

**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 March 31, 2021

or

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

Commission File Number: 0-23837

Surmodics, Inc.

(Exact name of registrant as specified in its charter)

MINNESOTA

(State or other jurisdiction of incorporation or organization)

41-1356149

(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 April 23, 2021 was 13,868,000.

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PART I. FINANCIAL INFORMATION

Item 1. Unaudited Condensed Financial Statements

Surmodics, Inc. and Subsidiaries

Condensed Consolidated Balance Sheets

<i>(In thousands, except per share data)</i>	<u>March 31, 2021</u>	<u>September 30, 2020</u>
	<i>(Unaudited)</i>	
ASSETS		
Current Assets:		
Cash and cash equivalents	\$ 48,159	\$ 30,785
Available-for-sale securities	17,792	30,313
Accounts receivable, net of allowances of \$118 and \$130 as of March 31, 2021 and September 30, 2020, respectively	9,096	7,675
Contract assets — royalties and license fees	6,622	6,108
Inventories, net	6,309	5,966
Income tax receivable	1,657	2,391
Prepays and other	3,406	3,370
Total Current Assets	<u>93,041</u>	<u>86,608</u>
Property and equipment, net	29,745	30,103
Available-for-sale securities	4,071	—
Deferred income taxes	6,507	7,315
Intangible assets, net	12,028	13,283
Goodwill	27,190	27,185
Other assets	4,513	4,269
Total Assets	<u>\$ 177,095</u>	<u>\$ 168,763</u>
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities:		
Accounts payable	\$ 1,593	\$ 1,515
Accrued liabilities:		
Compensation	4,437	6,630
Accrued other	4,162	5,547
Deferred revenue	5,507	5,200
Total Current Liabilities	<u>15,699</u>	<u>18,892</u>
Deferred revenue, less current portion	11,763	10,796
Other long-term liabilities	7,552	8,020
Total Liabilities	<u>35,014</u>	<u>37,708</u>
Commitments and Contingencies (Note 17)		
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; 13,868 and 13,672 shares issued and outstanding as of March 31, 2021 and September 30, 2020, respectively	693	684
Additional paid-in capital	18,516	15,369
Accumulated other comprehensive income	3,231	3,174
Retained earnings	119,641	111,828
Total Stockholders' Equity	<u>142,081</u>	<u>131,055</u>
Total Liabilities and Stockholders' Equity	<u>\$ 177,095</u>	<u>\$ 168,763</u>

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 March 31,		Six Months Ended March 31,	
	2021	2020	2021	2020
<i>(In thousands, except per share data)</i>	<i>(Unaudited)</i>		<i>(Unaudited)</i>	
Revenue:				
Product sales	\$ 11,783	\$ 11,770	\$ 21,885	\$ 21,744
Royalties and license fees	20,052	8,221	29,386	18,369
Research, development and other	3,160	2,831	6,021	5,325
Total revenue	34,995	22,822	57,292	45,438
Operating costs and expenses:				
Product costs	4,170	3,769	7,913	6,972
Research and development	12,875	11,935	23,757	24,077
Selling, general and administrative	7,907	6,733	14,930	13,676
Acquired intangible asset amortization	560	541	1,116	1,135
Total operating costs and expenses	25,512	22,978	47,716	45,860
Operating income (loss)	9,483	(156)	9,576	(422)
Other income (expense):				
Investment income, net	28	210	69	460
Interest expense	(59)	(30)	(119)	(70)
Foreign exchange gain (loss)	73	(30)	(107)	(77)
Impairment loss on strategic investment and other	—	(479)	—	(478)
Other income (expense)	42	(329)	(157)	(165)
Income (loss) before income taxes	9,525	(485)	9,419	(587)
Income tax (provision) benefit	(1,438)	1,947	(1,606)	2,197
Net income	\$ 8,087	\$ 1,462	\$ 7,813	\$ 1,610
Basic net income per share	\$ 0.59	\$ 0.11	\$ 0.57	\$ 0.12
Diluted net income per share	\$ 0.58	\$ 0.11	\$ 0.56	\$ 0.12
Weighted average number of shares outstanding:				
Basic	13,746	13,507	13,699	13,474
Diluted	13,981	13,751	13,915	13,779

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

Surmodics, Inc. and Subsidiaries

Condensed Consolidated Statements of Comprehensive Income

	Three Months Ended March 31,		Six Months Ended March 31,	
	2021	2020	2021	2020
<i>(In thousands)</i>	<i>(Unaudited)</i>		<i>(Unaudited)</i>	
Net income	\$ 8,087	\$ 1,462	\$ 7,813	\$ 1,610
Other comprehensive (loss) income:				
Net changes related to available-for-sale securities, net of tax	(7)	(174)	(7)	(179)
Foreign currency translation adjustments	(1,768)	(768)	64	273
Other comprehensive (loss) income	(1,775)	(942)	57	94
Comprehensive income	<u>\$ 6,312</u>	<u>\$ 520</u>	<u>\$ 7,870</u>	<u>\$ 1,704</u>

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 March 31, 2021 and 2020					
	<i>(Unaudited)</i>		Additional Paid-In Capital	Accumulated Other Comprehensive Income	Retained Earnings	Total Stockholders' Equity
	Common Stock Shares	Amount				
<i>(In thousands)</i>						
Balance at December 31, 2020	13,739	\$ 687	\$ 16,160	\$ 5,006	\$ 111,554	\$ 133,407
Net income	—	—	—	—	8,087	8,087
Other comprehensive loss, net of tax	—	—	—	(1,775)	—	(1,775)
Issuance of common stock	8	—	296	—	—	296
Common stock options exercised, net	122	6	2,228	—	—	2,234
Purchase of common stock to pay employee taxes	(1)	—	(1,597)	—	—	(1,597)
Stock-based compensation	—	—	1,429	—	—	1,429
Balance at March 31, 2021	<u>13,868</u>	<u>\$ 693</u>	<u>\$ 18,516</u>	<u>\$ 3,231</u>	<u>\$ 119,641</u>	<u>\$ 142,081</u>
Balance at December 31, 2019	13,593	\$ 680	\$ 10,361	\$ 1,432	\$ 110,853	\$ 123,326
Net income	—	—	—	—	1,462	1,462
Other comprehensive loss, net of tax	—	—	—	(942)	—	(942)
Issuance of common stock	5	—	218	—	—	218
Common stock options exercised, net	12	—	9	—	—	9
Purchase of common stock to pay employee taxes	(1)	—	(411)	—	—	(411)
Stock-based compensation	—	—	1,304	—	—	1,304
Balance at March 31, 2020	<u>13,609</u>	<u>\$ 680</u>	<u>\$ 11,481</u>	<u>\$ 490</u>	<u>\$ 112,315</u>	<u>\$ 124,966</u>

	Six Months Ended March 31, 2021 and 2020					
	<i>(Unaudited)</i>		Additional Paid-In Capital	Accumulated Other Comprehensive Income	Retained Earnings	Total Stockholders' Equity
	Common Stock Shares	Amount				
<i>(In thousands)</i>						
Balance at September 30, 2020	13,672	\$ 684	\$ 15,369	\$ 3,174	\$ 111,828	\$ 131,055
Net income	—	—	—	—	7,813	7,813
Other comprehensive income, net of tax	—	—	—	57	—	57
Issuance of common stock	89	4	292	—	—	296
Common stock options exercised, net	125	6	2,234	—	—	2,240
Purchase of common stock to pay employee taxes	(18)	(1)	(2,241)	—	—	(2,242)
Stock-based compensation	—	—	2,862	—	—	2,862
Balance at March 31, 2021	<u>13,868</u>	<u>\$ 693</u>	<u>\$ 18,516</u>	<u>\$ 3,231</u>	<u>\$ 119,641</u>	<u>\$ 142,081</u>
Balance at September 30, 2019	13,504	\$ 675	\$ 10,740	\$ 396	\$ 110,705	\$ 122,516
Net income	—	—	—	—	1,610	1,610
Other comprehensive income, net of tax	—	—	—	94	—	94
Issuance of common stock	130	7	211	—	—	218
Common stock options exercised, net	20	—	100	—	—	100
Purchase of common stock to pay employee taxes	(45)	(2)	(2,267)	—	—	(2,269)
Stock-based compensation	—	—	2,697	—	—	2,697
Balance at March 31, 2020	<u>13,609</u>	<u>\$ 680</u>	<u>\$ 11,481</u>	<u>\$ 490</u>	<u>\$ 112,315</u>	<u>\$ 124,966</u>

