UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D. C. 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended June 30, 2022

or

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

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 July 25, 2022 was 14,005,000.

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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)	June 30, 2022	September 30, 2021
	(Unaudited)	
ASSETS		
Current Assets:		
Cash and cash equivalents	$ 20,074	$ 31,153
Available-for-sale securities	2,012	7,717
Accounts receivable, net of allowances of $84 and $119 as of June 30, 2022 and September 30, 2021, respectively	9,382	9,169
Contract assets — royalties and license fees	7,584	7,091
Inventories, net	10,926	6,760
Income tax receivable	2,409	1,912
Prepaids and other	7,648	6,453
Total Current Assets	60,035	70,255
Property and equipment, net	28,289	30,090
Available-for-sale securities	—	2,002
Deferred income taxes	8,479	5,867
Intangible assets, net	30,752	37,054
Goodwill	42,590	45,606
Other assets	5,507	3,718
Total Assets	$ 175,652	$ 194,592
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities:		
Accounts payable	$ 1,928	$ 1,783
Accrued liabilities:		
Compensation	7,595	8,480
Accrued other	5,857	4,905
Short-term borrowings	10,000	10,000
Deferred revenue	4,007	4,647
Total Current Liabilities	29,387	29,815
Deferred revenue, less current portion	7,402	10,301
Deferred income taxes	2,227	2,742
Other long-term liabilities	11,524	11,649
Total Liabilities	50,540	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; 13,999 and 13,899 shares issued and outstanding as of June 30, 2022 and September 30, 2021, respectively	700	695
Additional paid-in capital	26,612	21,598
Accumulated other comprehensive (loss) income	(5,719)	1,727
Retained earnings	103,519	116,065
Total Stockholders' Equity	125,112	140,085
Total Liabilities and Stockholders' Equity	$ 175,652	$ 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

	Three Months Ended June 30,		Nine Months Ended June 30,	
	2022	2021	2022	2021
(In thousands, except per share data)	*(Unaudited)*		*(Unaudited)*	
Revenue:				
Product sales	$ 13,919	$ 12,084	$ 40,227	$ 33,969
Royalties and license fees	8,795	8,796	26,738	38,182
Research, development and other	2,140	2,993	6,998	9,014
Total revenue	24,854	23,873	73,963	81,165
Operating costs and expenses:				
Product costs	5,141	5,105	14,745	13,018
Research and development	12,975	12,246	38,350	36,003
Selling, general and administrative	12,854	7,885	33,159	22,815
Acquired intangible asset amortization	1,024	560	3,184	1,676
Acquisition transaction, integration and other costs	—	461	—	461
Contingent consideration expense	3	—	9	—
Total operating costs and expenses	31,997	26,257	89,447	73,973
Operating (loss) income	(7,143)	(2,384)	(15,484)	7,192
Other expense:				
Investment income, net	22	26	73	95
Interest expense	(145)	(59)	(410)	(178)
Foreign exchange gain (loss)	85	(94)	120	(201)
Other expense	(38)	(127)	(217)	(284)
(Loss) income before income taxes	(7,181)	(2,511)	(15,701)	6,908
Income tax benefit (provision)	1,530	(776)	3,155	(2,382)
Net (loss) income	$ (5,651)	$ (3,287)	$ (12,546)	$ 4,526
Basic net loss (income) per share	$ (0.41)	$ (0.24)	$ (0.90)	$ 0.33
Diluted net loss (income) per share	$ (0.41)	$ (0.24)	$ (0.90)	$ 0.32
Weighted average number of shares outstanding:				
Basic	13,929	13,837	13,907	13,740
Diluted	13,929	13,837	13,907	13,959

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 June 30,		Nine Months Ended June 30,	
	2022	2021	2022	2021
(In thousands)	*(Unaudited)*		*(Unaudited)*	
Net (loss) income	$ (5,651)	$ (3,287)	$ (12,546)	$ 4,526
Other comprehensive (loss) income:				
Net changes related to available-for-sale securities, net of tax	4	4	(7)	(3)
Foreign currency translation adjustments	(4,289)	524	(7,439)	588
Other comprehensive (loss) income	(4,285)	528	(7,446)	585
Comprehensive (loss) income	$ (9,936)	$ (2,759)	$ (19,992)	$ 5,111

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 June 30, 2022 and 2021					
	(Unaudited)					
	Common Stock		Additional Paid-In	Accumulated Other Comprehensive	Retained	Total Stockholders'
(In thousands)	Shares	Amount	Capital	(Loss) Income	Earnings	Equity
Balance at March 31, 2022	13,990	$ 700	$ 24,827	$ (1,434)	$ 109,170	$ 133,263
Net loss	—	—	—	—	(5,651)	(5,651)
Other comprehensive loss, net of tax	—	—	—	(4,285)	—	(4,285)
Issuance of common stock	9	—	—	—	—	—
Common stock options exercised, net	1	—	22	—	—	22
Purchase of common stock to pay employee taxes	(1)	—	(36)	—	—	(36)
Stock-based compensation	—	—	1,799	—	—	1,799
Balance at June 30, 2022	13,999	$ 700	$ 26,612	$ (5,719)	$ 103,519	$ 125,112
Balance at March 31, 2021	13,868	$ 693	$ 18,516	$ 3,231	$ 119,641	$ 142,081
Net loss	—	—	—	—	(3,287)	(3,287)
Other comprehensive income, net of tax	—	—	—	528	—	528
Issuance of common stock	2	1	—	—	—	1
Common stock options exercised, net	2	—	90	—	—	90
Purchase of common stock to pay employee taxes	—	—	(37)	—	—	(37)
Stock-based compensation	—	—	1,456	—	—	1,456
Balance at June 30, 2021	13,872	$ 694	$ 20,025	$ 3,759	$ 116,354	$ 140,832

