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, 2021**

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 1, 2022 was 13,976,000.

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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, 2021	September 30, 2021
	(Unaudited)	
ASSETS		
Current Assets:		
Cash and cash equivalents	$ 26,650	$ 31,153
Available-for-sale securities	5,693	7,717
Accounts receivable, net of allowances of $124 and $119 as of December 31, 2021 and September 30, 2021, respectively	8,010	9,169
Contract assets — royalties and license fees	6,668	7,091
Inventories, net	8,290	6,760
Income tax receivable	1,916	1,912
Prepaids and other	7,689	6,453
Total Current Assets	64,916	70,255
Property and equipment, net	29,319	30,090
Available-for-sale securities	—	2,002
Deferred income taxes	6,372	5,867
Intangible assets, net	35,238	37,054
Goodwill	44,900	45,606
Other assets	4,121	3,718
Total Assets	$ 184,866	$ 194,592
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities:		
Accounts payable	$ 1,845	$ 1,783
Accrued liabilities:		
Compensation	3,292	8,480
Accrued other	6,076	4,905
Short-term borrowings	10,000	10,000
Deferred revenue	4,430	4,647
Total Current Liabilities	25,643	29,815
Deferred revenue, less current portion	9,292	10,301
Deferred income taxes	2,547	2,742
Other long-term liabilities	10,713	11,649
Total Liabilities	48,195	54,507
Commitments and Contingencies (Note 10)		
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; 13,975 and 13,899 shares issued and outstanding as of December 31, 2021 and September 30, 2021, respectively	699	695
Additional paid-in capital	22,644	21,598
Accumulated other comprehensive income	75	1,727
Retained earnings	113,253	116,065
Total Stockholders' Equity	136,671	140,085
Total Liabilities and Stockholders' Equity	$ 184,866	$ 194,592

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, 2021	2020
	(Unaudited)	
Revenue:		
Product sales	$ 12,344	$ 10,102
Royalties and license fees	8,099	9,334
Research, development and other	2,560	2,861
Total revenue	23,003	22,297
Operating costs and expenses:		
Product costs	4,497	3,743
Research and development	11,663	10,882
Selling, general and administrative	9,192	7,023
Acquired intangible asset amortization	1,089	556
Contingent consideration expense	3	—
Total operating costs and expenses	26,444	22,204
Operating (loss) income	(3,441)	93
Other expense:		
Investment income, net	26	41
Interest expense	(136)	(60)
Foreign exchange gain (loss)	33	(180)
Other expense	(77)	(199)
Loss before income taxes	(3,518)	(106)
Income tax benefit (provision)	706	(168)
Net loss	$ (2,812)	$ (274)
Basic net loss per share	$ (0.20)	$ (0.02)
Diluted net loss per share	$ (0.20)	$ (0.02)
Weighted average number of shares outstanding:		
Basic	13,878	13,668
Diluted	13,878	13,668

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

Surmodics, Inc. and Subsidiaries

Condensed Consolidated Statements of Comprehensive (Loss) Income

	Three Months Ended December 31,	
	2021	2020
(In thousands)	*(Unaudited)*	
Net loss	$ (2,812)	$ (274)
Other comprehensive (loss) income:		
Net changes related to available-for-sale securities, net of tax	(5)	—
Foreign currency translation adjustments	(1,647)	1,832
Other comprehensive (loss) income	(1,652)	1,832
Comprehensive (loss) income	$ (4,464)	$ 1,558

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, 2021 and 2020					
	(Unaudited)					
	Common Stock					
(In thousands)	Shares	Amount	Additional Paid-In Capital	Accumulated Other Comprehensive Income	Retained Earnings	Total Stockholders' Equity
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
Balance at September 30, 2020	13,672	$ 684	$ 15,369	$ 3,174	$ 111,828	$ 131,055
Net loss	—	—	—	—	(274)	(274)
Other comprehensive income, net of tax	—	—	—	1,832	—	1,832
Issuance of common stock	81	4	(4)	—	—	—
Common stock options exercised, net	3	—	6	—	—	6
Purchase of common stock to pay employee taxes	(17)	(1)	(644)	—	—	(645)
Stock-based compensation	—	—	1,433	—	—	1,433
Balance at December 31, 2020	13,739	$ 687	$ 16,160	$ 5,006	$ 111,554	$ 133,407

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

Surmodics, Inc. and Subsidiaries

Condensed Consolidated Statements of Cash Flows

(In thousands)	Three Months Ended December 31, 2021	2020
	(Unaudited)	
Operating Activities:		
Net loss	$ (2,812)	$ (274)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	2,376	1,860
Stock-based compensation	1,680	1,433
Noncash lease expense	91	74
Provision for credit losses	4	(7)
Deferred taxes	(640)	310
Other	77	13
Change in operating assets and liabilities:		
Accounts receivable and contract assets	1,547	(830)
Inventories	(1,570)	(236)
Prepaids and other	(1,432)	(357)
Accounts payable	200	(485)
Accrued liabilities	(5,227)	(4,236)
Income taxes	(95)	(165)
Deferred revenue	(1,225)	(1,370)
Net cash used in operating activities	(7,026)	(4,270)
Investing Activities:		
Purchases of property and equipment	(782)	(1,319)
Payment for acquisition of intangible assets	—	(1,000)
Purchases of available-for-sale securities	—	(5,820)
Maturities of available-for-sale securities	4,000	18,013
Net cash provided by investing activities	3,218	9,874
Financing Activities:		
Issuance of common stock	230	6
Payments for taxes related to net share settlement of equity awards	(853)	(646)
Payments for acquisition of in-process research and development	—	(150)
Net cash used in financing activities	(623)	(790)
Effect of exchange rate changes on cash	(72)	155
Net change in cash and cash equivalents	(4,503)	4,969
Cash and Cash Equivalents:		
Beginning of period	31,153	30,785
End of period	$ 26,650	$ 35,754
Supplemental Information:		
Cash paid for income taxes	$ 3	$ 9
Cash paid for interest	82	—
Noncash investing and financing activities:		
Acquisition of property and equipment, net of refundable credits in other current assets and liabilities	137	82
Right-of-use assets obtained in exchange for new operating lease liabilities	350	44

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, 2021
(Unaudited)

1. Basis of Presentation

Overview

Surmodics, Inc. and subsidiaries ("Surmodics," the "Company," "we," "us," "our" and other like terms) is a leading provider of surface modification technologies for intravascular medical devices and chemical components for in vitro diagnostic ("IVD") immunoassay tests and microarrays. Surmodics is pursuing development and commercialization of highly differentiated 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 technologies, along with enhanced device design, development, and manufacturing capabilities. The Company mission remains to improve the detection and treatment of disease. Surmodics is headquartered in Eden Prairie, Minnesota.