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

Surmodics, Inc. and Subsidiaries

Condensed Consolidated Statements of Cash Flows

	Six Months Ended March 31,	
	2021	2020
<i>(In thousands)</i>	<i>(Unaudited)</i>	
Operating Activities:		
Net income	\$ 7,813	\$ 1,610
Adjustments to reconcile net income to net cash provided by operating activities:		
Depreciation and amortization	3,766	3,600
Stock-based compensation	2,862	2,697
Payment of contingent consideration obligations in excess of acquisition-date value	—	(608)
Deferred taxes	808	1,388
Loss on strategic investment	—	479
Provision for credit losses	(12)	137
Other	170	108
Change in operating assets and liabilities:		
Accounts receivable and contract asset	(1,908)	1,914
Inventories	(349)	(1,233)
Prepays and other	(409)	(622)
Accounts payable	(303)	(128)
Accrued liabilities	(2,705)	(1,826)
Income taxes	739	(3,615)
Deferred revenue	1,273	(2,644)
Net cash provided by operating activities	<u>11,745</u>	<u>1,257</u>
Investing Activities:		
Purchases of property and equipment	(1,973)	(2,311)
Payment for acquisition of intangible assets	(1,000)	—
Purchases of available-for-sale securities	(22,875)	(35,863)
Maturities of available-for-sale securities	31,318	27,425
Net cash provided by (used in) investing activities	<u>5,470</u>	<u>(10,749)</u>
Financing Activities:		
Issuance of common stock	2,536	318
Payments for taxes related to net share settlement of equity awards	(2,243)	(2,373)
Payment of contingent consideration obligations	—	(2,592)
Payments for acquisition of in-process research and development	(150)	(1,000)
Net cash provided by (used in) financing activities	<u>143</u>	<u>(5,647)</u>
Effect of exchange rate changes on cash	16	(14)
Net change in cash and cash equivalents	<u>17,374</u>	<u>(15,153)</u>
Cash and Cash Equivalents:		
Beginning of period	30,785	30,361
End of period	<u>\$ 48,159</u>	<u>\$ 15,208</u>
Supplemental Information:		
Cash paid for income taxes	\$ 16	\$ 6
Noncash investing and financing activities:		
Acquisition of property and equipment, net of refundable credits in other current assets and liabilities	641	87
Right-of-use assets obtained in exchange for new operating lease liabilities	44	597

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 March 31, 2021
(Unaudited)

1. Basis of Presentation

Overview

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

Basis of Presentation

The accompanying unaudited condensed consolidated financial statements include all accounts and wholly-owned subsidiaries and have been prepared in accordance with accounting principles generally accepted in the U.S. (“GAAP”). All intercompany transactions have been eliminated. The Company operates on a fiscal year ending on September 30. In accordance with the rules and regulations of the U.S. Securities and Exchange Commission (“SEC”), the Company has omitted footnote disclosures that would substantially duplicate the disclosures contained in the audited consolidated financial statements of the Company. These unaudited condensed consolidated financial statements should be read together with the audited consolidated financial statements for the fiscal year ended September 30, 2020, 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 assets and 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 six months ended March 31, 2021 are not necessarily indicative of the results that may be expected for the entire 2021 fiscal year.

Risk and Uncertainties

The COVID-19 pandemic is having, and may continue to have, an adverse effect on our business, results of operations, financial condition, and cash flows, and its future impacts remain highly uncertain and unpredictable. The Company has considered the disruptions caused by COVID-19, including lower than forecasted sales and customer demand and macroeconomic factors, that may impact its estimates. The Company has assessed the potential impact of the pandemic on certain accounting matters including, but not limited to, estimated sales-based royalties revenue; allowance for credit losses; inventory reserves; and the valuation of goodwill, intangible assets, other long-lived assets and investments, as of March 31, 2021 and through the date of this Quarterly Report on Form 10-Q. As of the date of issuance of these unaudited condensed consolidated financial statements, the extent to which the COVID-19 pandemic may materially impact the Company’s financial condition, liquidity or results of operations is uncertain. For further information, refer to “Risk Factors” in Part II, Item 1A of our Annual Report on Form 10-K for the fiscal year ended September 30, 2020.

New Accounting Pronouncements

Recently Adopted

In June 2016, the FASB issued ASU 2016-13, *Financial Instruments – Credit Losses, Measurement of Credit Losses on Financial Statements*. This ASU requires a financial asset (or a group of financial assets) measured at an amortized cost basis to be presented at the net amount expected to be collected. The allowance for credit losses is a valuation account that is deducted from the amortized cost basis of the financial asset(s) to present the net carrying value at the amount expected to be collected on the financial asset. We adopted this guidance using the modified retrospective method in the first quarter of fiscal 2021. The adoption of this guidance did not have a material impact on the Company’s condensed consolidated financial statements.

In December 2019, the FASB issued ASU 2019-12, *Simplifying the Accounting for Income Taxes*, which eliminates certain exceptions related to the approach for intraperiod tax allocation and to the methodology for calculating taxes during the quarters, as well as clarifies the accounting for enacted changes in tax laws. We adopted this guidance using a prospective approach in the first quarter of fiscal 2021. The adoption of this guidance did not have a material impact on the Company's condensed consolidated financial statements.

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

2. Revenue

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

(In thousands)	Three Months Ended March 31,		Six Months Ended March 31,	
	2021	2020	2021	2020
Medical Device				
Product sales	\$ 5,410	\$ 5,455	\$ 9,971	\$ 10,477
Royalties	7,474	6,714	15,383	15,613
Research, development and other	2,445	2,628	4,746	4,862
License fees	12,578	1,507	14,003	2,756
Total Revenue — Medical Device	27,907	16,304	44,103	33,708
In Vitro Diagnostics				
Product sales	6,373	6,315	11,914	11,267
Research, development and other	715	203	1,275	463
Total Revenue — In Vitro Diagnostics	7,088	6,518	13,189	11,730
Total Revenue	\$ 34,995	\$ 22,822	\$ 57,292	\$ 45,438

Contract assets totaled \$6.6 million and \$6.1 million as of March 31, 2021 and September 30, 2020, respectively. Fluctuations in the balance of contract assets result primarily from changes in sales-based and minimum royalties earned, but not collected at each balance sheet date due to payment timing and contractual changes in the normal course of business. For discussion of contract liability (deferred revenue) balances and remaining performance obligations, see Note 3 Collaborative Arrangements.

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") (the "Abbott Agreement"). Our *SurVeil* DCB is used to treat peripheral arterial disease in the upper leg (superficial femoral artery) and is currently being evaluated in our TRANSEND pivotal clinical trial. Abbott also received the option to negotiate an agreement for Surmodics' below-the-knee Sundance™ DCB product, which is currently being evaluated in a first-in-human trial. 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 the *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 March 31, 2021, the Company has received payments totaling \$60.8 million under the Abbott Agreement, which consist of the following: \$25 million upfront fee in fiscal 2018, \$10 million milestone payment in fiscal 2019, \$10.8 million milestone payment in the third quarter of fiscal 2020, and \$15 million milestone payment in the second quarter of fiscal 2021 upon receipt by Abbott of the clinical study report and related materials from the TRANSCEND pivotal trial that demonstrated the primary safety and primary clinical endpoints are non-inferior to the control device. As of March 31, 2021, the Company may receive an additional contingent milestone payment of up to \$30 million, pursuant to the terms of the Abbott Agreement, upon premarket approval (“PMA”) of our *SurVeil* DCB by the U.S. Food and Drug Administration. As of March 31, 2021, consideration from this potential regulatory milestone was fully constrained and excluded from the contract price, due to the high level of uncertainty of achievement as of March 31, 2021.