	Nine Months Ended June 30, 2022 and 2021					
	(Unaudited)					
	Common Stock		Additional Paid-In	Accumulated Other Comprehensive	Retained	Total Stockholders'
(In thousands)	Shares	Amount	Capital	Income (Loss)	Earnings	Equity
Balance at September 30, 2021	13,899	$ 695	$ 21,598	$ 1,727	$ 116,065	$ 140,085
Net loss	—	—	—	—	(12,546)	(12,546)
Other comprehensive loss, net of tax	—	—	—	(7,446)	—	(7,446)
Issuance of common stock	100	5	367	—	—	372
Common stock options exercised, net	21	1	390	—	—	391
Purchase of common stock to pay employee taxes	(21)	(1)	(941)	—	—	(942)
Stock-based compensation	—	—	5,198	—	—	5,198
Balance at June 30, 2022	13,999	$ 700	$ 26,612	$ (5,719)	$ 103,519	$ 125,112
Balance at September 30, 2020	13,672	$ 684	$ 15,369	$ 3,174	$ 111,828	$ 131,055
Net income	—	—	—	—	4,526	4,526
Other comprehensive income, net of tax	—	—	—	585	—	585
Issuance of common stock	91	5	292	—	—	297
Common stock options exercised, net	127	6	2,324	—	—	2,330
Purchase of common stock to pay employee taxes	(18)	(1)	(2,278)	—	—	(2,279)
Stock-based compensation	—	—	4,318	—	—	4,318
Balance at June 30, 2021	13,872	$ 694	$ 20,025	$ 3,759	$ 116,354	$ 140,832

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

Surmodics, Inc. and Subsidiaries

Condensed Consolidated Statements of Cash Flows

	Nine Months Ended June 30,	
	2022	2021
(In thousands)	***(Unaudited)***	
Operating Activities:		
Net (loss) income	$ (12,546)	$ 4,526
Adjustments to reconcile net (loss) income to net cash (used in) provided by operating activities:		
Depreciation and amortization	6,902	5,610
Stock-based compensation	5,198	4,318
Noncash lease expense	371	223
Provision for credit losses	8	(11)
Deferred taxes	(2,996)	947
Other	257	37
Change in operating assets and liabilities:		
Accounts receivable and contract assets	(847)	(1,809)
Inventories	(4,167)	(338)
Prepaids and other	(1,998)	(59)
Accounts payable	349	(27)
Accrued liabilities	(1,039)	(435)
Income taxes	(676)	1,327
Deferred revenue	(3,539)	191
Net cash (used in) provided by operating activities	(14,723)	14,500
Investing Activities:		
Purchases of property and equipment	(2,798)	(2,874)
Payment for acquisition of intangible assets	—	(1,000)
Purchases of available-for-sale securities	—	(22,799)
Maturities of available-for-sale securities	7,600	43,317
Net cash provided by investing activities	4,802	16,644
Financing Activities:		
Issuance of common stock	763	2,627
Payments for taxes related to net share settlement of equity awards	(936)	(2,279)
Payments for acquisition of in-process research and development	(500)	(150)
Net cash (used in) provided by financing activities	(673)	198
Effect of exchange rate changes on cash	(485)	50
Net change in cash and cash equivalents	(11,079)	31,392
Cash and Cash Equivalents:		
Beginning of period	31,153	30,785
End of period	$ 20,074	$ 62,177
Supplemental Information:		
Cash paid for income taxes	$ 395	$ 35
Cash paid for interest	256	—
Noncash investing and financing activities:		
Acquisition of property and equipment, net of refundable credits in other current assets and liabilities	90	345
Right-of-use assets obtained in exchange for new operating lease liabilities	1,732	234

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 June 30, 2022
(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 and nine months ended June 30, 2022 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 June 30,		Nine Months Ended June 30,	
(In thousands)	2022	2021	2022	2021
Medical Device				
Product sales	$ 6,741	$ 5,493	$ 19,970	$ 15,464
Royalties	7,771	7,752	23,015	23,135
License fees	1,024	1,044	3,723	15,047
Research, development and other	1,992	2,466	6,181	7,212
Medical Device Revenue	17,528	16,755	52,889	60,858
In Vitro Diagnostics				
Product sales	7,178	6,591	20,257	18,505
Research, development and other	148	527	817	1,802
In Vitro Diagnostics Revenue	7,326	7,118	21,074	20,307
Total Revenue	$ 24,854	$ 23,873	$ 73,963	$ 81,165

Contract assets totaled $7.6 million and $7.1 million as of June 30, 2022 and September 30, 2021, respectively, on the condensed consolidated balance sheets. Fluctuations in the balance of contract assets result primarily from changes in sales-based and minimum royalties earned, but not collected, at each balance sheet date due to payment timing and contractual changes in the normal course of business. For discussion of contract liability (deferred revenue) balances and remaining performance obligations, see Note 3 Collaborative Arrangement.

3. Collaborative Arrangement

On February 26, 2018, the Company entered into an agreement with Abbott Vascular, Inc. ("Abbott") whereby Abbott has exclusive worldwide commercialization rights for Surmodics' SurVeil™ drug-coated balloon ("DCB") to treat the superficial femoral artery (the "Abbott Agreement"). A premarket approval ("PMA") application for the *SurVeil* DCB was being evaluated by the U.S. Food and Drug Administration ("FDA") as of June 30, 2022.

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 June 30, 2022, 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 June 30, 2022, the Company may receive an additional contingent milestone payment upon PMA of our *SurVeil* DCB of $30 million (if PMA is received prior to December 31, 2022) or $27 million (if PMA is received after December 31, 2022), pursuant to the terms of the Abbott Agreement. As of June 30, 2022, 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 June 30, 2022.

Revenue recognized from the Abbott agreement totaled $1.0 million for both the three months ended June 30, 2022 and 2021 and $3.6 million and $14.8 million for the nine months ended June 30, 2022 and 2021, respectively. The amount of revenue recognized from the Abbott Agreement that was included in the respective beginning of fiscal year balances of deferred revenue on the condensed consolidated balance sheets totaled $3.6 million and $3.8 million for the nine months ended June 30, 2022 and 2021, respectively.

