UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, D. C. 20549

FORM 10-Q

(Mark One)

X

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

For the quarterly period ended June 30, 2020

or

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

Commission File Number: 0-23837



(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 \boxtimes No \square

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 \boxtimes No \square

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

 Large accelerated filer
 □
 Accelerated filer
 ⊠

 Non-accelerated filer
 □
 Smaller reporting company
 □
 Emerging Growth Company
 □

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

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

The number of shares of the registrant's Common Stock, \$0.05 par value per share, as of July 31, 2020 was 13,650,235.

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PART I. FINANCIAL INFORMATION

Item 1. Unaudited Condensed Financial Statements

Surmodics, Inc. and Subsidiaries

Condensed Consolidated Balance Sheets

		June 30, 2020	•	ember 30, 2019
(in thousands, except share and per share data) ASSETS		(Unauc	lited)	
Current Assets:				
Cash and cash equivalents	\$	36,386	\$	30,361
Available-for-sale securities	Ψ	24,178	Ψ	24,931
Accounts receivable, net of allowance for doubtful accounts of \$133 and \$200 as of		24,170		24,551
June 30, 2020 and September 30, 2019, respectively		8,657		8,993
Contract assets — royalties and license fees		4,248		8,210
Inventories, net		5,872		4,501
Income tax receivable		4,867		558
Prepaids and other		3,594		3,866
Total Current Assets		87,802	-	81,420
Property and equipment, net		28,939		29,748
Deferred income taxes		5,585		6,176
Intangible assets, net		12,585		14,226
Goodwill		26,563		26,171
Other assets		5,024		2,124
Total Assets	\$	166,498	\$	159,865
LIABILITIES AND STOCKHOLDERS' EQUITY				
Current Liabilities:				
Accounts payable	\$	1,375	\$	2,085
Accrued liabilities:				
Compensation		4,320		4,581
Accrued other		4,703		4,790
Deferred revenue		5,229		5,553
Contingent consideration				3,200
Total Current Liabilities		15,627		20,209
Deferred revenue, less current portion		12,423		11,628
Other long-term liabilities		7,865		5,512
Total Liabilities		35,915		37,349
Commitments and Contingencies (Note 16)				
Stockholders' Equity:				
Series A Preferred stock — \$.05 par value, 450,000 shares authorized; no shares				
issued and outstanding		_		_
Common stock — \$.05 par value, 45,000,000 shares authorized; 13,645,174 and				
13,504,102 shares issued and outstanding as of June 30, 2020 and				
September 30, 2019, respectively		682		675
Additional paid-in capital		13,658		10,740
Accumulated other comprehensive income		1,469		396
Retained earnings		114,774		110,705
Total Stockholders' Equity		130,583	+	122,516
Total Liabilities and Stockholders' Equity	\$	166,498	\$	159,865

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

Condensed Consolidated Statements of Operations

		Three Moi Jun		nded		Nine Mont June		30,	
		2020		2019		2020		2019	
(In thousands, except per share data)		(Unai	ıdited)		(Unaud				
Revenue:	^		<i>.</i>		<i>.</i>		<u>_</u>		
Product sales	\$	11,987	\$	9,870	\$	33,731	\$	29,508	
Royalties and license fees		12,398		11,624		30,767		31,652	
Research, development and other		2,498		2,850		7,823		8,101	
Total revenue		26,883		24,344		72,321		69,261	
Operating costs and expenses:									
Product costs		4,443		3,364		11,415		9,980	
Research and development		13,324		13,321		37,401		38,362	
Selling, general and administrative		7,416		5,939		21,092		16,764	
Acquired intangible asset amortization		536		599		1,671		1,809	
Contingent consideration expense (gain)			_	104				(248)	
Total operating costs and expenses		25,719		23,327		71,579		66,667	
Operating income		1,164		1,017		742		2,594	
Other income (expense):									
Investment income, net		124		269		584		850	
Interest expense		(29)		(38)		(99)		(112)	
Foreign exchange (loss) gain		(48)		(42)		(125)		99	
Impairment loss on strategic investment		—		—		(479)			
Other		_				1		9	
Other income (expense)		47		189		(118)		846	
Income before income taxes		1,211		1,206		624		3,440	
Income tax benefit		1,248		260		3,445		598	
Net income	\$	2,459	\$	1,466	\$	4,069	\$	4,038	
Basic net income per share	\$	0.18	\$	0.11	\$	0.30	\$	0.30	
Diluted net income per share	\$	0.18	\$	0.11	\$	0.30	\$	0.29	
Weighted average number of shares outstanding:									
Basic		13,601		13,394		13,577		13,384	
Diluted		13,786		13,726		13,775		13,776	

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

Condensed Consolidated Statements of Comprehensive Income

	Three Months Ended June 30,					Nine Mon Jun	ths End e 30,	led
		2020		2019		2020		2019
(In thousands)	(Unaud					(Unaud		
Net income	\$	2,459	\$	1,466	\$	4,069	\$	4,038
Other comprehensive income (loss):								
Unrealized holding gains on available-for-								
sale securities, net of tax		185		13		6		57
Foreign currency translation adjustments		794		520		1,067		(798)
Other comprehensive income (loss)		979		533		1,073		(741)
Comprehensive income	\$	3,438	\$	1,999	\$	5,142	\$	3,297

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

Condensed Consolidated Statements of Stockholders' Equity

		Thr	ee M	onths Ended		30, 2020 and	2019							
(In thousands)	Commo Shares	 ock Amount	Additional Paid-In Capital		Paid-In		Accumulated Other Comprehensive Income		Comprehensive			Retained Earnings	Sto	Total ockholders' Equity
Balance at March 31, 2020	13,609	\$ 680	\$	11,481	\$	490	\$	112,315	\$	124,966				
Net income		_		_		_		2,459		2,459				
Other comprehensive income, net of tax	—					979				979				
Issuance of common stock	3					_								
Common stock options exercised, net	33	2		849		—				851				
Purchase of common stock to pay employee taxes	—			(12)		_				(12)				
Stock-based compensation	—			1,340		—				1,340				
Balance at June 30, 2020	13,645	\$ 682	\$	13,658	\$	1,469	\$	114,774	\$	130,583				
Balance at March 31, 2019	13,489	\$ 674	\$	7,510	\$	1,444	\$	105,685	\$	115,313				
Net income	—					—		1,466		1,466				
Other comprehensive income, net of tax	—					533				533				
Issuance of common stock	1	1				—				1				
Common stock options exercised, net	1			12		—				12				
Purchase of common stock to pay employee taxes	(1)			(12)		—				(12)				
Stock-based compensation		 		1,319	_		_	_		1,319				
Balance at June 30, 2019	13,490	\$ 675	\$	8,829	\$	1,977	\$	107,151	\$	118,632				

			Nin	e Mo	onths Ended J		30, 2020 and 2 cumulated	019			
	Common Stock			Additional Paid-In		Other Comprehensive				Sto	Total ockholders'
(In thousands)	Shares	¢	Amount	¢	Capital	¢	Income		Earnings	¢	Equity
Balance at September 30, 2019	13,504	\$	675	\$	10,740	\$	396	\$	110,705	\$	122,516
Net income	_								4,069		4,069
Other comprehensive income, net of tax	—				—		1,073		—		1,073
Issuance of common stock	133		7		211		—				218
Common stock options exercised, net	53		2		949						951
Purchase of common stock to pay employee taxes	(45)		(2)		(2,279)				—		(2,281)
Stock-based compensation	—		_		4,037						4,037
Balance at June 30, 2020	13,645	\$	682	\$	13,658	\$	1,469	\$	114,774	\$	130,583
Balance at September 30, 2018	13,398	\$	670	\$	7,607	\$	2,718	\$	97,615	\$	108,610
Net impact from adoption of ASC Topic 606	—		_		—				5,498		5,498
Net income	_				_		_		4,038		4,038
Other comprehensive loss, net of tax	—				—		(741)				(741)
Issuance of common stock	135		7		203						210
Common stock options exercised, net	3				67						67
Purchase of common stock to pay employee taxes	(46)		(2)		(2,557)						(2,559)
Stock-based compensation	—		_		3,509				_		3,509
Balance at June 30, 2019	13,490	\$	675	\$	8,829	\$	1,977	\$	107,151	\$	118,632

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

Condensed Consolidated Statements of Cash Flows

		Nine Mont June		1
		2020		2019
(in thousands)		(Unau	dited)	
Operating Activities:	¢	4.000	¢	4.020
Net income	\$	4,069	\$	4,038
Adjustments to reconcile net income to net cash provided by (used in) operating activities:		F 200		E 400
Depreciation and amortization		5,390		5,462
Stock-based compensation		4,037		3,509
Payment of contingent consideration obligations in excess of acquisition-date value		(608)		(2,041)
Contingent consideration gain Deferred taxes		592		(248) (979)
Losses (gains) on strategic investments		479		(3/3)
Provision for bad debts		30		(7)
Other		176		(11)
Change in operating assets and liabilities:		170		(11)
Accounts receivable and contract asset		4,303		(1,009)
Inventories		(1,333)		(1,003)
Prepaids and other		(432)		(2,184)
Accounts payable		(489)		(2,104)
Accrued liabilities		116		(5,143)
Income taxes		(4,105)		(3,143)
Deferred revenue		471		(5,840)
Net cash provided by (used in) operating activities		12,696	-	(4,482)
Investing Activities:		12,050		(4,402)
Purchases of property and equipment		(2,627)		(4,135)
Purchases of available-for-sale securities		(45,766)		(26,117)
Maturities of available-for-sale securities		46,522		51,458
Cash proceeds from sales of property and equipment				10
Cash received from sale of strategic investment		_		7
Net cash (used in) provided by investing activities		(1,871)		21,223
Financing Activities:		(1,0/1)		21,225
Issuance of common stock		1,169		277
Payments for taxes related to net share settlement of equity awards		(2,385)		(2,688)
Payment of contingent consideration obligations		(2,592)		(9,064)
Payment of commigent consideration obligations Payments for acquisition of in process research and development		(1,000)		(3,004)
Net cash used in financing activities		· · · · · · · · · · · · · · · · · · ·		(11,475)
Effect of exchange rate changes on cash and cash equivalents		(4,808)		
				(18)
Net change in cash and cash equivalents		6,025		5,248
Cash and Cash Equivalents:		20.201		22.000
Beginning of period	<u>*</u>	30,361	<u>_</u>	23,668
End of period	\$	36,386	\$	28,916
Supplemental Information:				
Cash paid for income taxes	\$	9	\$	155
Noncash transactions from investing and financing activities:				
Acquisition of property and equipment, net of refundable credits in other current assets and liabilities		395		180
Right of use assets obtained in exchange for new operating lease liabilities		1,012		_

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

Surmodics, Inc. and Subsidiaries Notes to Condensed Consolidated Financial Statements Period Ended June 30, 2020 (Unaudited)

1. Basis of Presentation

The accompanying unaudited interim condensed consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America ("U.S.") ("GAAP") and, in the opinion of management, reflect all adjustments, consisting of normal recurring adjustments, needed to fairly present the financial results of Surmodics, Inc. and subsidiaries (referred to as "Surmodics", the "Company", "we," "us," "our" and other like terms) for the periods presented. 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, 2019, and footnotes thereto included in the Company's Annual Report on Form 10-K as filed with the SEC on December 3, 2019.

