended September 30, 2022 was \$136.9 million as compared to segment income of \$3.5 million for the nine months ended September 30, 2021. Segment loss for the three and nine month comparative periods ended September 30, 2022, was negatively impacted by the impairment of the goodwill associated with our ACS segment of \$129.4 million. For additional information, please refer to "Note 5. Goodwill and Intangible Assets" in the condensed consolidated financial statements in this Quarterly Report on Form 10-Q. Segment loss for the three and nine months ended September 30, 2022 was also negatively impacted by the declines in net revenue, as discussed above. These negative impacts were partially offset by the net favorable impacts of the change in fair value of a regulatory milestone-based contingent consideration arrangement associated with the TandemLife acquisition of \$5.5 million and \$14.3 million, for the three and nine month comparative periods respectively.

Cost of Sales and Expenses

The table below presents our comparative cost of sales and significant expenses as a percentage of sales:

	Three Months Ended September 30,			Nine Months Ended September 30,		
	2022	2021	Change	2022	2021	Change
Cost of sales	32.3 %	33.4 %	(1.1)%	29.9 %	34.1 %	(4.2)%
Selling, general and administrative	45.4 %	43.1 %	2.3 %	46.8 %	45.4 %	1.4 %
Research and development	14.1 %	16.6 %	(2.5)%	14.8 %	18.2 %	(3.4)%
Impairment of goodwill	51.2 %	— %	51.2 %	17.3 %	— %	17.3 %
Other operating expenses	9.2 %	0.4 %	8.8 %	3.3 %	5.6 %	(2.3)%

Cost of Sales

Cost of sales consists primarily of direct labor, allocated manufacturing overhead, the acquisition cost of raw materials and components.

Cost of sales as a percentage of net revenue was 32.3% and 29.9% for the three and nine months ended September 30, 2022, respectively, a decrease of 1.1% and 4.2% compared to the three and nine months ended September 30, 2021, respectively. The decrease for the three-month comparative period was primarily due to the net impact of the change in fair value of sales-based contingent consideration arrangements of \$2.8 million. The decrease for the nine-month comparative period was primarily due to favorable product mix, partially resulting from the sale of the Company's Heart Valves business during the second quarter of 2021, as well as the net impact of the change in fair value of a sales-based contingent consideration arrangements of \$22.0 million. These decreases were partially offset by increased costs driven by supply chain delays and interruptions, labor shortages, inflationary pressures and logistical issues in the wake of COVID-19.

Selling, General and Administrative ("SG&A") Expenses

SG&A expenses are comprised of sales, marketing, and general and administrative activities.

SG&A expenses as a percentage of net revenue was 45.4% for the three months ended September 30, 2022, an increase of 2.3% compared to the three months ended September 30, 2021. The increase was primarily due to an increase in sales and marketing expenses.

SG&A expenses as a percentage of net revenue was 46.8% for the nine months ended September 30, 2022, an increase of 1.4% compared to the nine months ended September 30, 2021. These increases was primarily due to business development expenses related to the acquisition of ALung, as well as increases in sales and marketing expenses. For additional information, please refer to "Note 2. Business Combinations" in the condensed consolidated financial statements in this Quarterly Report on Form 10-Q.

Research and Development (“R&D”) Expenses

R&D expenses consist of product design and development efforts, clinical study programs and regulatory activities, which are essential to our strategic portfolio initiatives, including DTD, OSA and heart failure.

R&D expenses as a percentage of net revenue was 14.1% and 14.8% for the three and nine months ended September 30, 2022, respectively, a decrease of 2.5% and 3.4% compared to the three and nine months ended September 30, 2021, respectively. The decrease was primarily due to a decline in R&D expenses resulting from changes in the fair value of milestone-based contingent consideration arrangements of \$10.2 million and \$29.1 million for the three and nine months ended September 30, 2022, respectively, compared to the prior year period. Additionally, R&D expenses for the nine months ended September 30, 2022 decreased by \$5.9 million compared to the prior year period as a result of the sale of the Company’s Heart Valve business on June 1, 2021. The aforementioned decreases in R&D expenses due to the changes in fair value of contingent consideration arrangements and the sale of the Company’s Heart Valve business were partially offset by increases associated with the Company’s RECOVER study and ANTHEM-HFrEF and OSPREY clinical trials totaling \$2.7 million and \$9.4 million for the three and nine months ended September 30, 2022, compared to the prior year period, respectively.