Revenue recognized from the Abbott agreement totaled \$12.5 million and \$1.5 million for the three months ended March 31, 2021 and 2020, respectively, and \$13.8 million and \$2.8 million for the six months ended March 31, 2021 and 2020, 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 \$3.0 million and \$2.8 million for the six months ended March 31, 2021 and 2020, respectively.

As of March 31, 2021 and September 30, 2020, deferred revenue from the upfront and milestone payments received under the Abbott Agreement of \$17.1 million and \$15.9 million, respectively, was recorded in the condensed consolidated balance sheets.

As of March 31, 2021, the estimated revenue expected to be recognized in future periods related to performance obligations that are unsatisfied for executed contracts with an original duration of one year or more totaled \$17.1 million. These remaining performance obligations relate to the Abbott Agreement, exclude the potential contingent milestone payment under the Abbott Agreement, and are expected to be recognized over the next five years through fiscal 2025 as services, principally the TRANSCEND clinical trial, are completed.

4. Fair Value Measurements

Assets and liabilities carried at fair value are classified and disclosed in one of the following three categories:

Level 1 — Quoted (unadjusted) prices in active markets for identical assets or liabilities.

Level 2 — Observable inputs other than quoted prices included in Level 1, such as quoted prices for similar assets or liabilities in active markets; quoted prices for identical or similar assets or liabilities in markets that are not active; or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the asset or liability.

Level 3 — Unobservable inputs to the valuation methodology that are supported by little or no market activity and that are significant to the measurement of the fair value of the assets or liabilities. Level 3 assets and liabilities include those whose fair value measurements are determined using pricing models, discounted cash flow methodologies or similar valuation techniques, as well as significant management judgment or estimation. In valuing Level 3 assets and liabilities, the Company is required to maximize the use of quoted market prices and minimize the use of unobservable inputs.

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

	March 31, 2021			
	Quoted Prices in Active Markets for Identical Instruments (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)	Total Fair Value
<i>(In thousands)</i>				
Assets				
Cash equivalents	\$ —	\$ 31,135	\$ —	\$ 31,135
Available-for-sale securities	—	21,863	—	21,863
Total assets	\$ —	\$ 52,998	\$ —	\$ 52,998

<i>(In thousands)</i>	September 30, 2020			
	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	\$ —	\$ 18,634	\$ —	\$ 18,634
Available-for-sale securities	—	30,313	—	\$ 30,313
Total assets	\$ —	\$ 48,947	\$ —	\$ 48,947

There were no transfers of assets between amounts measured using Level 3 fair value measurements during the six months ended March 31, 2021 and 2020.

5. Investments

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

<i>(In thousands)</i>	March 31, 2021				Balance Sheet Classification	
	Amortized Cost	Unrealized Gains	Unrealized Losses	Fair Value	Current Assets	Noncurrent Assets
Commercial paper and corporate bonds	\$ 21,870	\$ 1	\$ (8)	\$ 21,863	\$ 17,792	\$ 4,071
Total	\$ 21,870	\$ 1	\$ (8)	\$ 21,863	\$ 17,792	\$ 4,071

<i>(In thousands)</i>	September 30, 2020				Balance Sheet Classification	
	Amortized Cost	Unrealized Gains	Unrealized Losses	Fair Value	Current Assets	Noncurrent Assets
Commercial paper and corporate bonds	\$ 30,313	\$ 19	\$ (19)	\$ 30,313	\$ 30,313	\$ —
Total	\$ 30,313	\$ 19	\$ (19)	\$ 30,313	\$ 30,313	\$ —

6. Inventories

Inventories consisted of the following components:

<i>(In thousands)</i>	March 31, 2021	September 30, 2020
Raw materials	\$ 3,758	\$ 3,758
Work-in process	1,151	817
Finished products	1,400	1,391
Total	\$ 6,309	\$ 5,966

7. Other Assets

Other assets consisted of the following:

<i>(In thousands)</i>	March 31, 2021	September 30, 2020
Operating lease right-of-use assets	2,406	2,508
Other noncurrent assets	2,107	1,761
Other assets	\$ 4,513	\$ 4,269

9. Goodwill

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

<i>(In thousands)</i>	<u>In Vitro Diagnostics</u>	<u>Medical Device</u>	<u>Total</u>
Goodwill as of September 30, 2020	\$ 8,010	\$ 19,175	\$ 27,185
Currency translation adjustment	—	5	5
Goodwill as of March 31, 2021	<u>\$ 8,010</u>	<u>\$ 19,180</u>	<u>\$ 27,190</u>

10. Accrued Other Liabilities

Accrued other liabilities consisted of the following:

<i>(In thousands)</i>	<u>March 31, 2021</u>	<u>September 30, 2020</u>
Accrued professional fees	\$ 403	\$ 239
Accrued clinical study expense	1,708	2,206
Accrued purchases	810	647
Acquisition of in-process research and development and intangible assets	482	1,148
Due to customers	7	321
Construction-in-progress	—	272
Operating lease liability, current portion	464	436
Other	288	278
Total accrued other liabilities	<u>\$ 4,162</u>	<u>\$ 5,547</u>

11. Debt

On September 14, 2020, the Company entered into a secured revolving credit facility pursuant to a Loan and Security Agreement (the "Loan Agreement") with Bridgewater Bank (the "Bank"). The Loan Agreement provides for availability under a secured revolving line of credit of up to \$25 million (the "Loan"). The outstanding balance on the Loan was zero as of March 31, 2021 and September 30, 2020.

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

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

12. 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:

<i>(In thousands)</i>	Three Months Ended March 31,		Six Months Ended March 31,	
	2021	2020	2021	2020
Product costs	\$ 32	\$ 15	\$ 69	\$ 48
Research and development	305	168	589	430
Selling, general and administrative	1,092	1,121	2,204	2,219
Total	<u>\$ 1,429</u>	<u>\$ 1,304</u>	<u>\$ 2,862</u>	<u>\$ 2,697</u>

As of March 31, 2021, approximately \$10.1 million of total unrecognized compensation costs related to non-vested awards is expected to be recognized over a weighted average period of approximately 2.5 years.

Stock Option Awards

During the six months ended March 31, 2021 and 2020, the Company awarded 234,000 and 261,000 options to officers, directors and key employees with a weighted average grant date fair value per option of \$13.86 and \$14.24, respectively.

Restricted Stock Awards

During the six months ended March 31, 2021 and 2020, the Company awarded 65,000 and 60,000 restricted stock shares, respectively, to certain key employees and officers with a weighted average grant date fair value per share of \$37.48 and \$41.88, respectively.

Restricted Stock Unit Awards

During the six months ended March 31, 2021 and 2020, the Company awarded 12,000 and 17,000 restricted stock units, respectively, to directors and to key employees in foreign jurisdictions with a weighted average grant date fair value per unit of \$45.13 and \$40.73, respectively.

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. Shares issued under the ESPP totaled 8,000 and 7,000 for the six months ended March 31, 2021 and 2020, respectively.

13. Net Income Per Share Data

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

The following table sets forth the calculation of diluted weighted average shares outstanding:

<i>(In thousands)</i>	Three Months Ended March 31,		Six Months Ended March 31,	
	2021	2020	2021	2020
Basic weighted average shares outstanding	13,746	13,507	13,699	13,474
Dilutive effect of outstanding stock options, non-vested restricted stock, and non-vested restricted stock units	235	244	216	305
Diluted weighted average shares outstanding	<u>13,981</u>	<u>13,751</u>	<u>13,915</u>	<u>13,779</u>

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 both the three months ended March 31, 2021 and 2020 and 0.1 million and less than 0.1 million shares of common stock for the six months ended March 31, 2021 and 2020, respectively, as their inclusion would have had an antidilutive effect on diluted net income per share for the period.

14. Income Taxes

For interim income tax reporting, the Company estimates its annual effective tax rate and applies it to fiscal year-to-date pretax income (loss), excluding unusual or infrequently occurring discrete items. Tax jurisdictions with losses for which tax benefits cannot be realized are excluded. The Company recorded income tax expense of \$(1.4) million and income tax benefit of \$1.9 million for the three months ended March 31, 2021 and 2020, respectively, and income tax expense of \$(1.6) million and income tax benefit of \$2.2 million for the six months ended March 31, 2021 and 2020, respectively. For the three and six months ended March 31, 2020, the income tax benefit includes a discrete tax benefit of \$1.8 million as a result of our ability under the Coronavirus Aid, Relieve and Economic Security Act (the "CARES Act"), enacted in March 2020, to carry back net operating losses ("NOLs") incurred to periods when the statutory rate was 35% versus the current tax rate of 21%.