As of June 30, 2022 and September 30, 2021, deferred revenue on the condensed consolidated balance sheets included $11.3 million and $14.9 million, respectively, related to payments received under the Abbott Agreement. The $11.3 deferred revenue as of June 30, 2022, which represents the Company's performance obligations that are unsatisfied for executed contracts with an original duration of one year, is expected to be recognized as revenue over the next 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:

	June 30, 2022			
(In thousands)	Quoted Prices in Active Markets for Identical Instruments (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)	Total Fair Value
Assets				
Cash equivalents (1)	$ —	$ 16	$ —	$ 16
Available-for-sale securities (1)	—	2,012	—	2,012
Total assets	$ —	$ 2,028	$ —	$ 2,028
Liabilities				
Contingent consideration (2)	$ —	$ —	$ 826	$ 826
Total liabilities	$ —	$ —	$ 826	$ 826

	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 June 30, 2022 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	9
Foreign currency translation	—
Contingent consideration liability at June 30, 2022	$ 826

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:

	June 30, 2022					
	Valuation				Balance Sheet Classification	
(In thousands)	Amortized Cost	Unrealized Gains	Unrealized Losses	Fair Value	Current Assets	Noncurrent Assets
Commercial paper and corporate bonds	$ 2,018	$ —	$ (6)	$ 2,012	$ 2,012	$ —
Total	$ 2,018	$ —	$ (6)	$ 2,012	$ 2,012	$ —

	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)	June 30, 2022	September 30, 2021
Raw materials	$ 6,252	$ 4,165
Work-in process	1,943	1,295
Finished products	2,731	1,300
Total	$ 10,926	$ 6,760

Prepaids and Other Assets, Current

Prepaids and other current assets consisted of the following:

(In thousands)	June 30, 2022	September 30, 2021
Prepaid expenses	$ 3,208	$ 1,712
Irish research and development credits receivable	1,006	1,164
CARES Act employee retention credit receivable	3,434	3,577
Prepaids and other	$ 7,648	$ 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 benefit and corresponding receivable reflected anticipated reimbursement of personnel expenses we incurred in fiscal 2021 and 2020.

Intangible Assets

Intangible assets consisted of the following:

	June 30, 2022			
(In thousands)	Weighted Average Original Life (Years)	Gross Carrying Amount	Accumulated Amortization	Net
Definite-lived intangible assets:				
Customer lists and relationships	8.9	$ 12,032	$ (9,039)	$ 2,993
Developed technology	11.9	33,613	(7,565)	26,048
Patents and other	14.1	3,551	(2,420)	1,131
Total definite-lived intangible assets		49,196	(19,024)	30,172
Unamortized intangible assets:				
Trademarks and trade names		580	—	580
Total intangible assets		$ 49,776	$ (19,024)	$ 30,752

	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 $1.1 million and $0.6 million for the three months ended June 30, 2022 and 2021, respectively, and $3.4 million and $1.9 million for the nine months ended June 30, 2022 and 2021, respectively. Based on the intangible assets in service as of June 30, 2022, estimated amortization expense for future fiscal years is as follows:

(In thousands)	
Remainder of 2022	$ 1,063
2023	3,739
2024	3,656
2025	3,622
2026	2,754
2027	2,510
Thereafter	12,828
Definite-lived intangible assets	$ 30,172

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	—	(3,293)	(3,293)
Measurement period adjustment (1)	—	277	277
Goodwill as of June 30, 2022	$ 8,010	$ 34,580	$ 42,590

(1) During the third quarter of fiscal 2022, measurement period adjustments were recorded to finalize the allocation of purchase consideration for the fiscal 2021 Vetex acquisition (Note 11).

Other Assets, Noncurrent

Other noncurrent assets consisted of the following:

(In thousands)	June 30, 2022	September 30, 2021
Operating lease right-of-use assets	$ 3,796	$ 2,435
Other	1,711	1,283
Other assets	$ 5,507	$ 3,718

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

Accrued Other Liabilities

Accrued other liabilities consisted of the following:

(In thousands)	June 30, 2022	September 30, 2021
Accrued professional fees	$ 370	$ 489
Accrued clinical study expense	1,876	1,667
Accrued purchases	1,198	1,195
Acquisition of in-process research and development (1)	975	494
Operating lease liability, current portion	897	518
Other	541	542
Total accrued other liabilities	$ 5,857	$ 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)	June 30, 2022	September 30, 2021
Deferred consideration (1)	$ 4,235	$ 5,106
Contingent consideration (2)	826	817
Unrecognized tax benefits (3)	2,359	2,538
Operating lease liabilities (4)	4,104	3,188
Other long-term liabilities	$ 11,524	$ 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 and by a Second Amendment on March 7, 2022 (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 June 30, 2022 and September 30, 2021.

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. As of June 30, 2022 and September 30, 2021, the weighted average interest rate on outstanding borrowings on the Revolving Credit Facility was 4.5% and 3.3%, respectively. Unused commitment fees, reported within interest expense on the condensed consolidated statements of operations, totaled zero and less than $0.1 million for the nine months ended June 30, 2022 and 2021, respectively.