Impairment of Goodwill

We test goodwill for impairment on an annual basis on October 1 or when events or changes in circumstances indicate that a potential impairment exists. As part of our assessment as of September 30, 2022, we considered that revenue for our ACS reporting unit during the nine months ended September 30, 2022, had declined by approximately 29% compared to the prior year period, primarily as a result of a reduction in severe COVID-19 cases, hospital-related challenges and product mix. Furthermore, future revenue projections were reduced. Based on these circumstances, we concluded it was more likely than not that the goodwill of our ACS reporting unit was impaired, and we performed a quantitative assessment of the goodwill as of September 30, 2022, using management’s current estimate of future cash flows. Based on the valuation performed, we determined that the fair value of the ACS reporting unit was less than the carrying value and recognized a goodwill impairment of \$129.4 million, in our condensed consolidated statements of income (loss) for the three and nine months ended September 30, 2022.

Other Operating Expenses

Other operating expenses primarily consists of the provision for litigation involving our 3T Heater-Cooler device, restructuring expense, and merger and integration expense.

Other operating expenses as a percentage of net revenue was 9.2% for the three months ended September 30, 2022, an increase of 8.8% compared to the three months ended September 30, 2021. The increase was primarily due to an increase in the litigation provision related to our 3T Heater-Cooler device of \$18.8 million, as well as an increase in restructuring expense of \$4.0 million.

Other operating expenses as a percentage of net revenue was 3.3% for the nine months ended September 30, 2022, a decrease of 2.3% compared to the nine months ended September 30, 2021. The decrease was primarily due to a decrease in the litigation provision related to our 3T Heater-Cooler device of \$12.9 million, as well as a decrease in restructuring expense of \$5.2 million.

For additional information, please refer to “Note 4. Restructuring” and “Note 10. Commitments and Contingencies” in the condensed consolidated financial statements in this Quarterly Report on Form 10-Q.

Interest Expense

Interest expense for the three months ended September 30, 2022 increased to \$12.7 million compared to \$11.4 million for the three months ended September 30, 2021, primarily due to interest expense associated with the Initial Term Facility entered into on July 6, 2022, partially offset by the repayment of the Company’s 2020 senior secured term loan during the third quarter of 2021.

Interest expense for the nine months ended September 30, 2022 declined to \$34.9 million compared to \$43.8 million for the nine months ended September 30, 2021 primarily due to the repayment of the Company’s 2020 senior secured term loan during the third quarter of 2021, partially offset by interest expense associated with the February 2022 Bridge Loan Facility and the Initial Term Facility. For further details, refer to “Note 8. Financing Arrangements” in the condensed consolidated financial statements in this Quarterly Report on Form 10-Q.

Foreign Exchange and Other Income/(Expense)

Foreign exchange and other income/(expense) consist primarily of gains and losses arising from transactions denominated in a currency different from an entity's functional currency, foreign currency exchange rate derivative gains and losses and changes in the fair value of the embedded exchange feature and capped call derivatives.

Foreign exchange and other income/(expense) resulted in income of \$38.5 million and \$44.1 million for the three and nine months ended September 30, 2022, respectively, compared to income of \$13.6 million and \$7.4 million for the three and nine months ended September 30, 2021, respectively. For further details, refer to "Note 16. Supplemental Financial Information" in the condensed consolidated financial statements in this Quarterly Report on Form 10-Q.

Income Taxes

LivaNova PLC is resident in the UK for tax purposes. Our subsidiaries conduct operations and earn income in numerous countries and are subject to the laws of taxing jurisdictions within those countries, and the income tax rates imposed in the tax jurisdictions in which our subsidiaries conduct operations vary. Our effective income tax rate fluctuates based on, among other factors, changes in pretax income in countries with varying statutory tax rates, valuation allowances, tax credits and incentives, and unrecognized tax benefits associated with uncertain tax positions.

Our effective income tax rate for the three and nine months ended September 30, 2022 was (1.2)% and (7.8)%, respectively, compared with (4.5)% and (6.9)% for the three and nine months ended September 30, 2021, respectively. Compared with the three months ended September 30, 2021, the change in the effective tax rate for the three months ended September 30, 2022 was primarily attributable to discrete items and changes in income before tax in countries with varying statutory tax rates as compared to the discrete tax impact of the debt extinguishment during the three months ended September 30, 2021. Compared with the nine months ended September 30, 2021, the change in the effective tax rate for the nine months ended September 30, 2022 was primarily attributable to discrete items and changes in income before tax in countries with varying statutory tax rates as compared to changes in valuation allowances and other discrete items and the discrete tax impact of the sale of the Heart Valve business and the debt extinguishment during the nine months ended September 30, 2021.

