

SURMODICS INC
Form 10-Q
May 03, 2019

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D. C. 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended March 31, 2019

or

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

Commission File Number: 0-23837

Surmodics, Inc.

(Exact name of registrant as specified in its charter)

MINNESOTA 41-1356149

(State of incorporation) (I.R.S. Employer Identification No.)

9924 West 74th Street, Eden Prairie, Minnesota 55344

(Address of principal executive offices) (Zip Code)

Registrant's telephone number, including area code:

(952) 500-7000

Securities registered pursuant to Section 12(b) of the Securities Exchange Act of 1934:

Edgar Filing: SURMODICS INC - Form 10-Q

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

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

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or 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

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

The number of shares of the registrant’s Common Stock, \$0.05 par value per share, as of April 30, 2019 was 13,488,496

TABLE OF CONTENTS

PART I. FINANCIAL INFORMATION

Item 1.	<u>Unaudited Condensed Financial Statements</u>	3
Item 2.	<u>Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	24
Item 3.	<u>Quantitative and Qualitative Disclosures About Market Risk</u>	32
Item 4.	<u>Controls and Procedures</u>	33

PART II. OTHER INFORMATION

Item 1.	<u>Legal Proceedings</u>	34
Item 1A.	<u>Risk Factors</u>	34
Item 2.	<u>Unregistered Sales of Equity Securities and Use of Proceeds</u>	35
Item 3.	<u>Defaults Upon Senior Securities</u>	35
Item 4.	<u>Mine Safety Disclosures</u>	35
Item 5.	<u>Other Information</u>	35
Item 6.	<u>Exhibits</u>	36
	<u>SIGNATURES</u>	37

PART I. FINANCIAL INFORMATION

Item 1. Unaudited Condensed Financial Statements

Surmodics, Inc. and Subsidiaries

Condensed Consolidated Balance Sheets

	March 31, 2019	September 30, 2018
(in thousands, except share and per share data)		
	(Unaudited)	
ASSETS		
Current Assets:		
Cash and cash equivalents	\$22,470	\$23,318
Restricted cash	—	350
Available-for-sale securities	24,023	41,352
Accounts receivable, net of allowance for doubtful accounts of \$181 and \$147		
as of March 31, 2019 and September 30, 2018, respectively	9,312	8,877
Contract assets - royalties and license fees	7,065	—
Inventories, net	4,345	4,016
Income tax receivable	1,137	1,152
Prepays and other	3,165	2,462
Total Current Assets	71,517	81,527
Deferred tax assets	5,301	6,304
Property and equipment, net	29,512	30,143
Intangible assets, net	16,020	17,683
Goodwill	26,549	27,032
Other assets	2,081	1,446
Total Assets	\$150,980	\$164,135
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities:		
Accounts payable	\$3,746	\$2,546
Accrued liabilities:		
Compensation	2,107	5,635
Accrued other	5,097	6,265
Deferred revenue	6,385	9,646
Contingent consideration	3,009	11,041
Total Current Liabilities	20,344	35,133
Contingent consideration, less current portion	—	3,425
Deferred revenue, less current portion	10,470	11,247
Other long-term liabilities	4,853	5,720
Total Liabilities	35,667	55,525
Commitments and Contingencies (Note 15)		
Stockholders' Equity:		
Series A Preferred stock- \$.05 par value, 450,000 shares authorized; no shares issued and outstanding	—	—

Edgar Filing: SURMODICS INC - Form 10-Q

Common stock- \$.05 par value, 45,000,000 shares authorized; 13,488,738 and

13,397,647 shares issued and outstanding as of March 31, 2019 and

September 30, 2018, respectively	674	670
Additional paid-in capital	7,510	7,607
Accumulated other comprehensive income	1,444	2,718
Retained earnings	105,685	97,615
Total Stockholders' Equity	115,313	108,610
Total Liabilities and Stockholders' Equity	\$ 150,980	\$ 164,135

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

3

Surmodics, Inc. and Subsidiaries

Condensed Consolidated Statements of Operations

(In thousands, except per share data)	Three Months		Six Months Ended	
	Ended March 31, 2019 (Unaudited)	2018	2019 March 31, (Unaudited)	2018
Revenue:				
Product sales	\$9,887	\$8,686	\$19,638	\$16,774
Royalties and license fees	9,932	8,428	20,028	15,504
Research, development and other	2,857	1,944	5,251	3,793
Total revenue	22,676	19,058	44,917	36,071
Operating costs and expenses:				
Product costs	3,093	2,913	6,616	5,804
Research and development	13,555	10,774	25,041	18,605
Selling, general and administrative	4,876	6,440	10,825	11,628
Acquired intangible asset amortization	604	636	1,210	1,254
Contingent consideration gain	(317)	(2,230)	(352)	(1,112)
Total operating costs and expenses	21,811	18,533	43,340	36,179
Operating income (loss)	865	525	1,577	(108)
Other income (loss):				
Investment income, net	265	142	581	263
Interest expense	(37)	—	(74)	—
Foreign exchange gain (loss)	5	(353)	141	(539)
Gain on strategic investment and other	2	—	9	177
Other income (loss), net	235	(211)	657	(99)
Income (loss) before income taxes	1,100	314	2,234	(207)
Income tax benefit	162	1,220	338	185
Net income (loss)	\$1,262	\$1,534	\$2,572	\$(22)
Basic net income (loss) per share				
	\$0.09	\$0.12	\$0.19	\$(0.00)
Diluted net income (loss) per share				
	\$0.09	\$0.11	\$0.19	\$(0.00)
Weighted average number of shares outstanding:				
Basic	13,390	13,102	13,379	13,078
Diluted	13,785	13,465	13,816	13,078

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

Surmodics, Inc. and Subsidiaries

Condensed Consolidated Statements of Comprehensive Income (Loss)

	Three Months		Six Months	
	Ended		Ended	
	March 31,	March 31,	March 31,	March 31,
	2019	2018	2019	2018
(In thousands)	(Unaudited)		(Unaudited)	
Net income (loss)	\$1,262	\$1,534	\$2,572	\$(22)
Other comprehensive (loss) income:				
Unrealized holding gains (losses) on available-for-sale securities, net of tax	39	(28)	44	(41)
Foreign currency translation adjustments	(779)	1,207	(1,318)	1,837
Other comprehensive (loss) income	(740)	1,179	(1,274)	1,796
Comprehensive income	\$522	\$2,713	\$1,298	\$1,774

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

Surmodics, Inc. and Subsidiaries

Condensed Consolidated Statements of Stockholders' Equity

(In thousands)	Three Months Ended March 31, 2019 and 2018					
	Common Stock		Additional Paid-In Capital	Accumulated		Total Stockholders' Equity
	Shares	Amount		Other Comprehensive Income	Retained Earnings	
Balance at December 31, 2018	13,483	\$ 674	\$ 6,340	\$ 2,184	\$ 104,423	\$ 113,621
Net income	—	—	—	—	1,262	1,262
Other comprehensive loss, net of tax	—	—	—	(740)	—	(740)
Issuance of common stock	6	—	209	—	—	209
Common stock options exercised, net	1	—	19	—	—	19
Purchase of common stock to pay employee taxes	(1)	—	(17)	—	—	(17)
Stock-based compensation	—	—	959	—	—	959
Balance at March 31, 2019	13,489	\$ 674	\$ 7,510	\$ 1,444	\$ 105,685	\$ 115,313
Balance at December 31, 2017	13,196	\$ 660	\$ 5,337	\$ 4,034	\$ 100,516	\$ 110,547
Net income	—	—	—	—	1,534	1,534
Other comprehensive income, net of tax	—	—	—	1,179	—	1,179
Issuance of common stock	3	—	166	—	—	166
Common stock options exercised, net	159	8	54	—	—	62
Purchase of common stock to pay employee taxes	(111)	(6)	(1,225)	—	—	(1,231)
Stock-based compensation	—	—	1,099	—	—	1,099
Balance at March 31, 2018	13,247	\$ 662	\$ 5,431	\$ 5,213	\$ 102,050	\$ 113,356

(In thousands)	Six Months Ended March 31, 2019 and 2018					
	Common Stock		Additional Paid-In Capital	Accumulated		Total Stockholders' Equity
	Shares	Amount		Other Comprehensive Income	Retained Earnings	
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
(Note 2)	—	—	—	—	5,498	5,498
Net income	—	—	—	—	2,572	2,572
Other comprehensive loss, net of tax	—	—	—	(1,274)	—	(1,274)
Issuance of common stock	134	6	203	—	—	209
Common stock options exercised, net	2	0	55	—	—	55
Purchase of common stock to pay employee taxes	(45)	(2)	(2,545)	—	—	(2,547)
Stock-based compensation	—	—	2,190	—	—	2,190
Balance at March 31, 2019	13,489	\$ 674	\$ 7,510	\$ 1,444	\$ 105,685	\$ 115,313
Balance at September 30, 2017	13,095	\$ 655	\$ 5,413	\$ 3,417	\$ 102,072	\$ 111,557
Net loss	—	—	—	—	(22)	(22)
Other comprehensive income, net of tax	—	—	—	1,796	—	1,796

Edgar Filing: SURMODICS INC - Form 10-Q

Issuance of common stock	127	6	160	—	—	166
Common stock options exercised, net	171	8	209	—	—	217
Purchase of common stock to pay employee taxes	(146)	(7)	(2,354)	—	—	(2,361)
Stock-based compensation	—	—	2,003	—	—	2,003
Balance at March 31, 2018	13,247	\$ 662	\$ 5,431	\$ 5,213	\$102,050	\$ 113,356