The effective income tax rate for the three and six months ended March 31, 2021 and 2020 differs from the U.S. federal statutory tax rate of 21% primarily due to the discrete tax benefits recognized under the CARES Act in the second quarter of fiscal 2020, favorable impacts of the U.S. federal research and development tax credits, stock award activity, and operating results of our Irish subsidiary, where tax benefit is offset by a valuation allowance. The Company recognized discrete tax benefits related to stock-based compensation awards vested, expired, cancelled and exercised of \$0.7 million and less than \$0.1 million in the three months ended March 31, 2021 and 2020, respectively and \$0.7 million and \$0.3 million in the six months ended March 31, 2021 and 2020, respectively.

The total amount of unrecognized tax benefits, excluding interest and penalties that, if recognized, would affect the effective tax rate was \$3.1 million and \$2.7 million as of March 31, 2021 and September 30, 2020, respectively. Interest and penalties related to unrecognized tax benefits are recorded in the income tax benefit.

The Company files income tax returns, including returns for its subsidiaries, in the U.S. federal jurisdiction and in various state jurisdictions as well as several non-U.S. jurisdictions. Uncertain tax positions are related to tax years that remain subject to examination. U.S. income tax returns for years prior to fiscal 2017 are no longer subject to examination by federal tax authorities. For tax returns for state and local jurisdictions, the Company is no longer subject to examination for tax years generally before fiscal 2009. For tax returns for non-U.S. jurisdictions, the Company is no longer subject to income tax examination for years prior to 2014. Additionally, the Company has been indemnified of liability for any taxes relating to Creagh Medical and NorMedix for periods prior to their respective acquisition dates, pursuant to the terms of the related share purchase agreements. There were no undistributed earnings in foreign subsidiaries as of March 31, 2021 and September 30, 2020.

15. Segment Information

Operating segments are components of an enterprise about which separate financial information is available that is evaluated regularly by the chief operating decision maker, who is the Company's Chief Executive Officer, in deciding how to allocate resources and in assessing performance. We operate two reportable segments:

- **Medical Device:** Surface modification coating technologies to improve access, deliverability, and predictable deployment of medical devices, as well as drug-delivery coating technologies to provide site-specific drug-delivery from the surface of a medical device, with end markets that include coronary, peripheral, neuro-vascular, and structural heart, among others; and the design, development, and manufacture of interventional medical devices, primarily balloons and catheters, including drug-coated balloons, for peripheral arterial disease treatment and other applications; and
- **In Vitro Diagnostics ("IVD"):** Design, development and manufacture of component products and technologies for diagnostic immunoassay, as well as molecular tests and biomedical research applications, with products that include protein stabilization reagents, substrates, surface coatings and antigens.

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

<i>(In thousands)</i>	Three Months Ended March 31,		Six Months Ended March 31,	
	2021	2020	2021	2020
Revenue:				
Medical Device	\$ 27,907	\$ 16,304	\$ 44,103	\$ 33,708
In Vitro Diagnostics	7,088	6,518	13,189	11,730
Total revenue	<u>\$ 34,995</u>	<u>\$ 22,822</u>	<u>\$ 57,292</u>	<u>\$ 45,438</u>
Operating income (loss):				
Medical Device	\$ 8,564	\$ (1,453)	\$ 7,971	\$ (1,876)
In Vitro Diagnostics	3,809	3,462	7,029	6,061
Total segment operating income	12,373	2,009	15,000	4,185
Corporate	(2,890)	(2,165)	(5,424)	(4,607)
Total operating income (loss)	<u>\$ 9,483</u>	<u>\$ (156)</u>	<u>\$ 9,576</u>	<u>\$ (422)</u>
Depreciation and amortization:				
Medical Device	\$ 1,721	\$ 1,439	\$ 3,373	\$ 2,894
In Vitro Diagnostics	88	109	193	219
Corporate	97	248	200	487
Total depreciation and amortization	<u>\$ 1,906</u>	<u>\$ 1,796</u>	<u>\$ 3,766</u>	<u>\$ 3,600</u>

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

16. Leases

Operating lease right-of-use assets and lease liabilities were as follows:

<i>(In thousands)</i>	March 31, 2021	September 30, 2020
Right-of-use assets:		
Other assets	\$ 2,406	\$ 2,508
Operating lease liabilities:		
Other accrued liabilities	\$ 464	\$ 436
Other long-term liabilities	3,293	3,340
Total operating lease liabilities	<u>\$ 3,757</u>	<u>\$ 3,776</u>

As of March 31, 2021, operating lease maturities for the remainder of fiscal 2021 and each of the next five fiscal years were as follows:

<i>(In thousands)</i>	
Remainder of 2021	\$ 303
2022	612
2023	625
2024	638
2025	651
2026	595
Thereafter	894
Total expected operating lease payments	4,318
Less: Imputed interest	(561)
Total operating lease liabilities	\$ 3,757

Operating lease cost was \$0.2 million and \$0.1 million for the three months ended March 31, 2021 and 2020, respectively, and \$0.4 million and \$0.3 million for the six months ended March 31, 2021 and 2020, respectively. Cash paid for operating lease liabilities approximated operating lease cost for the three and six month periods ended March 31, 2021 and 2020.

17. Commitments and Contingencies

InnoCore Technologies BV. In 2006, the Company entered into a license agreement whereby the Company obtained an exclusive license to a drug-delivery coating for licensed products within the vascular field, which included peripheral, coronary and neurovascular biodurable stent products. The license requires an annual, minimum payment of approximately \$0.2 million (at the Euro to US dollar exchange rate as of March 31, 2021) until the last patent expires, which is currently estimated to be May 2027. The total minimum future payments associated with this license are approximately \$1.5 million as of March 31, 2021. The license is currently utilized by one of the Company's drug delivery customers.

Clinical Trials. The Company has engaged clinical trial clinical research organization ("CRO") consultants to assist with the administration of its ongoing clinical trials. The Company has executed separate contracts with two CROs for services rendered in connection with the TRANSCEND pivotal clinical trial for the *SurVeil* DCB, including pass-through expenses paid by the CROs, of up to approximately \$29 million in the aggregate. As of March 31, 2021, 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 \$35 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 the fiscal 2019, the Company acquired certain intellectual property assets supporting ongoing development of the Company's medical device pipeline and paid the sellers \$0.8 million in fiscal 2019 and \$0.2 million in the first quarter of fiscal 2021. An additional \$1.1 million in payments is contingent upon achievement of certain strategic milestones within a contingency period ending in 2022.

In fiscal 2018, the Company acquired certain intellectual property assets of Embolitech, LLC (the "Embolitech Transaction"). As part of the Embolitech Transaction, the Company paid the sellers \$5.0 million in fiscal 2018, \$1.0 million in the second quarter of fiscal 2020, and \$1.0 million in the first quarter of fiscal 2021. The Company is obligated to pay additional installments totaling \$2.5 million in fiscal 2022 through fiscal 2024. These payments may be accelerated upon the occurrence of certain sales and regulatory milestones. An additional \$1.0 million payment is contingent upon the achievement of certain regulatory milestones within a contingency period ending in 2033.

As of March 31, 2021, \$0.5 million and \$1.8 million related to these asset acquisitions was recorded in other accrued liabilities and other long-term liabilities, respectively, on the condensed consolidated balance sheets. As of September 30, 2020, \$1.1 million and \$2.2 million related to these asset acquisitions was reported in other accrued liabilities and other long-term liabilities, respectively, on the condensed consolidated balance sheets.

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, 2020. 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.