On August 16, 2022, the IRA was enacted in the U.S. The IRA is effective for tax years beginning after December 31, 2022 and introduces a 15% alternative minimum tax on corporations with an average annual adjusted financial statement income greater than \$1 billion and a 1% excise tax on the net fair market value of stock repurchases. While we do not anticipate a significant tax impact from the IRA, we will continue to evaluate as additional guidance becomes available.

Liquidity and Capital Resources

Based on our current business plan, we believe that our sources of liquidity, which primarily consist of cash and cash equivalents, future cash generated from operations and available borrowings under our current debt facilities, will be sufficient to fund our uses of liquidity, primarily consisting of purchase obligations for expected operating, working capital, capital expenditures, acquisitions, and debt service requirements over the twelve-month period beginning from the issuance date of these condensed consolidated financial statements. From time to time, we may decide to access debt and/or equity markets to optimize our capital structure, raise additional capital or increase liquidity as necessary. Our liquidity could be adversely impacted by the factors affecting future operating results, including those referred to in "Part I, Item 1A. Risk Factors" in the 2021 Form 10-K as supplemented by the factors referred to in "Part II, Item 1A. Risk Factors" in this Quarterly Reports on Form 10-Q as well as "Note 10. Commitments and Contingencies" in the condensed consolidated financial statements in this Quarterly Report on Form 10-Q.

Our operating and working capital obligations primarily consist of liabilities arising from the normal course of business including inventory supply contracts, the future settlement of derivative instruments, and future payments of operating leases, as well as contingent consideration arrangements resulting from acquisitions, and obligations associated with legal and other accruals. The following table presents selected financial information related to our liquidity as of September 30, 2022 and December 31, 2021 (in thousands):

	September 30, 2022	December 31, 2021
Sources of Liquidity		
Cash and cash equivalents	\$ 231,114	\$ 207,992
Accounts receivable, net	172,093	185,354
Inventories	122,041	105,840
Short-term derivative assets ⁽¹⁾	760	106,629
Long-term derivative assets ⁽¹⁾	48,223	—
Availability under the 2021 First Lien Credit Agreement ⁽²⁾	125,000	125,000
Availability under the Delayed Draw Term Facility ⁽²⁾	50,000	—
Short-term Uses of Liquidity		
Short-term debt ⁽²⁾	\$ 21,695	\$ 229,673
Short-term derivative liabilities ⁽¹⁾	3,572	183,109
Short-term operating leases	9,616	11,261
Short-term contingent consideration ⁽³⁾	—	11,552
Short-term 3T litigation provision ⁽⁴⁾	43,989	32,845
Long-term Uses of Liquidity		
Long-term debt ⁽²⁾	\$ 518,249	\$ 9,849
Long-term derivative liabilities ⁽¹⁾	83,145	—
Long-term operating leases	28,236	35,919
Long-term contingent consideration ⁽³⁾	81,850	86,830
Long-term Saluggia site liability ⁽⁴⁾	33,412	38,788
Long-term 3T litigation provision ⁽⁴⁾	2,768	6,625

(1) For additional information, please refer to “Note 9. Derivatives and Risk Management” in the condensed consolidated financial statements in this Quarterly Report on Form 10-Q.

(2) For additional information, please refer to “Note 8. Financing Arrangements” in the condensed consolidated financial statements in this Quarterly Report on Form 10-Q.

(3) For additional information, please refer to “Note 7. Fair Value Measurements” in the condensed consolidated financial statements in this Quarterly Report on Form 10-Q.

(4) For additional information, please refer to “Note 10. Commitments and Contingencies” in the condensed consolidated financial statements in this Quarterly Report on Form 10-Q.

Significant Liquidity Matters

On February 21, 2022, the Court of Appeal notified the Company that it granted the Company a suspension with respect to the payment of damages in the amount of €453.6 million (approximately \$443.3 million at September 30, 2022) in the SNIA litigation until a decision has been reached on our appeal to the Italian Supreme Court. This suspension was subject to providing the SNIA Litigation Guarantee of €270.0 million (approximately \$263.9 million at September 30, 2022) within 30 calendar days.

On February 24, 2022, LivaNova PLC and its wholly-owned subsidiary, LivaNova USA, Inc., entered into the Bridge Loan Facility. On March 16, 2022, LivaNova delivered a borrowing notice for \$220.0 million in connection with the Bridge Loan Facility, which was funded on March 17, 2022. LivaNova used the proceeds of the Bridge Loan Facility to post a portion of the cash collateral supporting the SNIA Litigation Guarantee.