Surmodics, Inc. and Subsidiaries

Condensed Consolidated Statements of Cash Flows

(in thousands)	Six Months Ended	
	2019	2018
	March 31, (Unaudited)	
Operating Activities:		
Net income (loss)	\$2,572	\$(22)
Adjustments to reconcile net income (loss) to net cash (used in) provided by operating activities:		
Depreciation and amortization	3,575	3,106
Stock-based compensation	2,190	2,003
Payment of contingent consideration obligations in excess of acquisition-date value	(2,041)	—
Contingent consideration gain	(352)	(1,112)
Unrealized foreign exchange gain	—	518
Deferred taxes (1)	(213)	701
Gain on strategic investment	(7)	(177)
Provision for bad debts	119	25
Other	(10)	92
Change in operating assets and liabilities:		
Accounts receivable and contract asset (1)	(756)	(15)
Inventories	(355)	(500)
Prepays and other	(1,430)	(1,366)
Accounts payable	1,273	(418)
Accrued liabilities	(4,071)	810
Income taxes (1)	(291)	(776)
Deferred revenue (1)	(4,141)	24,562
Net cash (used in) provided by operating activities	(3,938)	27,431
Investing Activities:		
Purchases of property and equipment	(3,118)	(4,020)
Purchases of available-for-sale securities	(20,085)	(43,517)
Maturities of available-for-sale securities	37,458	33,000
Cash proceeds from sales of property and equipment	10	4
Cash received from sale of strategic investment	7	177
Net cash provided by (used in) investing activities	14,272	(14,356)
Financing Activities:		
Issuance of common stock	264	377
Payments for taxes related to net share settlement of equity awards	(2,678)	(1,132)
Payment of contingent consideration obligations	(9,064)	(925)
Net cash used in financing activities	(11,478)	(1,680)
Effect of exchange rate changes on cash, restricted cash and cash equivalents	(54)	133
Net change in cash, restricted cash and cash equivalents	(1,198)	11,528
Cash, Restricted Cash and Cash Equivalents:		
Beginning of period	23,668	16,534
End of period	\$22,470	\$28,062
Supplemental Information:		
Cash paid for income taxes	\$150	\$782

Noncash transactions from investing and financing activities:

Acquisition of property and equipment, net of refundable credits in other current assets

and liabilities	\$65	\$329
Accrued taxes related to net share settlement of equity awards	—	1,222

(1) Amounts presented are net of impact from adoption of ASC Topic 606.

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

7

Surmodics, Inc. and Subsidiaries

Notes to Condensed Consolidated Financial Statements

Period Ended March 31, 2019

(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 (“Surmodics” or the “Company”) for the periods presented. 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 (loss) in the period in which the change in estimate is identified. The results of operations for the three and six months ended March 31, 2019 are not necessarily indicative of the results that may be expected for the entire 2019 fiscal year.

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, 2018, and footnotes thereto included in the Company’s Form 10-K as filed with the SEC on November 30, 2018.

New Accounting Pronouncements

Recently Adopted

In May 2014, the Financial Accounting Standards Board (“FASB”) Accounting Standards Codification (“ASC”) issued Update No. 2014-09, Revenue from Contracts with Customers (“ASC Topic 606”). The core principal of ASC Topic 606 is to recognize revenue in a manner that depicts the transfer of goods or services to customers in amounts that reflect the consideration an entity expects to be entitled to in exchange for those goods or services. The guidance also requires expanded disclosures relating to the nature, amount, timing, and uncertainty of revenue and cash flows arising from contracts with customers, as well as significant judgements and changes in judgements, which are described in Note 2 to the condensed consolidated financial statements. The Company adopted ASC Topic 606 in the first quarter of fiscal year 2019 using the modified retrospective method and applied the new revenue standard to all new customer contracts initiated on or after the effective date and contracts which had remaining performance obligations as of the effective date.

The adoption of ASC Topic 606 resulted in an acceleration of minimum license fees and sales-based royalty revenue earned under the Company’s hydrophilic coating technology license agreements by approximately one quarter. Prior to the adoption of ASC Topic 606, sales-based royalties were recognized in the period the Company’s customers reported the underlying sales, which is generally one quarter after the sales occurred. Additionally, minimum royalties were recognized in the period they were contractually owed to the Company. Upon adoption of ASC Topic 606, sales-based royalties are recognized in the period the underlying customer sale occurs, while the minimum royalties are recognized at each renewal of the license contract, which generally occurs on the last day of the quarter for minimum royalties contractually due in the following quarter. The adoption of ASC Topic 606 resulted in cumulative-effect

adjustments to opening retained earnings, contract assets, deferred tax assets and income tax receivable.

8

Edgar Filing: SURMODICS INC - Form 10-Q

The impact of the adoption of ASC Topic 606 on the opening consolidated balance sheet as of October 1, 2018, as compared with the consolidated balance sheet previously reported as of September 30, 2018, was as follows:

(Dollars in thousands)	September 30, 2018, As Reported	Adjustments for Adoption of Topic 606	October 1, 2018 Opening Balance
Assets			
Contract assets - royalties and license fees	\$ —	\$ 6,904	\$ 6,904
Deferred income taxes	6,304	(1,215)	5,089
Income tax receivable	1,152	(390)	762
Liabilities and Stockholders' Equity			
Deferred revenue, current portion	9,646	(18)	9,628
Deferred revenue, less current portion	11,247	(181)	11,066
Retained earnings	97,615	5,498	103,113

The impact of adoption of ASC Topic 606 to the Company's condensed consolidated statements of operations for three and six months ended March 31, 2019 was an increase of royalty and license fee revenue of \$0.3 million and \$0.1 million, respectively, as well as reduced income tax benefit of less than \$0.1 million for each period.

Not Yet Adopted

In February 2016, the FASB issued Accounting Standards Update ASU 2016-02, Leases (ASC Topic 842). The new guidance primarily affects lessee accounting, while accounting by lessors will not be significantly impacted by the update. The update maintains two classifications of leases: finance leases, which replace capital leases, and operating leases. Lessees will need to recognize a right-of-use asset and a lease liability on the statement of financial position for those leases previously classified as operating leases under the old guidance. The liability will be equal to the present value of remaining contractual lease payments. The asset will be based on the liability, subject to adjustment, such as for direct costs. The accounting standard will be effective for the Company beginning the first quarter of fiscal year 2020 (October 1, 2019) and will be applied using a modified retrospective approach. The Company is currently evaluating the impact that the adoption of this standard will have on the Company's results of operations, cash flows and financial position. The Company believes the impact will be material due to the right-of-use assets and lease liabilities that will be recorded on the Company's consolidated balance sheets upon adoption of the standard.

In June 2016, the FASB issued ASU No 2016-13, Financial Instruments – Credit Losses (ASC Topic 326), 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). Early adoption is permitted and the guidance will be applied using a modified retrospective approach. The Company is currently evaluating the impact that the adoption of this standard will have on the Company's results of operations, cash flows and financial position.

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

Effective October 1, 2018, the Company adopted ASC Topic 606 using the modified retrospective adoption method. Revenue is recognized when control of the promised goods or services is transferred to our customers, in an amount that reflects the consideration we expect to be entitled to receive in exchange for those goods or services.

The following tables presents our revenues disaggregated by product classification and by operating segment, excluding sales taxes collected and remitted to governmental authorities (in thousands, unaudited).

(In thousands)	Three Months Ended		Six Months Ended	
	March 31, 2019	March 31, 2018	March 31, 2019	March 31, 2018
Medical Device	(Unaudited)		(Unaudited)	
Product sales	\$4,558	\$3,687	\$9,336	\$7,537
Royalties	8,313	7,891	15,998	14,933
Research, development and other	2,811	1,937	5,195	3,785
License fees	1,619	537	4,030	571
Total Revenue - Medical Device	17,301	14,052	34,559	26,826
IVD				
Product sales	5,329	4,999	10,302	9,237
Other	46	7	56	8
Total Revenue - IVD	5,375	5,006	10,358	9,245
Total Revenue	\$22,676	\$19,058	\$44,917	\$36,071

Performance Obligations

The Company derives its revenue from three primary sources: (1) product revenues from the sale of reagent chemicals to licensees, the sale of stabilization products, antigens, substrates and surface coatings to the diagnostic and biomedical research markets as well as the sale of medical devices and related products (such as balloons and catheters) to original equipment manufacturer (OEM) suppliers and distributors; (2) royalties and license fees from licensing our proprietary surface modification and device drug delivery technologies to customers; and (3) research and commercial development fees generated on customer projects.

The Company recognizes revenue when control is transferred to the customer. The transfer of control varies by revenue classification and is described below.

Product sales – Revenue from product sales is recognized at the point in time control of the products is transferred, generally upon shipment based upon the standard contract terms. Shipping and handling activities are considered to be fulfillment activities rather than promised services and are not, therefore, considered to be separate performance obligations. The Company's sales terms provide no right of return outside of a standard warranty policy and returns are generally not significant. Payment terms for product sales are generally set at 30-45 days after the consideration becomes due and payable.

Royalties – Royalty revenue consists of sales-based and recurring minimum royalties earned under licenses of our surface modification technologies. Performance obligations under these licenses, which consist of the right to use the Company's proprietary technology, are satisfied at a point in time corresponding with delivery of the underlying technology rights to the customer, which is generally upon transfer of the licensed technology to the customer.

Sales-based royalty revenue represents variable consideration under the license agreements and is recognized in the period a customer sells products incorporating the Company's licensed technologies. The Company estimates sales-based royalty revenue earned but unpaid at each reporting period using the expected value method based on historical sales information, adjusted for known changes such as product launches and patent expirations. The Company's license arrangements also often provide for recurring fees (minimum royalties) which the Company recognizes at the later of the satisfaction of the underlying performance obligation or upon renewal of the contract, which is generally done on a quarterly basis. Sales-based and minimum royalties are generally due within 45 days of the end of each quarter.

