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 December 31, 2022

or

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

Commission File Number: 0-23837

Surmodics, Inc.

(Exact name of registrant as specified in its charter)

MINNESOTA	**41-1356149**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**

9924 West 74th Street, Eden Prairie, Minnesota 55344
(Address of principal executive offices) (Zip Code)

(952) 500-7000
(Registrant's telephone number, including area code)

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

Title of each class	Trading Symbol	Name of each exchange on which registered
Common Stock, $0.05 par value	**SRDX**	**Nasdaq Global Select Market**

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

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

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

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

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

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

The number of shares of the registrant's Common Stock, $0.05 par value per share, as of February 3, 2023 was 14,125,000.

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PART I. FINANCIAL INFORMATION

Item 1. Unaudited Condensed Consolidated Financial Statements

Surmodics, Inc. and Subsidiaries

Condensed Consolidated Balance Sheets

(In thousands, except per share data)	December 31, 2022	September 30, 2022
	(Unaudited)	
ASSETS		
Current Assets:		
Cash and cash equivalents	$ 26,430	$ 18,998
Accounts receivable, net of allowances of $140 and $81 as of December 31, 2022 and September 30, 2022, respectively	10,068	10,452
Contract assets — royalties and license fees	7,047	7,116
Inventories, net	12,724	11,819
Income tax receivable	121	2,438
Prepaids and other	8,072	6,764
Total Current Assets	64,462	57,587
Property and equipment, net	27,717	27,148
Intangible assets, net	29,262	28,145
Goodwill	43,308	40,710
Other assets	5,006	4,769
Total Assets	$ 169,755	$ 158,359
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities:		
Accounts payable	$ 2,035	$ 3,136
Accrued liabilities:		
Compensation	4,410	8,929
Accrued other	7,048	5,854
Short-term borrowings	—	10,000
Deferred revenue	3,771	4,160
Total Current Liabilities	17,264	32,079
Long-term debt, net	29,495	—
Deferred revenue, less current portion	4,115	5,088
Deferred income taxes	2,102	2,027
Other long-term liabilities	9,518	10,773
Total Liabilities	62,494	49,967
Commitments and Contingencies (Note 11)		
Stockholders' Equity:		
Series A Preferred stock — $.05 par value, 450 shares authorized; no shares issued and outstanding	—	—
Common stock — $.05 par value, 45,000 shares authorized; 14,126 and 14,029 shares issued and outstanding as of December 31, 2022 and September 30, 2022, respectively	706	701
Additional paid-in capital	30,224	28,774
Accumulated other comprehensive loss	(4,617)	(9,874)
Retained earnings	80,948	88,791
Total Stockholders' Equity	107,261	108,392
Total Liabilities and Stockholders' Equity	$ 169,755	$ 158,359

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

Surmodics, Inc. and Subsidiaries

Condensed Consolidated Statements of Operations

(In thousands, except per share data)	Three Months Ended December 31, 2022	2021
	(Unaudited)	
Revenue:		
Product sales	$ 14,234	$ 12,344
Royalties and license fees	8,765	8,099
Research, development and other	1,934	2,560
Total revenue	24,933	23,003
Operating costs and expenses:		
Product costs	5,267	4,497
Research and development	12,743	11,663
Selling, general and administrative	13,236	9,192
Acquired intangible asset amortization	913	1,089
Contingent consideration expense	3	3
Total operating costs and expenses	32,162	26,444
Operating loss	(7,229)	(3,441)
Other expense:		
Interest expense, net	(826)	(136)
Foreign exchange (loss) gain	(125)	33
Investment income, net	172	26
Other expense	(779)	(77)
Loss before income taxes	(8,008)	(3,518)
Income tax benefit	165	706
Net loss	$ (7,843)	$ (2,812)
Basic net loss per share	$ (0.56)	$ (0.20)
Diluted net loss per share	$ (0.56)	$ (0.20)
Weighted average number of shares outstanding:		
Basic	13,983	13,878
Diluted	13,983	13,878

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

Surmodics, Inc. and Subsidiaries

Condensed Consolidated Statements of Comprehensive Loss

	Three Months Ended December 31,	
	2022	2021
(In thousands)	*(Unaudited)*	
Net loss	$ (7,843)	$ (2,812)
Other comprehensive income (loss):		
Derivative instruments:		
Unrealized net loss	(444)	—
Net loss reclassified to earnings	31	—
Net changes related to available-for-sale securities, net of tax	—	(5)
Foreign currency translation adjustments	5,670	(1,647)
Other comprehensive income (loss)	5,257	(1,652)
Comprehensive loss	$ (2,586)	$ (4,464)

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

Surmodics, Inc. and Subsidiaries

Condensed Consolidated Statements of Stockholders' Equity

	Three Months Ended December 31, 2022 and 2021					
	(Unaudited)					
	Common Stock		Additional Paid-In Capital	Accumulated Other Comprehensive (Loss) Income	Retained Earnings	Total Stockholders' Equity
(In thousands)	Shares	Amount				
Balance at September 30, 2022	14,029	$ 701	$ 28,774	$ (9,874)	$ 88,791	$ 108,392
Net loss	—	—	—	—	(7,843)	(7,843)
Other comprehensive income, net of tax	—	—	—	5,257	—	5,257
Issuance of common stock	103	5	(5)	—	—	—
Common stock options exercised, net	17	1	346	—	—	347
Purchase of common stock to pay employee taxes	(23)	(1)	(856)	—	—	(857)
Stock-based compensation	—	—	1,965	—	—	1,965
Balance at December 31, 2022	14,126	$ 706	$ 30,224	$ (4,617)	$ 80,948	$ 107,261
Balance at September 30, 2021	13,899	$ 695	$ 21,598	$ 1,727	$ 116,065	$ 140,085
Net loss	—	—	—	—	(2,812)	(2,812)
Other comprehensive loss, net of tax	—	—	—	(1,652)	—	(1,652)
Issuance of common stock	81	4	(4)	—	—	—
Common stock options exercised, net	14	1	229	—	—	230
Purchase of common stock to pay employee taxes	(19)	(1)	(859)	—	—	(860)
Stock-based compensation	—	—	1,680	—	—	1,680
Balance at December 31, 2021	13,975	$ 699	$ 22,644	$ 75	$ 113,253	$ 136,671

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

Surmodics, Inc. and Subsidiaries

Condensed Consolidated Statements of Cash Flows

	Three Months Ended December 31,	
	2022	2021
(In thousands)	*(Unaudited)*	
Operating Activities:		
Net loss	$ (7,843)	$ (2,812)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	2,122	2,376
Stock-based compensation	1,965	1,680
Noncash lease expense	159	91
Amortization of debt issuance costs	78	11
Provision for credit losses	59	4
Deferred taxes	(107)	(640)
Other	78	66
Change in operating assets and liabilities:		
Accounts receivable and contract assets	546	1,547
Inventories	(905)	(1,570)
Prepaids and other	(1,857)	(1,432)
Accounts payable	(1,254)	200
Accrued liabilities	(4,700)	(5,227)
Income taxes	2,218	(95)
Deferred revenue	(1,361)	(1,225)
Net cash used in operating activities	(10,802)	(7,026)
Investing Activities:		
Purchases of property and equipment	(977)	(782)
Maturities of available-for-sale securities	—	4,000
Net cash (used in) provided by investing activities	(977)	3,218
Financing Activities:		
Payments of short-term borrowings	(10,000)	—
Proceeds from issuance of long-term debt	29,664	—
Payments of debt issuance costs	(353)	—
Issuance of common stock	347	230
Payments for taxes related to net share settlement of equity awards	(858)	(853)
Net cash provided by (used in) financing activities	18,800	(623)
Effect of exchange rate changes on cash	411	(72)
Net change in cash and cash equivalents	7,432	(4,503)
Cash and Cash Equivalents:		
Beginning of period	18,998	31,153
End of period	$ 26,430	$ 26,650
Supplemental Information:		
Cash paid for income taxes	$ 5	$ 3
Cash paid for interest	660	82
Noncash investing and financing activities:		
Acquisition of property and equipment, net of refundable credits in other current assets and liabilities	150	137
Right-of-use assets obtained in exchange for new operating lease liabilities	—	350

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

Surmodics, Inc. and Subsidiaries
Notes to Condensed Consolidated Financial Statements
Period Ended December 31, 2022
(Unaudited)

1. Organization

Description of Business

Surmodics, Inc. and subsidiaries (referred to as “Surmodics,” the “Company,” “we,” “us,” “our” and other like terms) is a leading provider of performance coating technologies for intravascular medical devices and chemical and biological components for in vitro diagnostic (“IVD”) immunoassay tests and microarrays. Surmodics develops and commercializes highly differentiated vascular intervention medical devices that are designed to address unmet clinical needs and engineered to the most demanding requirements. This key growth strategy leverages the combination of the Company’s expertise in proprietary surface modification and drug-delivery coating technologies, along with its device design, development and manufacturing capabilities. The Company’s mission is to improve the detection and treatment of disease. Surmodics is headquartered in Eden Prairie, Minnesota.

Basis of Presentation and Principles of Consolidation

The accompanying unaudited condensed consolidated financial statements include all accounts and wholly-owned subsidiaries and have been prepared in accordance with accounting principles generally accepted in the U.S. (“GAAP”). All intercompany transactions have been eliminated. The Company operates on a fiscal year ending on September 30. In accordance with the rules and regulations of the U.S. Securities and Exchange Commission (“SEC”), the Company has omitted footnote disclosures that would substantially duplicate the disclosures contained in the audited consolidated financial statements of the Company. These unaudited condensed consolidated financial statements should be read together with the audited consolidated financial statements for the fiscal year ended September 30, 2022, and notes thereto included in our Annual Report on Form 10-K as filed with the SEC.

Use of Estimates

The preparation of consolidated financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities, the disclosure of contingent liabilities at the date of the condensed consolidated financial statements and the reported amounts of revenue and expenses during the reporting period. Ultimate results could differ from those estimates. The results of operations for the three months ended December 31, 2022 are not necessarily indicative of the results that may be expected for the entire 2023 fiscal year.

Certain reclassifications have been made to the prior year's consolidated financial statements to conform to the current year presentation.

New Accounting Pronouncements

No new accounting pronouncement issued or effective has had, or is expected to have, a material impact on the Company’s condensed consolidated financial statements.

2. Revenue

The following table presents the Company's revenues disaggregated by product classification and by reportable segment.

(In thousands)	Three Months Ended December 31, 2022	2021
Medical Device		
Product sales	$ 8,380	$ 6,788
Royalties	7,409	6,886
License fees	1,356	1,213
Research, development and other	1,873	2,021
Medical Device Revenue	19,018	16,908
In Vitro Diagnostics		
Product sales	5,854	5,556
Research, development and other	61	539
In Vitro Diagnostics Revenue	5,915	6,095
Total Revenue	$ 24,933	$ 23,003

Contract assets totaled $7.0 million and $7.1 million as of December 31, 2022 and September 30, 2022, respectively, on the condensed consolidated balance sheets. Fluctuations in the balance of contract assets result primarily from changes in sales-based and minimum royalties earned, but not collected, at each balance sheet date due to payment timing and contractual changes in the normal course of business. For discussion of contract liability (deferred revenue) balances and remaining performance obligations, see Note 3 Collaborative Arrangement.