On March 18, 2022, LivaNova PLC, acting through its Italian branch, entered into an Indemnity Letter and an Account Pledge Agreement with Barclays, further to which Barclays issued the €270.0 million SNIA Litigation Guarantee. As security for the SNIA Litigation Guarantee, LivaNova is required to grant cash collateral to Barclays in USD in an amount equal to the USD equivalent of 105% of the amount of the SNIA Litigation Guarantee calibrated on a biweekly basis. At September 30, 2022, the cash collateral totaled \$275.2 million and was classified as Restricted Cash on the condensed consolidated balance sheet.

On March 21, 2022, LivaNova delivered the SNIA Litigation Guarantee as required by the Court of Appeal, thereby satisfying the condition to obtain the suspension for the payment of damages in connection with the SNIA litigation until review of such judgment by the Italian Supreme Court.

On July 6, 2022, LivaNova and its wholly-owned subsidiary, LivaNova USA, entered into the Incremental Amendment No. 2 to its 2021 First Lien Credit Agreement. The Incremental Amendment No. 2 provides for LivaNova USA to, among other things, obtain commitments for term loan facilities from a syndicate of lenders in an aggregate principal amount of \$350 million consisting of (i) the Initial Term Facility in an aggregate principal amount of \$300 million and (ii) the Delayed Draw Term Facility in an additional aggregate principal amount of \$50 million and, together, the Term Facilities.

Proceeds of the Initial Term Facility were used to repay in full the Bridge Loan Facility on July 6, 2022, with the remainder to be used for general corporate purposes of the Company. The Term Facilities have a maturity of the earlier of (i) five years or (ii) 91 days prior to December 15, 2025, the maturity date of the Notes, unless by that date LivaNova USA will have either redeemed or refinanced the Notes, or set aside an amount of cash equal to the then-outstanding principal amount of the Notes.

Refer to “Note 8. Financing Arrangements” in the condensed consolidated financial statements in this Quarterly Report on Form 10-Q for additional information regarding our debt and debt transactions.

Cash Flows

Net cash and cash equivalents provided by (used in) operating, investing and financing activities and the net increase in the balance of cash, cash equivalents and restricted cash were as follows (in thousands):

	Nine Months Ended September 30,	
	2022	2021
Operating activities	\$ 51,218	\$ 69,064
Investing activities	(27,461)	40,535
Financing activities	281,787	(178,183)
Effect of exchange rate changes on cash, cash equivalents and restricted cash	(7,257)	(2,402)
Net increase (decrease) in cash, cash equivalents and restricted cash	\$ 298,287	\$ (70,986)

Operating Activities

Cash provided by operating activities during the nine months ended September 30, 2022 decreased by \$17.8 million as compared to the same prior-year period. The decrease was primarily due to the net change in working capital largely associated with an increase in inventory to mitigate supply chain risk and increased payments under the Company’s short-term incentive plan. These decreases were partially offset by an increase in net income adjusted for non-cash items of \$30.8 million, primarily driven by an increase in Neuromodulation and Cardiopulmonary net revenue.

Investing Activities

Cash provided by investing activities during the nine months ended September 30, 2022 decreased \$68.0 million as compared to the same prior year period largely due to proceeds received during the nine months ended September 30, 2021, including \$40.2 million from the sale of the Company’s Heart Valves business as well as proceeds from the sale of LivaNova’s investment in and loan to Respicardia totaling \$23.1 million.

Financing Activities

Cash provided by financing activities during the nine months ended September 30, 2022 increased \$460.0 million as compared to the same prior year period. The increase was primarily due to net borrowings during the nine months ended September 30, 2022 of \$275.2 million compared to net repayments of borrowings of \$466.0 million, as well as a payment of \$35.6 million for the make-whole premium on long-term debt obligations, during the nine months ended September 30, 2021. These increases were partially offset by net proceeds from the issuance of ordinary shares of \$324.2 million during the nine months ended September 30, 2021.

Item 3. *Quantitative and Qualitative Disclosures About Market Risk*

We are exposed to certain market risks as part of our ongoing business operations, including risks from foreign currency exchange rates, equity price risk, interest rate risks and concentration of procurement suppliers that could adversely affect our consolidated financial position, results of operations or cash flows. We manage these risks through regular operating and financing activities and, at certain times, derivative financial instruments. Quantitative and qualitative disclosures about these risks are included in this Quarterly Report on Form 10-Q in “Part I, Note 9. Derivatives and Risk Management,” “Part I, Item 2. Management’s Discussion and Analysis of Financial Conditions and Results of Operations” and “Part II, Item 1A. Risk Factors” and in our 2021 Form 10-K in “Part II, Item 7. Management’s Discussion and Analysis of Financial Condition and Results of Operations” and “Part I, Item 1A. Risk Factors.”