License fees – For distinct license performance obligations, upfront license fees are recognized when the Company satisfies the underlying performance obligation. This generally occurs upon transfer of the right to use the Company's licensed technology to the customer, with the exception of the license of the Company's SurVeil® drug-coated balloon (the "SurVeil DCB") disclosed below and in Note 3 to the condensed consolidated financial statements. Certain license arrangements include contingent milestone payments,

which are due following achievement by our customers of specified sales or regulatory milestones. Contingent milestone payment terms vary by contract. The Company has generally fulfilled its performance obligation prior to achievement of these milestones. However, because of the uncertainty of the milestone achievement, and/or the dependence on sales of our customers, variable consideration for contingent milestones is fully constrained and excluded from the contract price until the milestone is achieved by our customer, to the extent collectability is reasonably certain.

Pursuant to the terms of the collaborative arrangement contract with Abbott Vascular, Inc. (“Abbott”) disclosed in Note 3 (the “Abbott Agreement”), the Company received an upfront payment of \$25 million in fiscal 2018. To the extent the Company achieves certain agreed-upon clinical and regulatory milestones, the Company may receive up to \$67 million of additional milestone payments. The performance obligation identified in this arrangement includes delivery of our licensed technology and completion of research and development activities, primarily clinical trial activities (together, “R&D and Clinical Activities”). These promises are not distinct performance obligations because the product necessary for completion of the R&D and Clinical Activities is currently only able to be manufactured by the Company due to the exclusive proprietary know-how and certain regulatory requirements associated with the manufacture of the product. The customer (Abbott) simultaneously receives and consumes the benefits of the R&D and Clinical Activities as study data are generated to support regulatory approval submissions. Control is effectively transferred over time as we complete the TRANSCEND clinical study of our SurVeil DCB. Revenue related to this contract is recognized using the cost-to-cost method which measures progress based on costs incurred to date relative to the expected total cost of the services, as the Company believes this represents a faithful depiction of the satisfaction of its performance obligation. Use of the cost-to-cost method requires significant estimates including the total cost of the TRANSCEND study, which is expected to be completed over the next six years. Revenue is recorded based on the cost-to-cost completion estimate relative to the transaction price, which is equal to the total upfront fee plus the expected value of the clinical and regulatory milestones. As of March 31, 2019, consideration from the clinical and regulatory milestones has been fully constrained and excluded from the contract price, due to the high level of uncertainty as to the achievement of the underlying regulatory approval(s) and/or clinical milestones. Significant judgment is used to estimate total revenue and cost at completion for this contract.

Research and development – The Company performs third-party research and development activities, which are typically charged to customers on a time-and-materials basis. Generally, revenue for research and development is recorded over time as the services are provided to the customer in the amount to which the Company has the right to invoice. These services are generally charged to the customer as they are provided. Payment terms for R&D services are generally set at 30-45 days after the consideration becomes due and payable.

If a contract contains more than one distinct performance obligation, the transaction price is allocated to each performance obligation based on relative standalone selling price.

Contract Assets, Deferred Revenue and Remaining Performance Obligations

Contract assets are generally short in duration given the nature of products produced and services provided by the Company. Contract assets consist of sales-based and minimum royalty revenue earned for which unconditional right to payment does not exist as of the balance sheet date. These assets are comprised of estimated sales-based royalties earned, but not yet reported by the Company’s customers, minimum royalties on non-cancellable contracts, and contingent milestones earned but not yet billable based on the terms of the contract. The increase in contract assets from October 1, 2018 to March 31, 2019 resulted primarily from changes in estimated sales-based royalties earned but not collected at each balance sheet date.

The Company records a contract liability, or deferred revenue, when there is an obligation to provide a product or service to the customer and payment is received or due in advance of performance, or when payment is received for a period outside the contract term. The Company’s deferred revenue at March 31, 2019 and September 30, 2018 is primarily related to the upfront payment received pursuant to the Abbott Agreement (Note 3).

Remaining performance obligations include deferred revenue and amounts the Company expects to receive for goods and services that have not yet been delivered or provided under existing, noncancellable contracts. For contracts that have an original duration of one year or less, the Company has elected the practical expedient applicable to such contracts and does not disclose the transaction price for remaining performance obligations at the end of each reporting period and when the Company expects to recognize this revenue. As of March 31, 2019, 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 was approximately \$16.7 million. This revenue is entirely related to the R&D and Clinical Services performance obligation in the Abbott Agreement from the upfront payment received in fiscal 2018 and does not include revenue from potential contingent milestone payments that may be received throughout the course of the agreement. The Company expects to recognize the remaining revenue from this

performance obligation over the next six years as the services, which are primarily comprised of the TRANSCEND clinical study, 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 DCB products, which are currently in pre-clinical development and a first-in human clinical study, respectively. 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 clinical trial. Abbott and Surmodics will participate on a joint development committee charged with providing guidance on the Company's clinical and regulatory activities with regard to the SurVeil product.

To account for the Abbott Agreement, the Company applied the guidance in ASC 808 as the parties are active participants and are exposed to significant risks and rewards dependent on commercial success of the collaborative activity. The Company has determined that the upfront and milestone payments represent consideration paid in a vendor-customer relationship and has thus applied the guidance in ASC Topic 606 to these payments and the related performance obligations, as further discussed in Note 2. The Company is the principal in the arrangement and the related development costs and the revenue and R&D costs will be reported gross in license fee revenue and research and development costs on the condensed consolidated statements of operations.

The Company has received a \$25 million upfront fee and may receive up to \$67 million of additional payments upon achievement of various clinical and regulatory milestones. For the three and six months ended March 31, 2019, the Company recognized revenue totaling \$1.6 million and \$4.0 million, respectively from the Abbott arrangement, all of which was previously included in deferred revenue. For both the three and six months ended March 31, 2018, the Company recognized revenue totaling \$0.5 million from the Abbott arrangement. As of March 31, 2019 and September 30, 2018, deferred revenue from the upfront payment received of \$16.7 million and \$20.6 million, respectively is 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 if and 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 March 31, 2019 and September 30, 2018.

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 March 31, 2019 and September 30, 2018 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.

The Level 3 liability as of March 31, 2019 consisted of contingent consideration obligations related to the fiscal 2016 acquisition of NorMedix, Inc. (“NorMedix”). Level 3 liabilities as of September 30, 2018 consisted of contingent consideration obligations related to the fiscal 2016 acquisitions of Creagh Medical Ltd. (“Creagh Medical”) and NorMedix. Consideration owed to the sellers of Creagh Medical from revenue and value-creating milestones achieved through September 30, 2018 was paid during the six months ended March 31, 2019. Consideration owed to the sellers of NorMedix upon achievement of revenue and value-creating milestones through September 30, 2019, if any, is due to be paid in first quarter of fiscal 2020. Contingent consideration included in current liabilities of \$3.0 million and \$11.0 million as of March 31, 2019 and September 30, 2018, respectively, represents the Company’s estimated fair value of amounts expected to be paid within one year of each respective balance sheet date. During the first quarter of fiscal 2019, the Company paid contingent consideration obligations related to the Creagh Medical acquisition totaling \$11.0 million, including \$9.1 million classified as cash flows used in financing activities on the condensed consolidated statement of cash flows. The financing portion of the contingent consideration payment is equal to the acquisition-date value of the contingent consideration obligation, in accordance with ASC 230 Statements of Cash Flows.

In valuing Level 3 assets and liabilities, the Company is required to maximize the use of quoted market prices and minimize the use of unobservable inputs.

Assets 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.

The following table presents information about the Company’s assets and liabilities measured at fair value on a recurring basis as of March 31, 2019:

	Quoted Prices in			Total Fair Value as of March 31, 2019
	Active Markets for Identical Instruments (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)	
(Dollars in thousands)				
Assets				
Cash equivalents	\$ —	\$ 17,950	\$ —	\$ 17,950
Available-for-sale securities	—	24,023	—	24,023
Total assets	\$ —	\$ 41,973	\$ —	\$ 41,973
Liabilities				
Contingent consideration	\$ —	\$ —	\$ (3,009)	\$ (3,009)

Total liabilities	\$	—	\$ —	\$ (3,009) \$(3,009)
-------------------	----	---	------	-----------	--------------

13

Edgar Filing: SURMODICS INC - Form 10-Q

The following table presents information about the Company's assets and liabilities measured at fair value on a recurring basis as of September 30, 2018:

(Dollars in thousands)	Quoted Prices in			Total Fair Value as of September 30, 2018
	Active Markets for Identical Instruments (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)	
Assets				
Cash equivalents	\$ —	\$ 13,999	\$ —	\$ 13,999
Available-for-sale securities	—	41,352	—	\$ 41,352
Total assets	\$ —	\$ 55,351	\$ —	\$ 55,351
Liabilities				
Contingent consideration	\$ —	\$ —	\$ (14,466)	\$ (14,466)
Total liabilities	\$ —	\$ —	\$ (14,466)	\$ (14,466)

The following table summarizes the changes in the contingent consideration liabilities measured at fair value using Level 3 inputs for the three and six months ended March 31, 2019 and 2018:

(Dollars in thousands)	Three Months Ended March 31,		Six Months Ended March 31,	
	2019	2018	2019	2018
Beginning balance	\$3,326	\$16,162	\$14,466	\$14,864
Additions	—	—	—	—
Fair value adjustments	(362)	(2,317)	(511)	(1,298)
Settlements	—	(925)	(10,979)	(925)
Interest accretion	45	87	159	186
Foreign currency translation loss (gain)	—	338	(126)	518
Ending balance	\$3,009	\$13,345	\$3,009	\$13,345

There were no transfers of assets or liabilities between amounts measured using Level 1, Level 2, or Level 3 fair value measurements during fiscal 2019 to date, or fiscal 2018.