These financial statements include amounts that are based on management's best estimates and judgments. These estimates may be adjusted as more information becomes available, and any adjustment could be significant. The impact of any change in estimates is included in the determination of net income in the period in which the change in estimate is identified. The results of operations for the three and nine months ended June 30, 2020 are not necessarily indicative of the results that may be expected for the entire 2020 fiscal year.

Risks and Uncertainties

We are subject to risks and uncertainties as a result of the COVID-19 pandemic caused by a novel strain of coronavirus first identified in Wuhan, China in December 2019. On March 18, 2020, the Centers for Medicare & Medicaid Services ("CMS") released guidance for U.S. healthcare providers to limit nonemergent elective medical procedures other than high acuity treatments in order to conserve personal protective equipment and limit exposure to COVID-19. On April 16, 2020, the White House issued "Guidelines for Opening Up America Again" (the "White House Guidelines") that described a phased resumption of economic activities with gating conditions for a region or state to move from one phase to another. On June 9, 2020, CMS issued recommendations for regions and states in Phase II of the White House Guidelines that non-emergent, non-COVID-19 care should be offered to patients, as clinically appropriate, in localities or facilities that have the resources to provide such care, as well as the ability to quickly respond to a surge in COVID-19 cases, if necessary.

Since the White House Guidelines and related CMS recommendations were issued, rates of COVID-19 have vacillated by region and state, in some cases surging. Accordingly, consistent with the CMS recommendations, the degree to which elective medical procedures have been offered varies by region, state, and even between healthcare systems within a state. Where elective procedures have been offered, and even for emergency procedures, some people appear to have avoided healthcare facilities, presumably out of concern for contracting COVID-19. In addition, hospitals and other healthcare providers vary in the degree to which they are permitting access to their facilities during the pandemic. Further, the COVID-19 pandemic has negatively impacted the global economy, disrupted global supply chains and healthcare delivery, led to social distancing recommendations, and created significant volatility in financial markets.

Many of our customers use our licensed technology and purchased materials to manufacture products used in elective procedures. In addition, our customers and business partners need access to healthcare providers and facilities to effectively market, distribute and sell products incorporating our coating and device technologies, as well as our whole-product solutions. Likewise, we and our business partners need access to healthcare providers and facilities to conduct clinical trials and other activities required to achieve regulatory clearing for our products under development.

We believe differences in the rates of delivery and utilization of elective procedures in response to CMS recommendations and the pandemic have had, and will continue to have, an adverse impact, which may be material, on the Company's financial condition, liquidity and results of operations. The severity of the impact of the COVID-19 pandemic on our business will depend on a number of factors, including, but not limited to, the duration and severity of the pandemic and the extent and severity of the impact on our customers, all of which are uncertain and cannot be predicted. As of the date of issuance of these 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 this Quarterly Report on Form 10-Q.



New Accounting Pronouncements

Recently Adopted

In February 2016, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") ASU 2016-02, *Leases* ("*ASC Topic 842*"). The update maintains two classifications of leases: finance leases, which replace capital leases, and operating leases. Lessees recognize a right-of-use asset and a lease liability on the consolidated balance sheets for those leases previously classified as operating leases under the previous guidance. The liability is equal to the present value of lease payments, while the asset is based on the liability, subject to adjustment, such as for direct costs.

Effective October 1, 2019, the Company adopted the new lease accounting standard using the optional transition method which allowed us to continue to apply the guidance under the lease standard in effect at the time in the comparative periods presented. In addition, the Company elected the package of practical expedients, including opting not to reassess whether any existing contracts contain a lease, historical lease classification as operating or finance leases, or initial direct costs. The Company has also elected the practical expedient to not separate the lease and non-lease components for all classes of underlying assets. The Company elected the short-term lease recognition exemption for all leases that qualified and has accordingly excluded short-term leases from the recognition of right-of-use assets and lease liabilities.

As a result of adoption of ASC Topic 842, we recorded operating lease right-of-use assets and corresponding operating lease liabilities of approximately \$1.7 million and \$2.9 million, respectively, as of October 1, 2019 with no impact on retained earnings. In addition, deferred rent liabilities related to escalating rent payments and tenant incentives totaling approximately \$1.2 million were eliminated upon adoption, as these items are netted against right-of-use assets. The condensed consolidated balance sheets for reporting periods beginning on or after October 1, 2019 are presented under the new guidance, while prior period amounts are not adjusted and continue to be reported in accordance with previous guidance.

Not Yet 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. The accounting standard will be effective for the Company beginning in the first quarter of fiscal 2021 (October 1, 2020), using a modified retrospective approach. We have evaluated the impact of this standard on the Company's results of operations, cash flows and financial position, including accounting policies, processes and systems. We continue to monitor economic implications of the COVID-19 pandemic; however, based on current market conditions, we do not expect the impact to be material upon adoption.

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. The accounting standard will be adopted by the Company in the first quarter of fiscal 2021 (October 1, 2020) using a prospective approach. We have evaluated the impact of this standard on the Company's results of operations, cash flows and financial position, and we do not expect the impact to be material upon adoption.

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 operating segment, excluding sales taxes collected and remitted to governmental authorities.

	 Three Mon June		Ended		Nine Moi Jur	nths l ne 30,	
(Dollars in thousands)	2020	2019	9 2020			2019	
Medical Device							
Product sales	\$ 5,763	\$	4,500	\$	16,240	\$	13,836
Royalties	4,752		9,605		20,365		25,603
Research, development and other	2,353		2,821		7,215		8,016
License fees	7,646		2,019		10,402		6,049
Total Revenue — Medical Device	20,514		18,945		54,222		53,504
In Vitro Diagnostics							
Product sales	6,224		5,370		17,491		15,672
Other	145		29		608		85
Total Revenue — In Vitro Diagnostics	6,369		5,399	_	18,099		15,757
Total Revenue	\$ 26,883	\$	24,344	\$	72,321	\$	69,261

Contract Assets, Deferred Revenue and Remaining Performance Obligations

Contract asset balances consist of estimated sales-based royalties earned but not collected at each balance sheet date and are subject to timing fluctuations at the end of a given period. The Company's deferred revenue, or contract liability, is primarily related to the upfront and milestone payments received pursuant to the collaborative license and commercialization agreement (the "Abbott Agreement") with Abbott Vascular, Inc. ("Abbott") for the Company's SurVeil[™] drug-coated balloon product ("*SurVeil* DCB") discussed in Note 3.

As of June 30, 2020, 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 approximately \$17.5 million. These remaining performance obligations relate to the Abbott Agreement (Note 3), exclude contingent milestone payments 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.

3. Collaborative Arrangement

Under the Abbott Agreement, Abbott will have exclusive worldwide commercialization rights for the *SurVeil* DCB to treat the superficial femoral artery, which is currently being evaluated in a U.S. pivotal clinical trial. Separately, Abbott also received options to negotiate agreements for Surmodics' below-the-knee and arteriovenous ("AV") fistula drug-coated balloon ("DCB") products. The below-the-knee DCB, our SundanceTM DCB, is currently in preclinical development. A first-in-human clinical study has been completed for the AV fistula DCB, our AvessTM DCB, and Abbott has informed the Company that it has elected not to negotiate for distribution rights for this product. Surmodics is responsible for conducting all necessary clinical trials and other activities required to achieve U.S. and European Union regulatory clearances 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.

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.

Under the Abbott Agreement, the Company has received payments totaling \$45.8 million which consisted of the following: \$25 million upfront fee in fiscal 2018, \$10.0 million milestone payment in the fourth quarter of fiscal 2019, and \$10.8 million milestone payment in the third quarter of fiscal 2020. The Company may receive up to \$45 million of additional payments under the Abbott Agreement upon achievement of certain clinical and regulatory milestones. Revenue recognized from the Abbott agreement totaled \$7.6 million and \$2.0 million in the three months ended June 30, 2020 and 2019, respectively, and \$10.4 million and \$5.9 million in the nine months ended June 30, 2020 and 2019, respectively. Revenue recognized from the Abbott Agreement, which was included in the respective beginning of fiscal year balances of deferred revenue in the consolidated balance sheets, totaled \$3.7 million and \$5.9 million for the nine months ended June 30, 2020 and 2019, respectively. As of June 30, 2020 and September 30, 2019, deferred



revenue from the upfront and milestone payments received of \$17.5 million and \$17.1 million, respectively, was recorded in the condensed consolidated balance sheets. Upon the commercialization of the *SurVeil* DCB, Surmodics will be responsible for the manufacture and supply of clinical and commercial quantities of the product. Revenue from these product sales, including a per-unit transfer price and a share of net profits resulting from third-party sales by Abbott, will be recognized when these products are shipped and control is transferred to the customer.

4. Fair Value Measurements

The accounting guidance on fair value measurements defines fair value, establishes a framework for measuring fair value under GAAP, and expands disclosures about fair value measurements. The guidance is applicable for all financial assets and financial liabilities and for all nonfinancial assets and nonfinancial liabilities recognized or disclosed at fair value in the financial statements on a recurring basis (at least annually). Fair value is defined as the exchange price that would be received from selling an asset or paid to transfer a liability (an exit price) in an orderly transaction between market participants at the measurement date. When determining the fair value measurements for assets and liabilities required or permitted to be recorded at fair value, the Company considers the principal or most advantageous market in which it would transact and also considers assumptions that market participants would use when pricing the asset or liability, such as inherent risk, transfer restrictions and risk of nonperformance.

Fair Value Hierarchy

Accounting guidance on fair value measurements requires that assets and liabilities carried at fair value be classified and disclosed in one of the following three categories:

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

The Company did not have any Level 1 assets as of June 30, 2020 and September 30, 2019.

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.

The Company's Level 2 assets as of June 30, 2020 and September 30, 2019 consisted of money market funds, commercial paper instruments and corporate bonds.

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.

The Company's Level 3 liability as of September 30, 2019 consisted of contingent consideration obligations related to the fiscal 2016 acquisition of NorMedix, Inc. ("NorMedix").

Assets and Liabilities Measured at Fair Value on a Recurring Basis

In instances where the inputs used to measure fair value fall into different levels of the fair value hierarchy, the fair value measurement has been determined based on the lowest level input that is significant to the fair value measurement in its entirety. The Company's assessment of the significance of a particular item to the fair value measurement in its entirety requires judgment, including the consideration of inputs specific to the asset or liability.