Basis of Presentation

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, 2021, and notes thereto included in our Annual Report on Form 10-K as filed with the SEC.

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 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, 2021 are not necessarily indicative of the results that may be expected for the entire 2022 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.

	Three Months Ended December 31,	
(In thousands)	2021	2020
Medical Device		
Product sales	$ 6,788	$ 4,561
Royalties	6,886	7,909
License fees	1,213	1,425
Research, development and other	2,021	2,301
Medical Device Revenue	16,908	16,196
In Vitro Diagnostics		
Product sales	5,556	5,541
Research, development and other	539	560
In Vitro Diagnostics Revenue	6,095	6,101
Total Revenue	$ 23,003	$ 22,297

Contract assets totaled $6.7 million and $7.1 million as of December 31, 2021 and September 30, 2021, respectively. 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 application (“PMA”) for the *SurVeil* DCB was being evaluated by the U.S. Food and Drug Administration (“FDA”) as of December 31, 2021. Separately, Abbott also received the option to negotiate an agreement for Surmodics' below-the-knee Sundance™ DCB product. As of December 31, 2021, six-month patient follow-up visits are complete for the SWING first-in-human, 35-patient clinical study of the *Sundance* DCB, and we are evaluating the results. 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 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. To account for the Abbott Agreement, the Company applied the guidance in ASC Topic 808 (Collaborative Arrangements) as the parties are active participants and are exposed to significant risks and rewards dependent on commercial success of the collaborative activity.

As of December 31, 2021, the Company has 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 the second quarter of fiscal 2021. As of December 31, 2021, the Company may receive an additional contingent milestone payment of up to $30 million, pursuant to the terms of the Abbott Agreement, upon PMA of our *SurVeil* DCB by the FDA. As of December 31, 2021, consideration from this potential regulatory milestone was excluded from the contract price (i.e., deemed fully constrained), due to the high level of uncertainty of achievement as of December 31, 2021.

Revenue recognized from the Abbott agreement totaled $1.2 million and $1.3 million for the three months ended December 31, 2021 and 2020, respectively, all of which was included in the respective beginning of fiscal year balances of deferred revenue on the condensed consolidated balance sheets.

As of December 31, 2021 and September 30, 2021, deferred revenue from the upfront and milestone payments received under the Abbott Agreement of $13.7 million and $14.9 million, respectively, was recorded on the condensed consolidated balance sheets.

As of December 31, 2021, the estimated revenue expected to be recognized in future periods related to performance obligations that are unsatisfied for executed contracts with an original duration of one year or more totaled $13.7 million. These remaining performance obligations relate to the Abbott Agreement, exclude the potential contingent milestone payment under the Abbott Agreement, and are expected to be recognized over the next four years through fiscal 2025 as services, principally the TRANSCEND clinical trial, are completed.

4. Fair Value Measurements

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

	December 31, 2021			
(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)	$ —	$ 2,333	$ —	$ 2,333
Available-for-sale securities (1)	—	5,693	—	5,693
Total assets	$ —	$ 8,026	$ —	$ 8,026
Liabilities				
Contingent consideration (2)	$ —	$ —	$ 820	$ 820
Total liabilities	$ —	$ —	$ 820	$ 820

	September 30, 2021			
(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)	$ —	$ 5,308	$ —	$ 5,308
Available-for-sale investments (1)	—	9,719	—	9,719
Total assets	$ —	$ 15,027	$ —	$ 15,027
Liabilities				
Contingent consideration (2)	$ —	$ —	$ 817	$ 817
Total liabilities	$ —	$ —	$ 817	$ 817

(1) Fair value of cash equivalents (money market funds) and available-for-sale investments (commercial paper and corporate bond securities) 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 the acquisition date and as of both December 31, 2021 and September 30, 2021.

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, 2021	$ 817
Additions	—
Fair value adjustments	—
Settlements	—
Interest accretion	3
Foreign currency translation	—
Contingent consideration liability at December 31, 2021	$ 820

Contingent consideration liabilities were associated with the fiscal 2021 acquisition of Vetex Medical Limited and were included in other long-term liabilities on the condensed consolidated balance sheets; see Note 11 Acquisitions for further disclosures.

5. Supplemental Balance Sheet Information

Investments

The amortized cost, unrealized holding gains and losses, and fair value of available-for-sale securities were as follows:

	December 31, 2021					
	Valuation				Balance Sheet Classification	
(In thousands)	Amortized Cost	Unrealized Gains	Unrealized Losses	Fair Value	Current Assets	Noncurrent Assets
Commercial paper and corporate bonds	$ 5,697	$ —	$ (4)	$ 5,693	$ 5,693	$ —
Total	$ 5,697	$ —	$ (4)	$ 5,693	$ 5,693	$ —

	September 30, 2021					
	Valuation				Balance Sheet Classification	
(In thousands)	Amortized Cost	Unrealized Gains	Unrealized Losses	Fair Value	Current Assets	Noncurrent Assets
Commercial paper and corporate bonds	$ 9,718	$ 2	$ (1)	$ 9,719	$ 7,717	$ 2,002
Total	$ 9,718	$ 2	$ (1)	$ 9,719	$ 7,717	$ 2,002

Inventories

Inventories consisted of the following components:

(In thousands)	December 31, 2021	September 30, 2021
Raw materials	$ 4,896	$ 4,165
Work-in process	1,650	1,295
Finished products	1,744	1,300
Total	$ 8,290	$ 6,760

Prepaids and Other Assets, Current

Prepaids and other current assets consisted of the following:

(In thousands)	December 31, 2021	September 30, 2021
Prepaid expenses	$ 2,972	$ 1,712
Irish research and development credits receivable	1,140	1,164
CARES Act employee retention credit receivable	3,577	3,577
Prepaids and other	$ 7,689	$ 6,453

In the fourth quarter of fiscal 2021, a benefit of $3.6 million was recorded to reduce operating costs and expenses 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") enacted in March 2020. This $3.6 million benefit and corresponding receivable reflect anticipated reimbursement of personnel expenses we incurred in fiscal 2021 and 2020.