Product Development

Our business model for our whole-product solutions strategy within our Medical Device segment is to design, develop and manufacture highly differentiated products that incorporate our proprietary catheter, balloon, thrombectomy and/or surface modification coating technologies to improve patient outcomes and reduce procedure costs, while maintaining patient safety. We are focused on developing devices that meet the needs of a spectrum of care settings ranging from hospitals, to ambulatory surgery centers, to office-based interventional labs in order to provide improved care and address unmet needs in the treatment of peripheral artery disease (“PAD”) and other vascular diseases.

Below is a brief summary of our pipeline of medical device products under development and recently commercialized, grouped by product platform.

Drug-coated balloons

- **SurVeil™ DCB** – paclitaxel-coated drug-coated balloon (“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.

We announced in January 2021 that our TRANSCEND clinical trial, the pivotal trial for the *SurVeil* DCB, met both the primary safety and primary efficacy endpoints, and the *SurVeil* DCB was found to be non-inferior in those endpoints to the Medtronic IN.PACT® Admiral® DCB, while delivering a substantially lower drug dose. In the second half of fiscal 2021, we expect to submit the PMA clinical report to the Food and Drug Administration (“FDA”) for premarket approval (“PMA”), including certain long-term vital status data required by the FDA.

In the second quarter of fiscal 2021, we delivered to Abbott the written clinical report and related materials that demonstrated the primary safety endpoint and primary efficacy endpoint for the TRANSCEND clinical study were met. As a result, we received a \$15 million milestone payment from Abbott in the second quarter of fiscal 2021, of which \$10.8 million was recognized as license fee revenue in the period.

- **Sundance™ DCB** – sirolimus-coated DCB to treat below-the-knee PAD. We commenced the SWING first-in-human, 35-patient clinical study of our *Sundance* DCB in the third quarter of fiscal 2020. In the second quarter of fiscal 2021, we completed enrollment in the SWING clinical study. We expect six-month results from the SWING clinical study to be available in the first quarter of fiscal 2022.

- **A vess™ 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 A vess DCB. In fiscal 2020, initial study results were received and demonstrated promising early safety data and performance insights, with greater than 90% of treated patients free from revascularization at six months. In fiscal 2021, we are completing the build out of the full matrix of A vess balloon sizes. In the second half of fiscal 2021, we plan to begin process and product validation efforts and to continue to assess the optimal regulatory and clinical strategy for our A vess DCB.

Thrombectomy

- **Pounce™ thrombectomy platform** – mechanical thrombectomy technology designed to remove thrombus or emboli (clots) from the vasculature. The *Pounce* technology platform has the potential to extend to other vascular indications beyond arterial with further development.

In the fourth quarter of fiscal 2020, we received FDA 510(k) clearance on our first thrombectomy device, the *Pounce* Thrombus Retrieval System, intended for the non-surgical removal of thrombi and emboli (clots) from the peripheral arterial vasculature. We expect to initiate limited product evaluation activities for our *Pounce* Thrombus Retrieval System in the second half of fiscal 2021 to assess human-use factors and product performance prior to commercialization.

Radial access

- **Sublime™ radial access platform** – access and therapeutic devices designed to provide radial (wrist) access to the peripheral vasculature. In fiscal 2019, we received FDA 510(k) clearance for our *Sublime* guide sheath, which enables the performance of lower extremity interventions from the radial artery. In the third quarter of fiscal 2020, we received FDA 510(k) clearance for the *Sublime* radial-access 0.014” percutaneous transluminal angioplasty (“PTA”) balloon catheter for treatment of lesions in arteries below the knee. An important precursor to commercialization of our radial access platform is establishment of product performance experience through physician evaluations in real-world case settings. These evaluations are designed to assess the human use factors and performance of these devices. Physician evaluations of both our *Sublime* guide sheath and 0.014” PTA balloon catheter products began in the second quarter of fiscal 2021 and are expected to continue through the second half of fiscal 2021.

In the third quarter of fiscal 2021, we submitted to the FDA for 510(k) clearance for our *Sublime* 0.018” PTA balloon catheter for treatment of lesions above the knee. Upon receipt of FDA clearance, we are targeting the first half of fiscal 2022 to initiate product evaluation activities for this product.

Specialty catheters

- **Telemark™** – coronary/peripheral support microcatheter. This product was commercialized in fiscal 2020 pursuant to an agreement with Medtronic plc (“Medtronic”) for distribution in the U.S. and Europe for coronary applications. Shipment of initial U.S. orders of our Telemark microcatheter commenced early in fiscal 2020. In the third quarter of fiscal 2020, we obtained CE Mark for our *Telemark* microcatheter and shipped initial European orders.
- **0.014” and 0.018” low-profile PTA balloon dilation catheters** – specialty PTA balloon catheters for difficult-to-treat lesions. These products were commercialized in fiscal 2020 pursuant to an agreement with Cook Medical for worldwide distribution, excluding Japan. Shipment of initial orders and the U.S. commercial launch commenced in the third quarter of fiscal 2020.

For more information regarding our product development and commercialization strategy, see Part I, Item 1 of our Annual Report on Form 10-K for the fiscal year ended September 30, 2020.

Coating Technology Patents

We generate royalties revenue from licensing our proprietary surface coating technology to customers. Medical Device royalties revenue was 30%, 35% and 38% of our total revenue for fiscal 2020, 2019 and 2018, respectively. The most significant source of royalties revenue was derived from our hydrophilic coating technology. The latest generation of our hydrophilic coating technology, our *Serene™* hydrophilic coating, is protected by a family of patents that begin to expire in 2033. Royalties revenue associated with our *Serene* hydrophilic coating technology increased approximately 27% in fiscal 2020, compared to the prior year, driven by customer product launches and resulting market share increases associated with customer device applications that incorporate this next-generation coating technology.

The family of patents that protected our fourth-generation PhotoLink™ hydrophilic coating technology expired in the first quarter of fiscal 2020 in all countries where patent coverage existed for the technology, except in Japan, where the relevant patent expired in the first quarter of fiscal 2021. Medical Device royalties revenue associated with our fourth-generation hydrophilic coating technology was approximately 14%, 21% and 21% of our total revenue for fiscal 2020, 2019 and 2018, respectively. Of the license agreements using our fourth-generation and early-generation *Photolink* technologies, most continue to generate royalties revenue for know-how and other proprietary rights, at a reduced royalty rate, beyond patent expiration. The amount of the decline in royalties and license fee revenue in fiscal 2020, compared to the prior year, related specifically to the expiration of fourth-generation hydrophilic coating patents was approximately \$5.5 million. In fiscal 2021, we expect a decline of less than \$2.0 million in royalties and license fee revenue, compared to the prior year, specific to the tail-end impact of these fourth-generation patent expirations, which reflects the mitigating impact of growth among our fourth-generation coating customers. In addition, we expect the decline in fourth-generation coating royalties to be more than offset by continued growth in our next-generation *Serene* hydrophilic coating royalties portfolio.

COVID-19 Pandemic

Our business, operations and financial condition and results have been and may continue to be impacted by the COVID-19 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-19. As fiscal 2021 has progressed, we are seeing a diminishing degree of Covid-related impacts to our reported revenue. However, the extent to which the COVID-19 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-19 and its variants, the resurgence of COVID-19 in regions that have begun to recover from the initial impact of the pandemic, the impact of COVID-19 on economic activity, and the actions to contain its impact on public health and the global economy. For further information, refer to "Risk Factors" in Part II, Item 1A of our Annual Report on Form 10-K for the fiscal year ended September 30, 2020.

Results of Operations

Three and Six Months Ended March 31, 2021

Revenue. Revenue for the second quarter of fiscal 2021 was \$35.0 million, an increase of 53.3%, compared to the second quarter of fiscal 2020. Revenue for the first six months of fiscal 2021 was \$57.3 million, an increase of 26.1%, compared to same prior-year period. The following is a summary of revenue by operating segment:

(In thousands)	Three Months Ended March 31,			Six Months Ended March 31,		
	2021	2020	% Change	2021	2020	% Change
Revenue						
Medical Device	\$ 27,907	\$ 16,304	71.2%	\$ 44,103	\$ 33,708	30.8%
In Vitro Diagnostics	7,088	6,518	8.7%	13,189	11,730	12.4%
Total Revenue	\$ 34,995	\$ 22,822	53.3%	\$ 57,292	\$ 45,438	26.1%

Medical Device. Medical Device revenue was \$27.9 million in the second quarter of fiscal 2021, an increase of 71.2% compared to \$16.3 million for the second quarter of fiscal 2020. Medical Device revenue for the six months ended March 31, 2021 was \$44.1 million, an increase of 30.8% as compared with \$33.7 million for the six months ended March 31, 2020.