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

				June 30	, 2020			
(Dollars in thousands)	Àctive M for Ide Instru	Quoted Prices in Active Markets for Identical Instruments (Level 1)		Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)		F	Total air Value
Assets								
Cash equivalents	\$	-	\$	29,714	\$	—	\$	29,714
Available-for-sale securities				24,178				24,178
Total assets	\$	_	\$	53,892	\$		\$	53,892
	Outed I		September 3 Significant Other Observable Inputs (Level 2)		30, 2019 Significant Unobservable Inputs (Level 3)		Total Fair Value	
(Dollars in thousands)	Active M for Ide Instrum (Leve	ntical ments	C	Other Observable Inputs	Uno	bservable Inputs	F	
Assets	Active M for Ide Instru (Leve	farkets ntical ments	0	Other Observable Inputs (Level 2)	Uno] (I	bservable Inputs		air Value
Assets Cash equivalents	Àctive M for Ide Instru	farkets ntical ments	C	Other Deservable Inputs (Level 2) 24,375	Uno	bservable Inputs	\$	air Value 24,375
Assets	Active M for Ide Instru (Leve	farkets ntical ments	0	Other Observable Inputs (Level 2)	Uno] (I	bservable Inputs		air Value
Assets Cash equivalents	Active M for Ide Instru (Leve	farkets ntical ments	0	Other Deservable Inputs (Level 2) 24,375	Uno] (I	bservable Inputs	\$	air Value 24,375
Assets Cash equivalents Available-for-sale securities	Active M for Ide Instrum (Leve	farkets ntical ments	\$	Other Diservable Inputs (Level 2) 24,375 24,931	Uno] (I \$	bservable Inputs	\$ \$	air Value 24,375 24,931
Assets Cash equivalents Available-for-sale securities Total assets	Active M for Ide Instrum (Leve	farkets ntical ments	\$	Other Diservable Inputs (Level 2) 24,375 24,931	Uno] (I \$	bservable Inputs	\$ \$	air Value 24,375 24,931

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

		Three Monti June 3		ded	Nine Mon June	e 30,			
(Dollars in thousands)	2020 2019				2020		2019		
Beginning balance	\$	—	\$	3,009	\$ 3,200	\$	14,466		
Additions		—		_					
Fair value adjustments		_		57			(454)		
Settlements		—		_	(3,200)		(10,979)		
Interest accretion		_		47			206		
Foreign currency translation loss (gain)		—		—			(126)		
Ending balance	\$		\$	3,113	\$ _	\$	3,113		

Settlements of contingent consideration liabilities consisted of payments to the sellers of NorMedix for revenue and value-creating milestones achieved. For the nine months ended June 30, 2020, acquisition-related contingent consideration payments totaling \$3.2 million were classified as \$0.6 million and \$2.6 million in cash flows used in operating and financing activities, respectively, in the condensed consolidated statements of cash flows. For the nine months ended June 30, 2019, acquisition-related contingent consideration payments totaling \$11.0 million were classified as \$2.0 million and \$9.0 million in cash flows used in operating and financing activities, respectively, in the condensed consolidated statements of cash flows.

There were no transfers of assets or liabilities between amounts measured using Level 1, Level 2, or Level 3 fair value measurements in fiscal 2020 and fiscal 2019.

Valuation Techniques

The valuation techniques used to measure the fair value of assets are as follows:

Cash equivalents — These assets are classified as Level 2 and are carried at historical cost, which is a reasonable estimate of fair value because of the relatively short time between origination of the instrument and its expected realization.

Available-for-sale securities — Fair market values for these assets are based on quoted vendor prices and broker pricing in active markets underlying the securities where all significant inputs are observable. To ensure the accuracy of quoted vendor prices and broker pricing, the Company performs regular reviews of investment returns to industry benchmarks and sample tests of individual securities to validate quoted vendor prices with other available market data.

5. Investments

Investments consisted principally of commercial paper and corporate bond securities and are classified as available-for-sale as of June 30, 2020 and September 30, 2019. These available-for-sale securities are reported at fair value with unrealized gains and losses, net of tax, excluded from the condensed consolidated statements of operations and reported in the condensed consolidated statements of comprehensive income as well as a separate component of stockholders' equity in the condensed consolidated balance sheets, except for other-than-temporary impairments, which are reported as a charge to current earnings as they occur. A loss would be recognized when there is an other-than-temporary impairment in the fair value of any individual security classified as available-for-sale, with the associated net unrealized loss reclassified out of accumulated other comprehensive income with a corresponding adjustment to other income. This adjustment would result in a new cost basis for the investment. Interest earned on debt securities, including amortization of premiums and accretion of discounts, is included in investment income, net within other income. Realized gains and losses from the sales of debt securities, which are included in other income, are determined using the specific identification method. Investment purchases are accounted for on the date the trade is executed, which may not be the same as the date the transaction is cash settled.

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

(Dollars in thousands)	A	Amortized Cost		Unrealized Gains		ealized osses		Fair Value
Commercial paper and corporate bonds	\$	24,161	\$	17	\$		\$	24,178
Total	\$	24,161	\$	17	\$		\$	24,178
				Septembe	er 30, 201	9		
(Dollars in thousands)	A	mortized Cost		ealized ains		ealized osses		Fair Value
Commercial paper and corporate bonds	\$	24,918	\$	13	\$		\$	24,931
T- (-)			+	4.0	÷		<i>_</i>	
Total	\$	24,918	\$	13	\$		\$	24,931

6. Inventories

Inventories are principally stated at the lower of cost or market using the specific identification method and include direct labor, materials and overhead, with cost of product sales determined on a first-in, first-out basis. Inventories consisted of the following components:

(Dollars in thousands)	J	une 30, 2020	Sept	tember 30, 2019
Raw materials	\$	3,394	\$	2,034
Work-in process		1,057		892
Finished products		1,421		1,575
Total	\$	5,872	\$	4,501

7. Other Assets

Other assets consisted of the following:

(Dollars in thousands)	ine 30, 2020	Sept	tember 30, 2019
ViaCyte, Inc.	\$ —	\$	479
Operating lease right-of-use assets	2,580		
Other noncurrent assets	2,444		1,645
Other assets	\$ 5,024	\$	2,124

The Company invested a total of \$5.3 million in ViaCyte, Inc. ("ViaCyte"), a privately-held California-based biotechnology firm that is developing a unique treatment for diabetes using coated islet cells, the cells that produce insulin in the human body. As of September 30, 2019, the balance of the investment of \$0.5 million, which was net of previously recorded other-than-temporary impairments of \$4.8 million, was accounted for under the cost method and represented less than a 1% ownership interest. The Company does not exert significant influence over ViaCyte's operating or financial activities.

The carrying value of each cost method investment is reviewed quarterly for changes in circumstances or the occurrence of events that suggest the Company's investment may not be recoverable. The fair value of cost method investments is not adjusted if there are no identified events or changes in circumstances that may have a material effect on the fair value of the investment. In the nine months ended June 30, 2020, the Company recorded a \$0.5 million other-than-temporary impairment loss based on a current financing round and market valuations to reduce the carrying value of the investment in ViaCyte to zero.

Operating lease right-of-use assets as of June 30, 2020 are recorded in accordance with ASC Topic 842, which we adopted as of October 1, 2019. Other noncurrent assets include prepaid expenses related to our ongoing clinical trials and a receivable related to refundable Irish research and development tax credits.

8. Intangible Assets

Intangible assets consist principally of acquired patents and technology, customer lists and relationships, licenses, and trademarks. Intangible asset amortization expense was \$0.6 million and \$0.7 million for the three months ended June 30, 2020 and 2019, respectively, and \$1.8 million and \$2.0 million for the nine months ended June 30, 2020 and 2019, respectively.

Intangible assets consisted of the following:

	June 30, 2020									
(Dollars in thousands) Definite-lived intangible assets:	Weighted Average Ca Original Life (Years) A assets:				ccumulated nortization	_	Net			
Customer lists and relationships	8.9	\$	17,698	\$	(11,847)	\$	5,851			
Developed technology	11.5		9,565		(3,904)		5,661			
Non-compete	5.0		230		(230)		_			
Patents and other	16.5		2,321		(1,828)		493			
Total definite-lived intangible assets			29,814		(17,809)		12,005			
Unamortized intangible assets:										
Trademarks and trade names			580				580			
Total intangible assets		\$	30,394	\$	(17,809)	\$	12,585			

	September 30, 2019								
(Dollars in thousands)	Weighted Average Original Life (Years)	Gr	Gross Carrying Amount		Accumulated Amortization		Net		
Definite-lived intangible assets:									
Customer lists and relationships	8.9	\$	17,374	\$	(10,661)	\$	6,713		
Developed technology	11.5		9,490		(3,196)		6,294		
Non-compete	5.0		230		(196)		34		
Patents and other	16.5		2,321		(1,716)		605		
Total definite-lived intangible assets			29,415	_	(15,769)		13,646		
Unamortized intangible assets:									
Trademarks and trade names			580				580		
Total intangible assets		\$	29,995	\$	(15,769)	\$	14,226		



Based on the intangible assets in service as of June 30, 2020, estimated amortization expense for the remainder of fiscal 2020 and each of the next five fiscal years is as follows (*in thousands*):

Remainder of 2020	\$ 591
2021	2,321
2022	2,281
2023	1,701
2024	1,612
2025	1,575

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

9. Goodwill

Goodwill represents the excess of the cost of an acquired entity over the fair value assigned to the assets purchased and liabilities assumed in connection with a business acquisition. Goodwill is not amortized but is subject, at a minimum, to annual tests for impairment in accordance with accounting guidance for goodwill. The carrying amount of goodwill is evaluated annually, and between annual evaluations if events occur or circumstances change and indicate that the carrying amount of goodwill may be impaired.

Goodwill in the Medical Device reporting unit represents the gross value from the fiscal 2016 acquisitions of Creagh Medical Limited ("Creagh Medical") and NorMedix. Goodwill in the In Vitro Diagnostics reporting unit represents the gross value from the acquisition of BioFX Laboratories, Inc. ("BioFX") in fiscal 2007.

Goodwill was not impaired in either reporting unit based on the outcome of the fiscal 2019 annual impairment test which utilized a quantitative assessment. The carrying amount of goodwill was evaluated as of June 30, 2020 with consideration of macroeconomic, industry and Company-specific events and circumstances. As of and for the nine months ended June 30, 2020, there have been no events or circumstances that have occurred to indicate it is more likely than not that goodwill was impaired for either of the Company's reporting units.

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

(Dollars in thousands)	I	In Vitro Diagnostics	Medical Device	Total
Balance as of September 30, 2019	\$	8,010	\$ 18,161	\$ 26,171
Currency translation adjustment			392	392
Balance as of June 30, 2020	\$	8,010	\$ 18,553	\$ 26,563

10. Accrued Other Liabilities

Accrued other liabilities consisted of the following:

(Dollars in thousands)	ne 30, 2020	September 30, 2019
Accrued professional fees	\$ 232	\$ 434
Accrued clinical study expense	2,588	2,163
Accrued purchases	686	679
Acquisition of in process research and development	146	989
Due to customers	438	19
Operating lease liability, current portion	397	_
Deferred rent, current portion		130
Other	216	376
Accrued other liabilities	\$ 4,703	\$ 4,790



11. Stock-based Compensation

The Company has stock-based compensation plans under which it grants stock options, restricted stock awards, performance share awards, restricted stock units and deferred stock units. The Company recognizes share-based payments as an operating expense, based on their fair values, over the requisite service period.

Stock-based compensation expense was reported as follows in the condensed consolidated statements of operations:

	Three Months Ended June 30,					Nine Mon Jun	ths E e 30,	nded
(Dollars in thousands)	2020 2019			2019	2020) 20	
Product costs	\$	34	\$	34	\$	82	\$	98
Research and development		189		225		619		617
Selling, general and administrative		1,117		1,060		3,336		2,794
Total	\$	1,340	\$	1,319	\$	4,037	\$	3,509

As of June 30, 2020, approximately \$8.5 million of total unrecognized compensation costs related to non-vested awards is expected to be recognized over a weighted average period of approximately 2.3 years.