3. Collaborative Arrangement

On February 26, 2018, the Company entered into an agreement with Abbott Vascular, Inc. ("Abbott") whereby Abbott has exclusive worldwide commercialization rights for Surmodics' SurVeil™ drug-coated balloon ("DCB") to treat the superficial femoral artery (the "Abbott Agreement"). A premarket approval ("PMA") application for the *SurVeil* DCB was being evaluated by the U.S. Food and Drug Administration ("FDA" or the "Agency") as of December 31, 2022. In January 2023, the FDA issued a letter to the Company indicating that the PMA application was not approvable based on the information submitted to the Agency to that time. The letter provided specific guidance on information, including additional testing and analysis, that would be required to put the application in approvable form.

Surmodics is responsible for conducting all necessary clinical trials and other activities required to achieve U.S. regulatory clearance for the *SurVeil* DCB, including completion of the ongoing TRANSCEND pivotal clinical trial. Abbott and Surmodics participate on a joint development committee charged with providing guidance on the Company's clinical and regulatory activities with regard to the *SurVeil* DCB product. Upon receipt of U.S. regulatory approval for our *SurVeil* DCB, Abbott will have the right to purchase commercial units from the Company, and Surmodics will realize revenue from product sales to Abbott at an agreed-upon transfer price, as well as a share of net profits resulting from third-party product sales by Abbott.

As of December 31, 2022, the Company had received payments totaling $60.8 million under the Abbott Agreement, which consist of the following: (i) $25 million upfront fee in fiscal 2018, (ii) $10 million milestone payment in fiscal 2019, (iii) $10.8 million milestone payment in fiscal 2020, and (iv) $15 million milestone payment in fiscal 2021. As of December 31, 2022, the Abbott Agreement provides that the Company may receive an additional contingent milestone payment upon PMA of our *SurVeil* DCB of $27 million (if PMA is received prior to June 30, 2023) or $24 million (if PMA is received on or after June 30, 2023). As of December 31, 2022, consideration from this potential regulatory milestone was fully excluded from the contract price (i.e., deemed fully constrained) due to the high level of uncertainty of achievement as of December 31, 2022. If PMA is not received by December 31, 2023, Abbott may terminate the Abbott Agreement and would have no further obligation to make the potential regulatory milestone payment after termination. In the period of termination, deferred revenue on the condensed consolidated balance sheets related to payments received under the Abbott Agreement would be recognized as revenue.

Revenue recognized from the Abbott Agreement totaled $1.3 million and $1.2 million for the three months ended December 31, 2022 and 2021, respectively. The amount of revenue recognized from the Abbott Agreement that was included in the respective beginning of fiscal year balances of deferred revenue on the condensed consolidated balance sheets totaled $1.3 million and $1.2 million for the three months ended December 31, 2022 and 2021, respectively.

As of December 31, 2022 and September 30, 2022, deferred revenue on the condensed consolidated balance sheets included $7.9 million and $9.2 million, respectively, related to payments received under the Abbott Agreement. The $7.9 million deferred revenue as of December 31, 2022, which represents the Company's performance obligations that are unsatisfied for executed contracts with an original duration of one year, is expected to be recognized as revenue over the next three years through fiscal 2025 as services, principally the TRANSCEND clinical trial, are completed.

4. Fair Value Measurements

Assets and liabilities measured at fair value on a recurring basis by level of the fair value hierarchy were as follows:

	December 31, 2022			
(In thousands)	Quoted Prices in Active Markets for Identical Instruments (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)	Total Fair Value
Assets				
Cash equivalents (1)	$ —	$ 17,134	$ —	$ 17,134
Total assets	$ —	$ 17,134	$ —	$ 17,134
Liabilities				
Contingent consideration (2)	$ —	$ —	$ 832	$ 832
Interest rate swap (3)	—	413	—	413
Total liabilities	$ —	$ 413	$ 832	$ 1,245

	September 30, 2022			
(In thousands)	Quoted Prices in Active Markets for Identical Instruments (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)	Total Fair Value
Assets				
Cash equivalents (1)	$ —	$ 2,035	$ —	$ 2,035
Total assets	$ —	$ 2,035	$ —	$ 2,035
Liabilities				
Contingent consideration (2)	$ —	$ —	$ 829	$ 829

(1) Fair value of cash equivalents (money market funds) is based on quoted vendor prices and broker pricing where all significant inputs are observable.

(2) Fair value of contingent consideration liabilities was determined based on discounted cash flow analyses that included probability and timing of development and regulatory milestone achievements and a discount rate, which are considered significant unobservable inputs as of both December 31, 2022 and September 30, 2022.

(3) Fair value of interest rate swap is based on forward-looking, one-month term secured overnight financing rate ("Term SOFR") spot rates and interest rate curves (Note 7).

Contingent consideration liabilities are remeasured to fair value each reporting period using discount rates, probabilities of payment and projected payment dates. Increases or decreases in the fair value of the contingent consideration liability can result from changes in the timing or likelihood of achieving milestones and changes in discount periods and rates. Projected contingent payment amounts are discounted back to the current period using a discount cash flow model. Interest accretion and fair value adjustments associated with contingent consideration liabilities are reported in contingent consideration expense (gain) on the condensed consolidated statements of operations.

Changes in the contingent consideration liabilities measured at fair value using Level 3 inputs were as follows:

(In thousands)	
Contingent consideration liability at September 30, 2022	$ 829
Additions	—
Fair value adjustments	—
Settlements	—
Interest accretion	3
Foreign currency translation	—
Contingent consideration liability at December 31, 2022	$ 832

Contingent consideration liabilities were associated with the fiscal 2021 acquisition of Vetex Medical Limited ("Vetex") and were included in other long-term liabilities on the condensed consolidated balance sheets.

5. Supplemental Balance Sheet Information

Inventories

Inventories consisted of the following components:

(In thousands)	December 31, 2022	September 30, 2022
Raw materials	$ 7,871	$ 6,102
Work-in process	1,534	1,595
Finished products	3,319	4,122
Total	$ 12,724	$ 11,819

Prepaids and Other Assets, Current

Prepaids and other current assets consisted of the following:

(In thousands)	December 31, 2022	September 30, 2022
Prepaid expenses	$ 3,809	$ 2,570
Irish research and development credits receivable	822	753
CARES Act employee retention credit receivable (1)	3,441	3,441
Prepaids and other	$ 8,072	$ 6,764

(1) Receivable consisted of anticipated reimbursement of personnel expenses incurred in fiscal periods prior to fiscal 2023 as a result of our eligibility for the employee retention credit under the provisions of the Coronavirus Aid, Relief and Economic Security Act (the "CARES Act").

Intangible Assets

Intangible assets consisted of the following:

		December 31, 2022		
(Dollars in thousands)	Weighted Average Original Life (Years)	Gross Carrying Amount	Accumulated Amortization	Net
Definite-lived intangible assets:				
Customer lists and relationships	8.9	$ 12,291	$ (9,797)	$ 2,494
Developed technology	11.9	34,251	(9,110)	25,141
Patents and other	14.1	3,551	(2,504)	1,047
Total definite-lived intangible assets		50,093	(21,411)	28,682
Unamortized intangible assets:				
Trademarks and trade names		580	—	580
Total intangible assets		$ 50,673	$ (21,411)	$ 29,262

(Dollars in thousands)	Weighted Average Original Life (Years)	September 30, 2022 Gross Carrying Amount	Accumulated Amortization	Net
Definite-lived intangible assets:				
Customer lists and relationships	8.9	$ 11,354	$ (8,827)	$ 2,527
Developed technology	11.9	31,943	(7,994)	23,949
Patents and other	14.1	3,551	(2,462)	1,089
Total definite-lived intangible assets		46,848	(19,283)	27,565
Unamortized intangible assets:				
Trademarks and trade names		580	—	580
Total intangible assets		$ 47,428	$ (19,283)	$ 28,145

Intangible asset amortization expense was $1.0 million and $1.2 million for the three months ended December 31, 2022 and 2021, respectively. Based on the intangible assets in service as of December 31, 2022, estimated amortization expense for future fiscal years is as follows:

(In thousands)	
Remainder of 2023	$ 2,795
2024	3,726
2025	3,691
2026	2,806
2027	2,559
2028	2,548
Thereafter	10,557
Definite-lived intangible assets	$ 28,682

Future amortization amounts presented above are estimates. Actual future amortization expense may be different as a result of future acquisitions, impairments, changes in amortization periods, foreign currency translation rates, or other factors.

Goodwill

Changes in the carrying amount of goodwill by segment were as follows:

(In thousands)	In Vitro Diagnostics	Medical Device	Total
Goodwill as of September 30, 2022	$ 8,010	$ 32,700	$ 40,710
Currency translation adjustment	—	2,598	2,598
Goodwill as of December 31, 2022	$ 8,010	$ 35,298	$ 43,308

Other Assets, Noncurrent

Other noncurrent assets consisted of the following:

(In thousands)	December 31, 2022	September 30, 2022
Operating lease right-of-use assets	$ 3,480	$ 3,633
Other	1,526	1,136
Other assets	$ 5,006	$ 4,769

Other noncurrent assets consisted primarily of prepaid expenses and receivables related to refundable Irish research and development tax credits.

Accrued Other Liabilities

Accrued other liabilities consisted of the following:

(In thousands)	December 31, 2022	September 30, 2022
Accrued professional fees	$ 264	$ 279
Accrued clinical study expense	1,903	1,425
Accrued purchases	1,562	1,655
Acquisition of in-process research and development (1)	1,933	981
Operating lease liability, current portion	1,027	963
Other	359	551
Total accrued other liabilities	$ 7,048	$ 5,854

(1) Acquisition of in-process research and development consists of the present value of guaranteed payments to be made (current portion) in connection with an asset acquisition in fiscal 2018 (Note 11).

Other Long-term Liabilities

Other long-term liabilities consisted of the following:

(In thousands)	December 31, 2022	September 30, 2022
Deferred consideration (1)	$ 3,361	$ 4,260
Contingent consideration (2)	832	829
Unrecognized tax benefits (3)	1,741	1,841
Operating lease liabilities (4)	3,584	3,843
Other long-term liabilities	$ 9,518	$ 10,773

(1) Deferred consideration consists of the present value of guaranteed payments to be made (noncurrent portion) in connection with the fiscal 2021 Vetex acquisition and with an asset acquisition in fiscal 2018 (Note 11).

(2) Contingent consideration consists of the fair value of contingent consideration liabilities associated with the fiscal 2021 Vetex acquisition (Note 11).

(3) Balance of unrecognized tax benefits (Note 10) includes accrued interest and penalties, if applicable.

(4) Operating lease liabilities consist of the non-current portion of the net present value of future minimum lease payments, reduced by the discounted value of leasehold improvement incentives paid or payable to the Company.