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.

Contingent consideration obligations — The values of the contingent consideration liabilities were determined based on discounted cash flow analyses that included revenue estimates, probability of strategic milestone achievement and a discount rate, which are considered significant unobservable inputs. For the NorMedix revenue-based milestones, the Company discounted forecasted revenue by 20.5%, which represents the Company's weighted average cost of capital for this transaction, adjusted for the short-term nature of the cash flows. The present value of forecasted revenue was used as an input into an option pricing approach, which also considered the Company's risk of non-payment of the NorMedix revenue-based milestones. Non-revenue milestones for the NorMedix acquisition that have not already been achieved were projected to have a 5%-100% probability of achievement and expected payments were discounted using the Company's estimated cost of debt of 6.0%. To the extent that actual results differ from these estimates, the fair value of the contingent consideration liabilities could change significantly during the contingency periods. Accretion expense is recorded as an increase to the contingent consideration liabilities due to the passage of time. Fair

value adjustments represent changes in the value of the obligations related to adjustments to forecasted revenue and probability of strategic milestone completion. The contingent consideration liability related to the Creagh Medical acquisition was denominated in Euros. Foreign currency translation gains and losses are recorded as this obligation is marked to exchange rates at period-end and on the date of settlement.

5. Investments

Investments consisted principally of commercial paper and corporate bond securities and are classified as available-for-sale as of March 31, 2019 and September 30, 2018. 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 (loss) 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)	March 31, 2019			
	Amortized Cost	Realized Gains	Unrealized Losses	Fair Value
Short-term commercial paper and corporate bonds	\$24,030	\$ —	\$ (7)	\$ 24,023
Total	\$24,030	\$ —	\$ (7)	\$ 24,023

(Dollars in thousands)	September 30, 2018			
	Amortized Cost	Realized Gains	Unrealized Losses	Fair Value
Short-term commercial paper and corporate bonds	\$41,403	\$ —	\$ (51)	\$ 41,352
Total	\$41,403	\$ —	\$ (51)	\$ 41,352

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:

Edgar Filing: SURMODICS INC - Form 10-Q

	March 31, 2019	September 30, 2018
(Dollars in thousands)		
Raw materials	\$1,969	\$ 1,890
Work-in process	807	780
Finished products	1,569	1,346
Total	\$4,345	\$ 4,016

7. Other Assets

Other assets consist of the following:

	March 31, 2019	September 30, 2018
(Dollars in thousands)		
ViaCyte, Inc.	\$479	\$ 479
Other noncurrent assets	1,602	967
Other assets, net	\$2,081	\$ 1,446

The Company has 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. The

balance of the investment of \$0.5 million, which is net of previously recorded other-than-temporary impairments of \$4.8 million, is accounted for under the cost method and represents 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.

8. Intangible Assets

Intangible assets consist principally of acquired patents and technology, customer lists and relationships, licenses and trademarks. The Company recorded amortization expense of \$0.7 million for both the three month periods ended March 31, 2019 and 2018. The Company recorded amortization expense of \$1.3 million and \$1.4 million for the six months ended March 31, 2019 and 2018, respectively.

Intangible assets consisted of the following:

(Dollars in thousands)	March 31, 2019			
	Weighted Average Original Cost	Carrying Amount	Accumulated Amortization	Net
Definite-lived intangible assets:				
Customer lists and relationships	8.9	\$ 17,687	\$ (10,022)	\$ 7,665
Developed technology	11.5	9,563	(2,780)	6,783
Non-compete	5.0	230	(173)	57
Patents and other	16.5	2,321	(1,644)	677
Subtotal		29,801	(14,619)	15,182
Unamortized intangible assets:				
In-process research and development		258	—	258
Trademarks and trade names		580	—	580
Total		\$ 30,639	\$ (14,619)	\$ 16,020

(Dollars in thousands)	September 30, 2018			
	Weighted Average Original Cost	Carrying Amount	Accumulated Amortization	Net
Definite-lived intangible assets:				
Customer lists and relationships	8.9	\$ 18,086	\$ (9,377)	\$ 8,709
Developed technology	11.5	9,656	(2,361)	7,295
Non-compete	5.0	230	(150)	80
Patents and other	16.5	2,321	(1,569)	752
Subtotal		30,293	(13,457)	16,836
Unamortized intangible assets:				

Edgar Filing: SURMODICS INC - Form 10-Q

In-process research and development	267	—	267
Trademarks and trade names	580	—	580
Total	\$ 31,140	\$ (13,457)	\$ 17,683

Based on the intangible assets in service as of March 31, 2019, excluding any possible future amortization associated with acquired in-process research and development (“IPR&D”), which has not met technological feasibility as of March 31, 2019, estimated amortization expense for the remainder of fiscal 2019 and each of the next five fiscal years is as follows (in thousands):

Remainder of 2019	\$ 1,317
2020	2,458
2021	2,319
2022	2,279
2023	1,685
2024	1,611

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

The Company defines IPR&D as the value of technology acquired for which the related projects have substance and are incomplete. IPR&D acquired in a business acquisition is recognized at fair value and requires the IPR&D to be capitalized as an indefinite-lived intangible asset until completion of the IPR&D project or abandonment. Upon completion of the development project (generally when regulatory approval to market the product is obtained), an impairment assessment is performed prior to amortizing the asset over its estimated useful life. If the IPR&D projects are abandoned, the related IPR&D assets would be written off.

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 indicating that the carrying amount of goodwill may be impaired.

Goodwill as of March 31, 2019 and September 30, 2018 totaled \$26.5 million and \$27.0 million, respectively. Goodwill in the Medical Device reporting unit represents the gross value from the fiscal 2016 acquisitions of 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 2018 annual impairment test, and there have been no events or circumstances that have occurred in the first six months of fiscal 2019 to indicate that goodwill has been impaired.

The change in the carrying amount of goodwill by segment for the six months ended March 31, 2019 was as follows:

(Dollars in thousands)	In Vitro Diagnostics	Medical Device	Total
Balance as of September 30, 2018	\$ 8,010	\$ 19,022	\$ 27,032
Currency translation adjustment	—	(483)	(483)
Balance as of March 31, 2019	\$ 8,010	\$ 18,539	\$ 26,549

10. Accrued Liabilities

Accrued liabilities consisted of the following:

March	September
31,	30,

Edgar Filing: SURMODICS INC - Form 10-Q

(Dollars in thousands)	2019	2018
Accrued professional fees	\$270	\$ 311
Accrued clinical study expense	1,876	2,839
Accrued purchases	1,389	533
Customer claim	—	1,000
Construction in progress	—	1,199
Deferred rent	125	121
Acquisition of in process research and development	965	—
Other	472	262
Total	\$5,097	\$ 6,265

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. Accounting guidance requires all share-based payments to be recognized as an operating expense, based on their fair values, over the requisite service period.

Edgar Filing: SURMODICS INC - Form 10-Q

The Company's stock-based compensation expenses were allocated to the following expense categories:

(Dollars in thousands)	Three Months Ended March 31,		Six Months Ended March 31,	
	2019	2018	2019	2018
Product costs	\$32	\$23	\$64	\$17
Research and development	178	179	391	337
Selling, general and administrative	749	899	1,735	1,649
Total	\$959	\$1,101	\$2,190	\$2,003

As of March 31, 2019, approximately \$9.2 million of total unrecognized compensation costs related to non-vested awards is expected to be recognized over a weighted average period of approximately 2.4 years. The unrecognized compensation costs above include \$0.2 million, remaining to be expensed over the life of the awards, based on payout levels associated with performance share awards that are currently anticipated to be fully expensed because the performance conditions are expected to exceed minimum threshold levels.

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. The weighted average per share fair values of stock options granted during the three months ended March 31, 2019 and 2018 were \$18.12 and \$9.00, respectively, and \$18.28 and \$10.32 during the six months ended March 31, 2019 and 2018, respectively.

	Three Months Ended March 31,		Six Months Ended March 31,	
	2019	2018	2019	2018
Risk-free interest rates	2.5 %	2.6 %	2.8 %	2.1 %
Expected life (years)	4.5	4.8	4.5	4.8
Expected volatility	34.9 %	33.0 %	33.4 %	33.0 %
Dividend yield	0.0 %	0.0 %	0.0 %	0.0 %

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 0.0% 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 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 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 table above includes stock option expenses recognized related to these awards, which totaled \$0.5 million and \$0.4 million for the three months ended March 31, 2019 and 2018, respectively, and \$1.0 million and \$0.8 million for the six months ended March 31, 2019 and 2018, respectively.

The total pre-tax intrinsic value of options exercised during the three months ended March 31, 2019 and 2018 was less than \$0.1 million and \$3.1 million, respectively, and \$0.1 million and \$3.3 million for the six months ended March 31, 2019 and 2018, respectively. The 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 six months ended March 31, 2019 and 2018, the Company awarded 43,713 and 53,455 Restricted Stock shares, respectively, to certain key employees and officers. Forfeiture of 800 and 3,482 Restricted Stock

shares occurred during the six months ended March 31, 2019 and 2018, respectively. As of March 31, 2019 and September 30, 2018, 94,971 and 85,424 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 \$0.4 million and \$0.3 million for the three months ended March 31, 2019 and 2018, respectively, and \$0.8 million and \$0.5 million for the six months ended March 31, 2019 and 2018, respectively.