Stock Option Awards

The Company uses the Black-Scholes option pricing model to determine the weighted average grant date fair value of stock options granted. Stock option fair value assumptions and the weighted average fair value of stock options granted were as follows:

	 Three Mor June	nded	_	nded			
	2020 2019			20	020		2019
Stock option fair value assumptions:							
Risk-free interest rates	0.3%		2.2%		1.5%	ó	2.8%
Expected life (years)	4.7 4.6		4.6		4.6		4.5
Expected volatility	42.5%		36.0%		38.4%		33.6%
Dividend yield	—%		%		—%	ó	—%
Weighted average grant date fair value of stock options granted	\$ 13.00	\$	13.38	\$	14.13	\$	17.91

The risk-free interest rate assumption was based on the U.S. Treasury's rates for U.S. Treasury zero-coupon bonds with maturities similar to those of the expected term of the awards. The expected life of options granted was determined based on the Company's experience. Expected volatility was based on the Company's stock price movement over a period approximating the expected term. Based on management's judgment, dividend yields were expected to be zero for the expected life of the options. The Company also estimated forfeitures of options granted, which were based on historical experience.

Non-qualified stock options are granted at fair market value on the date of grant. Non-qualified stock options expire in seven years, or upon termination of employment or service as a Board member. With respect to members of our Board, non-qualified stock options generally become exercisable on a monthly pro-rata basis within the one-year period following the date of grant. With respect to our employees, non-qualified stock options generally become exercisable with respect to 25% of the shares on each of the first four anniversaries following the grant date. The stock-based compensation expense table above includes stock option expenses recognized related to these awards, which totaled \$0.6 million for each of the three months ended June 30, 2020 and 2019 and \$1.8 million and \$1.6 million for the nine months ended June 30, 2020 and 2019, respectively.

The total pre-tax intrinsic value of options exercised was \$0.4 million and less than \$0.1 million for the three months ended June 30, 2020 and 2019, respectively, and \$1.5 million and \$0.1 million for the nine months ended June 30, 2020 and 2019, respectively. Intrinsic value represents the difference between the Company's common stock fair market value on the date of exercise and the option's exercise price.

Restricted Stock Awards

The Company has entered into restricted stock agreements with certain key employees, covering the issuance of common stock ("Restricted Stock"). Under accounting guidance, these shares are considered to be non-vested shares. The Restricted Stock is



released to the key employees if they are employed by the Company at the end of the vesting period. Restricted Stock vesting periods range from one to three years. During the nine months ended June 30, 2020 and 2019, the Company awarded 64,390 and 45,049 Restricted Stock shares, respectively, to certain key employees and officers. Forfeiture of 14,289 and 800 Restricted Stock shares occurred during the nine months ended June 30, 2020 and 2019, respectively. As of June 30, 2020 and September 30, 2019, 97,473 and 90,409 Restricted Stock shares were outstanding, respectively. Compensation expense has been recognized for the estimated fair value of the common shares, net of estimated forfeitures, and is being charged to operating expenses over the vesting term. The stock-based compensation expense table includes Restricted Stock expenses recognized related to these awards, which totaled \$0.5 million for each of the three months ended June 30, 2020 and 2019 and \$1.5 million and \$1.3 million for the nine months ended June 30, 2020 and 2019, respectively.

Performance Share Awards

In fiscal 2017, the Company entered into performance share agreements with certain key employees covering the issuance of common stock ("Performance Shares"). The Organization and Compensation Committee of the Board of Directors (the "Committee") established cumulative revenue and cumulative earnings before interest, income taxes, depreciation and amortization ("EBITDA") for the three-year performance period as the performance objectives for the fiscal 2017 awards. The fiscal 2017 awards also included performance objectives related to achievement of the Company's strategic initiatives. Awards granted in fiscal 2017 were finalized in the first quarter of fiscal 2020 and resulted in the issuance of 67,653 shares, with a value of \$2.8 million, based on the performance objectives relative to actual results achieved during the performance period. The per share compensation cost for each award was fixed on the grant date. The stock-based compensation expense table includes Performance Shares expense recognized related to these awards, which totaled \$0.1 million for both the three and nine months ended June 30, 2019. Performance Shares expense recognized in the three and nine months ended June 30, 2019.

The fair values of the Performance Shares, at target, were \$1.2 million for awards granted in fiscal 2017. There have been no Performance Share awards granted subsequent to fiscal 2017.

Restricted Stock Units and Deferred Stock Units

During the nine months ended June 30, 2020 and 2019, the Company awarded 18,376 and 11,871 restricted stock units ("RSUs"), respectively, to nonemployee directors and certain key employees in foreign jurisdictions. RSU awards are not considered issued or outstanding common stock of the Company until they vest. As of June 30, 2020 and September 30, 2019, outstanding, unvested RSUs totaled 69,320 and 62,242, respectively. Compensation expense has been recognized for the estimated fair value of the common shares and is being charged to operating expenses over the vesting term. The estimated fair value of the RSUs was calculated based on the closing market price of Surmodics' common stock on the grant date. The stock-based compensation expense table includes RSU expenses recognized related to these awards, which totaled \$0.1 million for each of the three months ended June 30, 2020 and 2019 and \$0.4 million for each of the nine months ended June 30, 2020 and 2019.

Directors may elect to receive their annual fees for services to the Board in deferred stock units ("DSUs"). Directors may elect this option annually. During the nine months ended June 30, 2020 and 2019, 2,634 and 2,099 units, respectively, were issued with a total fair value of \$0.1 million and less than \$0.1 million in each respective period. Outstanding, fully vested DSUs totaled 32,363 and 29,729 as of June 30, 2020 and September 30, 2019, respectively. Stock-based compensation expense related to DSU awards totaled less than \$0.1 million for each of the three months ended June 30, 2020 and 2019 and \$0.1 million for each of the nine months ended June 30, 2020 and 2019 and \$0.1 million for each of the nine months ended June 30, 2020 and 2019.

1999 Employee Stock Purchase Plan

Under the amended 1999 Employee Stock Purchase Plan ("Employee Stock Purchase Plan"), the Company is authorized to issue up to 600,000 shares of common stock. All full-time and part-time U.S. employees can choose to contribute up to 10% of their annual compensation, with a limit of \$25,000, to purchase the Company's common stock at purchase prices defined within the provisions of the Employee Stock Purchase Plan. Employee contributions to the Employee Stock Purchase Plan included in accrued liabilities in the condensed consolidated balance sheets totaled \$0.2 million and less than \$0.1 million as of June 30, 2020 and September 30, 2019, respectively. Stock-based compensation expense recognized related to the Employee Stock Purchase Plan totaled less than \$0.1 million for each of the three months ended June 30, 2020 and 2019 and \$0.1 million and less than \$0.1 million for the nine months ended June 30, 2020 and 2019, respectively. The stock-based compensation expense table includes the Employee Stock Purchase Plan expenses.

12. 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 dilutive common equivalent shares outstanding during the period. The Company's potentially dilutive common shares are those that result from dilutive common stock options, non-vested stock relating to restricted stock awards, restricted stock units, and deferred stock units, as well as performance shares in years prior to fiscal 2020. Options to purchase shares of common stock as well as unvested restricted stock and performance stock units are considered to be potentially dilutive common shares.

The calculation of weighted average diluted shares outstanding excludes outstanding stock options associated with the right to purchase less than 0.1 million and 0.2 million shares of common stock for the three months ended June 30, 2020 and 2019, respectively, and less than 0.1 million and 0.1 million shares of common stock for the nine months ended June 30, 2020 and 2019, respectively, as their inclusion would have had an antidilutive effect on diluted net income per share for those periods.

The following table sets forth the denominator for the computation of basic and diluted net income per share (in thousands):

		Three Mor June	nded	Nine Months Ended June 30,				
		2020		2019		2020		2019
Net income available to common shareholders	\$	2,459	\$	1,466	\$	4,069	\$	4,038
Basic weighted average shares outstanding		13,601		13,394		13,577		13,384
Dilutive effect of outstanding stock options, non-vested restricted stock, restricted stock units, deferred stock units and performance								
shares		185		332		198		392
Diluted weighted average shares outstanding	_	13,786		13,726		13,775		13,776

The Company's Board of Directors has authorized the repurchase of up to \$25.3 million of the Company's outstanding common stock. This authorization does not have an expiration date.

13. Income Taxes

The Company recorded an income tax benefit of \$1.2 million and \$0.3 million for the three months ended June 30, 2020 and 2019, respectively, and \$3.4 million and \$0.6 million for the nine months ended June 30, 2020 and 2019, respectively. In the nine months ended June 30, 2020, the income tax benefit includes 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") to carry back NOLs incurred to periods when the statutory tax rate was 35% versus our current tax rate of 21%.

The CARES Act was enacted on March 27, 2020 and includes significant business tax provisions. In particular, the CARES Act modified the rules associated with net operating losses ("NOLs") and made technical corrections to tax depreciation methods for qualified improvement property. Under the temporary provisions of CARES Act, NOL carryforwards and carrybacks may offset 100% of taxable income for taxable years beginning before 2021. In addition, NOLs arising in 2018, 2019 and 2020 taxable years may be carried back to each of the preceding five years to generate a refund.

The effective income tax rate for the three and nine months ended June 30, 2020 and 2019 differs from the U.S. federal statutory tax rate of 21% primarily due to the discrete tax benefits recognized under the CARES Act for the nine-month period, favorable impacts of the U.S. federal research and development tax credits in both periods, stock award activity in the nine-month period, 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 less than \$0.1 million in each of three months ended June 30, 2020 and 2019 and \$0.3 million and \$0.5 million in the nine months ended June 30, 2020 and 2019 and \$0.3 million and \$0.5 million in the nine months ended June 30, 2020 and 2019 and \$0.3 million and \$0.5 million in the nine months ended June 30, 2020 and 2019 and \$0.3 million and \$0.5 million in the nine months ended June 30, 2020 and 2019 and \$0.3 million and \$0.5 million in the nine months ended June 30, 2020 and 2019 and \$0.3 million and \$0.5 million in the nine months ended June 30, 2020 and 2019 and \$0.3 million and \$0.5 million in the nine months ended June 30, 2020 and 2019 and \$0.3 million and \$0.5 million in the nine months ended June 30, 2020 and 2019 and \$0.3 million and \$0.5 million in the nine months ended June 30, 2020 and 2019 and \$0.3 million and \$0.5 million in the nine months ended June 30, 2020 and 2019 and \$0.3 million and \$0.5 million in the nine months ended June 30, 2020 and 2019 and \$0.3 million and \$0.5 million in the nine months ended June 30, 2020 and 2019 and \$0.3 million and \$0.5 million in the nine months ended June 30, 2020 and 2019 and \$0.5 million and \$0.5 milli

The total amount of unrecognized tax benefits, excluding interest and penalties that, if recognized, would affect the effective tax rate was \$2.8 million and \$2.1 million as of June 30, 2020 and September 30, 2019, respectively. Interest and penalties related to unrecognized tax benefits are recorded in the income tax benefit.