Item 4. *Controls and Procedures*

Disclosure Controls and Procedures

(a) Evaluation of Disclosure Controls and Procedures

We maintain a system of disclosure controls and procedures, as defined in Rules 13a-15(e) and 15d-15(e) of the Exchange Act, that are designed to ensure that information required to be disclosed in our reports filed under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC’s rules and forms. This information is also accumulated and communicated to management, including our Chief Executive Officer (“CEO”) and Chief Financial Officer (“CFO”), as appropriate, to allow timely decisions regarding required disclosure. Our management, under the supervision and with the participation of our CEO and CFO, evaluated the effectiveness of the design and operation of our disclosure controls and procedures as of the end of the most recent fiscal quarter reported herein. Based on that evaluation, our CEO and CFO concluded that our disclosure controls and procedures were effective as of September 30, 2022.

(b) Changes in Internal Control Over Financial Reporting

No change in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-5(f) under the Exchange Act) occurred during the quarter ended September 30, 2022 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

PART II. OTHER INFORMATION

Item 1. *Legal Proceedings*

For a description of our material pending legal and regulatory proceedings and settlements, refer to “Note 10. Commitments and Contingencies” in our condensed consolidated financial statements included in this Quarterly Report on Form 10-Q.

Item 1A. *Risk Factors*

Other than as described below, there have been no material changes in our risk factors from those disclosed in Part I, Item 1A to our 2021 Annual Report on Form 10-K.

Reductions, interruptions or increased costs in the supply of the materials and components used in manufacturing our products may adversely affect our financial condition and business operations, particularly in the wake of COVID-19.

We maintain manufacturing operations in five countries located throughout the world and purchase many of the components and raw materials used in manufacturing these products from numerous suppliers in various countries. Any problem affecting a supplier (whether due to external or internal causes) could have a negative impact on us. Difficulties and delays in manufacturing, internally or through third-party providers or otherwise within the supply chain, may lead to voluntary or involuntary business interruptions or shutdowns, product shortages, withdrawals or suspensions of products from the market, and potential regulatory action.

In some cases, we purchase specific components and raw materials from primary or main suppliers (or in some cases, a single or sole supplier) for reasons related to quality assurance, cost-effectiveness and availability. While we work closely with our suppliers to ensure supply continuity, minimize the instances in which we rely on a sole supplier and take other countermeasures to reduce our supply chain risk, we cannot guarantee that our efforts will always be successful. Moreover, due to strict standards and regulations governing the manufacture and marketing of our products, we may not be able to locate new supply sources quickly or at all in response to a supply reduction or interruption, with negative effects on our ability to manufacture our products effectively and timely.

COVID-19 has exacerbated this risk by, among other things, causing global supply chain shortages and an increase in freight and labor costs. Like many companies, for example, we are experiencing supply chain delays and interruptions, labor shortages, inflationary pressures and logistical issues in the wake of COVID-19. Though, to date, our supply of raw materials and the production and distribution of finished products have not been materially affected, demand and low capacity worldwide have caused longer lead times and put price pressure on key raw materials. Moreover, freight and labor costs at our manufacturing facilities have increased substantially due to COVID-related disruptions and in the wake of inflation globally. We are managing our supply chain by giving long visibility to our suppliers, conducting regular supply critical risk reviews and closely monitoring our inventory, among other things, but any problem could quickly, negatively reverberate throughout the organization. To the extent we are unsuccessful in managing our supply chain, any such issues could have a material adverse effect on our business, results of operations, financial condition, cash flows and recoverability of our tangible and intangible assets.

Failure to comply with product-related government regulations may materially adversely affect our financial condition and business operations.