6. Debt

Debt consisted of the following:

(In thousands)	December 31, 2022	September 30, 2022
Short-term borrowings (1)	$ —	$ 10,000
Revolving Credit Facility, Term SOFR + 3.00%, maturing October 1, 2027	$ 5,000	$ —
Tranche 1 Term Loans, Term SOFR +5.75%, maturing October 1, 2027	25,000	—
Long-term debt, gross	30,000	—
Less: Unamortized debt issuance costs	(505)	—
Long-term debt, net	$ 29,495	$ —

(1) Consisted of the outstanding balance on the secured revolving credit facility with Bridgewater Bank; this balance was repaid and the credit agreement terminated on October 14, 2022. For further information, refer to the Notes to the Consolidated Financial Statements in Part II, Item 8 of our Annual Report on Form 10-K for the fiscal year ended September 30, 2022.

On October 14, 2022, the Company entered into a secured revolving credit facility and secured term loan facilities pursuant to a Credit, Security and Guaranty Agreement (the "MidCap Credit Agreement") with Mid Cap Funding IV Trust, as agent, and MidCap Financial Trust, as term loan servicer and the lenders from time to time party thereto. The MidCap Credit Agreement provides for availability under a secured revolving line of credit of up to $25.0 million (the "Revolving Credit Facility"), and proceeds may be used for transaction fees and for working capital needs and general corporate purposes. Availability under the Revolving Credit Facility is subject to a borrowing base.

The MidCap Credit Agreement also provides for up to $75.0 million in term loans (the "Term Loans"), consisting of a $25.0 million Tranche 1 ("Tranche 1") and a $50.0 million Tranche 2 ("Tranche 2"), which may be drawn in increments of at least $10.0 million. In addition, after the closing and prior to December 31, 2024, the Term Loan lenders may, in their sole discretion, fund an additional tranche of Term Loans of up to $25.0 million upon the written request of the Company. Upon closing, the Company borrowed $25.0 million of Tranche 1, borrowed $5.0 million on the Revolving Credit Facility, and used approximately $10.0 million of the proceeds to repay borrowings under the revolving credit facility with Bridgewater Bank, and intends to use the remaining proceeds to fund working capital needs and other general corporate purposes. Until December 31, 2024, the Company will be eligible to borrow Tranche 2 at the Company's option upon meeting certain conditions set forth in the MidCap Credit Agreement, including having no less than $60.0 million of rolling-four-quarter core net revenue as of the end of the prior fiscal quarter. Core net revenue is defined in the MidCap Credit Agreement as the sum of revenue from our In Vitro Diagnostics segment and revenues from performance coating technologies in our Medical Device segment.

Pursuant to the MidCap Credit Agreement, the Company provided a first priority security interest in all existing and future acquired assets, including intellectual property and real estate, owned by the Company. The MidCap Credit Agreement contains certain covenants that limit the Company's ability to engage in certain transactions. Subject to certain limited exceptions, these covenants limit the Company's ability to, among other things:

- create, incur, assume or permit to exist any additional indebtedness, or create, incur, allow or permit to exist any additional liens;
- enter into any amendment or other modification of certain agreements;
- effect certain changes in the Company's business, fiscal year, management, entity name or business locations;
- liquidate or dissolve, merge with or into, or consolidate with, any other company;
- pay cash dividends on, make any other distributions in respect of, or redeem, retire or repurchase, any shares of the Company's capital stock;
- make certain investments, other than limited permitted acquisitions; and
- enter into transactions with the Company's affiliates.

The MidCap Credit Agreement also contains customary indemnification obligations and customary events of default, including, among other things, (i) non-payment, (ii) breach of warranty, (iii) non-performance of covenants and obligations, (iv) default on other indebtedness, (v) judgments, (vi) change of control, (vii) bankruptcy and insolvency, (viii) impairment of security, (ix) termination of a pension plan, (x) regulatory matters, and (xi) material adverse effect.

In addition, the Company must maintain minimum core net revenue levels tested quarterly to the extent that Term Loans advanced under the MidCap Credit Agreement exceed $25.0 million. In the event of default under the MidCap Credit Agreement, the Company would be required to pay interest on principal and all other due and unpaid obligations at the current rate in effect plus 2%.

Borrowings under the MidCap Credit Agreement bear interest at the forward-looking, one-month secured overnight financing rate ("Term SOFR") as published by CME Group Benchmark Administration Limited plus 0.10% ("Adjusted Term SOFR"). The Revolving Credit Facility bears interest at an annual rate equal to 3.00% plus the greater of Adjusted Term SOFR or 1.50%, and the Term Loans bear interest at an annual rate equal to 5.75% plus the greater of Adjusted Term SOFR or 1.50%. The Company is required to make monthly interest payments on the Revolving Credit Facility with the entire principal payment due at maturity. The Company is required to make 48 monthly interest payments on the Term Loans beginning on November 1, 2022 (the "Interest-Only Period"). If the Company is in covenant compliance at the end of the Interest-Only Period, the Company will have the option to extend the Interest-Only Period through maturity with the entire principal payment due at maturity. If the Company is not in covenant compliance at the end of the Interest-Only Period, the Company is required to make 12 months of straight-line amortization payments with the entire principal amount due at maturity.

Subject to certain limitations, the Term Loans have a prepayment fee for payments made prior to the maturity date equal to 3.0% of the prepaid principal amount for the first year following the closing date of the MidCap Credit Agreement, 2.0% of the prepaid principal amount for the second year following the closing date and 1.0% of the prepaid principal amount for the third year following the closing date and thereafter. In addition, if the Revolving Credit Facility is terminated in whole or in part prior to the maturity date, the Company must pay a prepayment fee equal to 3.0% of the terminated commitment amount for the first year following the closing date of the MidCap Credit Agreement, 2.0% of the terminated commitment amount for the second year following the closing date of the MidCap Credit Agreement and 1.0% of the terminated commitment amount for the third year following the closing date and thereafter. The Company is also required to pay a full exit fee at the time of maturity or full prepayment event equal to 2.5% of the aggregate principal amount of the Term Loans made pursuant to the MidCap Credit Agreement and a partial exit fee at the time of any partial prepayment event equal to 2.5% of the amount prepaid. This exit fee is accreted over the remaining term of the Term Loans. The Company also is obligated to pay customary origination fees at the time of each funding of the Term Loans and a customary annual administrative fee based on the amount borrowed under the Term Loan, due on an annual basis. The customary fees on the Revolving Credit Facility include (i) an origination fee based on the commitment amount, which was paid on the closing date, (ii) an annual collateral management fee of 0.50% per annum based on the outstanding balance of the Revolving Credit Facility, payable monthly in arrears and (iii) an unused line fee of 0.50% per annum based on the average unused portion of the Revolving Credit Facility, payable monthly in arrears. The Company must also maintain a minimum balance of no less than 20% of availability under the Revolving Credit Facility or a minimum balance fee applies of 0.50% per annum. Expenses recognized for fees for the Revolving Credit Facility and Term Loans are reported in interest expense, net on the condensed consolidated statements of operations.

7. Derivative Financial Instruments

We periodically enter into interest rate swaps with major financial institutions of high credit quality to mitigate exposure to changes in interest rates on our floating-rate indebtedness. Since the fair value of these interest rate swaps is derived from current market rates, they are classified as derivative financial instruments. We do not use derivatives for speculative or trading purposes.

When the Company has multiple derivative financial instruments with the same counterparty subject to a master netting arrangement, we have elected to offset the amounts: (i) recorded as assets and liabilities and (ii) amounts recognized for the right to reclaim cash collateral we have deposited with the counterparty (i.e., cash collateral receivable). Such offset amounts are presented as either a net asset or liability by counterparty on the condensed consolidated balance sheets.

Cash Flow Hedge — Interest Rate Swap

On October 14, 2022, we entered into a floating-to-fixed interest rate swap agreement to mitigate exposure to interest rate increases related to our Term Loans. See Note 6 Debt for further information on our financing arrangements. The total notional amount of the interest rate swap was $25 million as of December 31, 2022. The interest rate swap agreement expires October 1, 2027. As a result of this agreement, every month we pay fixed interest at 4.455% in exchange for interest received at Term SOFR, and the fixed interest rate per annum on the first $25 million of notional value of the Term Loans will be 10.205% through its maturity. The interest rate swap agreement requires the Company to make deposits of cash collateral, which may increase or be refunded commensurate with fluctuations in current and forecasted interest rates. We have the contractual right to reclaim this cash collateral receivable.

The interest rate swap has been designated as a cash flow hedge. Consequently, changes in the fair value of the interest rate swap are recorded in accumulated other comprehensive loss ("AOCL") within stockholders' equity on the condensed consolidated balance sheets. The unrealized (losses) gains on the interest rate swap associated with the interest payments on the Term Loans that are still forecasted to occur are included in AOCL. These (losses) gains will be reclassified into interest expense on the condensed consolidated statements of operations over the life of the swap agreement as the hedged interest payments occur. Upon termination of the derivative instrument or a change in the hedged item, any remaining fair value recorded on the condensed consolidated balance sheets will be recorded as interest expense consistent with the cash flows associated with the underlying hedged item. Cash flows associated with the interest rate swap are included in cash flows from operating activities on the condensed consolidated statements of cash flows.

The net fair value of designated hedge derivatives subject to master netting arrangements reported on the condensed consolidated balance sheets was as follows:

	Asset (Liability)					
(In thousands)	Gross Recognized Amount	Gross Offset Amount	Net Amount Presented	Cash Collateral Receivable	Net Amount Reported	Balance Sheet Location
December 31, 2022						
Interest rate swap	$ (413)	$ —	$ (413)	$ 533	$ 120	Other assets, noncurrent
September 30, 2022						
—	$ —	$ —	$ —	$ —	$ —	—

The pretax amounts recognized in AOCL on the interest rate swap were as follows:

	Three Months Ended December 31,	
(In thousands)	2022	2021
Beginning unrealized net loss in AOCL	$ —	$ —
Net loss recognized in other comprehensive income (loss)	(444)	—
Net loss reclassified into interest expense	31	—
Ending unrealized net loss in AOCL	$ (413)	$ —

8. Stock-based Compensation Plans

The Company has stock-based compensation plans approved by its shareholders under which it grants stock options, restricted stock awards, restricted stock units and deferred stock units to officers, directors and key employees. Stock-based compensation expense was reported as follows in the condensed consolidated statements of operations:

	Three Months Ended December 31,	
(In thousands)	2022	2021
Product costs	$ 67	$ 30
Research and development	374	453
Selling, general and administrative	1,524	1,197
Total	$ 1,965	$ 1,680

As of December 31, 2022, unrecognized compensation costs related to non-vested awards totaled approximately $16.3 million, which is expected to be recognized over a weighted average period of approximately 2.7 years.