Intangible Assets

Intangible assets consisted of the following:

	December 31, 2021			
(In thousands)	Weighted Average Original Life (Years)	Gross Carrying Amount	Accumulated Amortization	Net
Definite-lived intangible assets:				
Customer lists and relationships	8.9	$ 12,959	$ (9,046)	$ 3,913
Developed technology	11.9	35,899	(6,370)	29,529
Patents and other	14.1	3,551	(2,335)	1,216
Total definite-lived intangible assets		52,409	(17,751)	34,658
Unamortized intangible assets:				
Trademarks and trade names		580	—	580
Total intangible assets		$ 52,989	$ (17,751)	$ 35,238

	September 30, 2021			
(In thousands)	Weighted Average Original Life (Years)	Gross Carrying Amount	Accumulated Amortization	Net
Definite-lived intangible assets:				
Customer lists and relationships	8.9	$ 13,216	$ (8,878)	$ 4,338
Developed technology	11.9	36,531	(5,652)	30,879
Patents and other	14.1	3,551	(2,294)	1,257
Total definite-lived intangible assets		53,298	(16,824)	36,474
Unamortized intangible assets:				
Trademarks and trade names		580	—	580
Total intangible assets		$ 53,878	$ (16,824)	$ 37,054

Intangible asset amortization expense was $1.2 million and $0.6 million for the three months ended December 31, 2021 and 2020, respectively. Based on the intangible assets in service as of December 31, 2021, estimated amortization expense for future fiscal years is as follows:

(In thousands)	
Remainder of 2022	$ 3,436
2023	3,998
2024	3,908
2025	3,871
2026	2,940
2027	2,684
Thereafter	13,821
Definite-lived intangible assets	$ 34,658

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, 2021	$ 8,010	$ 37,596	$ 45,606
Currency translation adjustment	—	(706)	(706)
Goodwill as of December 31, 2021	$ 8,010	$ 36,890	$ 44,900

Other Assets, Noncurrent

Other noncurrent assets consisted of the following:

(In thousands)	December 31, 2021	September 30, 2021
Operating lease right-of-use assets	$ 2,519	$ 2,435
Other	1,602	1,283
Other assets	$ 4,121	$ 3,718

Other noncurrent assets include prepaid expenses related to our ongoing clinical trials and a receivable related to refundable Irish research and development tax credits.

Accrued Other Liabilities

Accrued other liabilities consisted of the following:

(In thousands)	December 31, 2021	September 30, 2021
Accrued professional fees	$ 252	$ 489
Accrued clinical study expense	1,926	1,667
Accrued purchases	1,437	1,195
Acquisition of in-process research and development (1)	1,454	494
Operating lease liability, current portion	672	518
Other	335	542
Total accrued other liabilities	$ 6,076	$ 4,905

(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 10).

Other Long-term Liabilities

Other long-term liabilities consisted of the following:

(In thousands)	December 31, 2021	September 30, 2021
Deferred consideration (1)	$ 4,188	$ 5,106
Contingent consideration (2)	820	817
Unrecognized tax benefits (3)	2,446	2,538
Operating lease liabilities (4)	3,259	3,188
Other long-term liabilities	$ 10,713	$ 11,649

(1) Deferred consideration consists of the present value of guaranteed payments to be made (noncurrent portion) in connection with the fiscal 2021 Vetex acquisition (Note 11) and with an asset acquisition in fiscal 2018 (Note 10).

(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 9) 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

On September 14, 2020, the Company entered into a secured revolving credit facility pursuant to a Loan and Security Agreement, which was amended by a First Amendment on July 2, 2021 (as amended, the "Loan Agreement") with Bridgewater Bank (“Bridgewater”). The Loan Agreement provides for availability under a secured revolving line of credit of up to $25 million (the "Revolving Credit Facility"). The outstanding balance on the Revolving Credit Facility was $10.0 million as of both December 31, 2021 and September 30, 2021.

Availability under the Revolving Credit Facility is subject to a borrowing base that equals 80% of the margin value of securities collateral that has been pledged to Bridgewater. The Revolving Credit Facility was scheduled to mature on September 14, 2021, but the Company extended the maturity to September 14, 2022, as permitted under the Loan Agreement. The maturity date may be extended by the Company for up to one additional extension period of twelve months subject to certain conditions set forth in the Loan Agreement. The Company's obligations under the Loan Agreement are secured by substantially all of the Company’s and its material subsidiaries' assets, other than intellectual property, real estate and foreign assets, including equity in foreign subsidiaries. The Company has also pledged the stock of certain of its subsidiaries to secure such obligations. Interest under the Loan Agreement accrues at a rate per annum equal to the greater of (i) 3.25% per annum and (ii) the 90-day interest rate yield for U.S. Government Treasury Securities plus 2.75% per annum. A facility fee is payable on unused commitments at a rate of 0.075% quarterly. For the three months ended December 31, 2021 and 2020, unused commitment fees, reported within interest expense on the condensed consolidated statements of operations, totaled zero and less than $0.1 million, respectively.

The Loan Agreement contains affirmative and negative covenants customary for a transaction of this type which, among other things, require the Company to meet certain financial tests, including (i) minimum liquidity, (ii) minimum current ratio, (iii) minimum adjusted EBITDA, and (iv) minimum tangible net worth. The Loan Agreement also contains covenants which, among other things, limit the Company's ability to incur additional debt, make certain investments, create or permit certain liens, create or permit restrictions on the ability of subsidiaries to pay dividends or make other distributions, consolidate or merge, and engage in other activities customarily restricted in such agreements, in each case subject to exceptions permitted by the Loan Agreement. The Loan Agreement also contains customary events of default, the occurrence of which would permit Bridgewater to terminate its commitment and accelerate the Revolving Credit Facility.

7. 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)	**2021**	**2020**
Product costs	$ 30	$ 37
Research and development	453	284
Selling, general and administrative	1,197	1,112
Total	$ 1,680	$ 1,433

As of December 31, 2021, approximately $13.9 million of total unrecognized compensation costs related to non-vested awards is expected to be recognized over a weighted average period of approximately 2.8 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,	
	2021	**2020**
Stock option grant activity:		
Stock options granted	245,000	217,000
Weighted average grant date fair value	$ 16.36	$ 13.42
Weighted average exercise price	$ 43.93	$ 37.44

Restricted Stock Awards

During the three months ended December 31, 2021 and 2020, the Company awarded 78,000 and 65,000 restricted stock shares, respectively, to certain key employees and officers with a weighted average grant date fair value per share of $43.93 and $37.44, 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, 2021 and 2020, 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 $43.93 and $37.44, 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, 2021 and 2020, no shares were issued under the ESPP.

8. Net Loss Per Share Data

Basic net (loss) income per common share is calculated by dividing net (loss) income by the weighted average number of common shares outstanding during the period. Diluted net (loss) income per common share is computed by dividing net (loss) income 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. However, these items have been excluded from the calculation of diluted net loss per share for the three months ended December 31, 2021 and 2020 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, 2021 and 2020.