Performance Share Awards

The Company has entered into performance share agreements with certain key employees covering the issuance of common stock (“Performance Shares”). Performance Shares vest upon the achievement of all or a portion of certain performance objectives (which may include financial or project objectives), which must be achieved during the performance period. The Organization and Compensation Committee of the Board of Directors (the “Committee”) approves the performance objectives used for our executive compensation programs, which objectives were cumulative revenue and cumulative earnings before interest, income taxes, depreciation and amortization (“EBITDA”) for the three-year performance periods for awards granted in fiscal 2016 (2016 – 2018) and fiscal 2017 (2017 – 2019). The fiscal 2017 awards also include performance objectives related to achievement of the Company’s strategic initiatives. Assuming that the minimum performance level is attained, the number of shares that may actually vest will vary based on performance from 20% (minimum) to 200% (maximum) of the target number of shares. Shares will be issued to participants as soon as practicable following the end of each performance period, subject to Committee approval and verification of results. Awards granted in fiscal 2016 were finalized in the six months ended March 31, 2019 and resulted in the issuance of 76,396 shares (maximum was 132,676 shares) based on the performance objectives relative to actual results achieved during the performance period. The per share compensation cost for each award is fixed on the grant date. Compensation expense is recognized in each period based on management’s estimate of the achievement level of actual and forecasted results, as appropriate, compared with the specified performance objectives and the related impact on the number of Performance Shares expected to vest. The stock-based compensation expense table includes Performance Shares expense (benefit) recognized related to these awards, which totaled \$(0.2) million and \$0.2 million for the three months ended March 31, 2019 and 2018, respectively, and \$(0.1) million and \$0.4 million for the six months ended March 31, 2019 and 2018, respectively.

The fair values of the Performance Shares, at target, were \$1.2 million for awards granted in fiscal 2017. There were no Performance Share awards granted in fiscal 2018 and none, to date, in fiscal 2019.

The aggregate number of shares that could be awarded to our executives if the minimum, target and maximum performance goals are met, based on the fair value at the date of grant is as follows as of March 31, 2019:

	Minimum	Target	
Performance Period	Shares	Shares	Maximum Shares
Fiscal 2017 – 2019	9,352	46,758	93,516

Employee Stock Purchase Plan

Under the Employee Stock Purchase Plan (“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 have up to 10% of their annual compensation withheld, with a limit of \$25,000, to purchase the Company’s common stock at purchase prices defined within the provisions of the Stock Purchase Plan. As of March 31, 2019 and September 30, 2018, there was \$0.1 million of employee contributions included in accrued liabilities in the condensed consolidated balance sheets.

Stock compensation expense recognized related to the Stock Purchase Plan for the three and six months ended March 31, 2019 and 2018 totaled less than \$0.1 million in each respective period. The stock-based compensation table includes the Stock Purchase Plan expenses.

Restricted Stock and Deferred Stock Units

During the six months ended March 31, 2019 and 2018, the Company awarded 11,871 and 21,265 restricted stock units (“RSUs”), respectively, to non-employee directors and certain key employees in foreign jurisdictions. As of March 31, 2019 and September 30, 2018, 62,420 and 60,440 RSUs were outstanding, respectively. RSU awards are not considered issued or outstanding common stock of the Company until they vest. 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 table includes RSU expenses recognized related to these awards, which totaled \$0.1 million for both the three-month periods ended March 31, 2019 and 2018 and \$0.3 million and \$0.2 for the six months ended March 31, 2019 and 2018, respectively.

Directors may elect to receive their annual fees for services to the Board in deferred stock units (“DSUs”). Certain directors elected this option beginning on January 1, 2013 with subsequent deferral elections updated quarterly. During the six months ended March 31, 2019 and 2018, 1,422 and 1,432 units, respectively, were issued with a total fair value of less than \$0.1 million in each period. As of March 31, 2019 and September 30, 2018, outstanding, fully vested DSUs totaled 28,413 and 26,991, respectively. Stock-based compensation expense related to DSU awards totaled less than \$0.1 million for both the three-month periods ended March 31, 2019 and 2018 and \$0.1 million for both the six-month periods ended March 31, 2019 and 2018.

12. Net Income (Loss) Per Share Data

Basic net income (loss) per common share is calculated by dividing net income (loss) by the weighted average number of common shares outstanding during the period. Diluted net income (loss) per common share is computed by dividing net income (loss) 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, deferred stock units and performance shares. 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. However, these shares have been excluded from the calculation of diluted net loss per share as their effect is antidilutive for the six months ended March 31, 2018, as a result of the net loss incurred for the period. Therefore, diluted weighted average number of shares outstanding and diluted net loss per share were the same as basic weighted average number of shares outstanding and net loss per share for the six months ended March 31, 2018.

The calculation of weighted average diluted shares outstanding excludes outstanding stock options associated with the right to purchase 0.2 million shares of common stock for the three and six months ended March 31, 2019 and 2018, respectively, and \$0.2 million and 0.2 million shares of common stock in the six months ended March 31, 2019, 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 (loss) per share (in thousands):

	Three Months		Six Months Ended	
	Ended March 31, 2019	2018	March 31, 2019	2018
Net income (loss) available to common shareholders	\$1,262	\$1,534	\$2,572	\$(22)
Basic weighted average shares outstanding	13,390	13,102	13,379	13,078
Dilutive effect of outstanding stock options, non-vested restricted stock, restricted stock units, deferred stock units and performance shares	395	363	437	—
Diluted weighted average shares outstanding	13,785	13,465	13,816	13,078

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

For interim income tax reporting, the Company estimates its annual effective tax rate and applies it to year-to-date pretax income (loss), excluding unusual or infrequently occurring discrete items. Tax jurisdictions with losses for which tax benefits cannot be realized are excluded. The Company recorded income tax benefit of \$0.2 million and \$1.2 million for the three months ended March 31, 2019 and 2018, respectively. The Company recorded income tax benefit of \$0.3 million and \$0.2 million for the six months ended March 31, 2019 and 2018. In December 2017, the Tax Cuts and Jobs Act tax legislation was signed into law, which reduced the U.S. Federal statutory tax rate from 35% to 21%, among other changes. As a result of the enactment of this legislation, the tax provision for the first six months of fiscal 2018 included discrete tax expense of \$1.2 million from the Company's net deferred tax assets revaluation based on the enacted tax rate of 21%, as compared with the previous rate of 35%.

The effective income tax rate for the three and six months ended March 31, 2019 differs from the U.S. federal statutory tax rate of 21% primarily due to the favorable impacts of increased U.S. federal research and development tax credits in both periods, as well as stock award activity in the six-month period. These benefits were partly offset by non-deductible acquired intangible asset amortization, as well as operating losses incurred in Ireland, where tax benefits are offset by a valuation allowance. The effective income tax rate for the three and six months ended March 31, 2018 differs from the U.S. federal statutory tax rate of 24.5%

primarily due to operating losses incurred in Ireland, where tax benefits are offset by a valuation allowance, and non-deductible acquired intangible asset amortization, contingent consideration accretion, including fair value adjustments, as well as unrealized foreign currency translation losses on Euro-denominated contingent consideration liabilities. These increases to the effective income tax rate were partially offset by the U.S. federal research and development income tax credit. The effective income tax rate for the three months ended March 31, 2019 and 2018 was impacted by discrete tax benefits of less than \$0.1 million and \$0.2 million, respectively, related to share awards vested, expired, cancelled and exercised during the periods. The effective income tax rate for the six months ended March 31, 2019 and 2018 was impacted by discrete tax benefits of \$0.5 million and \$0.4 million, respectively, related to share awards vested, expired, cancelled and exercised during the periods.

The total amount of unrecognized tax benefits, excluding interest and penalties that, if recognized, would affect the effective tax rate is \$1.7 million and \$1.4 million as of March 31, 2019 and September 30, 2018, respectively. Interest and penalties related to unrecognized tax benefits are recorded in the income tax (benefit) provision.

The Company files income tax returns, including returns for its subsidiaries, in the U.S. federal jurisdiction and in various state jurisdictions as well as several non-U.S. jurisdictions. Uncertain tax positions are related to tax years that remain subject to examination. U.S. income tax returns for years prior to fiscal 2015 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 2007. For tax returns for non-U.S. jurisdictions, the Company is no longer subject to income tax examination for years prior to 2012. 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. As of March 31, 2019 and September 30, 2018, there were no undistributed earnings in foreign subsidiaries. The Internal Revenue Service (“IRS”) completed an examination of our fiscal 2016 U.S. federal income tax return in the third quarter of fiscal 2018, with an immaterial payment made associated primarily with timing adjustments.

14. Segment and Geographical 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 is comprised of manufacturing balloons and catheters used for a variety of interventional cardiology, peripheral and other applications, 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, and neurovascular, and urology, among others, and (2) the In Vitro Diagnostics unit, which consists of component products and technologies for diagnostic immunoassay as well as molecular tests and biomedical research applications, with products that include protein stabilization reagents, substrates, antigens and surface coatings.

Edgar Filing: SURMODICS INC - Form 10-Q

The tables below present segment revenue, operating income (loss) and depreciation and amortization, as follows:

(Dollars in thousands)	Three Months		Six Months Ended	
	Ended March 31, 2019	2018	March 31, 2019	2018
Revenue:				
Medical Device	\$17,301	\$14,052	\$34,559	\$26,826
In Vitro Diagnostics	5,375	5,006	10,358	9,245
Total revenue	\$22,676	\$19,058	\$44,917	\$36,071
Operating income (loss):				
Medical Device	\$(23)	\$232	\$334	\$(157)
In Vitro Diagnostics	2,915	2,423	5,370	4,093
Total segment operating income	2,892	2,655	5,704	3,936
Corporate	(2,027)	(2,130)	(4,127)	(4,044)
Total operating income (loss)	\$865	\$525	\$1,577	\$(108)
Depreciation and amortization:				
Medical Device	\$1,447	\$1,324	\$2,835	\$2,596
In Vitro Diagnostics	117	100	233	190
Corporate	255	162	507	320
Total depreciation and amortization	\$1,819	\$1,586	\$3,575	\$3,106

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, such as litigation, 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. 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.