Both before and after a product is commercially released, we have ongoing responsibilities under FDA and other applicable non-U.S. government agency regulations. For instance, many of our facilities and procedures and those of our suppliers are subject to periodic inspections by the FDA, which can result in inspectional observations on FDA’s Form-483, warning letters, or other forms of enforcement. If the FDA were to conclude that we are not in compliance with applicable laws or regulations, or that any of our medical products are ineffective or pose an unreasonable health risk, the FDA could ban such medical products, detain or seize adulterated or misbranded medical products, order a recall, repair, replacement, or refund of such products, refuse to grant pending PMA applications or require certificates of non-U.S. governments for exports, and/or require us to notify health professionals and others that the devices present unreasonable risks of substantial harm to the public health. In 2015, we received a warning letter from the FDA alleging certain violations of FDA regulations, which resulted in certain devices that were manufactured in Munich, Germany, to be denied admission to the U.S. until resolution of the issues set forth by the FDA in the warning letter. In April 2022, a Form 483 was issued at the conclusion of the FDA’s inspection of our Germany facility. See “Note 10. Commitments and Contingencies” in this Form 10-Q for additional information.

If the FDA accepts the proposed corrective or preventive actions in the response to the Form 483 but finds that we have not implemented them adequately, or if we otherwise fail to comply with applicable regulatory requirements, the FDA could decide not to close out the 2015 Warning Letter based on the most recent inspection, even if they agree with our most recent Form 483

response. In addition, the FDA could require that a successful re-inspection be completed in the future in order to close out that Warning Letter and/or the most recent inspection. Regardless, we remain subject to the terms of the 2015 Warning Letter, which subjected our legacy 3T devices to refusal of admission into the U.S. and which stated that premarket approval applications for Class III devices to which certain Quality System regulation deviations identified in the Warning Letter were reasonably related would not be approved until the violations had been corrected; however, with clearance for K191402, 3T devices manufactured in accordance with K191402 are not subjected to the import alert and the premarket approval restriction applied only to the Munich and Arvada facilities, which do not manufacture or design devices subject to Class III premarket approval.

While we work diligently to manage our ongoing responsibilities, the FDA and other non-U.S. government agencies could assess civil or criminal penalties against us, our officers or employees and impose operating restrictions on a company-wide basis. The FDA could also recommend prosecution to the U.S. Department of Justice. An adverse regulatory action could restrict us from effectively marketing and selling our products, limit our ability to obtain future pre-market clearances or PMAs, and result in a substantial modification to our business practices and operations. These potential consequences, as well as any adverse outcome from government investigations, could have a material adverse effect on our business, results of operations, financial condition, and cash flows.

In addition, in the U.S., device manufacturers are prohibited from promoting their products other than for the uses and indications set forth in the approved product labeling (so called “off-label uses”). Our VNS Therapy System, for example, is indicated in the U.S., as an adjunctive therapy in reducing the frequency of seizures in patients 4 years of age and older with partial onset seizures that are refractory to antiepileptic medications, yet a number of physicians elect to prescribe our device for certain patients suffering from generalized seizures. While physicians may exercise their discretion in prescribing a device off-label, any failure on the part of the device manufacturer to comply with off-label regulations could subject us to significant civil or criminal exposure, administrative obligations and costs, and/or other potential penalties from, and/or agreements with, the federal government.

Governmental regulations outside the U.S. have, and may continue to become, increasingly stringent and common. In the EU, for example, Reg MDR (Medical Device Regulation) became effective in May 2021, resulting in significant additional premarket and post-market requirements which must be in place by May 2024. During this transition period, the European Commission is allowing companies to use their MDD (Medical Device Directive) certifications. LivaNova is working to obtain all appropriate approvals and intends to be fully compliant by the May 2024 deadline, as penalties for regulatory non-compliance can be severe, including fines and revocation or suspension of a company’s business license, mandatory price reductions and criminal sanctions.

We are subject to environmental laws and regulations and the risk of environmental liabilities, violations and litigation.

Our operations involve the use of substances regulated under environmental laws, primarily those used in manufacturing and sterilization processes in the various jurisdictions where we operate. Regulations require sterilization of our products, and in 2021, we unveiled our new sterilization facility in Arvada, Colorado allowing the Company to sterilize certain of its products in-house. We also use third-party sterilizers for other products in our portfolio. The U.S. Environmental Protection Agency (EPA) and certain states have begun scrutinizing the levels of community exposure to ethylene oxide (EtO). Certain medical device operating facilities have been designated as “elevated risk” facilities, based on emission levels of EtO. LivaNova is not on the “elevated risk” list, nor is it in violation of any current local or federal regulations. However, to the extent we or our contract sterilizers are unable to sterilize our products, whether due to regulatory, legislative, or other constraints, including on the use of EtO, we may be unable to transition to alternative internal or external resources or methods in a timely or cost-effective manner or at all, which could have a material impact on our results of operations and financial condition.

We are subject to the risks of conducting business internationally.