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

(In thousands)	Three Months Ended December 31, 2021	2020
Basic weighted average shares outstanding	13,878	13,668
Dilutive effect of outstanding stock options, non-vested restricted stock, and non-vested restricted stock units	—	—
Diluted weighted average shares outstanding	13,878	13,668

9. 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) income, 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 $0.7 million and income tax expense of $(0.2) million for the three months ended December 31, 2021 and 2020, respectively.

The effective income tax rate for the three months ended December 31, 2021 and 2020 differs from the U.S. federal statutory tax rate of 21% primarily due to favorable impacts of the U.S. federal research and development tax credits, stock award activity, and operating results of our Irish subsidiary, where tax benefit is offset by a valuation allowance. The Company recognized discrete tax benefits related to stock-based compensation awards vested, expired, cancelled and exercised of $0.1 million and less than $0.1 million in the three months ended December 31, 2021 and 2020, respectively.

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 $2.7 million as of December 31, 2021 and September 30, 2021, respectively. Interest and penalties related to unrecognized tax benefits are recorded in the income tax benefit (provision).

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. U.S. federal income tax returns for years prior to fiscal 2018 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 2011. For tax returns for non-U.S. jurisdictions, the Company is no longer subject to income tax examination for years prior to 2017. Additionally, the Company has been indemnified of liability for any taxes relating to Creagh Medical, NorMedix 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, 2021 and September 30, 2021.

10. 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 $29 million in the aggregate. As of December 31, 2021, an estimated $7 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 2019, the Company acquired certain intellectual property assets supporting ongoing development of the Company’s medical device pipeline and paid the sellers $0.8 million in fiscal 2019 and $0.2 million in the first quarter of fiscal 2021. An additional $1.1 million in payments is contingent upon achievement of certain strategic milestones within a contingency period ending in fiscal 2022.

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, and $1.0 million in the first quarter of fiscal 2021. The Company is obligated to pay additional installments totaling $2.5 million in fiscal 2022 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.

Business Combinations. See Note 11 Acquisitions for disclosure of the fiscal 2021 acquisition of Vetex Medical Limited and associated deferred and contingent consideration liabilities.

11. Acquisitions

Vetex Medical Limited

On July 2, 2021, Surmodics acquired all of the outstanding shares of Vetex Medical Limited ("Vetex"). Vetex, which was formerly privately held and is based in Galway, Ireland, develops and manufactures medical devices focused on venous clot removal solutions. The transaction expanded Surmodics' thrombectomy portfolio with a second FDA 510(k)-cleared device, a mechanical venous thrombectomy device. The acquisition was accounted for as a business combination. The acquired assets, liabilities and operating results of Vetex have been included on our condensed consolidated financial statements within the Medical Device segment from the date of acquisition.

Surmodics acquired Vetex with an upfront cash payment of $39.9 million funded using cash on hand and $10.0 million from the Revolving Credit Facility. 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.

The acquisition date fair value of purchase consideration was as follows:

(In thousands)		
Consideration paid at closing	$	39,985
Deferred consideration		3,257
Contingent consideration		814
Total purchase consideration		44,056
Less: Cash acquired		(432)
Total purchase consideration, net of cash acquired	**$**	**43,624**

The fair value of contingent consideration was derived using a discounted cash flow approach based on Level 3 inputs. See Note 4 Fair Value Measurements for additional disclosures regarding contingent consideration.

As of December 31, 2021, the preliminary allocation of purchase consideration was as follows:

(In thousands)		
Asset (Liability)		
Current assets	$	66
Property and equipment		37
Intangible assets		27,600
Other non-current assets		133
Accrued compensation		(236)
Other accrued liabilities		(111)
Deferred income taxes		(2,954)
Net assets acquired		**24,535**
Goodwill		19,089
Total purchase consideration, net of cash acquired	**$**	**43,624**

The allocation of purchase consideration is considered preliminary as of December 31, 2021, with provisional amounts related to current assets, other non-current assets and deferred income taxes. We expect to finalize the allocation of purchase consideration no later than one year from the acquisition date.

Acquired intangible assets consist of developed technology. We used the income approach, specifically the discounted cash flow method and the incremental cash flow approach using Level 3 inputs, to derive the fair value of the developed technology. The developed technology is amortized on a straight-line basis over its estimated useful life of 12 years. The amortization of the acquired intangible assets is tax deductible.

The goodwill recorded from the Vetex acquisition is a result of expected synergies from integrating the Vetex business into the Company's Medical Device segment and from acquiring and retaining the existing Vetex workforce. The goodwill is not deductible for tax purposes.

12. Segment Information

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

(In thousands)	Three Months Ended December 31, 2021	2020
Revenue:		
Medical Device	$ 16,908	$ 16,196
In Vitro Diagnostics	6,095	6,101
Total revenue	$ 23,003	$ 22,297
Operating (loss) income:		
Medical Device	$ (3,792)	$ (593)
In Vitro Diagnostics	3,155	3,220
Total segment operating (loss) income	(637)	2,627
Corporate	(2,804)	(2,534)
Total operating (loss) income	$ (3,441)	$ 93
Depreciation and amortization:		
Medical Device	$ 2,194	$ 1,652
In Vitro Diagnostics	86	105
Corporate	96	103
Total depreciation and amortization	$ 2,376	$ 1,860

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.

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, 2021. 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. and subsidiaries (referred to as "Surmodics," the "Company," "we," "us," "our" and other like terms) is a leading provider of surface modification technologies for intravascular medical devices and chemical components for in vitro diagnostic ("IVD") immunoassay tests and microarrays. Surmodics is pursuing development and commercialization of highly differentiated 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 technologies, along with enhanced device design, development, and manufacturing capabilities. The Company mission remains to improve the detection and treatment of disease.

Acquisition of Vetex Medical Limited

In the fourth quarter of fiscal 2021, Surmodics completed the acquisition of all outstanding shares of Vetex Medical Limited ("Vetex"). Vetex, which was formerly privately held and is based in Galway, Ireland, develops and manufactures medical devices focused on venous clot removal solutions. Surmodics acquired Vetex with an upfront cash payment of $39.9 million funded using cash on hand and $10 million from the Company's $25 million revolving credit facility. Additional payments of up to $7 million, $3.5 million of which are guaranteed, may be made upon achievement of certain product development and regulatory milestones.