For interim income tax reporting, the Company estimates its annual effective tax rate and applies it to year-to-date pretax income, excluding unusual or infrequently occurring discrete items. Tax jurisdictions with losses for which tax benefits cannot be realized are

excluded. 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 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 June 30, 2020 and September 30, 2019.

14. Segment Information

The Company's management evaluates performance and allocates resources based on reported results for two reportable segments, as follows: (1) the Medical Device unit, which designs, develops and manufactures interventional medical devices, primarily for the peripheral vascular market; 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 urology, among others, and (2) the In Vitro Diagnostics unit, which consists of component products and technologies for diagnostic test kits and biomedical research applications, with products that include protein stabilization reagents, substrates, antigens and surface coatings.

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

		Three Mon June	nded		Nine Mont June		nded	
(Dollars in thousands)		2020 2019			2020	020		
Revenue:								
Medical Device	\$	20,514	\$	18,945	\$	54,222	\$	53,504
In Vitro Diagnostics		6,369		5,399		18,099		15,757
Total revenue	\$	26,883	\$	24,344	\$	72,321	\$	69,261
Operating income:								
Medical Device	\$	532	\$	753	\$	(1,344)	\$	1,087
In Vitro Diagnostics		3,254		2,475		9,315		7,845
Total segment operating income		3,786		3,228		7,971		8,932
Corporate		(2,622)		(2,211)		(7,229)		(6,338)
Total operating income	\$	1,164	\$	1,017	\$	742	\$	2,594
Depresiation and amoutination.								
Depreciation and amortization:	<i>.</i>		÷		÷		÷	
Medical Device	\$	1,424	\$	1,481	\$	4,318	\$	4,315
In Vitro Diagnostics		112		120		331		353
Corporate		254		286		741		794
Total depreciation and amortization	\$	1,790	\$	1,887	\$	5,390	\$	5,462

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

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

15. Leases

The Company leases facilities for research, office, manufacturing and warehousing. The Company determines whether a contract is a lease or contains a lease at inception date. Upon commencement, the Company recognizes a right-of-use asset and lease liability based on the net present value of the future minimum lease payments over the lease term at the commencement date. The net present value of future minimum lease payments recorded upon lease commencement is reduced by the discounted value of any leasehold improvement incentives payable to the Company considered to be in-substance fixed payments. The unamortized balance

of leasehold improvement incentives in the form of tenant allowances represents the primary difference between the balance of the right-of-use assets and operating lease liabilities. As the Company's leases typically do not provide an implicit rate, the Company's lease liabilities are measured on a discounted basis using the Company's incremental borrowing rate. Lease terms used in the recognition of right-of-use assets and lease liabilities include only options to extend the lease that are reasonably certain to be exercised. The condensed consolidated balance sheets do not include recognized assets or liabilities for leases that, at the commencement date, have a term of twelve months or less and do not include an option to purchase the underlying asset that is reasonably certain to be exercised. The Company recognizes such leases in the condensed consolidated statements of income on a straight-line basis over the lease term.

The Company's leases include one or more options to renew and extend the lease term at the Company's discretion. These renewal options are not included in right-of-use assets and lease liabilities as they are not reasonably certain of exercise. The Company regularly evaluates renewal options, and when they are reasonably certain to be exercised, the renewal period is included in the lease term.

Operating lease cost was \$0.2 million and \$0.5 million for the three and nine months ended June 30, 2020, respectively. Cash paid for operating lease liabilities approximated operating lease cost for the three and nine months ended June 30, 2020.

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

(Dollars in thousands) Right-of-use assets:	د 	June 30, 2020
Other assets	\$	2,580
Operating lease liabilities:		
Other accrued liabilities	\$	397
Other long-term liabilities		3,286
Total operating lease liabilities	\$	3,683

As of June 30, 2020, operating lease maturities for the remainder of fiscal 2020 and each of the next five fiscal years are as follows (in thousands):

\$ 114
586
612
625
638
651
1,521
4,747
(1,064)
\$ 3,683
\$ \$

As of June 30, 2020, the weighted average remaining lease term for operating leases was 7.6 years and the weighted average discount rate used to determine operating lease liabilities was 4.0%.

16. Commitments and Contingencies

Litigation. From time to time, the Company may become involved in various legal actions involving its operations, products and technologies, including intellectual property and employment disputes. The outcomes of these legal actions are not within the Company's complete control and may not be known for prolonged periods of time. In some actions, the claimants seek damages as well as other relief, including injunctions barring the sale of products that are the subject of the lawsuit, which if granted, could require significant expenditures or result in lost revenue. The Company records a liability in the condensed consolidated financial statements for these actions when a loss is known or considered probable and the amount can be reasonably estimated. If the reasonable estimate of a known or probable loss is a range, and no amount within the range is a better estimate, the minimum amount of the range is accrued.

If a loss is possible but not known or probable, and can be reasonably estimated, the estimated loss or range of loss is disclosed. In most cases, significant judgment is required to estimate the amount and timing of a loss to be recorded.

InnoCore Technologies BV. In fiscal 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 the Company to make an annual minimum payment of 200,000 euros (equivalent to \$225,000 using a euro to US dollar exchange rate of \$1.1228 to the Euro as of June 30, 2020) until the last patent expires, which is currently estimated to be September 2027. The total minimum future payments associated with this license are approximately \$1.7 million as of June 30, 2020. 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 \$26 million in the aggregate. As of June 30, 2020, an estimated \$10 million remains to be paid by the Company 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 fourth quarter of 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 addition, the Company is obligated to pay up to \$1.3 million of additional consideration upon achievement of certain strategic milestones within a contingency period ending in 2022, of which \$0.2 million is guaranteed to be paid in fiscal 2021.

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 and \$1.0 million in the second quarter of fiscal 2020. 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 \$2.0 million payment is contingent upon the achievement of certain regulatory milestones within a contingency period ending in 2033.

As of June 30, 2020, \$0.1 million and \$2.2 million related to these asset acquisitions is included in other accrued liabilities and other long-term liabilities, respectively, on the condensed consolidated balance sheets. As of September 30, 2019, \$1.0 million and \$2.1 million related to these asset acquisitions is included in other accrued liabilities and other long-term liabilities, respectively, on the 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, Inc. and subsidiaries (referred to as "Surmodics," the "Company," "we," "us," "our" and other like terms). 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 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, 2019. 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 is a leading provider of medical device and *in vitro* diagnostic technologies to the healthcare industry, with the mission of improving the detection and treatment of disease. We remain committed to developing medical device products and platforms leveraging the technologies and manufacturing capabilities in our Medical Device business unit for the treatment of peripheral arterial disease ("PAD") and other vascular diseases. Our primary focus has been the continued development of our drug-coated balloon ("DCB") platform, our radial access device platform, and our thrombectomy device platform.

COVID-19 Pandemic Update

A novel strain of coronavirus was first identified in Wuhan, China in December 2019. The disease caused by it, COVID-19, was declared a global pandemic by the World Health Organization in March 2020. On March 18, 2020, the Centers for Medicare & Medicaid Services ("CMS") released guidance for U.S. healthcare providers to limit non-emergent elective medical procedures other than high acuity treatments in order to conserve personal protective equipment and limit exposure to COVID-19. On April 16, 2020, the White House issued "Guidelines for Opening Up America Again" (the "White House Guidelines") that described a phased resumption of economic activities with gating conditions for a region or state to move from one phase to another. On June 9, 2020, CMS issued recommendations for regions and states in Phase II of the White House Guidelines that non-emergent, non-COVID-19 care should be offered to patients, as clinically appropriate, in localities or facilities that have the resources to provide such care, as well as the ability to quickly respond to a surge in COVID-19 cases, if necessary.

Since the White House Guidelines and related CMS recommendations were issued, rates of COVID-19 have vacillated by region and state, in some cases surging. Accordingly, consistent with the CMS recommendations, the degree to which elective medical procedures have been offered varies by region, state, and even between healthcare systems within a state. Where elective procedures have been offered, and even for emergency procedures, some people appear to have avoided healthcare facilities, presumably out of concern for contracting COVID-19. In addition, hospitals and other healthcare providers vary in the degree to which they are permitting access to their facilities during the pandemic. Further, the COVID-19 pandemic has negatively impacted the global economy, disrupted global supply chains and healthcare delivery, led to social distancing recommendations, and created significant volatility in financial markets.

In response to the pandemic and business disruptions, first and foremost, we have prioritized the health and safety of our employees, customers, suppliers and others with whom we partner in our business activities. We have instructed employees to work from home when possible and to maintain recommended physical distancing when working in our facilities. We also have eliminated non-essential in-person contact with customers, suppliers and other third parties.

Many of our customers use our licensed technology and purchased materials to manufacture products used in elective procedures. In addition, our customers and business partners need access to healthcare providers and facilities to effectively market, distribute and sell products incorporating our coating and device technologies, as well as our whole-product solutions. Likewise, we and our business partners need access to healthcare providers and facilities to conduct clinical trials and other activities required to achieve regulatory clearing for our products under development. We are carefully monitoring rapidly evolving changes in healthcare delivery systems and may adjust our operating and product development plans accordingly.

Given the unprecedented and dynamic nature of the COVID-19 pandemic, we cannot reasonably estimate the impacts it may have on our financial condition, results of operations or cash flows in the future. However, we expect that differences in the rates of delivery and utilization of elective procedures in response to CMS recommendations and the pandemic will have an adverse impact, which may be material, on our future revenues, profitability and cash flows. The extent and duration of that impact will depend upon the extent of procedure postponements and the duration of the pandemic.

Product Development

Our business model for our whole-product solutions strategy 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 consider the needs of various care settings ranging from hospitals, ambulatory surgery centers, to office-based interventional labs in order to provide improved care and address unmet needs in the treatment of PAD and other vascular diseases. Our strategy has been built on our investment in proprietary device technologies, as well as state-of-the-art medical device design, development and manufacturing capabilities. Over the past several years, we have made investments to enhance our clinical and regulatory capabilities, and in fiscal 2020, we have continued to make additional investments to obtain clinical data, reduce the time from product development to commercialization, and drive clinician engagement with our products after approval to optimize adoption.

Below is a brief summary of our pipeline of medical device products under development and recently commercialized, grouped by product family. All discussions of expectations and targeted timelines are subject to the uncertainty surrounding the COVID-19 pandemic.

Drug-coated balloons

SurVeilTM DCB – paclitaxel-coated DCB to treat PAD in the superficial femoral artery. In fiscal 2018, we entered into an agreement ("the Abbott Agreement") with Abbott Vascular, Inc. ("Abbott") that provided Abbott with exclusive worldwide commercialization rights to the *SurVeil* DCB product. Full enrollment in the TRANSCEND pivotal clinical trial of the *SurVeil* DCB was completed in the fourth quarter of fiscal 2020, patient follow-up visits are ongoing. We continue to engage with the FDA to determine how to treat data for the population of patients who are unable to complete their visit within the specified follow-up window as a result of COVID-19.

In the third quarter of fiscal 2020, we received Conformité Européenne Mark ("CE Mark") approval prerequisite for commercialization of the *SurVeil* DCB in the European Union. As a result, we received a \$10.8 million milestone payment from Abbott in the third quarter of fiscal 2020, of which \$6.7 million was recognized as license fee revenue in the period. As of the third quarter of fiscal 2020, the timeline for commercialization of the *SurVeil* DCB in the European Union is to be determined subject to the discretion of our partner, Abbott.