In April 2018, a customer notified the Company that it believed it overpaid hydrophilic coating royalties to the Company from January 2009 through December 2017. During fiscal 2018, the Company recorded \$1.0 million in selling, general and administrative expenses related to this claim, which was included in other accrued liabilities as of September 30, 2018. During the quarter ended March 31, 2019, the Company settled this claim and made a payment to the customer totaling \$0.4 million, resulting in a reduction of selling, general and administrative expenses of \$0.6 million for the three and six months ended March 31, 2019.

InnoCore Technologies BV. In March 2006, the Company entered into a license agreement whereby Surmodics obtained an exclusive license to a drug delivery coating for licensed products within the vascular field which included peripheral, coronary and neurovascular biodurable stent products. The license requires an annual minimum payment of 200,000 euros (equivalent to \$224,000 using a euro to US dollar exchange rate of \$1.1217 to the Euro as of March 31, 2019) until the last patent expires which is currently estimated to be September 2027. The total minimum future payments associated with this license are approximately \$2.0 million as of March 31, 2019. The license is currently utilized by one of the Company's drug delivery customers.

Operating Leases. The Company leases certain facilities under noncancelable operating lease agreements. Rent expense for the three and six months ended March 31, 2019 was \$0.1 million and \$0.2 million, respectively. Rent expense for the three and six months ended March 31, 2018 was \$0.1 million and \$0.2 million, respectively. In November 2017, the Company executed a lease for a 36,000 square feet facility in Eden Prairie, Minnesota. This facility will consolidate substantially all of our whole products solutions research and development operations into one location. Payments under the lease agreement over the ten-year lease term commenced in May 2018. In connection with this lease, the Company deposited \$0.4 million into a restricted cash account, which was returned to the Company during the six months ended March 31, 2019. Annual commitments pursuant to operating lease agreements in place as of March 31, 2019 for the remainder of fiscal 2019 and each of the next five fiscal years are as follows (in thousands):

Remainder of 2019	\$226
2020	458
2021	396
2022	391
2023	399
2024	407
Thereafter	1,526
Total minimum lease payments	\$3,803

Asset Acquisition. In May 2018, the Company entered into an asset purchase agreement with Embolitech, LLC to acquire certain intellectual property assets (the “Embolitech Transaction”). As part of the Embolitech Transaction, the Company paid the sellers \$5.0 million during fiscal 2018. Additionally, the Company is obligated to pay \$3.5 million in several installments beginning January 2020 and ending December 2023. 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 March 31, 2019 and September 30, 2018, \$2.1 million and \$2.9 million, respectively, is included in other long-term liabilities on the condensed consolidated balance sheets related to the Embolitech Transaction. As of March 31, 2019 \$1.0 million is included in other current liabilities on the condensed consolidated balance sheets related to the Embolitech Transaction.

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 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, 2018. 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. In fiscal 2019, our revenue performance continues to be driven by our core Medical Device and In Vitro Diagnostics ("IVD") businesses. Revenue in the Medical Device business is comprised of product sales, hydrophilic coatings royalties and license fees, and contract research and development services. Medical Device segment revenue increased 23% for the second quarter of fiscal 2019 as compared with the same prior-year period. Medical Device revenue was favorably impacted by increased medical device product sales, license fee revenue from our Abbott Vascular, Inc. ("Abbott") agreement described below, and contract research and development services. Our IVD business derives its revenue from diagnostic technology product sales. Revenue from the IVD segment increased 7% in the second quarter of fiscal 2019 as compared with the same prior-year period, driven by growth across several product categories.

We continue to derive our revenue from three primary sources: (1) product sales revenue from the sale of reagent chemicals to licensees, the sale of stabilization products, antigens, substrates and surface coatings to the diagnostic and biomedical research markets as well as the sale of medical devices and related products (such as balloons and catheters) to original equipment manufacturer (OEM) suppliers and distributors; (2) royalties and license fees from licensing our proprietary surface modification and device drug delivery technologies to customers; and (3) contract coating, design, research and commercial development fees generated on customer projects. Revenue fluctuates from quarter to quarter depending on, among other factors: orders of our medical device and diagnostics products; our customers' success in selling products incorporating our technologies; the timing of introductions of licensed products by us and our customers; the timing of introductions of products that compete with our customers' products; the number of and activity level associated with customer development projects; the number and terms of new license agreements that are finalized each quarter; and the value of reagent chemicals, medical device, diagnostic and other products sold to customers.

Since fiscal 2013, with our investment in our drug-coated balloon ("DCB") platform, we have been focused on a strategy to develop and manufacture proprietary medical device products that combine our surface modification coatings with medical devices or delivery systems ("whole-product solutions"). Our aim is to provide customers earlier access to highly differentiated whole-product solutions that address unmet clinical needs. On February 26, 2018, we entered into an agreement with Abbott (the "Abbott Agreement") whereby Abbott will have exclusive worldwide commercialization rights for Surmodics' SurVeil® DCB to treat the superficial femoral artery (the "SurVeil DCB"), 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 DCB products, which are currently in pre-clinical development and a first-in human clinical study, respectively. Upon the regulatory approval of the SurVeil DCB, Surmodics will be responsible for the manufacture and supply of clinical and commercial quantities of the product and will realize revenue from product sales to Abbott, which will include a share of profits resulting from third-party sales. In the quarter ended March 31, 2019, we recognized revenue of \$1.6 million related to the Abbott Agreement, which is included in royalties and license fees in our medical device segment. Revenue from the upfront fee is recognized as regulatory and clinical activities, primarily the TRANSCEND clinical trial, are performed.

Variable consideration from the contingent milestones is excluded from revenue until the underlying contingencies are resolved, at which point the milestone will be recognized as the promised regulatory and clinical activities are performed. In December 2018, we commenced a first-in-human clinical study of our A vess™ DCB for treatment of AV fistulae, commonly associated with hemodialysis. We expect to complete enrollment in this study by the end of fiscal 2019.

We have several U.S. and international issued patents and pending international patent applications protecting various aspects of proprietary surface modification technologies, including compositions, methods of manufacture and methods of coating devices. The expiration dates for these patents and the anticipated expiration dates of patent applications that cover our hydrophilic coating technologies range from fiscal 2020 to fiscal 2035. Our fourth-generation PhotoLink technology is protected by a family of patents that begin to expire in November 2019. The royalty revenue associated with our fourth-generation technology was approximately 21% of our consolidated fiscal 2018 revenue. Of the license agreements using our fourth-generation technology, most continue to generate royalty revenue at a reduced royalty rate beyond patent expiration. We also continue to generate significant royalty

revenue from license agreements leveraging our earlier generation coating technologies that continue to provide royalties for our “know-how” or other proprietary rights. Our remaining hydrophilic royalty revenue is primarily derived from other Surmodics coating technologies that are protected by a number of patents extending to fiscal 2035. While we are actively seeking to convert our customers to an advanced generation of our hydrophilic coating technology, there can be no assurance that we will be successful in doing so, or that those customers that have converted, or will convert, will sell products utilizing our technology which will generate earned royalty revenue for us.

Overview of Research and Development Activities

We continue to invest in our whole-product solutions strategy through research and development (“R&D”) activities in our proprietary products pipeline, including clinical and regulatory activities necessary to bring these products to market. The continued development of new products is critical to our strategy to offer whole-product solutions for the medical device industry. In April 2019, we received United States Food and Drug Administration (“FDA”) clearance for the Sublime™ guide sheath, designed to enable the delivery of lower extremity interventions from the radial artery. Radial artery access has been widely adopted for use in coronary procedures where devices have been developed to accommodate that need. The Sublime guide sheath is intended to introduce therapeutic or diagnostic devices into the vasculature, excluding the coronary and neuro vasculature. Radial access offers many benefits relative to femoral access including reduced puncture site bleeding complications, earlier ambulation, reduced length of hospital stay, and lower healthcare costs. We expect to submit for regulatory approval for additional medical device products in fiscal 2019.

In July 2017, we received an investigational device exemption (“IDE”) from the FDA to initiate a pivotal clinical trial of the SurVeil DCB. The randomized clinical trial, TRANSCEND, is now underway and is focused on evaluating the SurVeil DCB for treatment for PAD in the upper leg compared with the Medtronic IN.PACT® Admiral® DCB. The objective of the TRANSCEND clinical trial is to evaluate the safety and effectiveness of the SurVeil DCB device for treatment of subjects with symptomatic peripheral artery disease (“PAD”) due to stenosis of the femoral and/or popliteal arteries. If successful, the TRANSCEND clinical trial will be used to support regulatory approvals and reimbursement (U.S. and Europe). The trial will enroll up to 446 subjects at up to 60 sites in the U.S. and 18 outside the U.S. The trial’s primary efficacy endpoint is primary patency, defined as a composite of freedom from restenosis and clinically-driven target lesion revascularization through 12 months post-index procedure. All randomized subjects will be followed through 60 months post-index procedure. We began enrollment in the TRANSCEND clinical trial in the first quarter of fiscal 2018. Until regulatory approvals have been obtained, the SurVeil DCB is not approved for commercial sale. There is no assurance that the TRANSCEND clinical trial will support regulatory approval, or that any anticipated time frame will be met. We estimate that the total cost of the TRANSCEND clinical trial will range between \$32 million to \$40 million from inception to completion. To the extent that we achieve certain agreed-upon milestones in connection with the TRANSCEND clinical trial, we may receive up to \$67 million of additional milestone payments pursuant to the Abbott Agreement.