The transaction expands Surmodics' thrombectomy portfolio with a second Food and Drug Administration ("FDA") 510(k)-cleared device, which is marketed as our Pounce™ Venous Thrombectomy Catheter, for use in venous vascular beds that is specifically designed to remove large, mixed-morphology blood clots commonly found with venous thromboembolism ("VTE"). The *Pounce* Venous Thrombectomy Catheter has also received Conformité Européenne Mark ("CE Mark") approval, which is a prerequisite for commercialization in the European Union ("E.U."). The device's dual action technology efficiently removes mixed-morphology clot in a single session, minimizing the need for thrombolytics and without capital equipment.

Vascular Intervention Device Platforms

Within our Medical Device segment, we develop and manufacture our own proprietary vascular intervention medical device products, which leverage our expertise in surface modification 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 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 fiscal 2022 development and commercialization efforts. For both our thrombectomy and radial access platforms, we are pursuing commercialization in fiscal 2022 via a direct sales strategy leveraging a small team of experienced sales professionals and clinical specialists. Beginning in the third quarter of our fiscal 2022, we expect to see modest, but meaningful and growing revenue associated with the adoption, utilization, and sales of our Sublime™ and *Pounce* platform products.

Pounce Thrombectomy Platform

We have successfully developed, internally and through acquisitions, two FDA 510(k) approved 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 Catheter has received the CE Mark approval prerequisite for commercialization in the E.U. We believe that the ease of use, intuitive design and efficient performance of our thrombectomy products make these devices a viable first-line treatment option for interventionalists. These devices include:

- ***Pounce* Arterial Thrombo-embolectomy System** for removal of clots from arteries in the legs associated with peripheral arterial disease ("PAD"). Clinical product evaluations began in the second half of fiscal 2021 and are continuing into fiscal 2022. Commercial sales began in the first quarter of fiscal 2022.
- ***Pounce* Venous Thrombectomy Catheter** for removal of clots from veins in the legs generally associated with VTE. Process and manufacturing validations for our *Pounce* Venous Thrombectomy Catheter are underway and are expected to continue through the second quarter of fiscal 2022. We expect to initiate clinical product evaluation activities for our venous thrombectomy catheter in the second half of fiscal 2022, an important precursor to commercialization.

Sublime Radial Access Platform

We have successfully developed and secured FDA 510(k) regulatory approval for a suite of devices that enable vascular intervention via radial (wrist) access. 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.

Commercial sales began in the fourth quarter of fiscal 2021 for our *Sublime* guide sheath and *Sublime* .014 RX PTA dilatation catheter. For our *Sublime* .018 RX PTA dilatation catheter product, commercial sales began in the first quarter of fiscal 2022.

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** – 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 June 2021, we submitted the fourth and final module of our application to the FDA for premarket approval ("PMA") of our *Surveil* DCB, including certain long-term vital status data required by the FDA. The Agency has requested certain additional data, and we continue to work closely with the Agency to fulfill requirements regarding our PMA application. Receipt of PMA from the FDA, if granted, would be expected to fulfill the requirements for a $30 million (if received by December 31, 2022) or $27 million (if received after December 31, 2022) milestone payment pursuant to the Abbott Agreement.

- **Sundance™ DCB** – sirolimus-coated DCB 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. We expect to develop and finalize the clinical report for the SWING trial to provide to Abbott in the second quarter of fiscal 2022. Pursuant to the Abbott Agreement, Abbott has the option to negotiate for a commercialization agreement for the *Sundance* DCB product. We are working with our clinical investigators and advisors to identify and assess potential clinical strategies for our *Sundance* DCB, including pivotal study protocols and primary safety and efficacy end-points.

- **Avess™ DCB** – paclitaxel-coated DCB for the treatment of arteriovenous ("AV") fistulae commonly associated with hemodialysis. In fiscal 2019, we commenced and completed enrollment in a first in-human, 12-patient clinical study of our *Avess* DCB. In fiscal 2020, initial study results were received and demonstrated promising early safety data and performance insights, with greater than 90% of treated patients free from revascularization at six months. In fiscal 2021, we completed design verification for the full matrix of balloon sizes for the base balloon catheter and began the process validation work on the base catheter. Additionally, the FDA has provided high-level feedback on *Avess* pivotal clinical trial design considerations. In fiscal 2022, we plan to evaluate our strategy for further clinical investment in the *Avess* DCB based on the experience we gain from the PMA application process for our *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, 2021.

COVID Pandemic Update

Our business, operations and financial condition and results have been and may continue to be impacted by the COVID pandemic. In fiscal 2020, we experienced significant and unpredictable reductions in both royalties and license fee revenue and product sales, primarily in our Medical Device business, as our customers were negatively impacted by the decline in the volume of elective procedures that resulted from the global healthcare system's response to COVID. As fiscal 2021 progressed, we observed a diminishing degree of COVID-related impacts to our reported revenue. However, in fiscal 2022, we are continuing to see COVID-related impacts to our reported revenue. The extent to which the COVID pandemic continues to impact the Company's results of operations and financial condition will depend on future developments that are highly uncertain and cannot be predicted, including new information that may emerge concerning the severity and longevity of COVID and its variants, the resurgence of COVID in regions that have begun to recover from the initial impact of the pandemic, the impact of COVID on economic activity, the emergence of new variants of COVID, and the actions to contain its impact on public health and the global economy. For further information, refer to "Risk Factors" in Part II, Item 1A of our Annual Report on Form 10-K for the fiscal year ended September 30, 2021.

Results of Operations

Three Months Ended December 31, 2021 and 2020

Revenue. Revenue for the first quarter of fiscal 2022 was $23.0 million, an increase of 3.2% compared to the same prior-year period. The following is a summary of revenue streams within each reportable segment.

	Three Months Ended December 31,			
(In thousands)	**2021**	**2020**	**$ Change**	**% Change**
Medical Device				
Product sales	$ 6,788	$ 4,561	$ 2,227	49%
Royalties	6,886	7,909	(1,023)	(13)%
License fees	1,213	1,425	(212)	(15)%
Research, development and other	2,021	2,301	(280)	(12)%
Medical Device Revenue	**16,908**	**16,196**	**712**	**4%**
In Vitro Diagnostics				
Product sales	5,556	5,541	15	—%
Research, development and other	539	560	(21)	(4)%
In Vitro Diagnostics Revenue	**6,095**	**6,101**	**(6)**	—%
Total Revenue	**$ 23,003**	**$ 22,297**	**$ 706**	**3%**

Medical Device. Medical Device revenue was $16.9 million in the first quarter of fiscal 2022, an increase of 4.4% compared to $16.2 million for the same prior-year period.