Stock Option Awards

The Company awards stock options to officers, directors and key employees and uses the Black-Scholes option pricing model to determine the fair value of stock options as of the date of each grant. Stock option grant activity was as follows:

	Three Months Ended December 31,	
	2022	2021
Stock option grant activity:		
Stock options granted	269,000	245,000
Weighted average grant date fair value	$ 15.53	$ 16.36
Weighted average exercise price	$ 35.97	$ 43.93

Restricted Stock Awards

During the three months ended December 31, 2022 and 2021, the Company awarded 99,000 and 78,000 restricted stock shares, respectively, to certain key employees and officers with a weighted average grant date fair value per share of $36.05 and $43.93, respectively. Restricted Stock is valued based on the market value of the shares as of the date of grant.

Restricted Stock Unit Awards

During each of the three months ended December 31, 2022 and 2021, the Company awarded 6,000 restricted stock units ("RSUs") to directors and to key employees in foreign jurisdictions with a weighted average grant date fair value per unit of $36.13 and $43.93, respectively. RSUs are valued based on the market value of the shares as of the date of grant.

Employee Stock Purchase Plan

Our U.S. employees are eligible to participate in the amended 1999 Employee Stock Purchase Plan ("ESPP") approved by our shareholders. During the three months ended December 31, 2022 and 2021, no shares were issued under the ESPP, respectively.

9. Net Loss Per Share Data

Basic net loss per common share is calculated by dividing net loss by the weighted average number of common shares outstanding during the period. Diluted net loss per common share is computed by dividing net loss by the weighted average number of common and common equivalent shares outstanding during the period. The Company's potentially dilutive common shares are those that result from dilutive common stock options and non-vested stock relating to restricted stock awards and restricted stock units. For the three months ended December 31, 2022 and 2021, 0.1 million and 0.2 million in weighted-average shares, respectively, were excluded from the calculation of diluted net loss per share as their effect was anti-dilutive as a result of the net loss incurred for those periods. Therefore, diluted weighted average number of shares outstanding and diluted net loss per share were the same as basic weighted average number of shares outstanding and net loss per share for the three months ended December 31, 2022 and 2021.

The following table presents the denominator for the computation of diluted weighted average shares outstanding:

	Three Months Ended December 31,	
(In thousands)	**2022**	**2021**
Basic weighted average shares outstanding	13,983	13,878
Dilutive effect of outstanding stock options, non-vested restricted stock, and non-vested restricted stock units	—	—
Diluted weighted average shares outstanding	13,983	13,878

10. Income Taxes

For interim income tax reporting, the Company estimates its annual effective tax rate and applies it to fiscal year-to-date pretax loss, excluding unusual or infrequently occurring discrete items. Tax jurisdictions with losses for which tax benefits cannot be realized are excluded. The Company reported income tax benefit of $0.2 million and $0.7 million for the three months ended December 31, 2022 and 2021, respectively.

Each reporting period, we evaluate the realizability of our net deferred tax assets and perform an assessment of both positive and negative evidence. Based on our evaluation of all available positive and negative evidence, and by placing greater weight on the objective negative evidence associated with our three-year cumulative U.S. pre-tax loss adjusted for permanent adjustments, we determined, as of December 31, 2022 and September 30, 2022, that it is more likely than not that our net U.S. deferred tax assets will not be realized. Accordingly, a full valuation allowance is recorded against our net U.S. deferred tax assets as of December 31, 2022 and September 30, 2022. Due to significant estimates used to establish the valuation allowance and the potential for changes in facts and circumstances, it is reasonably possible that we will be required to record additional adjustments to the valuation allowance in future reporting periods that could have a material effect on our results of operations.

In addition to the impact of the valuation allowance against our U.S. deferred tax assets, recurring items cause our effective tax rate to differ from the U.S. federal statutory rate of 21%, including U.S. federal and Irish R&D credits, Irish and U.S. state tax rates, and excess tax benefits associated with stock-based compensation.

The Company recognized discrete tax benefits related to stock-based compensation awards vested, expired, canceled and exercised of $0.1 million for each of the three months ended December 31, 2022 and 2021. The total amount of unrecognized tax benefits, excluding interest and penalties that, if recognized, would affect the effective tax rate was $3.0 million and $2.5 million as of December 31, 2022 and September 30, 2022, respectively. Interest and penalties related to unrecognized tax benefits are recorded in the income tax benefit.

The Company files income tax returns, including returns for its subsidiaries, in the U.S. federal jurisdiction and in various state jurisdictions, as well as several non-U.S. jurisdictions. Uncertain tax positions are related to tax years that remain subject to examination. The Internal Revenue Service commenced an examination of the Company's fiscal 2019 U.S. federal tax return in fiscal 2022; the examination has not been completed. U.S. federal income tax returns for years prior to fiscal 2019 are no longer subject to examination by federal tax authorities. For tax returns for U.S. state and local jurisdictions, the Company is no longer subject to examination for tax years generally before fiscal 2012. For tax returns for non-U.S. jurisdictions, the Company is no longer subject to income tax examination for years prior to 2018. Additionally, the Company has been indemnified of liability for any taxes relating to Creagh Medical, Ltd.; NorMedix, Inc.; and Vetex for periods prior to the respective acquisition dates, pursuant to the terms of the related share purchase agreements. There were no undistributed earnings in foreign subsidiaries as of December 31, 2022 and September 30, 2022.

11. Commitments and Contingencies

Clinical Trials. The Company has engaged clinical trial clinical research organization ("CRO") consultants to assist with the administration of its ongoing clinical trials. The Company has executed separate contracts with two CROs for services rendered in connection with the TRANSCEND pivotal clinical trial for the *SurVeil* DCB, including pass-through expenses paid by the CROs, of up to approximately $30 million in the aggregate. As of December 31, 2022, an estimated $5 million remains to be paid on these contracts, which may vary depending on actual pass-through expenses incurred to execute the trial. The Company estimates that the total cost of the TRANSCEND clinical trial will be in the range of $37 million to $40 million from inception to completion. In the event the Company were to terminate any trial, it may incur certain financial penalties which would become payable to the CRO for costs to wind down the terminated trial.

Asset Acquisitions. In fiscal 2018, the Company acquired certain intellectual property assets of Embolitech, LLC (the "Embolitech Transaction"). As part of the Embolitech Transaction, the Company paid the sellers $5.0 million in fiscal 2018, $1.0 million in fiscal 2020, $1.0 million in fiscal 2021, and $0.5 million in fiscal 2022. The Company is obligated to pay additional installments totaling $2.0 million in fiscal 2023 through fiscal 2024. These payments may be accelerated upon the occurrence of certain sales and regulatory milestones. An additional $1.0 million payment is contingent upon the achievement of certain regulatory milestones within a contingency period ending in 2033.

Vetex Acquisition. In fiscal 2021, Surmodics acquired all of the outstanding shares of Vetex with an upfront cash payment of $39.9 million. The Company is obligated to pay additional installments totaling $3.5 million in fiscal 2024 through fiscal 2027. These payments may be accelerated upon the occurrence of certain product development and regulatory milestones. An additional $3.5 million in payments is contingent upon the achievement of certain product development and regulatory milestones within a contingency period ending in fiscal 2027.

12. Segment Information

Segment revenue, operating loss, and depreciation and amortization were as follows:

(In thousands)	Three Months Ended December 31, 2022	2021
Revenue:		
Medical Device	$ 19,018	$ 16,908
In Vitro Diagnostics	5,915	6,095
Total revenue	$ 24,933	$ 23,003
Operating (loss) income:		
Medical Device	$ (7,235)	$ (3,792)
In Vitro Diagnostics	2,948	3,155
Total segment operating (loss) income	(4,287)	(637)
Corporate	(2,942)	(2,804)
Total operating (loss) income	$ (7,229)	$ (3,441)
Depreciation and amortization:		
Medical Device	$ 1,953	$ 2,194
In Vitro Diagnostics	77	86
Corporate	92	96
Total depreciation and amortization	$ 2,122	$ 2,376

The Corporate category includes expenses that are not fully allocated to the Medical Device and In Vitro Diagnostics segments. These Corporate costs are related to administrative corporate functions, such as executive management, corporate accounting, information technology, legal, human resources and Board of Directors. Corporate may also include expenses, such as acquisition-related costs and litigation, which are not specific to a segment and thus not allocated to the reportable segments.

Asset information by segment is not presented because the Company does not provide its chief operating decision maker assets by segment, as the data is not readily available.

13. Subsequent Events

In the second quarter of fiscal 2023, we initiated certain organizational changes to reduce our use of cash by reducing the Company's workforce by approximately 13%, primarily in our Medical Device segment. We expect to incur $1.0 million to $1.2 million of pre-tax restructuring expense for severance and related charges in the second quarter of fiscal 2023. The workforce reduction is expected to be completed, including the majority of cash paid, within the second quarter of fiscal 2023.

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

The following discussion and analysis provides information management believes is useful in understanding the operating results, cash flows and financial condition of Surmodics. The discussion should be read in conjunction with both the unaudited condensed consolidated financial statements and related notes included in this Quarterly Report on Form 10-Q and our audited consolidated financial statements and related notes and Management's Discussion and Analysis of Financial Condition and Results of Operations, each included in our Annual Report on Form 10-K for the fiscal year ended September 30, 2022. This discussion contains various "Forward-Looking Statements" within the meaning of the Private Securities Litigation Reform Act of 1995. We refer readers to the statement entitled "Forward-Looking Statements" located at the end of this Item 2.

Overview

Surmodics, Inc. (referred to as "Surmodics," the "Company," "we," "us," "our" and other like terms) is a leading provider of performance coating technologies for intravascular medical devices and chemical and biological components for in vitro diagnostic ("IVD") immunoassay tests and microarrays. Surmodics develops and commercializes highly differentiated vascular intervention medical devices that are designed to address unmet clinical needs and engineered to the most demanding requirements. This key growth strategy leverages the combination of the Company's expertise in proprietary surface modification and drug-delivery coating technologies, along with its device design, development and manufacturing capabilities. The Company's mission is to improve the detection and treatment of disease. Surmodics is headquartered in Eden Prairie, Minnesota.

Vascular Intervention Medical Device Platforms

Within our Medical Device segment, we develop and manufacture our own proprietary vascular intervention medical device products, which leverage our expertise in performance coating technologies, product design and engineering capabilities. We believe our strategy of developing our own medical device products has increased, and will continue to increase, our relevance in the medical device industry. This strategy is key to our future growth and profitability, providing us with the opportunity to capture more revenue and operating margin with vascular intervention device products than we would by licensing our device-enabling technologies.

Highlighted below are select medical device products within our development pipeline that are a focus for development and commercialization efforts. For both our thrombectomy and radial access platforms, we are pursuing commercialization via a direct sales strategy leveraging a small team of experienced sales professionals and clinical specialists. Beginning in fiscal 2022, we began to see modest, but meaningful and growing revenue associated with the adoption, utilization and sales of our Pounce™ and Sublime™ platform products.