- AvessTM DCB paclitaxel-coated DCB for the treatment of arteriovenous ("AV") fistulae commonly associated with hemodialysis. We commenced and completed enrollment in a first-in-human clinical study of our *Avess* DCB in fiscal 2019. Initial study results received in the third quarter of fiscal 2020 demonstrated promising early safety data and performance insights. As of the third quarter of fiscal 2020, we continue to explore avenues with the study's principal investigators to publish study results. The Abbott Agreement includes options to negotiate further agreements for our *Avess* and SundanceTM DCB products. Abbott has informed the Company that it has elected not to negotiate for distribution rights for the *Avess* DCB product. We are currently assessing commercialization opportunities for our *Avess* DCB. We are targeting fiscal 2021 for the next regulatory milestone for our *Avess* DCB, attainment of the FDA investigational device exemption required to commence a pivotal clinical trial for this product.
- *Sundance* DCB sirolimus-coated DCB for the treatment of below-the-knee PAD. In the third quarter of fiscal 2020, we commenced enrollment in a first-in-human clinical study of this product. As of the third quarter of fiscal 2020, we are targeting completion of enrollment in this trial for the second half of fiscal 2021.

Radial access

• Sublime[™] radial access platform – access and therapeutic devices designed to provide access to and treat the peripheral vasculature via the radial (wrist) artery. In fiscal 2019, we received FDA 510(k) clearance for our *Sublime* guide sheath, which enables the delivery 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. An important precursor to commercialization of our radial access platform is establishment of clinical use within a market evaluation to assess the human use factors and clinical performance of these devices. As of the third quarter of fiscal 2020, we expect to begin market evaluation activities for our *Sublime* guide sheath and 0.014" PTA balloon catheter in fiscal 2021.

Thrombectomy

• **Pounce™ thrombectomy platform** – mechanical thrombectomy device designed to remove difficult, organized blood clots with potential applications for multiple vascular indications. Our goal is to expand our thrombectomy platform beyond arterial to include devices designed to treat deep vein thrombosis and pulmonary embolism. As of the third quarter of fiscal 2020, we have filed for FDA 510(k) clearance for our first indication, treatment of clots in the peripheral arteries, and are in review with the FDA. We are targeting 510(k) clearance for this first indication in fiscal 2020.

Specialty catheters

- *Telemark*[™] coronary/peripheral support microcatheter. In fiscal 2019, we executed an agreement with Medtronic plc ("Medtronic") to distribute our *Telemark* microcatheter in the U.S. and Europe. 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 *Telemark* 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. In fiscal 2019, we executed an agreement with Cook Medical for worldwide distribution, excluding Japan, of these products. 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, 2019.

PhotolinkTM Fourth-Generation Patents

Our fourth-generation *PhotoLink* hydrophilic coating technology is protected by a family of patents that expired in the first quarter of fiscal 2020 in all countries where patent coverage existed for this technology. The Medical Device business royalties revenue associated with our fourth-generation hydrophilic coating technology was approximately 21% of our fiscal 2019 revenue. Of the license agreements using our early-generation technologies, most continue to generate royalties revenue for know-how and other proprietary rights, at a reduced royalty rate, beyond patent expiration. The remainder of our royalties revenue are derived from our other coatings that are protected by a number of patents that extend to at least fiscal 2035.

Critical Accounting Policies and Significant Estimates

Critical accounting policies are those policies that require the application of management's most challenging, subjective or complex judgment, often as a result of the need to make estimates about the effect of matters that are inherently uncertain and may change in subsequent periods. Critical accounting policies involve judgments and uncertainties that are sufficiently likely to result in materially different results under different assumptions and conditions. For the nine months ended June 30, 2020, 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, 2019.

Results of Operations

Three and Nine Months Ended June 30, 2020

Revenue. Revenue for the third quarter of fiscal 2020 was \$26.9 million, an increase of 10.4%, as compared with the third quarter of fiscal 2019. Revenue for the nine months ended June 30, 2020 was \$72.3 million, an increase of 4.4%, as compared with the nine months ended June 30, 2019. The following is a summary of revenue by operating segment.

	 Three	Mon	ths Ended Ju	ıne 30,	Nine Months Ended June 30,					
(Dollars in thousands)	2020		% 2019 Change		2020		2019		% Change	
Revenue	 									
Medical Device	\$ 20,514	\$	18,945	8.3%	\$	54,222	\$	53,504	1.3%	
In Vitro Diagnostics	6,369		5,399	18.0%		18,099		15,757	14.9%	
Total Revenue	\$ 26,883	\$	24,344	10.4%	\$	72,321	\$	69,261	4.4%	



Medical Device. Medical Device revenue was \$20.5 million in the third quarter of fiscal 2020, an increase of 8.3% as compared with \$18.9 million for the third quarter of fiscal 2019. Medical Device revenue for the nine months ended June 30, 2020 was \$54.2 million, an increase of 1.3% as compared with \$53.5 million for the nine months ended June 30, 2019.

Product sales increased 28.1%, or \$1.3 million, for the third quarter of fiscal 2020 as compared with the prior-year quarter and increased 17.4%, or \$2.4 million, for the first nine months of fiscal 2020 compared to the same prior-year period. This increase was due primarily to the fiscal 2020 impact from recently commercialized medical device products, partly offset by the impact of a decline in legacy balloon catheter sales as a result of COVID-19 procedure reductions.

Royalties and license fee revenue increased 6.7%, or \$0.8 million, for the third quarter of fiscal 2020 and decreased 2.8%, or \$(0.9) million, for the first nine months of fiscal 2020, as compared with the same prior year periods. Abbott Agreement license fee revenue increased to \$7.6 million in the third quarter of fiscal 2020, as compared to \$2.0 million in the prior-year quarter, driven primarily by \$6.7 million in revenue recognized from a \$10.8 million milestone payment received in the third quarter of fiscal 2020. In the first nine months of fiscal 2020 and 2019, Abbott Agreement license revenue was \$10.4 million and \$5.9 million, respectively. Royalties revenue for the third quarter and first nine months of fiscal 2020 was significantly impacted by the reduction in procedures as a result of COVID-19. In addition, royalties revenue for the third quarter and first nine months of fiscal 2020 was negatively impacted by the previously communicated expiration of our fourth-generation hydrophilic patents, as well as by \$1.0 million in revenue recognized in the third quarter of fiscal 2019 associated with a license extension.

Research, development and other revenue decreased \$0.5 million for the third quarter of fiscal 2020 and decreased \$0.8 million for the first nine months of fiscal 2020 compared to the same prior year periods. These decreases were due to the timing of new product development projects with several of our contract R&D customers, as well as by a decline in coating services order volume as a result of COVID-19.

In Vitro Diagnostics. In Vitro Diagnostics revenue increased 18.0%, or \$1.0 million, for the third quarter of fiscal 2020 and increased 14.9%, or \$2.3 million, for the first nine months of fiscal 2020, as compared with the same prior year periods. For the third quarter of fiscal 2020, the increase in revenue was driven by continued demand for our microarray DNA slide products, as well as by growth of our protein stabilizer and BioFXTM substrate products. For the first nine months of fiscal 2020, revenue growth was driven by increases in our microarray DNA slide products, *BioFX* slide products and antigens.

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

	Th	ree Months E	nded June 3	80,	Nine Months Ended June 30,						
	202	20	20	19	202	20	203	19			
(Dollars in thousands)	Amount	% Total Revenue	Amount	% Total Revenue	Amount	% Total Revenue	Amount	% Total Revenue			
Product costs	\$ 4,443	17%	\$ 3,364	14%	\$11,415	16%	\$ 9,980	14%			
Research and development	13,324	50%	13,321	55%	37,401	52%	38,362	55%			
Selling, general and administrative	7,416	28%	5,939	24%	21,092	29%	16,764	24%			
Acquired intangible asset amortization	536	2%	599	2%	1,671	2%	1,809	3%			

Product costs. Product gross margin (defined as product revenue less related product costs) was 62.9% and 65.9% of product revenue for the third quarter of fiscal 2020 and 2019, respectively, and 66.2% of product revenue for both the first nine months of fiscal 2020 and 2019. For the third quarter of fiscal 2020, product gross margin was unfavorably impacted by the shift in Medical Device business product mix as growth in revenue volume from newly commercialized medical device products more than offset reductions in order volume as a result of COVID-19 procedure reductions. In the third quarter of fiscal 2020, this decrease was offset, in part, by the favorable impact of In Vitro Diagnostics from both product mix and leverage on higher revenue volume. Gross margin for the first nine months of fiscal 2020 was impacted by the same factors, however to a lesser degree by the unfavorable impact from Medical Device business product mix.

Research and development (R&D) expenses. R&D expenses for the third quarter of fiscal 2020 were essentially flat as compared to the same prior-year quarter and were 50% of revenue, as compared with 55% of revenue for the same prior-year period. For the first nine months of fiscal 2020, R&D expenses decreased \$1.0 million to 52% of revenue, as compared to 55% of revenue for the same prior-year period. Clinical trial spending decreased in the third quarter and first nine months of fiscal 2020, principally for the TRANSCEND clinical trial for our *SurVeil* DCB with the progression from active enrollment in fiscal 2019 to patient follow up in fiscal 2020. This decrease was partly offset by increased R&D expenses for personnel investments in quality, technical, regulatory, and

proprietary product development, as well as current-year clinical trial expenses for the first-in-human clinical study for our Sundance DCB.

Selling, general and administrative (SG&A) expenses. SG&A expenses increased \$1.5 million to 28% of revenue for the third quarter of fiscal 2020, as compared with 24% of revenue for the same prior-year period. For the first nine months of fiscal 2020, SG&A expenses increased \$4.3 million to 29% of revenue, as compared with 24% of revenue for the same prior-year period. The increase in SG&A expenses for the third quarter and first nine months of fiscal 2020 was primarily driven by personnel and other investments to support product development and strategic initiatives. Also contributing to the increase in SG&A expense or the year-to-date period was a \$0.6 million reduction to expense in the second quarter of fiscal 2019 resulting from a claim that was settled for less than the amount we had reserved.

Acquired intangible asset amortization. As part of our fiscal 2016 acquisitions in our Medical Device business, we acquired certain intangible assets, which are being amortized over periods ranging from 4 to 14 years. In addition, we own certain intangible assets related to the fiscal 2007 BioFx acquisition. Amortization expense was consistent with the prior-year period for both the third quarter and first nine months of fiscal 2020.

Contingent consideration expense (gain). We recorded net expense of \$0.1 million and net gain of \$(0.2) million in the three and nine months ended June 30, 2019, respectively, related to contingent consideration liabilities from prior-year acquisitions. Fiscal 2019 gains related to changes in estimated probabilities of achievement of certain revenue and strategic milestones, partly offset by accretion expense. In the first quarter of fiscal 2020, we completed the final contingent consideration payment of \$3.2 million to the sellers of NorMedix, Inc. ("NorMedix").