- Medical Device product sales increased 48.8% to $6.8 million for the first quarter of fiscal 2022, compared to $4.6 million in the first quarter of fiscal 2021. The increase in product sales was driven by sustained growth in demand for our coating reagent products, as well as by higher sales of both distributed specialty catheters and legacy, contract-manufactured balloon catheters.

- Medical Device coatings royalties revenue decreased 12.9% to $6.9 million for the first quarter of fiscal 2022, compared to $7.9 million in the prior-year quarter. Reported royalties revenue is impacted by variances in estimated vs. customer-reported royalties, and this impact was unfavorable to royalties revenue in the first quarter of fiscal 2022 and favorable to royalties revenue in the prior-year quarter, largely related to unpredictable and evolving COVID impacts.
- License fee revenue from the Abbott Agreement for our *SurVeil* DCB was $1.2 million and $1.3 million for the first quarter of fiscal 2022 and 2021, respectively.

  Abbott Agreement license fee revenue is recognized as costs are incurred on a proportional basis to total expected costs for the TRANSCEND pivotal clinical trial. The percentage of costs incurred relative to total estimated costs for the TRANSCEND pivotal clinical trial of our *SurVeil* DCB was approximately 80% and 76% as of December 31, 2021 and September 30, 2021, respectively. We estimate this percentage will be approximately 83% by the end of fiscal 2022, with the remaining 17% of costs incurred and revenue recognized over the subsequent final three years of the TRANSCEND trial follow-up and clinical reporting period.

  Future license fee revenue related to the Abbott Agreement will depend extensively on whether and when we receive the milestone payment of up to $30 million associated with receipt of the PMA of the *SurVeil* DCB. Approximately $25 million of the $30 million milestone payment would be recognized as license fee revenue in the period in which it is received. If PMA is received after December 31, 2022, the milestone payment is reduced to $27 million pursuant to the terms of the Abbott Agreement.
- Medical Device research, development and other revenue decreased by $(0.3) million in the first quarter of fiscal 2021, compared to the same prior-year period, driven by lower coating services volume from supply chain challenges related to customer supplied components and from lifecycle attrition for certain customer products.

In Vitro Diagnostics. In Vitro Diagnostics revenue totaled $6.1 million for the first quarter of fiscal 2022 and was flat compared to the same prior-year period.

- IVD product revenue was $5.6 million for the first quarter of fiscal 2022 and was consistent with the same prior-year period. Sales of our protein stabilization and colorimetric substrate products delivered double-digit growth year-over-year in the first quarter of fiscal 2022. This was offset by a year-over-year decline in sales of our microarray slide/surface products in the first quarter of fiscal 2022.
- IVD research, development and other revenue was $0.5 million for the first quarter of fiscal 2022 and was consistent with the same prior-year period.

Operating costs and expenses. Major costs and expenses as a percentage of total revenue were as follows:

	Three Months Ended December 31,			
	2021		2020	
(In thousands)	**Amount**	**% Total Revenue**	**Amount**	**% Total Revenue**
Product costs	$ 4,497	20%	$ 3,743	17%
Research and development	11,663	51%	10,882	49%
Selling, general and administrative	9,192	40%	7,023	32%
Acquired intangible asset amortization	1,089	5%	556	3%
Contingent consideration expense	3	—%	—	—%

Product costs. Product gross margins (defined as product sales less related product costs, as a percentage of product sales) were 63.6% and 62.9% for the first quarter of fiscal 2022 and 2021, respectively. The benefit to product gross margin from leverage on higher sales volume, compared to the prior year period, was offset by a net unfavorable impact from product mix.

Research and development ("R&D") expense. For the first quarter of fiscal 2022, R&D expense increased 7.2%, or $0.8 million, compared to the prior-year quarter. R&D expense as a percentage of revenue was 50.7% and 48.8% for the first quarter of fiscal 2022 and 2021, respectively. The fiscal 2021 Vetex acquisition added $0.5 million in R&D expense for the first quarter of fiscal 2022, compared to the prior year. We anticipate R&D expenses will continue to be significant in fiscal 2022, primarily related to medical device product development, including support for commercialization of our *Pounce* and *Sublime* platforms.

Selling, general and administrative ("SG&A") expense. For the first quarter of fiscal 2022, SG&A expense increased 30.9%, or $2.2 million, compared the prior-year quarter, related to sales and marketing activities, including new hires, to support the commercialization of our *Sublime* and *Pounce* products. SG&A expense as a percentage of revenue was 40.0% and 31.5% for the first quarter of fiscal 2022 and 2021, respectively. For full-year fiscal 2022, we anticipate an increase in SG&A expenditures of between $11 million and $15 million, compared to the prior year, as we invest in sales and marketing personnel and infrastructure to support commercialization of our *Sublime* and *Pounce* platforms.

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. For the first quarter of fiscal 2022, acquired intangible asset amortization increased $0.6 million, compared to the prior-year quarter, as a result of the developed technology associated with the fiscal 2021 Vetex acquisition.

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 2022, contingent consideration expense consists of accretion for liabilities associated with the fiscal 2021 Vetex acquisition.

Other expense. Other expense was $(0.1) million and $(0.2) million for the first quarter of fiscal 2022 and 2021, respectively. Interest expense increased in the first quarter of fiscal 2022, compared to the same prior-year quarter, due to utilization of our revolving credit facility. Foreign currency gains totaled less than $0.1 million in the first quarter of fiscal 2022, compared to foreign currency losses of $(0.2) million in the first quarter of fiscal 2021. Foreign currency gains (losses) result primarily from the impact of U.S. to Euro exchange rate fluctuations on certain intercompany obligations. Foreign currency gains (losses) reflect weakening (strengthening) of the Euro relative to the U.S. dollar in each respective period.

Income tax benefit (provision). For the first quarter of fiscal 2022, income tax benefit was $0.7 million, compared to income tax expense of $(0.2) million in the prior-year quarter. The Company's effective tax rate reflects the impact of state income taxes, permanent tax items and discrete tax benefits, as well as operating results in Ireland, where tax expense or benefit is offset by a valuation allowance. The tax benefit (expense) recognized in the first quarter of fiscal 2022 and 2021 reflected expected full-year pre-tax operating results, impacted by our estimated U.S. federal R&D tax credit, and by excess tax benefits related to stock-based compensation due to equity award exercise activity.

Segment Operating Results

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

	Three Months Ended December 31,		
(In thousands)	**2021**	**2020**	**$ Change**
Operating (loss) income:			
Medical Device	$ (3,792)	$ (593)	$ (3,199)
In Vitro Diagnostics	3,155	3,220	(65)
Total segment operating (loss) income	(637)	2,627	(3,264)
Corporate	(2,804)	(2,534)	(270)
Total operating (loss) income	$ (3,441)	$ 93	$ (3,534)

Medical Device. Our Medical Device business reported an operating loss of $(3.8) million and $(0.6) million for the first quarter of fiscal 2022 and 2021, respectively, representing (22.4)% and (3.7)% of revenue, respectively.