The Loan Agreement contains affirmative and negative covenants customary for a facility 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 quarterly revenue, 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 June 30,		Nine Months Ended June 30,	
(In thousands)	**2022**	**2021**	**2022**	**2021**
Product costs	$ 62	$ 23	$ 170	$ 92
Research and development	355	329	1,086	918
Selling, general and administrative	1,382	1,104	3,942	3,308
Total	$ 1,799	$ 1,456	$ 5,198	$ 4,318

As of June 30, 2022, unrecognized compensation costs related to non-vested awards totaled approximately $11.7 million, which is expected to be recognized over a weighted average period of approximately 2.4 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:

	Nine Months Ended June 30,	
	2022	**2021**
Stock option grant activity:		
Stock options granted	312,000	244,000
Weighted average grant date fair value	$ 16.11	$ 14.08
Weighted average exercise price	$ 42.78	$ 39.24

Restricted Stock Awards

During the nine months ended June 30, 2022 and 2021, the Company awarded 90,000 and 68,000 restricted stock shares, respectively, to certain key employees and officers with a weighted average grant date fair value per share of $43.02 and $38.06, respectively. Restricted Stock is valued based on the market value of the shares as of the date of grant.

Restricted Stock Unit Awards

During the nine months ended June 30, 2022 and 2021, the Company awarded 14,000 and 12,000 restricted stock units, respectively, (“RSUs”) to directors and to key employees in foreign jurisdictions with a weighted average grant date fair value per unit of $42.79 and $45.13, 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 nine months ended June 30, 2022 and 2021, 10,000 and 8,000 shares were issued under the ESPP, respectively.

8. Net (Loss) Income 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 and nine months ended June 30, 2022 and for the three months ended June 20, 2021 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 and nine months ended June 30, 2022 and for the three months ended June 30, 2021.

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

	Three Months Ended June 30,		Nine Months Ended June 30,	
(In thousands)	2022	2021	2022	2021
Basic weighted average shares outstanding	13,929	13,837	13,907	13,740
Dilutive effect of outstanding stock options, non-vested restricted stock, and non-vested restricted stock units	—	—	—	219
Diluted weighted average shares outstanding	13,929	13,837	13,907	13,959

The calculation of weighted average diluted shares outstanding excludes outstanding stock options associated with the right to purchase less than 0.1 million shares of common stock for the nine months ended June 30, 2021, as their inclusion would have had an antidilutive effect on diluted net income per share for those periods.

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 $1.5 million and income tax expense of $(0.8) million for the three months ended June 30, 2022 and 2021, respectively, and income tax benefit of $3.2 million and income tax expense of $(2.4) million for the nine months ended June 30, 2022 and 2021, respectively.

The effective income tax rate for the three and nine months ended June 30, 2022 and 2021 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, operating results of one of our Irish subsidiaries for which tax benefit is offset by a valuation allowance, and the effects of equity compensation. The Company recognized discrete tax benefits related to stock-based compensation awards vested, expired, cancelled and exercised of less than $0.1 million for both the three months ended June 30, 2022 and 2021 and $0.1 million and $0.7 million for the nine months ended June 30, 2022 and 2021, 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 June 30, 2022 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. The Internal Revenue Service commenced an examination of the Company's fiscal 2019 U.S. federal tax return in the second quarter of fiscal 2022; the examination has not been completed. 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 June 30, 2022 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 $30 million in the aggregate. As of June 30, 2022, an estimated $8 million remains to be paid on these contracts, which may vary depending on actual pass-through expenses incurred to execute the trial. The Company estimates that the total cost of the TRANSCEND clinical trial will be in the range of $37 million to $40 million from inception to completion. In the event the Company were to terminate any trial, it may incur certain financial penalties which would become payable to the CRO for costs to wind down the terminated trial.

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

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.

The final allocation of purchase consideration as of the acquisition date was as follows:

(In thousands)	
Asset (Liability)	
Current assets	$ 18
Property and equipment	37
Intangible assets	27,600
Other non-current assets	37
Accrued compensation	(236)
Other accrued liabilities	(111)
Deferred income taxes	(3,087)
Net assets acquired	**24,258**
Goodwill	19,366
Total purchase consideration, net of cash acquired	**$ 43,624**

During the third quarter of fiscal 2022, the Company recorded measurement adjustments to provisional amounts previously recognized, which resulted in a $0.3 increase in goodwill and a corresponding decrease in net identifiable assets acquired. The Company finalized the accounting for the Vetex acquisition in the third quarter of fiscal 2022.

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:

	Three Months Ended June 30,		Nine Months Ended June 30,	
(In thousands)	2022	2021	2022	2021
Revenue:				
Medical Device	$ 17,528	$ 16,755	$ 52,889	$ 60,858
In Vitro Diagnostics	7,326	7,118	21,074	20,307
Total revenue	$ 24,854	$ 23,873	$ 73,963	$ 81,165
Operating (loss) income:				
Medical Device	$ (7,308)	$ (2,491)	$ (16,712)	$ 5,480
In Vitro Diagnostics	3,387	3,378	10,262	10,407
Total segment operating (loss) income	(3,921)	887	(6,450)	15,887
Corporate	(3,222)	(3,271)	(9,034)	(8,695)
Total operating (loss) income	$ (7,143)	$ (2,384)	$ (15,484)	$ 7,192
Depreciation and amortization:				
Medical Device	$ 2,020	$ 1,631	$ 6,347	$ 5,004
In Vitro Diagnostics	88	121	260	314
Corporate	98	92	295	292
Total depreciation and amortization	$ 2,206	$ 1,844	$ 6,902	$ 5,610

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. We have begun to see modest, but meaningful and growing revenue associated with the adoption, utilization, and sales of our *Pounce* and Sublime™ platform products.

Pounce Thrombectomy Platform

We have successfully developed, internally and through acquisitions, two 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 viable first-line treatment options 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 continued 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 expected to continue into fiscal 2023, followed by clinical product evaluation activities, which are 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. In fiscal 2022, we finalized the clinical report for the SWING trial, which demonstrated promising early safety data and performance insights. Pursuant to the Abbott Agreement, Abbott had an exclusive option period to negotiate for a commercialization agreement for the *Sundance* DCB product, and this option period has expired. We are assessing next steps in the clinical development and future commercialization of the *Sundance* DCB.