Medical Device royalties and license fee revenue increased 143.9%, or \$11.8 million, for the second quarter of fiscal 2021 and increased 60.0%, or \$11.0 million, for the first six months of fiscal 2021, compared to the same prior-year periods. Abbott Agreement license fee revenue increased to \$12.5 million for the second quarter of fiscal 2021, compared to \$1.5 million in the prior-year quarter, driven primarily by \$10.8 million in revenue recognized from the \$15 million milestone payment received in the second quarter of fiscal 2021. For the first six months of fiscal 2021 and 2020, Abbott Agreement license revenue was \$13.8 million and \$2.8 million, respectively. Royalties revenue increased 11.3% to \$7.5 million for the second quarter of fiscal 2021, compared to \$6.7 million in the prior-year quarter, and royalties revenue declined 1.5% to \$15.4 million for the first six months of fiscal 2021, compared to \$15.6 million in the same prior-year period. Royalties revenue benefited from broad-based, year-over-year growth, most notably from our *Serene* coating customers. For the first six months of fiscal 2021, the year-over-year impact of the expiration our fourth-generation hydrophilic coatings was approximately \$1.0 million, largely in the first quarter. With respect to the impacts of COVID-19, in the second quarter of fiscal 2021, we experienced the lowest degree of impact to royalties revenue since the onset of the pandemic.

Medical Device product sales of \$5.4 million for the second quarter of fiscal 2021 were essentially flat compared to the same prior-year period. For the first six months of fiscal 2021, Medical Device product sales declined 4.8% to \$10.0 million, compared to the same prior-year period. For both the second quarter and first six months of fiscal 2021, product sales benefited from recently commercialized medical device products, compared to the prior year, and conversely, were unfavorably impacted by softness in legacy balloon catheter sales volume. Products sales of chemical reagents in the second quarter of fiscal 2021 were consistent with the prior year. For the first six months of fiscal 2021, product sales were unfavorably impacted by lower demand for chemical reagents early in the fiscal period as our customers managed inventory levels that had previously been increased in response to COVID-19.

In Vitro Diagnostics. In Vitro Diagnostics revenue increased 8.7% to a record \$7.1 million for the second quarter of fiscal 2021 and increased 12.4% to \$13.2 million for the first six months of fiscal 2021, compared to the same respective prior-year periods. Revenue growth in both the three- and six-month periods was driven by broad-based demand for our microarray slide/surface products and development projects, as well as for our protein stabilization and colorimetric substrate reagent products. For the second quarter of fiscal 2021, this growth was partly offset by unfavorable order timing for our distributed antigen products.

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

<i>(In thousands)</i>	Three Months Ended March 31,				Six Months Ended March 31,			
	2021		2020		2021		2020	
	Amount	% Total Revenue	Amount	% Total Revenue	Amount	% Total Revenue	Amount	% Total Revenue
Product costs	\$ 4,170	12%	\$ 3,769	17%	\$ 7,913	14%	\$ 6,972	15%
Research and development	12,875	37%	11,935	52%	23,757	42%	24,077	53%
Selling, general and administrative	7,907	23%	6,733	30%	14,930	26%	13,676	30%
Acquired intangible asset amortization	560	2%	541	2%	1,116	2%	1,135	3%

Product costs. Product gross margins (defined as product sales less related product costs, as a percentage of product sales) were 65% and 68% for the second quarter of fiscal 2021 and 2020, respectively, and 64% and 68% for the first six months of fiscal 2021 and 2020, respectively. For the second quarter of fiscal 2021, product gross margins were impacted unfavorably by product mix with a shift to lower margin product lines. For the first six months of fiscal 2021, product gross margin was unfavorably impacted by lower Medical Device revenue volume from a Covid-related decline in sales of coating reagents early in the fiscal period. This was offset, in part, by the favorable impact of In Vitro Diagnostics from both leverage on higher revenue volume and product mix in the first six months of fiscal 2021.

Research and development ("R&D") expense. For the second quarter of fiscal 2021, R&D expense increased 7.9%, or \$0.9 million, compared the same prior-year quarter. For the first six months of fiscal 2021, R&D expense declined 1.3%, or \$(0.3) million, compared the same prior-year period. R&D expense as a percentage of revenue was 37% and 52% for the second quarter of fiscal 2021 and 2020, respectively, and 42% and 53% for the first six months of fiscal 2021 and 2020, respectively. The decline in R&D expense as a percentage of revenue reflects the impact of higher revenue in the second quarter and first six months of fiscal 2021, principally from the \$10.8 million in license fee revenue recognized in the period upon receipt of the \$15 million clinical report

milestone payment under the Abbott Agreement. Clinical trial spending and other costs related to our *SurVeil* DCB declined for both the second quarter and first six months of fiscal 2021, compared to the same respective prior-year periods, with the progression of the TRANSCEND clinical trial from patient follow up in fiscal 2020 to preparation of the clinical report and PMA submission in fiscal 2021. For both the second quarter and first six months of fiscal 2021, the prior-year fiscal 2020 period is an unfavorable comparison with respect to incentive compensation resulting from the uncertainty in the prior year at the onset of the Covid pandemic.

Selling, general and administrative (“SG&A”) expense. For the second quarter of fiscal 2021, SG&A expense increased 17%, or \$1.2 million, compared the same prior year quarter. For the first six months of fiscal 2021, SG&A expense increased 9%, or \$1.3 million, compared the same prior-year period. SG&A expense as a percentage of revenue was 23% and 30% for the second quarter of fiscal 2021 and 2020, respectively, and 26% and 30% for the first six months of fiscal 2021 and 2020, respectively. The decline in SG&A expense as a percentage of revenue reflects the impact of higher revenue in the second quarter and first six months of fiscal 2021, principally from the \$10.8 million in license fee revenue recognized in the period upon receipt of the \$15 million clinical report milestone payment under the Abbott Agreement. For both the second quarter and first six months of fiscal 2021, the prior-year fiscal 2020 period is an unfavorable comparison with respect to incentive compensation resulting from the uncertainty in the prior year at the onset of the Covid pandemic.

Acquired intangible asset amortization. We have previously acquired certain intangible assets through business combinations. Amortization expense on acquired intangible assets was consistent for both the second quarter and first six months of fiscal 2021, compared the same respective prior-year periods.

Other income (expense). Other income was less than \$0.1 million for the second quarter of fiscal 2021, compared to other expense of \$(0.3) million for the second quarter of fiscal 2020. Other expense was \$(0.2) million for both the first six months of fiscal 2021 and 2020. The second quarter and first six months of fiscal 2020 includes a \$0.5 million impairment loss on a strategic investment to reduce the carrying value to zero. Investment income declined in the second quarter and first six months of fiscal 2021 relative to the prior year commensurate with a decline in interest rates. Foreign currency gains (losses) were \$0.1 million in gains in the second quarter of fiscal 2021, compared to less than \$(0.1) million in losses in the same prior year quarter. For both the first six months of fiscal 2021 and 2020, foreign currency losses were approximately \$(0.1) million. Foreign currency gains (losses) result primarily from the impact of U.S. to Euro exchange rate fluctuations on certain intercompany obligations. Foreign currency gains (losses) reflect weakening (strengthening) of the Euro relative to the U.S. dollar in each respective period.

Income tax (provision) benefit. For the second quarter of fiscal 2021, income tax expense was \$(1.4) million, compared to income tax benefit of \$1.9 million in the same prior-year quarter. For the first six months of fiscal 2021, income tax expense was \$(1.6) million, compared to income tax benefit of \$2.2 million in the same prior-year period. The fiscal 2021 tax expense aligns with the year-over-year increase in pretax income, primarily driven by the receipt of the Abbott milestone payment. In the second quarter of fiscal 2020, we recorded a discrete tax benefit of \$1.8 million as result of our ability under the Coronavirus Aid, Relief and Economic Security Act (the “CARES Act”), enacted in March 2020, to carry back net operating losses incurred to periods when the statutory tax rate was 35% versus our current tax rate of 21%.