We develop, manufacture, distribute and sell our products globally, and we intend to continue to pursue growth opportunities worldwide. Our international operations are subject to risks that are inherent in conducting business globally and under non-U.S. laws, regulations and customs. These risks include possible nationalization, invasions, wars, negative consequences associated with Brexit, expropriation, importation limitations, pricing restrictions, government shutdowns and violations of laws, and the resulting issues from any such risks. In February 2022, for example, Russia launched an invasion in Ukraine which caused us to assess our ability to sell in the market due to international sanctions, to consider the potential impact of raw material sourced from the region, and to determine whether we are able to transact in a compliant fashion. Although the region represented 1% of our total net revenue for 2021, the Russian invasion of Ukraine has increased economic uncertainties, and a significant escalation and/or continuation of the conflict could have a material, global impact on our operating results. In addition, our Russian employees and local subsidiary are subject to evolving laws and regulations imposed by the Russian authorities in response to international sanctions. Our profitability and operations are, and will continue to be, subject to a

number of risks and potential costs, including: local product preferences and product requirements; longer-term receivables than are typical in the EU or the U.S.; difficulty enforcing agreements; creditworthiness of customers; trade protection measures and import and export licensing requirements; imposition of sanctions; different labor regulations and workforce instability; higher danger of terrorist activity, war or civil unrest; selling our products through distributors and agents; and political and economic instability. Any of the aforementioned risks could adversely affect our business, results of operations, financial conditions and cash flows.

From time to time, certain of our subsidiaries have limited business dealings in countries subject to comprehensive sanctions, including Iran, Sudan, Syria and now Russia. These business dealings represent an insignificant amount of our consolidated revenues and income, but expose us to a heightened risk of violating applicable sanctions regulations. Violations of these regulations are punishable by civil penalties including fines, denial of export privileges, injunctions, asset seizures, debarment from government contracts and revocations or restriction of licenses, as well as criminal fines and imprisonment. We have established policies and procedures designed to assist with our compliance with such laws and regulations, but there can be no assurance that our policies and procedures will prevent us from violating these regulations in every transaction in which we may engage, and such a violation could adversely affect our reputation, business, results of operations, financial conditions and cash flows.

Our functional currency is the U.S. dollar; however, a portion of the revenues earned and expenses incurred by certain of our subsidiaries are denominated in currencies other than the U.S. dollar. We determine the functional currency of our subsidiaries that exist and operate in different economic and currency environments based on the primary economic environment in which the subsidiary operates, that is, the currency of the environment in which an entity primarily generates and expends cash. For transactions denominated in currencies other than our functional currencies, fluctuations in the exchange rate will impact our results of operations and financial condition. During the nine months ended September 30, 2022, our net revenue and profitability were negatively affected by the unfavorable foreign currency exchange impact of the strengthened U.S. dollar against a number of currencies. Although we may elect to hedge certain foreign currency exposure, we cannot be certain that the hedging activity will eliminate our currency risk.

In addition, in many of the countries where we operate, employees are covered by various laws and/or collective bargaining agreements that endow them, through their local or national representatives, with the right to be consulted in relation to specific issues, including the downsizing or closing of departments and staff reductions. The laws and/or collective bargaining agreements that are applicable to these agreements could have an impact on our flexibility, as they apply to programs to redefine and/or strategically reposition our activities. Our ability to implement staff downsizing programs or even temporary interruptions of employment relationships is predicated on the approval of government entities and the consent of labor unions. A negative response from a works council or union-organized work stoppages by employees could have a negative impact on our business.

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*

Disclosure Pursuant to Section 13(r) of the Exchange Act of 1934

Section 13(r) of the Exchange Act requires issuers to disclose in their quarterly reports certain types of dealings with Iran, including transactions or dealings with government-owned entities, even when those activities are lawful and do not involve U.S. persons. One of our non-U.S. subsidiaries currently sells medical devices, including cardiopulmonary, cardiac surgery and neuromodulation products, to privately held distributors in Iran.

We have limited visibility into the identity of these distributors' customers in Iran. It is possible that their customers include entities, such as government-owned hospitals or sub-distributors, that are owned or controlled directly or indirectly by the Iranian government. To the best of our knowledge at this time, we do not have any contracts or commercial arrangements with the Iranian government.

Our net revenue and net profits attributable to the above-mentioned Iranian activities were \$1.5 million and \$0.6 million for the three months ended September 30, 2022, respectively, and \$4.5 million and \$2.0 million for the nine months ended September 30, 2022, respectively.