- **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. We continue to evaluate our strategy for further clinical development and future commercialization of the *Avess* 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 macroeconomic impacts to our reported revenue, as our customers are affected by supply chain disruptions and pressures on procedure volumes. In fiscal 2022, our operations have also been affected by supply chain disruptions. 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, regional waves of COVID, 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 I, Item 1A of our Annual Report on Form 10-K for the fiscal year ended September 30, 2021.

Results of Operations

Three and Nine Months Ended June 30, 2022 and 2021

Revenue. Revenue for the third quarter of fiscal 2022 was $24.9 million, an increase of 4.1% compared to the same prior-year period. Revenue for the first nine months of fiscal 2022 was $74.0 million, a decrease of 8.9% compared to the same prior-year period. The following is a summary of revenue streams within each reportable segment.

	Three Months Ended June 30,				Nine Months Ended June 30,			
(In thousands)	2022	2021	$ Change	% Change	2022	2021	$ Change	% Change
Medical Device								
Product sales	$ 6,741	$ 5,493	$ 1,248	23%	$ 19,970	$ 15,464	$ 4,506	29%
Royalties	7,771	7,752	19	0%	23,015	23,135	(120)	(1)%
License fees	1,024	1,044	(20)	(2)%	3,723	15,047	(11,324)	(75)%
R&D and other	1,992	2,466	(474)	(19)%	6,181	7,212	(1,031)	(14)%
Medical Device Revenue	**17,528**	**16,755**	**773**	**5%**	**52,889**	**60,858**	**(7,969)**	**(13)%**
In Vitro Diagnostics								
Product sales	7,178	6,591	587	9%	20,257	18,505	1,752	9%
R&D and other	148	527	(379)	(72)%	817	1,802	(985)	(55)%
In Vitro Diagnostics Revenue	**7,326**	**7,118**	**208**	**3%**	**21,074**	**20,307**	**767**	4%
Total Revenue	**$ 24,854**	**$ 23,873**	**$ 981**	**4%**	**$ 73,963**	**$ 81,165**	**$ (7,202)**	**(9)%**

Medical Device. Medical Device revenue was $17.5 million for the third quarter of fiscal 2022, an increase of 4.6% compared to $16.8 million for the same prior-year period. Medical Device revenue was $52.9 million for the first nine months of fiscal 2022, a decrease of 13.1% compared to $60.9 million for the same prior-year period.

- Medical Device product sales increased 22.7% to $6.7 million for the third quarter of fiscal 2022, compared to $5.5 million for the third quarter of fiscal 2021. Medical Device product sales increased 29.1% to $20.0 million in the first nine months of fiscal 2022, compared to $15.5 million for the same prior-year period. For both the third quarter and first nine months of fiscal 2022, broad-based growth in sales of medical device products and coating reagent products drove the increase in revenue year-over-year. Sales of medical device products includes contract-manufactured balloon catheters, proprietary specialty catheters distributed by strategic partners, and recently commercialized *Pounce* and *Sublime* products. Sales of contract-manufactured balloon catheters for the third quarter and first nine months of fiscal 2022 were adversely impacted by supply chain challenges related to certain packaging components, and in the same prior-year periods, sales of contract-manufactured balloon catheters were adversely impacted by a product replacement matter.
- Medical Device coatings royalties revenue was $7.8 million for both the third quarter of fiscal 2022 and 2021. For the first nine months of fiscal 2022, Medical Device coatings royalties revenue was $23.0 million, compared to $23.1 million for the same prior-year period. For the third quarter and first nine months of fiscal 2022, we continued to see solid growth in royalties revenue from customers utilizing our Serene™ coating. This was offset by several macroeconomic factors, including pressure on procedure volumes from hospital capacity constraints and customer supply chain disruptions, as well as by customer devices maturing through their product life cycles.

- License fee revenue from the Abbott Agreement for our *SurVeil* DCB was $1.0 million for both the third quarter of fiscal 2022 and 2021. For the first nine months of fiscal 2022 and 2021, license fee revenue from the Abbott Agreement was $3.6 million and $14.8 million, respectively. The first nine months of fiscal 2021 included $11.0 million in license fee revenue recognized from the $15 million milestone payment received in the second quarter of fiscal 2021.

  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 81% and 76% as of June 30, 2022 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 R&D and other revenue declined by $(0.5) million and $(1.0) million for the third quarter and first nine months of fiscal 2022, respectively, compared to the same respective prior-year periods, driven by lower coating services volume from supply chain challenges related to customer supplied components.

In Vitro Diagnostics. In Vitro Diagnostics revenue increased 2.9% to $7.3 million for the third quarter of fiscal 2022, compared to $7.1 million for the third quarter of fiscal 2021. In Vitro Diagnostics revenue increased 3.8% to $21.1 million for the first nine months of fiscal 2022, compared to $20.3 million for the same prior-year period.

- IVD product revenue was $7.2 million for the third quarter of fiscal 2022, an increase of 8.9% compared to the same prior-year period. For the first nine months of fiscal 2022, IVD product revenue was $20.3 million, an increase of 9.5% compared to the same prior-year period. For the third quarter of fiscal 2022, sales of microarray slide/surface, protein stabilization, and distributed antigen products contributed to product revenue growth year-over-year. For the first nine months of fiscal 2022, sales of distributed antigen, protein stabilization, and colorimetric substrate products contributed to product revenue growth year-over-year.

- IVD R&D and other revenue declined by $(0.4) million and $(1.0) million for the third quarter and first nine months of fiscal 2022, respectively, compared to the same respective prior-year periods. The decline in R&D and other revenue was primarily related to the completion of a customer development program.