On March 15, 2019, the FDA issued a communication (the “March 15 communication”) to healthcare providers about the potential for increased long-term mortality after use of paclitaxel-coated balloons and paclitaxel-eluting stents (collectively “paclitaxel-coated products”) to treat peripheral arterial disease (“PAD”) in the femoropopliteal artery. The communication updates a previous notification from the FDA on the same topic, which was in response to meta-analysis of randomized trials published in the Journal of the American Heart Association in December 2018. Following the March 15 communication, the Company temporarily paused patient enrollment in TRANSCEND and sought guidance from the FDA regarding the recommendations contained in the communication and their impact on the TRANSCEND trial. Based on discussions with FDA, the Company took several actions in response to the FDA’s recommendations, including updates to investigator communications, patient Informed Consent Forms (“ICF”), and data safety review and patient follow-up procedures. Many of the TRANSCEND clinical trial sites have secured Institutional Review Board or Ethics Committee approval of the updated ICF and are actively enrolling and randomizing patients. The March 15 communication and ensuing developments have resulted in uncertainty regarding our goal to complete enrollment in the TRANSCEND clinical trial before the end of our fiscal year. As a result, we

anticipate fiscal 2019 revenue from the \$25 million upfront payment of \$7.0 to \$7.5 million from the Abbott Agreement, of which \$4.0 million has been recognized through March 31, 2019.

We are executing on our plan to develop and commercialize 12-15 medical device products by the end of fiscal 2023. Additional planned activities include initiation of surface modification experiments that improve medical device performance, as well as incorporation of our catheter and thrombectomy technology platforms into various other devices intended for the emerging peripheral vascular treatment market. We are also continuing to develop other products that utilize our DCB platform, including DCB's for treatment of PAD below-the-knee and AV fistulae. We may also acquire technologies, when appropriate, to complement or integrate with our existing proprietary products.

We prioritize our internal R&D programs based on a number of factors, including a program’s strategic fit, commercial impact and market size, potential competitive advantages, technical feasibility, and the amount of investment required. The measures and metrics used to monitor a program’s progress vary, but typically include key deliverables, milestones, timelines, and an overall program budget. We typically make decisions to continue or terminate a program based on research results (relative to the above measures and metrics) and other factors, including our own strategic and/or business priorities, and the amount of additional investment required to complete development.

With respect to cost components, R&D expenses consist of labor, materials and overhead costs (for example, utilities, depreciation, and indirect labor) for both customer R&D and internal R&D programs. We manage our R&D organization in a flexible manner, balancing workloads/resources between internal R&D and customer R&D programs, based on the level of customer program activity and resource needs for our internally developed product programs. Therefore, costs incurred for customer R&D and internal R&D can shift as customer and internal project activity increases or decreases.

Critical Accounting Policies

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, and are updated at least quarterly. For the six months ended March 31, 2019, there were no significant changes in our critical accounting policies, other than those required by the adoption of ASC Topic 606 - Revenue from Contracts with Customers. See Notes 1 and 2 to our Condensed Consolidated Financial Statements included in Item 1 of Part I of this Quarterly Report on Form 10-Q for disclosure of these policies, as well as a summary of the impact of the adoption of ASC Topic 606 on the opening consolidated balance sheet as of October 1, 2018, as compared with the consolidated balance sheet previously presented as of September 30, 2018.

For a detailed description of our other critical accounting policies, 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, 2018.

Results of Operations – Three and Six Months Ended March 31

Revenue. Revenue for the second quarter of fiscal 2019 was \$22.7 million, an increase of \$3.6 million, or 19.0%, as compared with the second quarter of fiscal 2018. Revenue for the first six months of fiscal 2019 was \$44.9 million, an increase of \$8.8 million, or 24.5%, compared with the first six months of fiscal 2018. The following is a summary of revenue by segment.

(Dollars in thousands)	Three Months Ended March 31,			Six Months Ended March 31,		
	2019	2018	% Change	2019	2018	% Change
Revenue						
Medical Device	\$17,301	\$14,052	23.1 %	\$34,559	\$26,826	28.8 %
In Vitro Diagnostics	5,375	5,006	7.4 %	10,358	9,245	12.0 %
Total Revenue	\$22,676	\$19,058	19.0 %	\$44,917	\$36,071	24.5 %

Medical Device. Medical Device revenue was \$17.3 million in the second quarter of fiscal 2019, an increase of 23.1% as compared with \$14.1 million for the second quarter of fiscal 2018. Medical Device revenue was \$34.6 million in

the first six months of fiscal 2019, an increase of 29% as compared with \$26.8 million for first six months of fiscal 2018.

Product sales increased 23.6%, or \$0.9 million, in the current quarter as compared with the prior-year quarter, due primarily to a \$0.8 million increase in balloon catheter sales. Additionally, royalties and license fee revenue increased 17.9%, or \$1.5 million, in the current-year second quarter as compared with the prior-year second quarter, as a result of a \$1.1 million increase in license fee revenue from the Abbott Agreement, as well as growth in royalties from our hydrophilic coatings customers. Additionally, a \$0.9 million increase in research, development and other revenue in the fiscal 2019 second quarter as compared with the prior year period resulted from increased revenue from projects with several of our contract R&D customers.

Product sales increased 23.9%, or \$1.8 million, for the first six months of fiscal 2019 as compared with the same prior-year period, due primarily to a \$1.9 million increase in balloon catheter sales. Additionally, royalties and license fee revenue increased 29.2%, or \$4.5 million, for the first six months of fiscal 2019 as compared with the same prior-year period, as a result of a \$3.5 million increase in license fee revenue from the Abbott Agreement, as well as growth in royalties from our hydrophilic coatings customers.

Additionally, a \$1.4 million increase in research, development and other revenue for the first six months of fiscal 2019 as compared with the same prior year period resulted from increased revenue from projects with several of our contract R&D customers.

In Vitro Diagnostics. In Vitro Diagnostics revenue increased 7.4% to \$5.4 million in the second quarter of fiscal 2019 as compared with \$5.0 million for the second quarter of fiscal 2018, primarily due to an increase in sales of our chemical components used in diagnostics tests and microarray slides, partly offset by a decline in sales of distributed antigens. In Vitro Diagnostics revenue increased 12.0% to \$10.4 million for the first six months of fiscal 2019 as compared with \$9.2 million in the same prior-year period, primarily due to an increase in sales across several product categories, partly offset by a decline in sales of distributed antigens.

Costs and Operating Expenses

The following is a summary of major costs and expenses as a percent of total revenue:

(Dollars in thousands)	Three Months Ended March 31,				Six Months Ended March 31,			
	2019		2018		2019		2018	
	Amount	% Total Revenue	Amount	% Total Revenue	Amount	% Total Revenue	Amount	% Total Revenue
Product costs	\$3,093	14 %	\$2,913	15 %	\$6,616	15 %	\$5,804	16 %
Research and development	13,555	60	10,774	57	25,041	56	18,605	52
Selling, general and administrative	4,876	22	6,440	34	10,825	24	11,628	32
Acquired intangible asset amortization	604	3	636	3	1,210	3	1,254	3
Contingent consideration gain	(317)	(1)	(2,230)	(12)	(352)	(1)	(1,112)	(3)

Product costs. Product gross margin (defined as product sales less related product costs) was 68.7% and 66.5% of product sales for the second quarter of fiscal 2019 and 2018, respectively. Product gross margin was 66.3% and 65.4% of product sales for the first six months of fiscal 2019 and 2018, respectively. The increase in product gross margin percentage in the three and six months ended March 31, 2019, as compared with the same prior-year periods, was due to increased revenue and product mix changes in our IVD business, as well as favorable impacts of production volume increases in our Irish manufacturing facility. As previously disclosed, the scale-up of our Irish manufacturing facility and growth in sales from that facility are expected to negatively impact product gross margins in our Medical Device business in fiscal 2019 relative to prior years.

Research and development (R&D) expenses. R&D expenses increased \$2.8 million in the second quarter of fiscal 2019, as compared with the same prior-year period. R&D expenses in the first six months of fiscal 2019 increased \$6.4 million as compared with the same prior-year period. These increases were primarily the result of higher planned spending for our DCB and proprietary product development and clinical activities, including our TRANSCEND clinical trial. We plan to continue current levels of R&D spending throughout the remainder of fiscal 2019 to support our whole-product solutions strategy, including similar levels of clinical and regulatory costs as we continue enrollment in the TRANSCEND clinical trial for our SurVeil DCB and the first-in-human trial for our Avers DCB. We anticipate fiscal 2019 R&D expense will be in the mid-fifties as a percent of fiscal 2019 revenue.

Selling, general and administrative (SG&A) expenses. SG&A expenses decreased \$1.6 million in the second quarter of fiscal 2019 as compared with the same prior-year period. SG&A expenses decreased \$0.8 million in the first six months of fiscal 2019, as compared with the same prior-year period. The decreases in SG&A expenses from the prior-year periods is primarily due to a \$0.6 million benefit from a customer claim settlement in the second quarter of

fiscal 2019 which was settled for less than the amount previously accrued. The prior-year periods included a \$1.0 million charge to SG&A for the estimated customer claim accrual. We expect fiscal 2019 SG&A expenses will range between 24% and 26%, as a percent of revenue.

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 BioFx acquisition in fiscal 2007. We recognized \$0.6 million in amortization expense related to these acquisitions in the three months ended March 31, 2019 and 2018. We recognized \$1.2 million and \$1.3 million in amortization expense related to these acquisitions in the first six months of fiscal 2019 and 2018, respectively. Acquired intangible asset amortization is estimated to total \$2.4 million in fiscal 2019.