The Company’s effective tax rate reflects the impact of state income taxes, permanent tax items and discrete tax benefits, as well as operating results in Ireland, where tax expense or benefit is offset by a valuation allowance. The tax (expense) benefit recognized in the second quarter and first six months of fiscal 2021 and 2020 reflect expected full-year pre-tax operating results, impacted by our estimated U.S. federal R&D tax credit and by excess tax benefits related to stock-based compensation due to equity award exercise activity.

Segment Operating Results

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

<i>(In thousands)</i>	Three Months Ended March 31,		Six Months Ended March 31,	
	2021	2020	2021	2020
Operating income (loss):				
Medical Device	\$ 8,564	\$ (1,453)	\$ 7,971	\$ (1,876)
In Vitro Diagnostics	3,809	3,462	7,029	6,061
Total segment operating income	12,373	2,009	15,000	4,185
Corporate	(2,890)	(2,165)	(5,424)	(4,607)
Total operating income (loss)	\$ 9,483	\$ (156)	\$ 9,576	\$ (422)

Medical Device. Our Medical Device business reported operating income of \$8.6 million and an operating loss of \$(1.5) million for the second quarter of fiscal 2021 and 2020, respectively, representing 30.7% and (8.9)% of revenue, respectively. For the first six months of fiscal 2021 and 2020, our Medical Device business reported operating income of \$8.0 million and an operating loss of \$(1.9) million, respectively, representing 18.1% and (5.6)% of revenue, respectively. The year-over-year increase in royalties and license fees contributed \$11.8 million and \$11.0 million to operating income for the second quarter and first six months of fiscal 2021, respectively, primarily as result of the Abbott milestone payment as previously discussed.

Medical Device product gross margins were 58.8% and 66.9% for the second quarter of fiscal 2021 and 2020, respectively, and 56.5% and 66.5% for the first six months of fiscal 2021 and 2020, respectively. For the second quarter of fiscal 2021, product gross margins were unfavorably impacted by product mix. For the first six months of fiscal 2021, product gross margins were unfavorably impacted by leverage on lower revenue volume and by product mix. Medical Device operating expenses, excluding product costs, increased \$1.2 million and decreased \$(0.3) million for the second quarter and first six months of fiscal 2021 and 2020, respectively, compared to the prior year, primarily driven by increased incentive compensation expense, partly offset by a decline in *SurVeil*-related R&D expense.

In Vitro Diagnostics. Our In Vitro Diagnostics business reported operating income of \$3.8 million and \$3.5 million for the second quarter of fiscal 2021 and 2020, respectively, representing 53.7% and 53.1% of revenue, respectively. For the first six months of fiscal 2021 and 2020, our In Vitro Diagnostics business reported operating income of \$7.0 million and \$6.1 million, respectively, representing 53.3% and 51.7% of revenue, respectively. Product gross margins were 69.5% and 68.9% in the second quarter fiscal 2021 and 2020, respectively, and 70.0% and 69.3% for the first six months of fiscal 2021 and 2020, respectively. For the second quarter of fiscal 2021, product margins benefited from the favorable impact of product mix. For the first six months of fiscal 2021, product gross margins benefited from leverage on higher revenue volume and the favorable impact of product mix.

Corporate. The Corporate category includes expenses for administrative corporate functions, such as executive, corporate accounting, legal, human resources and Board of Directors related fees and expenses, which have not been fully allocated to the Medical Device and IVD segments. Corporate operating expenses increased by \$0.7 million and \$0.8 million in the second quarter and first six months of fiscal 2021, respectively, compared to the same prior-year periods, related primarily to incentive compensation.

Liquidity and Capital Resources

As of March 31, 2021, working capital totaled \$77.3 million, an increase of \$9.6 million from September 30, 2020. Working capital is defined by us as current assets minus current liabilities. Cash and cash equivalents and available-for-sale investments totaled \$70.0 million as of March 31, 2021, an increase of \$8.9 million from \$61.1 million as of September 30, 2020. This change was primarily driven by the \$15 million clinical report milestone payment received under the Abbott Agreement, partly offset by \$2.7 million payments of accrued liabilities, \$2.0 million in capital expenditures, and the \$1.0 million payment to Embolitech, LLC as a result of the achievement of a contingent milestone in fiscal 2020.

Surmodics maintains access to capital to support liquidity and continued growth. In fiscal 2020, the Company entered into a secured revolving credit facility pursuant to a Loan and Security Agreement (the "Loan Agreement"). The Loan Agreement provides for availability of up to \$25 million under a secured revolving line of credit. The outstanding balance on the revolving credit facility was zero as of March 31, 2021. In fiscal 2020, the Company filed a universal shelf registration statement with the SEC as a matter of standard corporate governance to provide the flexibility to access public capital markets in order to respond to future business needs and opportunities. The shelf registration statement became effective on May 29, 2020 and 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 money market, corporate bond and commercial paper securities and are reported at fair value as available-for-sale investments totaling \$21.9 million as of March 31, 2021. Our investment policy requires that no more than 5% of investments be held in any one credit or issue, excluding U.S. government and government agency obligations. The primary investment objective of the portfolio is to provide for the safety of principal and appropriate liquidity, while generating an above-benchmark (Barclays Short Treasury 1-3 Month Index) total rate of return on a pre-tax basis.

We believe that our existing cash and cash equivalents and available-for-sale investments, which totaled \$70.0 million as of March 31, 2021, together with cash flow from operations, will provide liquidity sufficient to meet our cash needs and fund our operations and planned capital expenditures for the next twelve months. There can be no assurance, however, that our business will continue to generate cash flows at historic levels.

Cash Flow Operating Results. Cash flow results were are as follows:

<i>(In thousands)</i>	Six Months Ended March 31,	
	2021	2020
Cash provided by (used in):		
Operating activities	\$ 11,745	\$ 1,257
Investing activities	5,470	(10,749)
Financing activities	143	(5,647)
Effect of exchange rates on changes in cash and cash equivalents	16	(14)
Net change in cash and cash equivalents	<u>\$ 17,374</u>	<u>\$ (15,153)</u>

Operating Activities. Cash provided by operating activities totaled \$11.7 million for the first half of fiscal 2021, compared to cash provided of \$1.3 million in the same prior-year period. Net income was \$7.8 million and \$1.6 million for the first six months of fiscal 2021 and 2020, respectively. Net changes in operating assets and liabilities reduced cash flows from operating activities by \$3.7 million and \$8.2 million during the first six months of fiscal 2021 and 2020, respectively. Significant changes in operating assets and liabilities affecting cash flows during these periods included:

- Cash provided by deferred revenue was \$1.3 million for the first six months of fiscal 2021, compared to cash used of \$(2.6) million in the same prior-year period, due to the \$15 million milestone payment received from Abbott in the second quarter of fiscal 2021.
- Cash (used in) provided by accounts receivable and contract asset totaled \$(1.9) million cash used in the first six months of fiscal 2021, compared to cash provided of \$1.9 million in the same prior-year period. This was primarily due to timing fluctuations in accounts receivable balances and in contract asset balances, which were unfavorable to cash flow in the current-year quarter and favorable to cash flow in the prior-year quarter.

In the prior-year period, income taxes also impacted cash provided by operating activities. As a result of the NOL carryback provisions of the CARES Act, enacted in March 2020, income tax receivable increased to \$4.3 million as of March 31, 2020, compared to \$0.6 million as of September 30, 2019, and deferred income taxes decreased to \$4.8 million as of March 31, 2020, compared to \$6.2 million as of September 30, 2019. In the current-year fiscal 2021 period, income tax receivable decreased to \$1.7 million as of March 31, 2021, compared to \$2.4 million as of September 30, 2020, and deferred income taxes decreased to \$6.5 million as of March 31, 2021, compared to \$7.3 million as of September 30, 2020.

Additionally, the portion of acquisition-related contingent consideration and other payments classified as reduction of cash flows from operations was \$0.6 million in the first six months of fiscal 2020, as it related to accretion expense, which increased these obligations from the acquisition date through settlement.