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

	Three Months Ended June 30,				Nine Months Ended June 30,			
	2022		2021		2022		2021	
(In thousands)	Amount	% Total Revenue	Amount	% Total Revenue	Amount	% Total Revenue	Amount	% Total Revenue
Product costs	$ 5,141	21%	$ 5,105	21%	$ 14,745	20%	$ 13,018	16%
Research and development	12,975	52%	12,246	51%	38,350	52%	36,003	44%
Selling, general and administrative	12,854	52%	7,885	33%	33,159	45%	22,815	28%
Acquired intangible asset amortization	1,024	4%	560	2%	3,184	4%	1,676	2%
Acquisition transaction, integration and other costs	—	—%	461	2%	—	—%	461	1%
Contingent consideration expense	3	—%	—	—%	9	—%	—	—%

Product costs. Product gross margins (defined as product sales less related product costs, as a percentage of product sales) were 63.1% and 57.8% for the third quarter of fiscal 2022 and 2021, respectively, and 63.3% and 61.7% for the first nine months of fiscal 2022 and 2021, respectively. Prior-year gross margins for the third quarter and first nine months of fiscal 2021 were unfavorably impacted by $0.7 million in charges related to a product replacement matter for one of the contract-manufactured products in our Medical Device business. The benefit to product gross margins for the third quarter and first nine months of fiscal 2022 from leverage on higher sales volume, compared to the same respective prior-year periods, was partly offset by a net unfavorable impact from product mix, as well as by certain manufacturing inefficiencies associated with ramp up of production of new products.

Research and development ("R&D") expense. For the third quarter of fiscal 2022, R&D expense increased 6.0%, or $0.7 million, compared to the prior-year quarter. For the first nine months of fiscal 2022, R&D expense increased 6.5%, or $2.3 million, compared to the same prior-year period. R&D expense as a percentage of revenue was 52.2% and 51.3% for the third quarter of fiscal 2022 and 2021, respectively, and 51.9% and 44.4% for the first nine months of fiscal 2022 and 2021, respectively. R&D expense as a percentage of revenue for the first nine months of fiscal 2021 reflected the impact of the $11.0 million in revenue recognized on the previously discussed Abbott milestone payment. For the third quarter and first nine months of fiscal 2022, the fiscal 2021 Vetex acquisition added $0.4 million and $1.3 million in R&D expense, respectively, compared to the same respective prior-year periods. The year-over-year increase in R&D expense for the third quarter and first nine months of fiscal 2022 was 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 third quarter of fiscal 2022, SG&A expense increased 63.0%, or $5.0 million, compared the prior-year quarter. For the first nine months of fiscal 2022, SG&A expense increased 45.3%, or $10.3 million, compared the same prior-year period. The increase in SG&A expense year-over-year for the third quarter and first nine months of fiscal 2022 was related to sales and marketing activities, including new hires and infrastructure investments, to support the commercialization of our *Pounce* and *Sublime* products. SG&A expense as a percentage of revenue was 51.7% and 33.0% for the third quarter of fiscal 2022 and 2021, respectively, and 44.8% and 28.1% for the first nine months of fiscal 2022 and 2021, respectively. SG&A expense as a percentage of revenue for the first nine months of fiscal 2021 reflected the impact of the $11.0 million in revenue recognized on the previously discussed Abbott milestone payment. We expect SG&A expenditures to continue to increase, as we continue to 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 third quarter and first nine months of fiscal 2022, acquired intangible asset amortization increased by $0.5 million and $1.5 million, respectively, compared to the same respective prior-year periods, as a result of the developed technology associated with the fiscal 2021 Vetex acquisition.

Acquisition transaction, integration and other costs. Both the third quarter and first nine months of fiscal 2021 included $0.5 million in legal, accounting and other due diligence costs specifically related to 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 consisted of accretion for liabilities associated with the fiscal 2021 Vetex acquisition.

Other expense. We reported other expense of $(0.1) million for both the third quarter of fiscal 2022 and 2021 and other expense of $(0.2) million and $(0.3) million for the first nine months of fiscal 2022 and 2021, respectively. Interest expense increased for the third quarter and first nine months of fiscal 2022, compared to the same respective prior-year periods, due to utilization of our revolving credit facility. Foreign currency gains largely offset the increase in interest expense year-over-year for the third quarter and first nine months of fiscal 2022. 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) reflected weakening (strengthening) of the Euro relative to the U.S. dollar in each respective period. We expect interest expense to increase in future periods. The weighted average interest rate on outstanding borrowings under our Revolving Credit Facility increased from 3.3% as of September 30, 2021 to 4.5% as of June 30, 2022. Further increases in interest rates on our borrowings, or additional borrowings, will increase quarterly interest expense above the level for the third quarter of fiscal 2022.

Income tax benefit (provision). For the third quarter of fiscal 2022, income tax benefit was $1.5 million, compared to income tax expense of $(0.8) million in the prior-year quarter. For the first nine months of fiscal 2022, income tax benefit was $3.2 million, compared to income tax expense of $(2.4) million in the same prior-year period. The prior-year fiscal 2021 tax expense reflected the impact to pretax income of the $11.0 million in license fee revenue recognized on the Abbott milestone payment received in the second quarter of fiscal 2021. The Company's effective tax rate reflected the impact of state income taxes, permanent tax items and discrete tax benefits, as well as operating results for one of our Ireland subsidiaries for which tax expense or benefit is offset by a valuation allowance. The tax benefit (expense) recognized in the third quarter and first nine months 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 the effects of equity compensation.

Segment Operating Results

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

	Three Months Ended June 30,			Nine Months Ended June 30,		
(In thousands)	**2022**	**2021**	**$ Change**	**2022**	**2021**	**$ Change**
Operating (loss) income:						
Medical Device	$ (7,308)	$ (2,491)	$ (4,817)	$ (16,712)	$ 5,480	$ (22,192)
In Vitro Diagnostics	3,387	3,378	9	10,262	10,407	(145)
Total segment operating (loss) income	(3,921)	887	(4,808)	(6,450)	15,887	(22,337)
Corporate	(3,222)	(3,271)	49	(9,034)	(8,695)	(339)
Total operating (loss) income	$ (7,143)	$ (2,384)	$ (4,759)	$ (15,484)	$ 7,192	$ (22,676)

Medical Device. Our Medical Device business reported an operating loss of $(7.3) million and $(2.5) million for the third quarter of fiscal 2022 and 2021, respectively, representing (41.7)% and (14.9)% of revenue, respectively. For the first nine months of fiscal 2022 and 2021, our Medical Device business reported an operating loss of $(16.7) million and operating income of $5.5 million, respectively, representing (31.6)% and 9.0% of revenue, respectively.