Other (expense) income. Other (expense) income totaled less than \$(0.1) million and \$(0.2) million for the third quarter of fiscal 2020 and 2019, respectively, and \$(0.1) million and \$0.8 million for the first nine months of fiscal 2020 and 2019, respectively. In the second quarter of fiscal 2020, we recognized a \$0.5 million impairment loss on our investment in ViaCyte, Inc. to reduce the carrying value to zero. In the third quarter and first nine months of fiscal 2020, investment income declined commensurate with lower current-year interest rates. Additionally, for the first nine months of fiscal 2020, the impact of U.S. dollar to Euro foreign currency fluctuations resulted in losses in the current fiscal year and gains in the same prior-year period.

Income tax benefit. For the third quarter of fiscal 2020 and 2019, we recorded an income tax benefit of \$1.2 million and \$0.3 million, respectively. For the first nine months of fiscal 2020 and 2019, we recorded an income tax benefit of \$3.4 million and \$0.6 million, respectively. The Coronavirus Aid, Relief and Economic Security Act (the "CARES Act") was enacted on March 27, 2020 and includes significant business tax provisions. In particular, the CARES Act modified the rules associated with net operating losses ("NOLs"). In the second quarter of fiscal 2020, we recorded a discrete tax benefit of \$1.8 million as result of our ability under the CARES Act to carry back NOLs 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 benefits recognized in the three and nine months ended June 30, 2020 and 2019 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:

	Three Months Ended June 30,				Nine Months Ended June 30,					
(Dollars in thousands)		2020 2019 % Change			% Change		2020		2019	% Change
Operating income:										
Medical Device	\$	532	\$	753	(29)%	\$	(1,344)	\$	1,087	(224)%
In Vitro Diagnostics		3,254		2,475	32%		9,315		7,845	19%
Total segment operating income		3,786		3,228			7,971		8,932	
Corporate		(2,622)		(2,211)	19%		(7,229)		(6,338)	14%
Total operating income	\$	1,164	\$	1,017	15%	\$	742	\$	2,594	(71)%

Medical Device. Our Medical Device business reported operating income of \$0.5 million and \$0.8 million for the third quarter of fiscal 2020 and 2019, respectively, representing 2.6% and 4.0% of revenue, respectively. For the first nine months of fiscal 2020, the Medical Device business reported operating losses of \$(1.3) million, or (2.5)% of revenue, as compared with operating income of \$1.1 million, or 2.0% of revenue, in the same prior-year period.

Product gross margins declined to 54.2% and 62.1% for the third quarter and first nine months of fiscal 2020, respectively, as compared with 66.7% and 62.6% in the same prior-year respective periods, due primarily to the unfavorable impact of fiscal 2020 product mix. In the third quarter of fiscal 2020, certain legacy medical device customers reduced order volume as a result of COVID-19, and revenue volume increased from initial orders of newly developed specialty catheter products. Operating expenses, excluding product costs, increased \$0.7 million and \$2.2 million for the third quarter and first nine months of fiscal 2020, respectively. For the third quarter and first nine months of fiscal 2020, increases in SG&A to support our whole product solutions strategy were offset by a decline in R&D from higher clinical study costs in fiscal 2019. SG&A increased in fiscal 2020 as we continue to invest in commercial infrastructure to support upstream marketing and clinical evaluation activities associated with our cleared products, including additional headcount, to support our whole-product solutions strategy. For the first nine-months of fiscal 2020, the increase in SG&A expenses also reflects the impacts of the prior-year \$0.6 million expense reduction from a claim settlement and the prior-year \$0.3 contingent consideration gain.

In Vitro Diagnostics. Our In Vitro Diagnostics business reported operating income of \$3.3 million and \$2.5 million for the third quarter of fiscal 2020 and 2019, respectively, representing 51.1% and 45.8% of revenue, respectively. For the first nine months of fiscal 2020 and 2019, In Vitro Diagnostics operating income totaled \$9.3 million and \$7.8 million, respectively, representing 51.5% and 49.8% of revenue, respectively. Product gross margins were 71.0% and 69.9% in the third quarter and first nine months of fiscal 2020, respectively, compared to 65.3% and 69.3% in the same prior-year respective periods. Product gross margins were favorably impacted by a shift in revenue mix towards products with relatively higher gross margins, as well as by leverage on revenue growth.

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 In Vitro Diagnostics segments. Corporate also includes expenses, such as litigation, which are not specific to a segment and thus not allocated to our operating segments.

Liquidity and Capital Resources

As of June 30, 2020, working capital totaled \$72.2 million, an increase of \$11.0 million from September 30, 2019. Working capital is defined by us as current assets minus current liabilities. Cash and cash equivalents and available-for-sale investments totaled \$60.6 million as of June 30, 2020, an increase of \$5.3 million from \$55.3 million as of September 30, 2019. This change was primarily driven by the \$10.8 million *SurVeil* DCB milestone payment received from Abbott, less the \$3.2 million contingent consideration payment related to the NorMedix acquisition, \$2.6 million in capital expenditures, \$2.4 million cash payments for taxes related to net share settlement of equity awards, and the \$1.0 million payment to Embolitech, LLC for acquisition of in process R&D.

In the third quarter of 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 potentially offer 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 \$53.9 million as of June 30, 2020. 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. Management plans to continue to direct its investment advisors to manage the Company's securities investments primarily for the safety of principal and the enhancement of liquidity for the time being as it continues to assess the impact of the COVID-19 pandemic on the Company, its business and its cash flows.

We believe that our existing cash, and cash equivalents and investments, which totaled \$60.6 million as of June 30, 2020, 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. Uncertainty related to the COVID-19 pandemic may cause us to seek additional funding to meet our operating needs. We cannot be certain that additional funding will be available on acceptable terms, if at all. If we do not have, or



are not able to obtain, sufficient funds, we may have to delay development or commercialization of our products or otherwise curtail our operations.

Cash Flow Operating Results. The following table is a summary of cash provided by (used in) operating, investing, and financing activities, the effect of exchange rate changes on cash and cash equivalents, and the net change in cash and cash equivalents:

	Nine Months Ended June 30,				
(Dollars in thousands)	2020	_	2019		
Cash provided by (used in):					
Operating activities	12,696		(4,482)		
Investing activities	(1,871)		21,223		
Financing activities	(4,808)		(11,475)		
Effect of exchange rates on changes in cash and cash equivalents	8		(18)		
Net change in cash and cash equivalents	\$ 6,025	\$	5,248		

Operating Activities. Cash provided by operating activities totaled \$12.7 million for the first nine months of fiscal 2020, compared to cash used of \$4.5 million in the same prior-year period. Net income was \$4.1 million and \$4.0 million during the first nine months of fiscal 2020 and 2019, respectively. Net changes in operating assets and liabilities reduced cash flows from operating activities by \$1.5 million and \$14.3 million during the first nine months of fiscal 2020 and 2019, respectively. Net fiscal 2020 and 2019, respectively. Significant changes in operating assets and liabilities affecting cash flows during these periods included:

- Cash provided by deferred revenue was \$0.5 million for the nine months of fiscal 2020, as compared with cash used of \$5.8 million in the same prioryear period, due to the \$10.8 million milestone payment received from Abbott in fiscal 2020.
- Cash provided by accounts receivable and contract asset totaled \$4.3 million in the first nine months of fiscal 2020, as compared with cash used of \$1.0 million in the same prior-year period, due to the current-year reduction in contract asset related to reduced royalty payments receivable from customers.
- Cash provided by accrued liabilities totaled \$0.1 million in the first nine months of fiscal 2020, as compared with cash used of \$5.1 million in the same prior-year period. The decrease in cash used is primarily due to accrued clinical trial expenses and other accrued expenses, including accruals at the inception of the prior fiscal year that were paid or settled during the prior year for both construction in progress and a \$1.0 claim settlement.

Income taxes also impacted cash provided by operating activities. Primarily as a result of the NOL carryback provisions of the CARES Act, income tax receivable increased to \$4.9 million as of June 30, 2020, as compared with \$0.6 million as of September 30, 2019, and deferred income taxes decreased to \$5.6 million, as compared with \$6.2 million as of September 30, 2019.

Additionally, the portion of acquisition-related contingent consideration payments classified as reduction of cash flows from operations was \$0.6 million and \$2.0 million in the first nine months of fiscal 2020 and 2019, respectively, as it related to accretion expense, which increased these obligations from the acquisition date through settlement.

Investing Activities. Cash used in investing activities totaled \$1.9 million in the first nine months of fiscal 2020, as compared with cash provided by investing activities of \$21.2 million in the same prior-year period. In the first nine months of fiscal 2020 and 2019, net purchases and maturities of available-for-sale investments were a source of cash of \$0.8 million and \$25.3 million, respectively. Capital expenditures for property, plant and equipment totaled \$2.6 million and \$4.1 million in the first nine months of fiscal 2020 and 2019, respectively.

Financing Activities. Cash used in financing activities totaled \$4.8 million and \$11.5 million in the first nine months of fiscal 2020 and 2019, respectively. Contingent consideration payments of \$3.2 million in the first nine months of fiscal 2020 related to the NorMedix acquisition, with \$0.6 million and \$2.6 million classified as cash used by operating and financing activities, respectively. In the first nine months of fiscal 2019, we paid contingent consideration of \$11.0 million related to the Creagh Medical acquisition, with \$2.0 million and \$9.1 million classified as cash used by operating and financing activities, respectively. In the first nine months of process common stock to pay employee taxes resulting from the exercise of stock options and vesting of other stock awards. In the first nine months of fiscal 2020, we paid \$1.0 million to Embolitech, LLC related to our fiscal 2018 acquisition of in process R&D.

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 2019. These same customers each comprised 20% and 13% of our consolidated revenue for the nine months ended June 30, 2020, respectively. Abbott has several separately licensed products, including the *SurVeil* DCB license, which generate royalties revenue for Surmodics, none of which represented more than 15% of total revenue for the nine months ended June 30, 2020. 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 nine months ended June 30, 2020. No other individual customer constitutes more than 10% of Surmodics' total fiscal 2020 to date or fiscal 2019 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 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.

Off-Balance Sheet Arrangements

As of June 30, 2020 and September 30, 2019, 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.