Pounce™ Thrombectomy Platform

We have successfully developed, internally and through acquisitions, two U.S. Food and Drug Administration ("FDA" or the "Agency") 510(k)-cleared mechanical thrombectomy devices for the non-surgical removal of thrombi and emboli (clots) from the peripheral vasculature (legs). In addition to FDA clearance, our *Pounce* Venous Thrombectomy System has received the Conformité Européenne Mark ("CE Mark") approval prerequisite for commercialization in the European Union ("E.U."). We believe that the ease of use, intuitive design and efficient performance of our thrombectomy products make these devices viable first-line treatment options for interventionalists. These devices include:

- ***Pounce* Arterial Thrombectomy System** for removal of clots from arteries in the legs associated with peripheral arterial disease ("PAD"). Commercial sales began in the first quarter of fiscal 2022.
- ***Pounce* Venous Thrombectomy System** for removal of clots from veins in the legs generally associated with venous thromboembolism ("VTE"). Limited market evaluations began in fiscal 2023 and are expected to continue in fiscal 2023 to obtain physician feedback across a variety of cases and clinical conditions.

Sublime Radial Access Platform

We have successfully developed and secured FDA 510(k) regulatory clearance for a suite of devices that enable vascular intervention via radial (wrist) access for which commercial sales began in the first quarter of fiscal 2022. These devices include:

- ***Sublime* guide sheath** to provide the conduit for peripheral intervention with an access point at the wrist that enables treatment all the way to the pedal loop of the foot;
- ***Sublime* .014 RX PTA dilatation catheter** for treatment of lesions in arteries below the knee all the way to the patient's foot and around the pedal loop; and
- ***Sublime* .018 RX PTA dilatation catheter** for treatment of lesions in arteries above and below the knee.

Drug-coated Balloon Platform

Surmodics' drug-coated balloons ("DCBs") are designed for vascular interventions to treat PAD, a condition that causes a narrowing of the blood vessels supplying the extremities.

- **SurVeil™ DCB** is a paclitaxel-coated DCB to treat PAD in the upper leg (superficial femoral artery). In fiscal 2018, we entered into an agreement (the "Abbott Agreement") with Abbott Vascular, Inc. ("Abbott") that provides Abbott with exclusive worldwide commercialization rights to the *SurVeil* DCB product. Our *SurVeil* DCB utilizes a proprietary paclitaxel drug-excipient formulation for a durable balloon coating and is manufactured using an innovative process to improve coating uniformity.

  The *SurVeil* DCB has the necessary regulatory approval for commercialization in the E.U., and timing of commercialization in the E.U. is at the discretion of our exclusive distribution partner, Abbott. In fiscal 2021, the TRANSCEND pivotal clinical trial of our *SurVeil* DCB met both the primary safety and primary efficacy endpoints and was found to be non-inferior to the control device in those endpoints.

  In the third quarter of fiscal 2021, we submitted the fourth and final module of our application to the FDA for premarket approval ("PMA") of our *SurVeil* DCB, including data from the TRANSCEND trial as requested by the Agency. In the fourth quarter of fiscal 2021, the FDA provided us with comments on the PMA application and requested additional data to support its review of the application. In October 2022, we submitted a complete response to the FDA's comments, including certain additional data requested by the Agency. In January 2023, the FDA issued a letter to us indicating that the PMA application was not approvable based on the information submitted to the Agency to that time. The letter provided specific guidance on information, including additional testing and analysis, that would be required to put the application in approvable form. We are evaluating the issues raised in the FDA's letter and plan to meet with Agency representatives regarding its contents. Based on our discussion with the Agency, our team and external advisors will determine the appropriate path forward regarding our PMA application for our *SurVeil* DCB. Unless and until FDA approval has been obtained, our *SurVeil* DCB may not be offered for commercial sale in the U.S.

- **Sundance™ DCB** is a sirolimus-coated DCB used for the treatment of below-the-knee PAD. We completed six-month patient follow-up visits in the fourth quarter of fiscal 2021 for the SWING first-in-human, 35-patient clinical study of our *Sundance* DCB. In fiscal 2022, we finalized the clinical report for the SWING trial, which demonstrated promising early safety data and performance insights. We plan to evaluate our strategy for further clinical investment in the *Sundance* DCB based on the experience we gain from the PMA application process for the *SurVeil* DCB.

For more information regarding our vascular intervention medical devices, see Part I, Item 1 of our Annual Report on Form 10-K for the fiscal year ended September 30, 2022.

Results of Operations

Three Months Ended December 31, 2022 and 2021

Revenue. Revenue in the first quarter of fiscal 2023 was $24.9 million, a $1.9 million or 8% increase compared to the prior-year quarter. The following is a summary of revenue streams within each reportable segment.

	Three Months Ended December 31,			
(Dollars in thousands)	**2022**	**2021**	**Increase/(Decrease)**	
Medical Device				
Product sales	$ 8,380	$ 6,788	$ 1,592	23%
Royalties	7,409	6,886	523	8%
License fees	1,356	1,213	143	12%
Research, development and other	1,873	2,021	(148)	(7)%
Medical Device Revenue	**19,018**	**16,908**	**2,110**	**12%**
In Vitro Diagnostics				
Product sales	5,854	5,556	298	5%
Research, development and other	61	539	(478)	(89)%
In Vitro Diagnostics Revenue	**5,915**	**6,095**	**(180)**	**(3)%**
Total Revenue	**$ 24,933**	**$ 23,003**	**$ 1,930**	**8%**

Medical Device. Revenue in our Medical Device segment was $19.0 million in the first quarter of fiscal 2023, a 12% increase from $16.9 million in the prior-year quarter.

- Medical Device product sales increased 23% to $8.4 million in the first quarter of fiscal 2023, compared to $6.8 million in the prior-year quarter, driven by growth in sales of performance coating reagent products and device products. Contributing to the growth in device sales were our *Pounce* thrombectomy and *Sublime* radial access products, which were commercialized in fiscal 2022, and sales of contract-manufactured balloon catheters. The growth in device product sales was offset, in part, by a year-over-year decline in sales of proprietary specialty catheters distributed by strategic partners.
- Medical Device performance coating royalties revenue increased 8% to $7.4 million in the first quarter of fiscal 2023, compared to $6.9 million in the prior-year quarter. For the first quarter of fiscal 2023, royalties revenue from customers utilizing our Serene™ coating contributed to year-over-year growth. Performance coating royalties revenue for the first quarter of fiscal 2023 was impacted by macroeconomic factors to a lesser degree relative to the prior-year quarter. Macroeconomic factors include pressure on procedure volumes from hospital capacity constraints and customer supply chain disruptions, as well as customer devices maturing through their product life cycle.
- License fee revenue from the Abbott Agreement for our *SurVeil* DCB was $1.3 million and $1.2 million in the first quarter of fiscal 2023 and 2022, respectively.

  Future license fee revenue related to the Abbott Agreement will depend extensively on whether and when we receive the milestone payment of up to $27 million associated with receipt of the PMA of the *SurVeil* DCB. Approximately $25 million of a $27 million milestone payment would be recognized as license fee revenue in the period in which it is received. If PMA is received after June 30, 2023, the milestone payment is reduced to $24 million pursuant to the terms of the Abbott Agreement. Approximately $22 million of a $24 million milestone payment would be recognized as license fee revenue in the period in which it is received. If PMA is not received by December 31, 2023, Abbott may terminate the Abbott Agreement and would have no further obligation to make the potential regulatory milestone payment after termination.
- Medical Device R&D and other revenue declined by $(0.1) million in the first quarter of fiscal 2023, compared to the prior-year quarter, driven by the timing of customer development programs.

In Vitro Diagnostics. Revenue in our In Vitro Diagnostics segment was $5.9 million in the first quarter of fiscal 2023, a 3% decrease from $6.1 million in the prior-year quarter.

- IVD product sales increased 5% to $5.9 million in the first quarter of fiscal 2023, compared to $5.6 million in the prior-year quarter. Growth in sales of our microarray slide/surface and protein stabilization products was offset by unfavorable order timing for our distributed antigen products.
- IVD R&D and other revenue declined by $(0.5) million for the first quarter of fiscal 2023, compared to the prior-year quarter, due to the completion of a customer development program.

Product sales, product costs, product gross profit, product gross margin, and operating costs were as follows:

	Three Months Ended December 31,			
(Dollars in thousands)	**2022**	**2021**	**Increase/(Decrease)**	
Product sales	$ 14,234	$ 12,344	$ 1,890	15 %
Product costs	5,267	4,497	770	17 %
Product gross profit (1)	8,967	7,847	1,120	14 %
% Product gross margin (2)	63.0 %	63.6 %	(0.6) ppt	
Research and development	12,743	11,663	1,080	9 %
% Total revenue	51 %	51 %		
Selling, general and administrative	13,236	9,192	4,044	44 %
% Total revenue	53 %	40 %		
Acquired intangible asset amortization	913	1,089	(176)	(16)%
Contingent consideration expense	3	3	—	

(1) Product gross profit is defined as product sales less related product costs.

(2) Product gross margin is defined as product gross profit as a percentage of product sales.

Product gross margins. Product gross margins were 63.0% and 63.6% for the first quarter of fiscal 2023 and 2022, respectively. Product gross margin in the first quarter of fiscal 2023 was impacted by certain manufacturing inefficiencies associated with ramp up of production of new products, which was partly offset by the favorable impact of product mix primarily driven by increased sales of performance coating reagents and decreased sales of relatively lower margin IVD distributed antigen products.

Research and development ("R&D") expense. For the first quarter of fiscal 2023, R&D expense increased 9%, or $1.1 million, compared to the prior-year quarter. R&D expense as a percentage of revenue was 51% for both the first quarter of fiscal 2023 and 2022. The year-over-year increase in R&D expense was primarily related to medical device product development, including continued investment in our *Pounce* product platform and costs associated with our *SurVeil* DCB.

Selling, general and administrative ("SG&A") expense. For the first quarter of fiscal 2023, SG&A expense increased 44%, or $4.0 million, compared to the prior-year quarter primarily driven by a year-over-year increase in headcount. Throughout fiscal 2022, we invested in a medical device direct salesforce to support the fiscal 2022 commercialization of our *Pounce* and *Sublime* product platforms. We expect SG&A expense for full-year fiscal 2023 to increase between $5.5 million and $6.5 million, compared to fiscal 2022, primarily due to higher average SG&A headcount levels in fiscal 2023 than in fiscal 2022.

Acquired intangible asset amortization. We have previously acquired certain intangible assets through business combinations, which are amortized over periods ranging from six to 14 years.

Contingent consideration expense. We have contingent consideration obligations related to business combinations. Expense (gain) recognized is related to changes in the probability and timing of achieving certain contractual milestones, as well as accretion expense for the passage of time. In fiscal 2023 and 2022, contingent consideration expense consisted of accretion for liabilities associated with the fiscal 2021 acquisition of Vetex Medical Limited.

Other expense. Major classifications of other expense were as follows:

	Three Months Ended December 31,	
(In thousands)	**2022**	**2021**
Interest expense, net	$ (826)	$ (136)
Foreign exchange (loss) gain	(125)	33
Investment income, net	172	26
Other expense	$ (779)	$ (77)

Interest expense, net increased in the first quarter of fiscal 2023, compared to the prior-year quarter, due to increased borrowing and higher interest rates. Refer to "Liquidity and Capital Resources" for further discussion of financing arrangements and expectations for fiscal 2023 interest expense. Foreign currency exchange (losses) gains result primarily from the impact of U.S. dollar to Euro exchange rate fluctuations on certain intercompany transactions and balances. Investment income, net increased in the first quarter of fiscal 2023, compared to the prior-year quarter, due to increased cash equivalents and higher interest rates.