- Medical Device operating expenses, excluding product costs, increased $5.7 million and $13.2 million year-over-year for the third quarter and first nine months of fiscal 2022, respectively, primarily driven by investments in sales and marketing personnel and infrastructure to execute our long-term growth strategy. The fiscal 2021 Vetex acquisition added $1.0 million and $3.0 million in operating expenses, excluding product costs, for the third quarter and first nine months of fiscal 2022, respectively, primarily for R&D personnel and acquired intangible asset amortization. The third quarter of fiscal 2021 also included $0.5 million in Vetex acquisition-related costs.
- The year-over-year contribution to operating (loss) income from royalties and license fee revenue was consistent year-over-year for the third quarter of fiscal 2022 and declined $(11.4) million year-over-year for the first nine months of fiscal 2022. The decline in royalties and license fee revenue for the nine-month period was primarily driven by $11.0 million in license fee revenue recognized on the Abbott milestone payment received in the second quarter of fiscal 2021.
- Medical Device product gross profit increased $1.3 million and $3.4 million year-over-year for the third quarter and first nine months of fiscal 2022, respectively, on broad-based product sales growth. Product gross margins were 61.3% and 51.0% for the third quarter of fiscal 2022 and 2021, respectively, and 59.5% and 54.5% for the first nine months of fiscal 2022 and 2021, respectively. Prior-year gross margins for the third quarter and first nine months of fiscal 2021 were unfavorably impacted by $0.7 million in charges related to a product replacement matter for one of our contract-manufactured products. For the third quarter and first nine months of fiscal 2022, gross margins benefited from leverage on higher sales volume, in particular from sales of coating reagents. This was offset, in part, by the net unfavorable impact of product mix, as well as certain manufacturing inefficiencies associated with ramp up of production of new products.

In Vitro Diagnostics. Our In Vitro Diagnostics business reported operating income of $3.4 million for both the third quarter of fiscal 2022 and 2021, representing 46.2% and 47.5% of revenue, respectively. For the first nine months of fiscal 2022 and 2021, our In Vitro Diagnostics business reported operating income of $10.3 million and $10.4 million, respectively, representing 48.7% and 51.2% of revenue, respectively.

- IVD product gross profit increased $0.5 million and $1.1 million year-over-year for the third quarter and first nine months of fiscal 2022, respectively. IVD product gross margins were 64.8% and 63.4% for the third quarter fiscal 2022 and 2021, respectively, and 67.1% and 67.6% for the first nine months of fiscal 2022 and 2021, respectively. Year-over-year growth in sales of distributed antigen products provided an unfavorable mix impact to product gross margins for both the third quarter and first nine months of fiscal 2022. For the third quarter of fiscal 2022, this impact was more than offset by the favorable impact of leverage on higher sales volume, which benefited gross margins for both the third quarter and first nine months of fiscal 2022.
- IVD R&D and other revenue declined $0.4 million and $1.0 million year-over-year for the third quarter and first nine months of fiscal 2022, respectively, related to the completion of a customer development program.

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 $(3.2) million and $(3.3) million for the third quarter of fiscal 2022 and 2021, respectively, and $(9.0) million and $(8.7) million for the first nine months of fiscal 2022 and 2021, respectively. For both the third quarter and first nine months of fiscal 2021, Corporate expense included $0.5 million in legal, accounting and other due diligence costs specifically related to the fiscal 2021 Vetex acquisition.

Cash Flow Operating Results

The following is a summary of cash flow results:

	Nine Months Ended June 30,	
(In thousands)	**2022**	**2021**
Cash (used in) provided by:		
Operating activities	$ (14,723)	$ 14,500
Investing activities	4,802	16,644
Financing activities	(673)	198
Effect of exchange rates on changes in cash and cash equivalents	(485)	50
Net change in cash and cash equivalents	$ (11,079)	$ 31,392

Operating Activities. Cash used in operating activities totaled $(14.7) million for the first nine months of fiscal 2022, compared to cash provided of $14.5 million in the same prior-year period. Net loss was $(12.5) million for the first nine months of fiscal 2022, compared to net income of $4.5 million for the first nine months of fiscal 2021. Net changes in operating assets and liabilities reduced cash flows from operating activities by $(11.9) million and $(1.2) million during the first nine months of fiscal 2022 and 2021, respectively. Significant changes in operating assets and liabilities affecting cash flows during these periods included:

- Cash used in inventories was $(4.2) million for the first nine months of fiscal 2022, compared to cash used of $(0.3) million in the same prior-year period. The current-year cash used in inventories was primarily driven by the commercialization of *Pounce* and *Sublime* platforms in our Medical Device business, as well as prudent management of safety stock to mitigate supply chain risks.
- Cash used in deferred revenue was $(3.5) million for the first nine months of fiscal 2022, compared to cash provided of $0.2 million in the same prior-year period, due to the $15 million milestone payment received from Abbott in the second quarter of fiscal 2021, offset by related license fee revenue recognition.
- Cash used in prepaids and other was $(2.0) million for the first nine months of fiscal 2022, compared to cash used of $(0.1) million in the same prior-year period. The current-year cash used in prepaids and other was primarily driven by an increase in prepaid software licenses and implementation costs related to sales infrastructure investments, as well as the renewal of annual insurance premiums. In the prior-year period, cash used in prepaids and other was primarily related to an increase in Irish R&D tax credits receivable and the renewal of annual insurance premiums, offset by receipt of a $0.8 million Irish Development Authority grant payment.