- Medical Device operating expenses, excluding product costs, increased $3.1 million for the first quarter of fiscal 2022, compared to the prior year, primarily driven by investments in sales and marketing personnel and infrastructure to execute our long-term growth strategy. The fiscal 2021 Vetex acquisition added $1.1 million in expenses for the first quarter of fiscal 2022 for R&D personnel and acquired intangible asset amortization.
- The year-over-year contribution to operating (loss) income from royalties and license fee revenue declined $(1.2) million for the first quarter of fiscal 2022 related to unfavorable impacts from estimated vs. customer-reported royalties.
- Medical Device product gross profit increased $1.4 million year-over-year for the first quarter of fiscal 2022 on revenue growth. Product gross margins were 57.2% and 53.8% for the first quarter of fiscal 2022 and 2021, respectively. Growth in sales of coating reagents in the first quarter of fiscal 2022, compared to the prior year, was favorable to product gross margin.

In Vitro Diagnostics. Our In Vitro Diagnostics business reported operating income of $3.2 million for both the first quarter of fiscal 2022 and 2021, representing 51.8% and 52.8% of revenue, respectively.

- IVD product gross profit was $4.0 million for the first quarter of fiscal 2022 and was consistent with the prior year. IVD product gross margins were 71.4% and 70.5% in the first quarter fiscal 2022 and 2021, respectively. Product gross margin for the first quarter of fiscal 2022 was favorably impacted by a shift product mix relative to the same prior-year period.

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 $(2.8) million and $(2.5) million for the first quarter of fiscal 2022 and 2021, respectively.

Cash Flow Operating Results

The following is a summary of cash flow results:

	Three Months Ended December 31,	
(In thousands)	**2021**	**2020**
Cash (used in) provided by:		
Operating activities	$ (7,026)	$ (4,270)
Investing activities	3,218	9,874
Financing activities	(623)	(790)
Effect of exchange rates on changes in cash and cash equivalents	(72)	155
Net change in cash and cash equivalents	$ (4,503)	$ 4,969

Operating Activities. Cash used in operating activities totaled $(7.0) million for the first quarter of fiscal 2022, compared to cash used of $(4.3) million in the same prior-year period. Net loss was $(2.8) million and $(0.3) million for the first quarter of fiscal 2022 and 2021, respectively. Net changes in operating assets and liabilities reduced cash flows from operating activities by $(7.8) million and $(7.5) million during the first quarter of fiscal 2022 and 2021, respectively. Significant changes in operating assets and liabilities affecting cash flows during these periods included:

- Cash used in accrued liabilities was $(5.2) million and $(4.2) million for the first quarter of fiscal 2022 and 2021, respectively, primarily related to annual bonus payments.

- Cash used in inventories was $(1.6) million for the first quarter of fiscal 2022, compared to cash used of $(0.2) million in the same prior-year period. The current year cash used by inventories was primarily driven by the commercialization of *Pounce* and *Sublime* platforms in our Medical Device business.

- Cash used in prepaids and other was $(1.4) million for the first quarter of fiscal 2022, compared to cash used of $(0.4) million in the same prior-year period. In the prior-year period, the use of cash associated with the renewal of annual insurance premiums in our first quarter was offset, in part, by receipt of the final $0.8 million Irish Development Authority grant payment.

- Cash provided by (used in) accounts receivable and contract assets was $1.6 million cash provided in the first quarter of fiscal 2022, compared to $(0.8) million cash used in the same prior-year period. Royalty payments receivable from customers (contract assets) decreased in the current period, reflecting the reemergence of COVID-related impacts, whereas the contract assets balance increased in the same prior-year period, reflecting diminishing COVID-related impacts. In addition, timing fluctuations in accounts receivable balances were favorable to cash flow in the fiscal 2022 period and slightly unfavorable to cash flow in the same prior-year period.

Investing Activities. Cash provided by investing activities totaled $3.2 million and $9.9 million for the first quarter of fiscal 2022 and 2021, respectively. Net purchases and maturities of available-for-sale investments were a source of cash of $4.0 million and $12.2 million in the first quarter of fiscal 2022 and 2021, respectively. In the first quarter of fiscal 2021, the Company paid $1.0 million for acquisition of intangible assets (patents) to the sellers of Embolitech, LLC as a result of the achievement of a contingent milestone in fiscal 2020. Capital expenditures for property, plant and equipment totaled $0.8 million and $1.3 million for the first quarter of fiscal 2022 and 2021, respectively.

Financing Activities. Cash used in financing activities totaled $(0.6) million and $(0.8) million for the first quarter of fiscal 2022 and 2021, respectively, primarily related to the purchase of common stock to pay employee taxes resulting from the exercise of stock options and vesting of other stock awards.

Liquidity and Capital Resources

As of December 31, 2021, working capital totaled $39.3 million, a decrease of $1.2 million from September 30, 2021. We define working capital as current assets minus current liabilities. Cash and cash equivalents and available-for-sale investments totaled $32.3 million as of December 31, 2021, a decrease of $8.6 million from $40.9 million as of September 30, 2021. This change was primarily driven by payment of annual bonuses and planned personnel, inventory and other operational expenditures related to commercialization of the *Pounce* and *Sublime* platforms in our Medical Device business.

Subject to the terms of the Abbott Agreement, the Company is to receive a $30 million PMA milestone payment under the Abbott Agreement if the *SurVeil* DCB receives PMA on or before December 31, 2022. The PMA milestone payment is reduced to $27 million under the Abbott Agreement if PMA is received after December 31, 2022. The Company cannot be sure whether the PMA milestone payment will be received on or before December 31, 2022, if at all.

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 availability of up to $25 million subject to borrowing base constraints. The outstanding balance on the revolving credit facility was $10 million as of December 31, 2021. The current scheduled maturity date of the revolving credit facility is September 14, 2022, and the Company has one additional extension period remaining. If we elect to extend the maturity date at least 60 days prior to the scheduled maturity date, and if the extension conditions are met, which include no material adverse effect, default, or event of default under the revolving credit facility, the revolving credit facility will mature, and any outstanding balance will become payable, on September 14, 2023.

As of December 31, 2021, the Company’s shelf registration statement with the Securities and Exchange Commission 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.