Income tax benefit. We reported income tax benefit of $0.2 million and $0.7 million in the first quarter of fiscal 2023 and 2022, respectively. Our effective tax rate was 2% and 20% for the first quarter of fiscal 2023 and 2022, respectively.

- In the fourth quarter of fiscal 2022, we established a full valuation allowance against U.S. net deferred tax assets as of September 30, 2022. As a result, in fiscal 2023, we are no longer recording a tax benefit for U.S. pretax losses. A valuation allowance is required to be recognized against deferred tax assets if, based on the available evidence, it is more likely than not (defined as a likelihood of more than 50%) that all or a portion of such assets will not be realized. The relevant guidance weighs available evidence such as historical cumulative taxable losses more heavily than future profitability. The valuation allowance has no impact on the availability of U.S. net deferred tax assets to offset future tax liabilities.
- Recurring items cause our effective tax rate to differ from the U.S. federal statutory rate of 21%, including U.S. federal and Irish R&D credits, Irish and U.S. state tax rates, and excess tax benefits associated with stock-based compensation.

Segment Operating Results

Operating results for each of our reportable segments were as follows:

(In thousands)	Three Months Ended December 31, 2022	2021	$ Change
Operating (loss) income:			
Medical Device	$ (7,235)	$ (3,792)	$ (3,443)
In Vitro Diagnostics	2,948	3,155	(207)
Total segment operating (loss) income	(4,287)	(637)	(3,650)
Corporate	(2,942)	(2,804)	(138)
Total operating (loss) income	$ (7,229)	$ (3,441)	$ (3,788)

Medical Device. Our Medical Device business reported operating losses of $(7.2) million and $(3.8) million in the first quarter of fiscal 2023 and 2022, respectively, representing (38)% and (22)% of revenue, respectively.

- Medical Device operating expenses, excluding product costs, increased $5.0 million year-over-year in the first quarter of fiscal 2023. SG&A expense in our medical device business increased year-over-year primarily related to increased headcount. Throughout fiscal 2022, we invested in a medical device direct salesforce to support the fiscal 2022 commercialization of our *Pounce* and *Sublime* product platforms. R&D expenditures in our Medical Device segment increased year-over-year in the first quarter of fiscal 2023 related to product development, including continued investment in our *Pounce* product platform and costs associated with our *SurVeil* DCB.
- Medical Device product gross profit increased $1.0 million year-over-year in the first quarter of fiscal 2023 driven by growth in sales of performance coating reagents and devices. Product gross margins were 58.6% and 57.2% in the first quarter of fiscal 2023 and 2022, respectively. Product gross margin in the first quarter of fiscal 2023 benefited from the favorable mix impact from growth in sales of performance coating reagents, which was partly offset by the impact of certain manufacturing inefficiencies associated with ramp up of production of new products.
- Royalties and license fee revenue increased $0.7 million year-over-year in the first quarter of fiscal 2023. Performance coating royalties revenue for the first quarter of fiscal 2023 was impacted by macroeconomic factors to a lesser degree relative to the prior-year quarter.

In Vitro Diagnostics. Our In Vitro Diagnostics business reported operating income of $2.9 million and $3.2 million in the first quarter of fiscal 2023 and 2022, respectively, representing 50% and 52% of revenue, respectively.

- IVD R&D and other revenue declined $0.5 million year-over-year in the first quarter of fiscal 2023 related to the completion of a customer development program.
- IVD product gross profit increased $0.1 million year-over-year in the first quarter of fiscal 2023. IVD product gross margins were 69.4% and 71.4% in the first quarter fiscal 2023 and 2022, respectively. Product gross margin in the first quarter of fiscal 2023 was impacted by higher absorption of fixed costs relative to the prior year, which was partly offset by the favorable mix impact from a year-over-year decline in sales of relatively lower margin distributed antigen products.

Corporate. The Corporate category includes expenses for administrative corporate functions, such as executive management, corporate accounting, information technology, legal, human resources and Board of Directors related fees and expenses, which we do not fully allocate to the Medical Device and IVD segments. Corporate also includes expenses, such as acquisition-related costs and litigation, which are not specific to a segment and thus not allocated to our reportable segments. The unallocated Corporate expense operating loss was $(2.9) million and $(2.8) million in the first quarter of fiscal 2023 and 2022, respectively.

Cash Flow Operating Results

The following is a summary of cash flow results:

(In thousands)	Three Months Ended December 31, 2022	2021
Cash provided by (used in):		
Operating activities	$ (10,802)	$ (7,026)
Investing activities	(977)	3,218
Financing activities	18,800	(623)
Effect of exchange rates on changes in cash and cash equivalents	411	(72)
Net change in cash and cash equivalents	$ 7,432	$ (4,503)

Operating Activities. Cash used in operating activities totaled $(10.8) million and $(7.0) million for the first three months of fiscal 2023 and 2022, respectively. Net loss was $(7.8) million and $(2.8) million for the first three months of fiscal 2023 and 2022, respectively. Net changes in operating assets and liabilities reduced cash flows from operating activities by $(7.3) million and $(7.8) million during the first three months of fiscal 2023 and 2022, respectively. Significant changes in operating assets and liabilities affecting cash flows during these periods included:

- Cash used in accrued liabilities was $(4.7) million for the first three months of fiscal 2023, compared to cash used of $(5.2) million in the same prior-year period, primarily related to annual bonus payments.
- Cash provided by income taxes was $2.2 million for the first three months of fiscal 2023, compared to cash used of $(0.1) million in the same prior-year period, as the result of the fiscal 2023 receipt of an income tax refund under the net operating loss carryback provisions of the Coronavirus Aid, Relief and Economic Security Act (the "CARES Act").

Investing Activities. Cash used in investing activities totaled $(1.0) million for the first three months of fiscal 2023, compared to cash provided of $3.2 million in the same prior-year period. Capital expenditures for property and equipment totaled $1.0 million and $0.8 million for the first three months of fiscal 2023 and 2022, respectively. In the prior-year period, maturities of available-for-sale investments were a source of cash of $4.0 million.

Financing Activities. Cash provided by financing activities totaled $18.8 million for the first three months of fiscal 2023, compared to cash used of $(0.6) million in the same prior-year period. In the first quarter of fiscal 2023, the Company entered into a new, five-year secured credit agreement with MidCap Funding IV Trust, as agent, and MidCap Financial Trust, as term loan servicer and the lenders from time to time party thereto (together “MidCap”). The Company drew $25 million on the term loan and $5 million on the revolving credit facility at close. These proceeds were partially used to retire the Company’s existing revolving credit facility with Bridgewater Bank, of which $10 million was outstanding, as well as to pay a total of $0.7 million in debt issuance costs, including fees to MidCap and legal and other expenses directly associated with the financing transaction.

Liquidity and Capital Resources

As of December 31, 2022, working capital totaled $47.2 million, an increase of $21.7 million from September 30, 2022. We define working capital as current assets minus current liabilities. Cash and cash equivalents totaled $26.4 million as of December 31, 2022, an increase of $7.4 million from $19.0 million as of September 30, 2022.

The Abbott Agreement provides that the Company will receive a milestone payment if the *SurVeil* DCB receives PMA with the amount of the milestone payment of $27 million (if PMA is received prior to June 30, 2023) or $24 million (if PMA is received on or after June 30, 2023). Abbott may terminate the Abbott Agreement, and would not have an obligation to make an additional milestone payment after termination, if PMA for the *SurVeil* DCB is not obtained by December 31, 2023.

Following receipt of the FDA letter that we announced on January 19, 2023, related to our *SurVeil* DCB, we initiated certain organizational changes to reduce our use of cash by reducing our workforce by approximately 13%, primarily in our Medical Device segment. We expect to incur $1.0 million to $1.2 million of pre-tax restructuring expense for severance and related charges in the second quarter of fiscal 2023. The workforce reduction is expected to be completed, including the majority of cash paid, within the second quarter of fiscal 2023.

The Company proactively manages its access to capital to support liquidity and continued growth. Surmodics has access to a revolving credit facility, which provides for maximum availability of $25 million, subject to a borrowing base. As of December 31, 2022, the outstanding balance on the revolving credit facility was $5 million, and total availability based on borrowing base eligibility requirements was $13.9 million. The maturity date of the revolving credit facility is October 1, 2027.

On October 14, 2022, Surmodics entered into a new, five-year secured credit agreement with MidCap, comprised of up to $100 million in term loans ($25 million of which is at the sole discretion of MidCap) and a $25 million revolving credit facility. The Company drew $25 million on the term loan and $5 million on the revolving credit facility at close. These proceeds were partially used to retire the Company's existing $25 million revolving credit facility with Bridgewater Bank, of which $10 million was outstanding. Upon closing, the Company's cash balance increased by $19.5 million. Additional draws on the term loan may be made in increments of at least $10 million, up to a total of $50 million through December 31, 2024 subject to certain conditions, including having no less than $60 million of core net revenue on a rolling four quarter basis. A second tranche of up to $25 million may be available through December 31, 2024 at MidCap's sole discretion. Availability to draw on the five-year, $25 million revolving credit facility is based on a borrowing base consisting primarily of the Company's inventory and receivable balances. The credit agreement calls for interest-only payments on the term loan over the first four years, which can be extended to five years if certain criteria are met. The revolving credit facility matures in five years. The Company has also entered into an interest rate swap arrangement with Wells Fargo, whereby the initial borrowing on term loan's variable base rate was fixed at 10.205% per annum for the five-year loan term. The revolving credit facility has an annual interest rate equal to 3.00% plus the greater of Term SOFR (as defined in the credit agreement) or 1.50%. The Company expects total interest expense under the credit agreement to be approximately $3.4 million in fiscal 2023.

As of December 31, 2022, the Company's shelf registration statement with the SEC allows the Company to offer potentially up to $200 million in debt securities, common stock, preferred stock, warrants, and other securities or any such combination of such securities in amounts, at prices, and on terms announced if and when the securities are ever offered.

In fiscal 2023, we anticipate a year-over-year increase in SG&A expenditures of between $5.5 million and $6.5 million. We expect that increasing SG&A expenditures in fiscal 2023 will exceed any associated increases in revenues, and therefore will reduce our cash flow from operations. We also anticipate R&D expenses will continue to be significant in fiscal 2023, primarily related to medical device product development, including continued investments to pursue PMA for our *SurVeil* DCB and in our *Pounce* and *Sublime* product platforms. We believe that our existing cash and cash equivalents, which totaled $26.4 million as of December 31, 2022, together with cash flow from operations and our revolving credit facility and term loans, will provide liquidity sufficient to meet our cash needs and fund our operations and planned capital expenditures for fiscal 2023. There can be no assurance, however, that our business will continue to generate cash flows at historic levels.