Investing Activities. Cash provided by investing activities totaled $4.8 million and $16.6 million for the first nine months of fiscal 2022 and 2021, respectively. Maturities of available-for-sale investments, net of purchases, were a source of cash of $7.6 million and $20.5 million in the first nine months of fiscal 2022 and 2021, respectively. In the first nine months 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 $2.8 million and $2.9 million for the first nine months of fiscal 2022 and 2021, respectively.

Financing Activities. Cash used in financing activities totaled $(0.7) million for the first nine months of fiscal 2022, compared to cash provided of $0.2 million in the same prior-year period, 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. In the first nine months of fiscal 2022, the Company paid $0.5 million for acquisition of in-process R&D to satisfy a guaranteed milestone payment to the sellers of Embolitech, LLC.

Liquidity and Capital Resources

As of June 30, 2022, working capital totaled $30.6 million, a decrease of $9.8 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 $22.1 million as of June 30, 2022, a decrease of $18.8 million from $40.9 million as of September 30, 2021. This change was primarily driven by planned personnel, inventory and other operational expenditures related to commercialization of the *Pounce* and *Sublime* platforms in our Medical Device business, as well as payment of annual bonuses in the first quarter of fiscal 2022.

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. The outstanding balance on the revolving credit facility was $10 million as of June 30, 2022. 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 June 30, 2022, 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 $2.0 million as of June 30, 2022. 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.

We expect that increasing SG&A expenditures in fiscal 2022 related to sales and marketing activities, including new hires, to support the commercialization of our *Pounce* and *Sublime* products 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 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 $22.1 million as of June 30, 2022, 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 cash requirements also will be significantly impacted by the level of our investment in commercialization of our vascular intervention products, which we expect to continue, and whether we make future corporate transactions. We are evaluating and 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, Abbott and Medtronic, each comprised 10% and 14%, respectively, of our consolidated revenue for the nine months ended June 30, 2022. Revenue generated under our *SurVeil* DCB license agreement with Abbott represented 5% of total revenue for the nine months ended June 30, 2022. Apart from the *SurVeil* DCB license, Abbott has several separately licensed products which generate revenue for Surmodics, none of which represented more than 4% of total revenue for the nine months ended June 30, 2022. Medtronic has several separately licensed products that generate revenue for Surmodics, none of which represented more than 5% of our total revenue for the nine months ended June 30, 2022.

Critical Accounting Policies and Significant Estimates

Critical accounting policies are those policies that require the application of management's most challenging subjective or complex judgment, often as a result of the need to make estimates about the effect of matters that are inherently uncertain and may change in subsequent periods. Critical accounting policies involve judgments and uncertainties that are sufficiently likely to result in materially different results under different assumptions and conditions. For the nine months ended June 30, 2022, there were no significant changes in our critical accounting policies. For a detailed description of our other critical accounting policies and significant estimates, see Management's Discussion and Analysis of Financial Condition and Results of Operations under Item 7 in our Annual Report on Form 10-K for the fiscal year ended September 30, 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 pandemic and the effects of responses to it on healthcare systems, the general economy, our business partners, and our operations; our strategies for growth; the potential results of our strategies; potential clinical strategies for our products; our intent to evaluate further clinical investment in our products; our intent to pursue certain regulatory actions; the potential impact of U.S. Food and Drug Administration ("FDA") communications; the expected timing and duration of process and manufacturing validations for our products; our expected initiations of 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; 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 and interest expense; 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 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 June 30, 2022, we held $2.0 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.

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 June 30, 2022. Based on that evaluation, the Company’s Certifying Officers concluded that, as of the end of the period covered by this report, the Company’s disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) of the Exchange Act) were effective to ensure that information required to be disclosed by the Company in reports that it files under the Exchange Act is recorded, processed, summarized and reported within the time period specified in the Securities and Exchange Commission rules and forms, and to ensure that information required to be disclosed by the Company in the reports the Company files or submits under the Exchange Act is accumulated and communicated to the Company’s management, including its Certifying Officers, as appropriate, to allow timely decisions regarding required disclosures.

Changes in Internal Controls over Financial Reporting

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

PART II — OTHER INFORMATION

Item 1. Legal Proceedings

From time to time, 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 I, Item 1A, "Risk Factors" could affect our financial performance and could cause our actual results for future periods to differ materially from our anticipated results or other expectations, including those expressed in any forward-looking statements made in this Quarterly Report on Form 10-Q.

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

The following table presents the information with respect to purchases made by or on behalf of Surmodics, Inc. or any "affiliated purchaser" (as defined in Rule 10b-18(a)(3) under the Securities Exchange Act of 1934), of our common stock during the three months ended June 30, 2022.

	Total Number of Shares Purchased (1)	Average Price Paid Per Share	Total Number of Shares Purchased as Part of Publicly Announced Programs	Maximum Dollar Value of Shares that May Yet Be Purchased Under the Programs
Period:				
April 1 – 30, 2022	—	$ —	—	$ 25,300,000
May 1 – 31, 2022	718	34.62	—	25,300,000
June 1 – 30, 2022	282	38.91	—	25,300,000
Total	1,000	$ 35.83	—	

(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 June 30, 2022, 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.

July 27, 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: July 27, 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: July 27, 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 June 30, 2022, as filed with the Securities and Exchange Commission (the "Report"), I, Gary R. Maharaj, certify, pursuant to 18 U.S.C. §1350, as adopted pursuant to §906 of the Sarbanes-Oxley Act of 2002, that:

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

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

Dated: July 27, 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 June 30, 2022, as filed with the Securities and Exchange Commission (the "Report"), I, Timothy J. Arens, certify, pursuant to 18 U.S.C. §1350, as adopted pursuant to §906 of the Sarbanes-Oxley Act of 2002, that:

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

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

Dated: July 27, 2022

Signature: /s/ Timothy J. Arens

Timothy J. Arens
Senior Vice President of Finance and Chief Financial Officer