The Company’s investment policy excludes ownership of collateralized mortgage obligations, mortgage-backed derivatives and other derivative securities without prior written approval of the Board of Directors. Our investments primarily consist of commercial paper and corporate bond securities and are reported at fair value as available-for-sale investments and totaled $5.7 million as of December 31, 2021. Our investment policy requires that no more than 5% of investments be held in any one credit or issue, excluding U.S. government and government agency obligations. The primary investment objective of the portfolio is to provide for the safety of principal and appropriate liquidity, while generating an above-benchmark (Barclays Short Treasury 1-3 Month Index) total rate of return on a pre-tax basis.

For full-year fiscal 2022, we anticipate an increase in SG&A expenditures of between $11 million and $15 million, as well as an increase in capital expenditures of up to $3 million, related to sales and marketing activities, including new hires, to support the commercialization of our *Sublime* and *Pounce* products. We expect that increasing SG&A expenditures in fiscal 2022 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 full-year fiscal 2022, primarily related to medical device product development, including readiness for commercialization of our *Pounce* and *Sublime* platforms. We believe that our existing cash and cash equivalents and available-for-sale investments, which totaled $32.3 million as of December 31, 2021, together with cash flow from operations and our revolving credit facility, will provide liquidity sufficient to meet our cash needs and fund our operations and planned capital expenditures through fiscal 2022. There can be no assurance, however, that our business will continue to generate cash flows at historic levels.

Beyond fiscal 2022, 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. Our long-term cash requirements also will be significantly impacted by the level of our investment in commercialization of our vascular intervention 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 cashflow. 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 21% and 13%, respectively, of our consolidated revenue for fiscal 2021. These same customers each comprised 10% and 14%, respectively, of our consolidated revenue for the three months ended December 31, 2021. Revenue generated under our *SurVeil* DCB license agreement with Abbott represented 5% of total revenue for the three months ended December 31, 2021. Apart from the *SurVeil* DCB license, Abbott has several separately licensed products which generate royalties revenue for Surmodics, none of which represented more than 3% of total revenue for the three months ended December 31, 2021. Medtronic has several separately licensed products that generate royalties revenue for Surmodics, none of which represented more than 4% of our total revenue for the three months ended December 31, 2021.

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, 2021, 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, 2021.

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, expectations concerning: the impacts, duration and severity of the global COVID-19 pandemic and the effects of responses to it on healthcare systems, the general economy, our business partners, and our operations; the potential results of clinical studies and the potential future clinical studies; our strategies for growth; the expected timing of clinical evaluations; the expected duration of process and manufacturing validations; the potential results of our strategies; regulatory submissions and approvals; our intent to pursue certain regulatory actions; the potential impact of U.S. Food and Drug Administration ("FDA") communications; expectation regarding the receipt of results of clinical studies; expectation regarding delivery of clinical reports; our initiations for product evaluation activities; the potential for a future milestone payment related to our SurVeil™ drug-coated balloon ("DCB") and the revenue that would be recognized on that milestone payment; revenue potential related to the potential commercial launch of the *SurVeil* DCB; the expected timing of completion and delivery of the SWING first-in-human clinical trial results; anticipated future revenue from particular products; future revenue growth, our longer-term valuation-creation strategy, and our future potential; estimated future amortization expense; expectations regarding operating expenses; recognition of unrecognized compensation costs; research and development plans and expenses, including the estimated cost associated with the TRANSCEND clinical trial and the timing of those costs; anticipated cash requirements; the anticipated maturity date of our revolving credit facility; future cash flow and sources of funding, and their ability together with existing cash, cash equivalents, and investments to provide liquidity sufficient to meet our cash needs and fund our operations and planned capital expenditures through fiscal 2022; future cash requirements; plans regarding our securities investments and the potential impact of interest rate fluctuations; expectations regarding the maturity of debt; 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, 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; expected future income tax (expense) benefit; whether changes in our internal control over financial reporting are reasonably likely to materially affect our internal control over financial reporting; 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, 2021. 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:

- the impacts, duration and severity of the global COVID-19 pandemic, which has impacted, and may continue to impact, our revenue, operations, the conduct of clinical studies, and our ability to access healthcare professionals and facilities;
- 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;
- 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;
- our ability to successfully develop, obtain regulatory approval for, and commercialize our *SurVeil* DCB product, 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;
- general economic conditions that are beyond our control, such as the impact of recessions, customer mergers and acquisitions, supply chain disruptions, 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;
- a decrease in our available cash or failure to generate cash flows from operations, which could impact short-term liquidity requirements and expected capital and other expenditures;
- our ability to comply with the covenants in our credit facility;
- 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 U.S. 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;
- whether operating expenses that we incur related to the development and commercialization of new technologies and products are effective;
- our ability to successfully perform product development activities, the related R&D expense impact and governmental and regulatory compliance activities, which we have not previously undertaken in any significant manner;
- our ability to identify and execute new acquisition opportunities and successfully managing the risks associated with acquisitions, which include the potential inability to integrate acquired operations, personnel, technology, information systems, and internal control systems and products; a lack of understanding of tax, legal and cultural differences for non-U.S. acquisitions; diversion of management's attention; difficulties and uncertainties in transitioning the customers or other business relationships from the acquired entity to us; the loss of key employees of acquired companies; and potential impacts on cash flows; and
- other factors described under "Risk Factors" in Part I, Item 1A of our Annual Report on Form 10-K for the fiscal year ended September 30, 2021, 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. We do not use derivative financial instruments to manage interest rate risk or to speculate on future changes in interest rates. As of December 31, 2021, we held $5.7 million in available-for-sale debt securities with maturity dates of less than one year. Therefore, interest rate fluctuations 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.

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, 2021. 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, 2021 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

The risks identified in our Annual Report on Form 10-K for the fiscal year ended September 30, 2021, filed with the Securities and Exchange Commission on November 24, 2021, under Part 1, 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, 2021.

	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, 2021	232	$ 56.58	—	$ 25,300,000
November 1 – 30, 2021	18,425	45.65	—	25,300,000
December 1 – 31, 2021	—	—	—	25,300,000
Total	18,657	$ 45.78	—	

(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.

As of December 31, 2021, the Company had an aggregate of $25.3 million available for future common stock repurchases under an authorization approved by the Board of Directors for up to $20.0 million on November 6, 2015, all of which is remaining, and an authorization approved by the Board of Directors on November 5, 2014 of which $5.3 million is remaining. These authorizations for share repurchases do not have a fixed expiration date.

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.
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.
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 3, 2022

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 3, 2022

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 3, 2022

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, 2021, 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 3, 2022

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, 2021, 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 3, 2022

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