We believe our activities are consistent with applicable law, including U.S., EU, and other applicable sanctions laws, though such laws are complex and continue to evolve rapidly. We intend to continue our business in Iran.

Retirement of Keyna Skeffington

On June 14, 2022, the Company filed a Current Report on Form 8-K that, among other things, announced the retirement of Keyna Skeffington, General Counsel and Company Secretary. Ms. Skeffington will transfer her responsibilities November 14, 2022 to Michael Hutchinson, incoming Chief Legal Officer and Company Secretary, and assist with the transition until her retirement from the Company on June 30, 2023.

Item 6. *Exhibits*

The exhibits marked with the asterisk symbol (*) are filed or furnished (in the case of Exhibit 32.1) with this Quarterly Report on Form 10-Q. Exhibits marked with the cross symbol (†), if any, are management contracts or compensatory plans or arrangements filed pursuant to Item 601(b)(10)(iii) of Regulation S-K.

Exhibit Number	Document Description
31.1*	Certification of the Chief Executive Officer of LivaNova PLC pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
31.2*	Certification of the Chief Financial Officer of LivaNova PLC pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
32.1*	Certification of the Chief Executive Officer and Chief Financial Officer of LivaNova PLC pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
101*	Interactive Data Files Pursuant to Rule 405 of Regulation S-T formatted in Inline XBRL: (i) the Condensed Consolidated Statements of Income (Loss) for the three and nine months ended September 30, 2022 and 2021, (ii) the Condensed Consolidated Statements of Comprehensive Income (Loss) for the three and nine months ended September 30, 2022 and 2021, (iii) the Condensed Consolidated Balance Sheet as of September 30, 2022 and December 31, 2021, (iv) the Condensed Consolidated Statements of Cash Flows for the nine months ended September 30, 2022 and 2021, and (v) the Notes to the Condensed Consolidated Financial Statements
104*	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101)

SIGNATURE

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.

LIVANOVA PLC

Date: November 2, 2022 By: /s/ DAMIEN MCDONALD
Damien McDonald
Chief Executive Officer
(Principal Executive Officer)

LIVANOVA PLC

Date: November 2, 2022 By: /s/ ALEX SHVARTSBURG
Alex Shvartsburg
Chief Financial Officer
(Principal Accounting and Financial Officer)

CERTIFICATION OF CHIEF EXECUTIVE OFFICER
PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Damien McDonald, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q for the quarterly period ended September 30, 2022 of LivaNova PLC and its consolidated subsidiaries;
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 and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) of the Securities Exchange Act of 1934 (the "Exchange Act")) and internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) of the Exchange Act) 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 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: November 2, 2022

/s/ DAMIEN MCDONALD

Damien McDonald
Chief Executive Officer
(Principal Executive Officer)

CERTIFICATION OF CHIEF FINANCIAL OFFICER
PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Alex Shvartsburg, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q for the quarterly period ended September 30, 2022 of LivaNova PLC and its consolidated subsidiaries;
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 and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) of the Securities Exchange Act of 1934 (the "Exchange Act")) and internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) of the Exchange Act) 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 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: November 2, 2022

/s/ ALEX SHVARTSBURG

Alex Shvartsburg

Chief Financial Officer

(Principal Accounting and Financial Officer)

**CERTIFICATION OF THE
CHIEF EXECUTIVE OFFICER AND
CHIEF FINANCIAL OFFICER
OF LIVANOVA PLC
PURSUANT TO 18 U.S.C. SECTION 1350
AS ADOPTED PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

Each of Damien McDonald, Chief Executive Officer of LivaNova PLC (the “Company”), and Alex Shvartsburg, Chief Financial Officer of the Company, each hereby certifies pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to the best of his knowledge:

(a) the Quarterly Report on Form 10-Q of the Company and its consolidated subsidiaries for the quarterly period ended September 30, 2022, as filed with the Securities and Exchange Commission on the date hereof (the “Report”) fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and

(b) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: November 2, 2022

/s/ DAMIEN MCDONALD

Damien McDonald
Chief Executive Officer
(Principal Executive Officer)

/s/ ALEX SHVARTSBURG

Alex Shvartsburg
Chief Financial Officer
(Principal Accounting and Financial Officer)

A signed original of this written statement required by Section 906 has been provided to the Company and will be retained by the Company and furnished to the Securities and Exchange Commission or its staff upon request.

The foregoing certification is being furnished solely pursuant to 18 U.S.C. Section 1350 and is not being filed as a part of this report or on a separate disclosure document.