Beyond fiscal 2023, our cash requirements will depend extensively on the timing of market introduction and extent of market acceptance of products in our medical device product portfolio, including our *SurVeil* DCB if PMA is received. Our long-term cash requirements also will be significantly impacted by the level of our investment in commercialization of our vascular intervention device products and whether we make future corporate transactions. We cannot accurately predict our long-term cash requirements at this time. We may seek additional sources of liquidity and capital resources, including through borrowing, debt or equity financing or corporate transactions to generate cash flow. There can be no assurance that such transactions will be available to us on favorable terms, if at all.

Customer Concentrations

We have agreements with a diverse base of customers and certain customers have multiple products using our technology. Abbott and Medtronic are our largest customers, comprising 11% and 13%, respectively, of our consolidated revenue for fiscal 2022. These same customers, Abbott and Medtronic, each comprised 10% and 13%, respectively, of our consolidated revenue for the three months ended December 31, 2022. Revenue generated under our *SurVeil* DCB license agreement with Abbott represented 5% of total revenue for the three months ended December 31, 2022. Apart from the *SurVeil* DCB license, Abbott has several separately licensed products which generate revenue for Surmodics, none of which represented more than 4% of total revenue for the three months ended December 31, 2022. Medtronic has several separately licensed products that generate revenue for Surmodics, none of which represented more than 4% of our total revenue for the three months ended December 31, 2022.

Critical Accounting Policies and Significant Estimates

Critical accounting policies are those policies that require the application of management's most challenging subjective or complex judgment, often as a result of the need to make estimates about the effect of matters that are inherently uncertain and may change in subsequent periods. Critical accounting policies involve judgments and uncertainties that are sufficiently likely to result in materially different results under different assumptions and conditions. For the three months ended December 31, 2022, there were no significant changes in our critical accounting policies. For a detailed description of our other critical accounting policies and significant estimates, see Management's Discussion and Analysis of Financial Condition and Results of Operations under Item 7 in our Annual Report on Form 10-K for the fiscal year ended September 30, 2022.

Forward-looking Statements

This Quarterly Report on Form 10-Q, including "Management's Discussion and Analysis of Financial Condition and Results of Operations" in Item 2, contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. These statements include, but are not limited to, our strategies for growth, including our ability to sign new license agreements, conduct clinical evaluations, and bring new products to market; planned limited market evaluations for our products; the development of future products and their anticipated attributes; regulatory submissions and approvals; our intent to pursue certain regulatory actions; the potential impact of U.S. Food and Drug Administration ("FDA") communications; our plans for meetings and communications with the FDA; our plans for determining the appropriate path forward regarding the PMA application for our SurVeil DCB; our initiations for product evaluation activities; potential future milestone payments related to our SurVeil DCB; the potential consequence to deferred revenue of Abbott terminating the Abbott Agreement; implementation of organizational changes, their timing, and their expected impact on our use of cash; revenue potential related to the potential commercial launch of the SurVeil DCB; our plans to evaluate our strategy for further clinical investment in the Sundance DCB; future revenue growth, our longer-term valuation-creation strategy, and our future potential; plans for future clinical investment in new products; future opportunities and goals related to new product offerings; future gross margins and operating expenses; estimated future amortization expense; expectations regarding operating expenses, including restructuring expense for severance and related charges, and interest expense, and their impact on our cash flows; recognition of unrecognized compensation costs; anticipated patent expirations and their potential impacts on our royalties revenue; potential future customer actions; research and development plans and expenses, including the estimated cost associated with the TRANSCEND clinical trial; anticipated cash requirements; future cash flow and sources of funding, and their ability together with existing cash, and cash equivalents, to provide liquidity sufficient to meet our cash needs and fund our operations and planned capital expenditures for fiscal 2023; future property and equipment investment levels; expectations regarding declaring or paying dividends; expectations regarding capital available under our secured revolving credit facility and secured term loan facilities; expectations regarding the maturity of debt; future impacts of our interest rate swap transactions; the impact of potential lawsuits or claims; the impact of potential change in raw material prices, sources of raw materials and our ability to manufacture raw materials ourselves; the impact of Abbott and Medtronic, as well as other significant customers; our ability to recognize the expected benefits of our acquisitions; our strategic transformation to become a provider of vascular intervention medical device products; future income tax expense (benefit), including from the Coronavirus Aid, Relief and Economic Security Act (the "CARES Act"); our future ability to realize the benefits of our deferred tax assets; the future impact of off-balance sheet arrangements and contractual obligations; and the impact of the adoption of new accounting pronouncements. Without limiting the foregoing, words or phrases such as "anticipate," "believe," "could," "estimate," "expect," "forecast," "intend," "may," "plan," "possible," "project," "will" and similar terminology, generally identify forward-looking statements. Forward-looking statements may also represent challenging goals for us. These statements, which represent our expectations or beliefs concerning various future events, are based on current expectations that involve a number of risks and uncertainties that could cause actual results to differ materially from those of such forward-looking statements. We caution that undue reliance should not be placed on such forward-looking statements, which speak only as of the date made. Some of the factors which could cause results to differ from those expressed in any forward-looking statement are set forth under "Risk Factors" in Part I, Item 1A of our Annual Report on Form 10-K for the fiscal year ended September 30, 2022 and under "Risk Factors" in Part II, Item 1A of this Quarterly Report on Form 10-Q. We disclaim any intent or obligation to update publicly these forward-looking statements, whether because of new information, future events or otherwise.

Although it is not possible to create a comprehensive list of all factors that may cause actual results to differ from our forward-looking statements, such factors include, among others:

1. ongoing operating losses, increased interest expense, and failure to generate cash flows from operations, which could impact expected expenditures and investments in growth initiatives;

2. our reliance on a small number of significant customers, including our largest customers, Abbott and Medtronic, which causes our financial results and stock price to be subject to factors affecting those significant customers and their products, the timing of market introduction of their or competing products, product safety or efficacy concerns and intellectual property litigation impacting such customers, which could adversely affect our growth strategy and the royalties revenue we derive;
3. clinical and regulatory developments relating to the evaluation of risks associated with paclitaxel-coated products, which developments may adversely impact our ability to complete our TRANSCEND clinical trial on any particular time frame, obtain marketing approval (or the timing of any such approval) for our *SurVeil* DCB and other paclitaxel-coated products, to treat peripheral artery disease in the femoral and/or popliteal arteries;
4. our ability to successfully develop, obtain regulatory approval for, commercialize, and manufacture at commercial volumes our *SurVeil* and other DCB products, including our reliance on clinical research organizations to manage the TRANSCEND clinical trial and uncertainty related to the impacts of any clinical research relative to drug-coated balloons, including our Avess™ DCB, other DCB products and other catheter and balloon-based products, which will impact our ability to receive additional milestone payments under our agreement with Abbott;
5. general economic conditions that are beyond our control, such as the impact of recession, inflation, rising interest rates, customer mergers and acquisitions, business investment, changes in consumer confidence, and medical epidemics or pandemics such as the COVID-19 pandemic, which has negatively impacted, and will likely continue to negatively impact, our business and results from operations;
6. our ability to successfully and profitably commercialize our vascular intervention products, including our *Pounce* Venous Thrombectomy System, through our direct salesforce, or otherwise;
7. our ability to comply with the terms of our secured revolving credit facility and secured term loan facilities;
8. the difficulties and uncertainties associated with the lengthy and costly new product development and foreign and domestic regulatory approval processes, such as delays, difficulties or failures in achieving acceptable clinical results or obtaining foreign or FDA marketing clearances or approvals, which may result in lost market opportunities, failure to bring new products to market or postpone or preclude product commercialization by licensees or ourselves;
9. whether operating expenses that we incur related to the development and commercialization of new technologies and products are effective;
10. our ability to successfully perform product development activities, the related research and development expense impact, and governmental and regulatory compliance activities, which we have not previously undertaken in any significant manner;
11. impairment of goodwill and intangible assets or the establishment of reserves against other assets on our balance sheet; and
12. other factors described under "Risk Factors" in Part II, Item 1A of this Quarterly Report on Form 10-Q and under “Risk Factors” in Part I, Item 1A of our Annual Report on Form 10-K for the fiscal year ended September 30, 2022, which you are encouraged to read carefully.

Many of these factors are outside our control and knowledge and could result in increased volatility in period-to-period results. Investors are advised not to place undue reliance upon our forward-looking statements and to consult any further disclosures by us on this subject in our filings with the Securities and Exchange Commission.

Item 3. Quantitative and Qualitative Disclosures About Market Risk

Our investment policy requires investments with high credit quality issuers and limits the amount of credit exposure to any one issuer. Our investments consist principally of interest-bearing corporate debt securities with varying maturity dates, which generally are less than one year. Because of the credit criteria of our investment policies, the primary market risk associated with these investments is interest rate risk. As of December 31, 2022, we did not hold any available-for-sale debt securities. Therefore, interest rate fluctuations relating to investments would have an insignificant impact on our results of operations or cash flows. Our policy also allows the Company to hold a substantial portion of funds in cash and cash equivalents, which are defined as financial instruments with original maturities of three months or less and may include money market instruments, certificates of deposit, repurchase agreements and commercial paper instruments.

Loans under the Midcap credit agreement bear interest at floating rates tied to Term SOFR. As a result, changes in Term SOFR can affect our results of operation and cash flows to the extent we do not have effective interest rate swap arrangements in place. On October 14, 2022, we entered into a five-year interest rate swap transaction with Wells Fargo Bank, N.A. with respect to $25.0 million of notional value of the term loans funded under the MidCap credit agreement. The interest rate swap transaction fixes at 4.455% the one-month Term SOFR portion of interest rate under the $25.0 million initial Term Loan funded such that the interest rate on the initial Term Loan will be 10.205% through its maturity. We have no other swap arrangements in place for any other loans under the Midcap credit agreement.

Management believes that a reasonable change in raw material prices would not have a material impact on future earnings or cash flows because the Company's inventory exposure is not material.

We are exposed to increasing Euro currency risk with respect to our manufacturing operations in Ireland. In a period where the U.S. dollar is strengthening or weakening relative to the Euro, our revenue and expenses denominated in Euro currency are translated into U.S. dollars at a lower or higher value than they would be in an otherwise constant currency exchange rate environment. All sales transactions are denominated in U.S. dollars or Euros. We generate royalties revenue from the sale of customer products in foreign jurisdictions. Royalties generated in foreign jurisdictions by customers are converted and paid in U.S. dollars per contractual terms. Substantially all of our purchasing transactions are denominated in U.S. dollars or Euros. To date, we have not entered into any foreign currency forward exchange contracts or other derivative financial instruments to hedge the effects of adverse fluctuations in foreign currency exchange rates.