Investing Activities. Cash provided by investing activities totaled \$5.5 million for the first six months of fiscal 2021, compared to cash used of \$(10.7) million in the same prior-year period. Net purchases and maturities of available-for-sale investments were a source of cash of \$8.4 million in the first six months of fiscal 2021 and a use of cash of \$(8.4) million in the first six months of fiscal 2020. In the first quarter of fiscal 2021, the Company paid \$1.0 million for acquisition of intangible assets (patents) to the sellers of Embolitech, LLC as a result of the achievement of a contingent milestone in fiscal 2020. Capital expenditures for property, plant and equipment totaled \$2.0 million and \$2.3 million for the first six months of fiscal 2021 and 2020, respectively.

Financing Activities. Cash provided by financing activities totaled \$0.1 million for the first six months of fiscal 2021, compared to cash used of \$(5.6) million in the same prior-year period. Issuance of common stock upon the exercise of stock options and vesting of other stock awards was a source of cash of \$2.5 million and \$0.3 million for the first six months of fiscal 2021 and 2020, respectively. In the first six months of fiscal 2021 and 2020, we paid \$2.2 million and \$2.4 million, respectively, to purchase common stock to pay employee taxes resulting from the exercise of stock options and vesting of other stock awards. In the first six months of fiscal 2020, contingent consideration payments totaled \$3.2 million related to the acquisition of NorMedix, Inc., with \$0.6 million and \$2.6 million classified as cash used in operating and financing activities, respectively.

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 19% and 14%, respectively, of our consolidated revenue for fiscal 2020. These same customers each comprised 30% and 11%, respectively, of our consolidated revenue for the six months ended March 31, 2021. Revenue generated under our *SurVeil* DCB license agreement with Abbott represented 24% of total revenue for the six months ended March 31, 2021. Apart from the *SurVeil* DCB license, Abbott has several separately licensed products which generate royalties revenue for Surmodics, none of which represented more than 3% of total revenue for the six months ended March 31, 2021. Medtronic has several separately licensed products that generate royalties revenue for Surmodics, none of which represented more than 4% of our total revenue for the six months ended March 31, 2021. No other individual customer constitutes more than 10% of Surmodics' total fiscal 2021 to date or fiscal 2020 revenue.

Share Purchase Activity

Our Board of Directors has authorized the repurchase of up to an additional \$25.3 million of the Company's outstanding common stock in open-market purchases, privately negotiated transactions, block trades, accelerated share repurchase transactions, tender offers or by any combination of such methods. The authorization has no fixed expiration date. No shares were repurchased in the six months ended March 31, 2021.

Off-Balance Sheet Arrangements

As of March 31, 2021 and September 30, 2020, we did not have any off-balance sheet arrangements that have, or are reasonably likely to have, a current or future effect on our financial condition, changes in financial condition, revenue or expenses, results of operations, liquidity, capital expenditures or capital resources that is material to investors.

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 six months ended March 31, 2021, there were no significant changes in our critical accounting policies. For a detailed description of our other critical accounting policies and significant estimates, see Management's Discussion and Analysis of Financial Condition and Results of Operations under Item 7 in our Annual Report on Form 10-K for the fiscal year ended September 30, 2020.

Forward-looking Statements

This Quarterly Report on Form 10-Q, including “Management’s Discussion and Analysis of Financial Condition and Results of Operations” in Item 2, contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. These statements include, but are not limited to, expectations concerning: the impacts, duration and severity of the global COVID-19 pandemic; clinical studies, the expected timing of their results, and the potential timing of future clinical studies; our business and growth strategy, including our ability to conduct market evaluations, and bring new products to market; the development of future products and their anticipated attributes; anticipated regulatory submissions and approvals, including the expected timing thereof; the initiation or continuation of product evaluation activities; revenue potential related to the potential commercial launch of the SurVeil™ drug-coated balloon (“DCB”) following its regulatory approval; estimated revenue expected to be recognized in future periods; future revenue growth and our future success; future gross margins and operating expenses; estimated future amortization expense; future operating lease maturities; recognition of unrecognized compensation costs; anticipated patent expirations and their potential impacts on our royalties revenue; expectation regarding specific product royalties portfolios; potential future customer actions; the potential for a future milestone payment under our agreement with Abbott; research and development plans and expenses, including the estimated cost associated with the TRANSCEND clinical trial; 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 for the next twelve months; extension of our revolving credit facility; future property and equipment investment levels; plans regarding our securities investments; the impact of potential lawsuits or claims; the impact of potential change in raw material prices; the impact of Abbott, Medtronic, as well as other significant customers; our ability to recognize the expected benefits of our acquisitions; our estimated tax rate for fiscal 2021; the future impact of off-balance sheet arrangements and contractual obligations, including future payments to clinical research organizations; estimated revenue expected to be recognized in future periods related to performance obligations that are unsatisfied for executed contracts; 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, 2020. 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 *A vess*™ 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 recession, customer mergers and acquisitions, business investment, changes in consumer confidence, and medical epidemics or pandemics such as the COVID-19 pandemic, which has negatively impacted, and will likely continue to negatively impact, our business and results from operations;
- 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 United States (“U.S.,”) Food and Drug Administration (“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 this Annual Report on Form 10-K, 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 SEC.

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 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 March 31, 2021, we held \$21.9 million in available-for-sale debt securities, of which \$17.8 million had maturity dates of less than one year. Therefore, interest rate fluctuations would have an insignificant impact on our results of operations or cash flows. Our policy also allows the Company to hold a substantial portion of funds in cash and cash equivalents, which are defined as financial instruments with original maturities of three months or less and may include money market instruments, certificates of deposit, repurchase agreements and commercial paper instruments.

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

We are exposed to increasing Euro currency risk with respect to our manufacturing operations in Ireland. In a period where the U.S. dollar is strengthening or weakening relative to the Euro, our revenue and expenses denominated in Euro currency are translated into U.S. dollars at a lower or higher value, respectively, 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 March 31, 2021. Based on that evaluation, the Company’s Certifying Officers concluded that, as of the end of the period covered by this report, the Company’s disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) of the Exchange Act) were effective to ensure that information required to be disclosed by the Company in reports that it files under the Exchange Act is recorded, processed, summarized and reported within the time period specified in the Securities and Exchange Commission rules and forms, and to ensure that information required to be disclosed by the Company in the reports the Company files or submits under the Exchange Act is accumulated and communicated to the Company’s management, including its Certifying Officers, as appropriate, to allow timely decisions regarding required disclosures.

Changes in Internal Controls over Financial Reporting

There were no changes in our internal control over financial reporting (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act) during the three months ended March 31, 2021 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II — OTHER INFORMATION

Item 1. Legal Proceedings

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

Item 1A. Risk Factors

In our Annual Report on Form 10-K for the fiscal year ended September 30, 2020, filed with the SEC on December 2, 2020, we identify under Part 1, Item 1A, “Risk Factors” important factors which 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.

There have been no material changes in our risk factors subsequent to the filing of our Annual Report on Form 10-K for the fiscal year ended September 30, 2020.

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

(c) Issuer Purchases of Equity Securities

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

Item 3. Defaults Upon Senior Securities

None.

Item 4. Mine Safety Disclosures

Not Applicable.

Item 5. Other Information

None.

Item 6. Exhibits

EXHIBIT INDEX

<u>Exhibit</u>	<u>Description</u>
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.
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.

April 28, 2021

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)

**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: April 28, 2021

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

**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: April 28, 2021

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

**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 March 31, 2021, as filed with the Securities and Exchange Commission (the "Report"), I, Gary R. Maharaj, certify, pursuant to 18 U.S.C. §1350, as adopted pursuant to §906 of the Sarbanes-Oxley Act of 2002, that:

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

Dated: April 28, 2021

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

**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 March 31, 2021, as filed with the Securities and Exchange Commission (the "Report"), I, Timothy J. Arens, certify, pursuant to 18 U.S.C. §1350, as adopted pursuant to §906 of the Sarbanes-Oxley Act of 2002, that:

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

Dated: April 28, 2021

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