Forward-Looking Statements

This Quarterly Report on Form 10-Q, including "Management's Discussion and Analysis of Financial Condition and Results of Operations" in Item 2, contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. These statements include, but are not limited to, expectations concerning: the impacts, duration and severity of the global COVID-19 pandemic and the effects of responses to it on healthcare systems, the general economy, our business partners, and our operations; clinical studies; our growth strategy, including our ability to sign new license agreements, conduct market evaluations, and bring new products to market; investments to obtain clinical data, reduce the time from product development to commercialization, and drive clinician engagement with our products after approval to optimize adoption; the development and receipt or pursuit of regulatory clearance for future products; estimated future revenue recognition; estimated future amortization expense; recognition of unrecognized compensation costs; the impact of patent expirations on our hydrophilic coatings royalties revenue; product development programs; various milestone achievements; 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; 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 and the Company's strategy to transform to a provider of whole-product solutions; the timing, impact, and success of the clinical evaluation of the SurVeil DCB; fiscal 2020 income tax (benefit) expense; 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 the Company's 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 II, Item 1A of this Quarterly Report on Form 10-Q and under "Risk Factors" in Part I, Item 1A of our Annual Report on Form 10-K for the fiscal year ended September 30, 2019. 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:

- 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 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 PAD in the femoral and/or popliteal arteries;
- our ability to successfully develop, obtain regulatory approval for, and commercialize our *SurVeil* DCB product, including our reliance on clinical
 research organizations to manage the TRANSCEND clinical trial and uncertainty related to the impacts of any clinical research relative to drug-coated
 balloons, including our Avess™ DCB, other DCB products and other catheter and balloon-based products, which will impact our ability to receive
 additional milestone payments under our agreement with Abbott;
- general economic conditions which 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, and will likely continue, to negatively impact our business and results from operations (as further described under "Part II, Item 1A. Risk Factors" of this Quarterly Report on Form 10-Q);
- a decrease in our available cash or failure to generate cash flows from operations could impact short-term liquidity requirements and expected capital and other expenditures;
- the difficulties and uncertainties associated with the lengthy and costly new product development and foreign and domestic regulatory approval processes, such as delays, difficulties or failures in achieving acceptable clinical results or obtaining foreign

or FDA marketing clearances or approvals, which may result in lost market opportunities, failure to bring new products to market or postpone or preclude product commercialization by licensees or ourselves;

- the development of new products or technologies by competitors, technological obsolescence and other changes in competitive factors;
- our ability to perform successfully with respect to certain 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 successfully convert our customers from the fourth generation of our PhotoLinkTM hydrophilic technology protected by a family of
 patents which expired in the first quarter of fiscal 2020 (in the U.S.) to one of our advanced generation technologies or extend the royalty-bearing term
 of the customer license agreements, and to offset any decline in revenue from customers that we are unable to convert;
- our ability to identify and execute new acquisition opportunities as well as the process of integrating acquired businesses poses numerous risks, including an 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; 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;
- other factors described under "Risk Factors" in Part II, Item 1A of this Quarterly Report on Form 10-Q and in "Risk Factors" and other sections of our Annual Report on Form 10-K for the fiscal year ended September 30, 2019, which you are encouraged to read carefully.

Many of these factors are outside the control and knowledge of us 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 June 30, 2020, we held \$24.2 million in available-for-sale debt securities, all with maturity dates of less than one year, therefore interest rate fluctuations would have an insignificant impact on our results of operations or cash flows. Our policy also allows the Company to hold a substantial portion of funds in cash and cash equivalents, which are defined as financial instruments with original maturities of three months or less and may include money market instruments, certificates of deposit, repurchase agreements, corporate bonds 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 as compared with the Euro, our revenue and expenses denominated in Euro currency are translated into U.S. dollars at a lower or higher value than they would be in an otherwise constant currency exchange rate environment. All sales transactions are denominated in U.S. dollars or Euros. We generate royalties revenue from the sale of customer products in foreign jurisdictions. Royalties generated in foreign jurisdictions by customers are converted and paid in U.S. dollars or Euros. 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.

³¹

Item 4. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

The Company maintains disclosure controls and procedures as defined in Rules 13a-15(e) and 15d-15(e) of the Securities Exchange Act of 1934, as amended (the "Exchange Act"). The Company's management, under the supervision and with the participation of the Company's Chief Executive Officer and Chief Financial Officer, referred to collectively herein as the Certifying Officers, carried out an evaluation of the effectiveness of the design and operation of the Company's disclosure controls and procedures as of June 30, 2020. 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 files or submits under the Exchange Act is accumulated and communicated to the Company's management, including its Certifying Officers, as appropriate, to allow timely decisions regarding required disclosures.

Changes in Internal Controls over Financial Reporting

There were no changes in our internal control over financial reporting (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act) during the three months ended June 30, 2020 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II - OTHER INFORMATION

Item 1. Legal Proceedings

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

Item 1A. Risk Factors

The risks described below and those identified in our Annual Report on Form 10-K for the fiscal year ended September 30, 2019, filed with the SEC on December 3, 2019, under "Part 1, Item 1A. Risk Factors" could affect our financial performance and could cause our actual results for future periods to differ materially from our anticipated results or other expectations, including those expressed in any forward-looking statements made in this Quarterly Report on Form 10-Q.

The COVID-19 pandemic has had an adverse effect on our business and results of operations and is expected to continue to have further adverse effects, which could be material, on our business, results of operations, financial condition, liquidity, and capital investments.

On March 11, 2020, the World Health Organization declared the COVID-19 outbreak a global pandemic. The COVID-19 pandemic has negatively impacted the global economy, disrupted supply chains and created significant volatility in financial markets. We have implemented business policies intended to protect our employees from the spread of COVID-19. Those policies include employees working from home when possible and employees in our facilities increasing physical distancing.

On March 18, 2020, the Centers for Medicare & Medicaid Services ("CMS") released guidance for U.S. healthcare providers to limit non-emergent elective medical procedures other than high acuity treatments in order to conserve personal protective equipment and limit exposure to COVID-19. On April 16, 2020, the White House issued "Guidelines for Opening Up America Again" (the "White House Guidelines") that described a phased resumption of economic activities with gating conditions for a region or state to move from one phase to another. On June 9, 2020, CMS issued recommendations for regions and states in Phase II of the White House Guidelines that non-emergent, non-COVID-19 care should be offered to patients, as clinically appropriate, in localities or facilities that have the resources to provide such care, as well as the ability to quickly respond to a surge in COVID-19 cases, if necessary.

Since the White House Guidelines and related CMS recommendations were issued, rates of COVID-19 have vacillated by region and state, in some cases surging. Accordingly, consistent with the CMS recommendations, the degree to which elective medical procedures have been offered varies by region, state, and even between healthcare systems within a state. Where elective procedures have been offered, and even for emergency procedures, some people appear to have avoided healthcare facilities, presumably out of concern for contracting COVID-19. Many of our customers use our licensed technology and purchased materials to manufacture products used in procedures impacted by the guidance and recommendations. Based on the CMS guidance and recommendations, as well as industry data regarding elective procedures volumes, we adjusted the assumptions used in our royalties revenue recognition for the quarters ended March 31, 2020 and June 30, 2020, which resulted in reduced in royalties revenue in both periods relative to the revenue that would have been recognized under our prior assumptions. In addition to limiting medical procedures, hospitals and other healthcare providers vary in the degree to which they are permitting access to their facilities during the pandemic.

In early July 2020, we suspended production for one week in one production work cell in our facility in Eden Prairie when two of the employees in the cell were identified as having COVID-19. The production suspension did not have a material impact on our operations and the cell has since resumed normal operations.

We cannot predict the duration or scope of the pandemic, actions that may be taken by governments and businesses in response to the pandemic, or the impacts of the pandemic on healthcare systems. The impacts of the pandemic may include, but not be limited to:

- Reduced revenues from our customers, including our major customers, whose products are impacted by reductions in the delivery of elective medical procedures or patients' unwillingness to visit healthcare facilities for medical procedures;
- Diminished ability or willingness of third parties to market, distribute and sell products incorporating our coating and device technologies, as well as our whole-product solutions, due to reduced demand from, or lack of access to, healthcare facilities and providers;
- Diminished ability, or inability, to complete clinical trials and other activities required to achieve regulatory clearing for our products under development due to lack of access to healthcare facilities, healthcare providers and patients;



- Diminished or lost access to third party service providers that we use in our research and development or marketing efforts;
- Loss of manufacturing capacity, which could lead to failures to meet product delivery commitments, or increased operating costs if our facilities were to experience additional incidents of COVID-19;
- Reduced cash flow from our operations due to reductions in revenues or collections from our customers and increases in operating costs related to
 actions we have taken in response to the pandemic;
- Reduced business productivity due to inefficiencies in employees working from home or increasing physical distancing and other pandemic response
 protocols in our production facilities;
- Increased susceptibility to the risk of information technology security breaches and other disruptions due to increased volumes of remote access to our information systems from our employees working at home;
- Inability to source sufficient components used in our products due to disruptions in supply chains;
- Diminished ability to identify, evaluate and acquire, or effectively integrate, complementary businesses, products, materials or technologies due to travel restrictions, physical distancing protocols, and lack of access to third party service providers related to our development activities;
- Difficulties in assessing and securing intellectual property rights due to lack of access to, or delayed responsiveness of, third party service providers or governmental agencies;
- Impairment of goodwill or other assets due to reductions in the fair value of our reporting units;
- Diminished ability to retain personnel over concerns about workplace exposure to COVID-19, or to hire and effectively train new personnel, due to
 physical distancing protocols; and
- Increased volatility in our stock price due to financial market instability.

These and other factors relating to, or arising from, the pandemic could have material adverse effects on our business, results of operations, cash flows, financial condition, and capital investments. Actual or anticipated adverse effects on our cash flows or financial condition may lead us to seek additional funding. Any future debt financing into which we enter may impose upon us covenants that restrict our operations, including limitations on our ability to incur liens or additional debt, pay dividends, repurchase our common stock, make certain investments and engage in certain merger, consolidation or asset sale transactions. We cannot be certain that additional funding will be available on acceptable terms, if at all. If we do not have, or are not able to obtain, sufficient funds, we may have to delay development or commercialization of our products or otherwise curtail our operations. Any of these events could materially harm our business and operating results.

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 June 30, 2020. As of June 30, 2020, 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	EXHIBIT INDEX Description
<u>2.1</u>	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 8-K filed on November 27, 2015, SEC File No. 0-23837.
<u>2.2</u>	Put and Call Option Agreement by and among Surmodics, Inc. and the shareholders of Creagh Medical Ltd. dated as of November 20, 2015 — incorporated by reference to Exhibit 2.2 to the Company's 8-K filed on November 27, 2015, SEC File No. 0-23837.
<u>2.3</u>	Stock Purchase Agreement, dated January 8, 2016, by and 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 8-K filed on January 13, 2016, SEC File No. 0-23837.
<u>3.1</u>	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, SEC File No. 0-23837.
<u>3.2</u>	<u>Restated Bylaws of Surmodics, Inc., as amended December 18, 2015 — incorporated by reference to Exhibit 3.2 of the Company's</u> <u>Current Report on Form 8-K filed on December 23, 2015, SEC File No. 0-23837</u> .
<u>31.1*</u>	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.
<u>31.2*</u>	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.
<u>32.1*</u>	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.
<u>32.2*</u>	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.
<u>101.INS*</u>	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.
<u>101.SCH*</u>	Inline XBRL Taxonomy Extension Schema.
<u>101.CAL*</u>	Inline XBRL Taxonomy Extension Calculation Linkbase.
<u>101.DEF*</u>	Inline XBRL Taxonomy Extension Definition Linkbase.
<u>101.LAB*</u>	Inline XBRL Taxonomy Extension Label Linkbase.
<u>101.PRE*</u>	Inline XBRL Taxonomy Extension Presentation Linkbase.
<u>104*</u>	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.

August 5, 2020

Surmodics, Inc.

By: /s/ Timothy J. Arens

Timothy J. Arens 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: August 5, 2020

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
 - 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: August 5, 2020

5.

Signature:

/s/ Timothy J. Arens

Timothy J. Arens 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 June 30, 2020, 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: August 5, 2020

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 June 30, 2020, 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: August 5, 2020

Signature:

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