Item 4. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

The Company maintains disclosure controls and procedures as defined in Rules 13a-15(e) and 15d-15(e) of the Securities Exchange Act of 1934, as amended (the "Exchange Act"). The Company's management, under the supervision and with the participation of the Company's Chief Executive Officer and Chief Financial Officer, referred to collectively herein as the Certifying Officers, carried out an evaluation of the effectiveness of the design and operation of the Company's disclosure controls and procedures as of December 31, 2022. Based on that evaluation, the Company's Certifying Officers concluded that, as of the end of the period covered by this report, the Company's disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) of the Exchange Act) were effective to ensure that information required to be disclosed by the Company in reports that it files under the Exchange Act is recorded, processed, summarized and reported within the time period specified in the Securities and Exchange Commission rules and forms, and to ensure that information required to be disclosed by the Company in the reports the Company files or submits under the Exchange Act is accumulated and communicated to the Company's management, including its Certifying Officers, as appropriate, to allow timely decisions regarding required disclosures.

Changes in Internal Controls over Financial Reporting

There were no changes in our internal control over financial reporting (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act) during the three months ended December 31, 2022 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II — OTHER INFORMATION

Item 1. Legal Proceedings

From time to time, the Company has been involved in various legal actions involving its operations, products and technologies, including intellectual property and employment disputes.

Item 1A. Risk Factors

In January 2023, the U.S. Food and Drug Administration ("FDA" or the "Agency") issued a letter to us indicating that the premarket approval ("PMA") application for our SurVeil™ drug-coating balloon ("DCB") was not approvable based on the information submitted to the Agency to that time and providing specific guidance on information that would be required to put the application in approvable form. The costs and effort to obtain PMA for the product, or failure to do so, may have a significant adverse impact on our balance sheet, operating results, and cash flows.

In June 2021, we submitted the fourth and final module of the PMA application to the FDA related to our *SurVeil* DCB. In September 2021, the FDA provided us with comments on the PMA application and requested additional testing data in order to evaluate the product and its unique technologies. In October 2022, we submitted a complete response, including additional testing data, to the FDA's comments on our PMA application for the *SurVeil* DCB. In January 2023, the FDA issued a letter to us indicating that the PMA application was not approvable based on the information submitted to the Agency to that time. The letter provided specific guidance on information, including additional testing and analysis, that would be required to put the application in approvable form.

We are evaluating the issues raised in the FDA's letter and plan to meet with Agency representatives regarding its contents. Based on our discussion with the Agency, our team and external advisors will determine the appropriate path forward regarding the PMA application for our *SurVeil* DCB. If we determine to continue to pursue the PMA application, we expect to incur additional costs and effort to do so, which may include additional testing and analysis, and which may be significant. Such costs and efforts may have a material adverse impact on our operating results and cash flow. There can be no assurance that the *SurVeil* DCB will receive FDA approval.

If we do not continue to pursue the PMA for the *SurVeil* DCB, or if the product does not receive FDA approval, we may be required to recognize impairment of, or record additional reserves against, assets on our balance sheet related to the product and its commercialization, including inventory, property and equipment, intangible assets and goodwill. Such impairments or reserves may have a material adverse impact on our operating results. In addition, if PMA is not received by December 31, 2023, Abbott may terminate the Abbott Agreement and would have no further obligation to make the potential regulatory milestone payment or commercialize the product after termination. If we do not continue to pursue the PMA for the *SurVeil* DCB, Abbott terminates the Abbott Agreement, or the product does not receive FDA approval, we will not receive a milestone payment that would be due from Abbott following receipt of PMA or revenues from Abbott's commercialization of the product, which could have a material adverse impact on our results of operations and cash flows.

Our plan to reduce our use of cash announced in the second quarter of fiscal 2023 may not result in anticipated savings or operational efficiencies, could result in total costs and expenses that are greater than expected, and could disrupt our business.

In the second quarter of fiscal 2023, we announced a plan to initiate certain organizational changes to reduce our use of cash by reducing our workforce by approximately 13%. We may incur additional expenses associated with the reduction in our workforce not contemplated by our plan, which may have an impact on other areas of our liabilities and obligations and contribute to losses in future periods. We may not realize, in full or in part, the anticipated benefits and savings from our plan due to unforeseen difficulties, delays or unexpected costs. If we are unable to realize the expected operational efficiencies and cost savings, our operating results and financial condition would be adversely affected.

Furthermore, implementation of our plan may be disruptive to our operations. For example, our workforce reduction could result in attrition beyond planned staff reductions, increased difficulties in our day-to-day operations and reduced employee morale. If employees who were not affected by the reduction in force seek alternative employment, we could incur unplanned additional expense to ensure adequate resourcing and fail to attract and retain qualified management, sales and marketing personnel who are critical to our business. Our failure to do so could harm our business and our future performance.

In addition, the risks identified in our Annual Report on Form 10-K for the fiscal year ended September 30, 2022, filed with the Securities and Exchange Commission on November 23, 2022, under Part I, Item 1A, "Risk Factors" could affect our financial performance and could cause our actual results for future periods to differ materially from our anticipated results or other expectations, including those expressed in any forward-looking statements made in this Quarterly Report on Form 10-Q.

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

The following table presents the information with respect to purchases made by or on behalf of Surmodics, Inc. or any "affiliated purchaser" (as defined in Rule 10b-18(a)(3) under the Securities Exchange Act of 1934), of our common stock during the three months ended December 31, 2022.

	Total Number of Shares Purchased (1)	Average Price Paid Per Share	Total Number of Shares Purchased as Part of Publicly Announced Programs	Maximum Dollar Value of Shares that May Yet Be Purchased Under the Programs
Period:				
October 1 – 31, 2022	409	$ 30.66	—	$ 25,300,000
November 1 – 30, 2022	23,403	36.10	—	25,300,000
December 1 – 31, 2022	—	—	—	25,300,000
Total	23,812	36.01	—	

(1) All shares reported were delivered by employees in connection with the satisfaction of tax withholding obligations related to the vesting of shares of restricted stock.

The Company has an aggregate of $25.3 million available for future common stock purchases under the current authorizations. The MidCap credit agreement restricts our ability to repurchase our common stock.

Item 3. Defaults Upon Senior Securities

None.

Item 4. Mine Safety Disclosures

Not Applicable.

Item 5. Other Information

None.

Item 6. Exhibits

EXHIBIT INDEX

Exhibit	Description
2.1	Agreement of Merger dated January 18, 2005 among Surmodics, Inc., SIRx, InnoRx, et al. — incorporated by reference to Exhibit 2.1 to the Company's Current Report on Form 8-K dated January 24, 2005.
2.2	Share Purchase Agreement by and among Surmodics, Inc. and the shareholders of Creagh Medical Ltd. dated as of November 20, 2015 — incorporated by reference to Exhibit 2.1 to the Company's Current Report on Form 8-K dated November 27, 2015.
2.3	Stock Purchase Agreement, dated January 8, 2016, among Surmodics, Inc. and the shareholders of NorMedix, Inc. and Gregg Sutton as Seller's Agent — incorporated by reference to Exhibit 2.1 to the Company's Form Current Report on Form 8-K filed on January 13, 2016.
2.4	Share Purchase Agreement by and among Surmodics, Inc., SurModics MD, LLC, and the shareholders of Vetex Medical Limited named therein dated as of July 2, 2021 — incorporated by reference to Exhibit 2.1 to the Company's Current Report on Form 8-K dated July 2, 2021.
2.5	Put and Call Option Agreement by and among SurModics MD, LLC and the shareholders of Vetex Medical Limited named therein dated as of July 2, 2021 — incorporated by reference to Exhibit 2.2 to the Company's Current Report on Form 8-K dated July 2, 2021.
3.1	Restated Articles of Incorporation, as amended — incorporated by reference to Exhibit 3.1 of the Company's Quarterly Report on Form 10-Q filed on July 29, 2016.
3.2	Restated Bylaws of Surmodics, Inc., as amended December 18, 2015 — incorporated by reference to Exhibit 3.2 of the Company's Current Report on Form 8-K filed on December 23, 2015.
10.1	Credit, Security and Guaranty Agreement dated as of October 14, 2022 by and among Surmodics, Inc., Surmodics Shared Services, LLC, Surmodics Holdings, LLC, Surmodics Coatings, LLC, SurModics MD, LLC, Surmodics Coatings Mfg, LLC, Surmodics IVD, Inc., NorMedix, Inc., and Surmodics MD Operations, LLC, as borrowers, the guarantors from time to time party thereto, MidCap Funding IV Trust and MidCap Financial Trust and the lenders from time to time party thereto – incorporated by reference to Exhibit 10.1 of the Company's Current Report on Form 8-K filed on October 17, 2022.
31.1*	Certification of Chief Executive Officer pursuant to 18 U.S.C. Sec. 1350 as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2*	Certification of Chief Financial Officer pursuant to 18 U.S.C. Sec. 1350 as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1*	Certification of Chief Executive Officer pursuant to 18 U.S.C. Sec. 1350 as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2*	Certification of Chief Financial Officer pursuant to 18 U.S.C. Sec. 1350 as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101.INS*	Inline XBRL Instance Document – the instance document does not appear in the Interactive Data File as its XBRL tags are embedded within the inline XBRL document.
101.SCH*	Inline XBRL Taxonomy Extension Schema.
101.CAL*	Inline XBRL Taxonomy Extension Calculation Linkbase.
101.DEF*	Inline XBRL Taxonomy Extension Definition Linkbase.
101.LAB*	Inline XBRL Taxonomy Extension Label Linkbase.
101.PRE*	Inline XBRL Taxonomy Extension Presentation Linkbase.

Exhibit	Description
104*	Cover Page Interactive Data File (formatted as inline XBRL and contained in Exhibit 101).

* Filed herewith

SIGNATURES

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

February 6, 2023

Surmodics, Inc.

By: /s/ Timothy J. Arens
Timothy J. Arens
Senior Vice President of Finance and Chief Financial Officer

(duly authorized signatory and principal financial officer)

EXHIBIT 31.1

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

I, Gary R. Maharaj, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Surmodics, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and we 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.

Dated: February 6, 2023

Signature: /s/ Gary R. Maharaj
Gary R. Maharaj
President and
Chief Executive Officer

EXHIBIT 31.2

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

I, Timothy J. Arens, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Surmodics, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and we 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.

Dated: February 6, 2023

Signature: /s/ Timothy J. Arens
Timothy J. Arens
Senior Vice President of Finance and Chief Financial Officer

EXHIBIT 32.1

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Quarterly Report of Surmodics, Inc. (the "Company") on Form 10-Q for the quarter ended December 31, 2022, as filed with the Securities and Exchange Commission (the "Report"), I, Gary R. Maharaj, certify, pursuant to 18 U.S.C. §1350, as adopted pursuant to §906 of the Sarbanes-Oxley Act of 2002, that:

(1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and

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

Dated: February 6, 2023

Signature: /s/ Gary R. Maharaj
Gary R. Maharaj
President and
Chief Executive Officer

EXHIBIT 32.2

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Quarterly Report of Surmodics, Inc. (the "Company") on Form 10-Q for the quarter ended December 31, 2022, as filed with the Securities and Exchange Commission (the "Report"), I, Timothy J. Arens, certify, pursuant to 18 U.S.C. §1350, as adopted pursuant to §906 of the Sarbanes-Oxley Act of 2002, that:

(1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

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

Dated: February 6, 2023

Signature: /s/ Timothy J. Arens
Timothy J. Arens
Senior Vice President of Finance and Chief Financial Officer