Contingent consideration gain. For the three months ended March 31, 2019 and 2018, we recorded net gains of \$0.3 million and \$2.2 million, respectively, related to our contingent consideration liabilities from prior-year acquisitions. For the first six months of fiscal 2019 and 2018, we recorded net gains of \$0.4 million and \$1.1 million, respectively, related to our contingent consideration liabilities from prior-year acquisitions. The contingent consideration gains in each period are related to changes in estimated probabilities of achievement of certain revenue and strategic milestones partly offset by normally scheduled accretion expense related to the passage of time. In fiscal 2019, if there are changes in the amount, probability or timing of achievement of contingent consideration milestones, there may be material adjustments in the consolidated statements of operations to reflect changes in the fair value of contingent consideration liabilities. All remaining contingent consideration obligations are expected to be paid in December 2019.

Other income, net. Major classifications of other income, net are as follows:

	Three		Six Months	
	Months		Months	
	Ended		Ended	
	March 31,		March 31,	
(Dollars in thousands)	2019	2018	2019	2018
Investment income, net	\$265	\$142	\$581	\$263
Interest expense	(37)	—	(74)	—
Foreign exchange gain (loss)	5	(353)	141	(539)
Gains on strategic investment and other	2	—	9	177
Other income (loss), net	\$235	\$(211)	\$657	\$(99)

The increase in investment income in the second quarter and first six months of fiscal 2019, as compared with the prior-year periods, is the result of higher interest rates on debt investments, as well as an increase in investment principal. Interest expense in the fiscal 2019 periods is related to the outstanding obligations stemming from our acquisition of technology from Embolitech in the third quarter of fiscal 2018. The foreign exchange gain (loss) in the six months ended March 31, 2019 and the three and six months ended March 31, 2018 are primarily related to the change in exchange rates associated with the Euro-denominated contingent consideration liability from the Creagh Medical acquisition, which was paid in the first quarter of fiscal 2019. As these amounts have now been settled, we do not expect foreign currency exchange gains or losses to be significant for the remainder of fiscal 2019. We recognized a gain on a previously sold strategic investment in the first six months of fiscal 2018 as additional consideration was released from escrow.

Income tax provision. The income tax benefit was \$0.2 million and \$1.2 million for three months ended March 31, 2019 and 2018, respectively. The income tax benefit was \$0.3 million and \$0.2 million for the six months ended March 31, 2019 and 2018, respectively. In December 2017, the Tax Cuts and Jobs Act tax legislation was signed into law, which reduced the U.S. Federal statutory tax rate from 35% to 21%, among other changes. As a result of the enactment of this legislation, the Company's net loss for the six months ended March 31, 2018 included discrete tax expense of \$1.2 million from our net deferred tax assets revaluation based on the change in the statutory tax rate. 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 months ended March 31, 2019 and 2018 reflect expected full-year pre-tax operating results, impacted by our estimated U.S. federal R&D tax credit. The tax benefits recognized in the six months ended March 31, 2019 and 2018 reflect expected full-year pre-tax operating results, impacted by excess tax benefits related to stock-based compensation due to equity award exercise activity and estimated U.S. federal R&D

tax credit. In the six months ended March 31, 2018, the tax benefit was reduced by the aforementioned \$1.2 million revaluation of deferred tax assets as a result of the tax rate.

Discrete tax benefit from excess tax benefits realized from share awards vested, expired, cancelled and exercised of less than \$0.1 and \$0.2 million were recognized in the second quarter of fiscal 2019 and 2018, respectively, and \$0.5 and \$0.4 million in the first six months of fiscal 2019 and 2018, respectively.

We expect income tax benefit to be in the range of \$0.4 million to \$0.8 million for fiscal 2019. Currently, income and losses generated in Ireland from our Creagh Medical acquisition do not reflect an Irish income tax expense (benefit) as they are offset by a valuation allowance. Therefore, taxable income or losses in Ireland, where the statutory tax rate is 12.5%, will result in no reported tax benefit or expense in fiscal 2019. Certain provisions of the Tax Cuts and Jobs Act significantly change the treatment of accumulated and future earnings of foreign subsidiaries. While we do not have accumulated earnings subject to a repatriation tax under the law, we may be subject to additional U.S. tax on our foreign subsidiary's income in future years.

Segment Operating Results

Operating income (loss) for each of our reportable segments is as follows:

(Dollars in thousands)	Three Months Ended March 31,			Six Months Ended March 31,		
	2019	2018	Change	2019	2018	Change
Operating income (loss):						
Medical Device	\$(23)	\$232	(110)%	\$334	\$(157)	NM
In Vitro Diagnostics	2,915	2,423	20 %	5,370	4,093	31 %
Total segment operating income	2,892	2,655		5,704	3,936	
Corporate	(2,027)	(2,130)	(5)%	(4,127)	(4,044)	2 %
Total operating income (loss)	\$865	\$525	65 %	\$1,577	\$(108)	NM

Medical Device. In the second quarter of fiscal 2019, our Medical Device business incurred an operating loss of less than \$0.1 million, as compared with operating income of \$0.2 million in the prior-year quarter. Operating income in the first six months of fiscal 2019 improved by \$0.5 million to \$0.3 million, from an operating loss of \$0.2 million in the same prior-year period. Operating (loss) income as a percentage of revenue was (0.1)% and 1.7% in the second quarter of fiscal 2019 and 2018, respectively. Operating income (loss) as a percentage of revenue was 1.0% and (0.6)% in the first six months of fiscal 2019 and 2018, respectively. Impacting operating results in the second quarter were a \$2.8 million increase in R&D expenses related to our planned investment in our DCB and proprietary medical device product development and clinical programs, as well as a \$1.9 million reduction in the gain related to our contingent consideration obligations as compared with the prior-year quarter. These items were partly offset by a \$3.3 million increase in revenue and a \$1.5 million reduction in SG&A expenses related to the aforementioned customer claim settlement.

Operating results improved in the first six months of fiscal 2019 from the comparable prior-year period as a result of a \$7.7 million increase in revenue and a \$0.7 million reduction of SG&A expenses, partly offset by a \$6.4 million increase in R&D expenses related to our planned investment in our DCB and proprietary medical device product development and clinical programs. Additionally, we recognized a gain of \$0.4 million related to our contingent consideration obligations in the first six months of fiscal 2019, as compared with a gain of \$1.1 million in the prior-year period.

In Vitro Diagnostics. Operating income improved by \$0.5 million in the second quarter of fiscal 2019, as compared with the prior-year quarter. Operating income improved by \$1.3 million in the first six months of fiscal 2019, as compared with the same prior-year period. Operating income as a percentage of revenue was 54.2% and 48.4% in the second quarter of fiscal 2019 and 2018 respectively. Operating income as a percentage of revenue was 51.8% and 46.8% in the first six months of fiscal 2019 and 2018 respectively. Product gross margins increased to 72.5% and 71.9% in the three and six months ended March 31, 2019, respectively, from 71.4% and 68.4%, in the respective prior-year periods. Product gross margins and operating income have increased in fiscal 2019 due to increased revenue, favorable product mix and manufacturing leverage.

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 March 31, 2019, we had working capital of \$51.2 million, an increase of \$4.8 million from September 30, 2018. Working capital is defined by us as current assets minus current liabilities. The increase from the prior year-end is a result of contract assets totaling \$7.1 million recorded during fiscal 2019 as a result of the adoption of ASC Topic 606, as well as increases in operating income from the prior year, partly offset by payments for capital expenditures totaling \$3.1 million. Our cash and cash equivalents and available-for-sale investments totaled \$46.5 million at March 31, 2019, a decrease of \$18.5 million from \$65.0 million at September 30, 2018. This change was primarily driven by the \$11.0 million contingent consideration payment related to the Creagh Medical acquisition, as well as payment of accrued compensation liabilities totaling \$4.1 million, capital expenditures of \$3.1 million and \$2.7 million of cash payments for taxes related to net share settlement of equity awards. These outflows were partly offset by growth in operating income in the current fiscal year to date, as compared with the same prior-year period.

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. 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 for the foreseeable future as it continues to assess other investment opportunities and uses of its cash and securities investments, including those described below.

Summary of Cash Flows

(Dollars in thousands)	Six Months Ended	
	2019	2018
Cash (used in) provided by:		
Operating activities	(3,938)	27,431
Investing activities	14,272	(14,356)
Financing activities	(11,478)	(1,680)
Effect of exchange rates on changes in cash and cash equivalents	(54)	133
Net change in cash and cash equivalents	\$(1,198)	\$11,528

Operating Activities. We used cash for operating activities of approximately \$3.9 million in the six months ended March 31, 2019 as compared with cash generated from operating activities of \$27.4 million in the same prior-year period. During the six months ended March 31, 2019 and 2018, we had net income (loss) of \$2.6 million and \$(0.1) million, respectively. Additionally, in the fiscal 2019 period, \$2.0 million of the \$11.0 million payment of contingent consideration obligations related to the Creagh Medical acquisition was recorded as a reduction of cash flows from operations as it related to accretion expense which increased these obligations from the acquisition date through final settlement. Net changes in operating assets and liabilities had a negative impact on cash flows of \$9.8 million in the six months ended March 31, 2019 as compared with a positive impact of \$22.3 million in the same prior-year period, which included the \$25 million upfront payment received from Abbott. Significant changes in operating assets and liabilities during these periods included:

- Cash used by deferred revenue was \$4.1 million in the fiscal 2019 period, as compared with cash provided by deferred revenue of \$24.6 million in the fiscal 2018 period. This change is entirely related to the timing of recognition of revenue and receipt of the \$25 million upfront payment from Abbott in each respective period.
- Cash used by accrued liabilities was \$4.1 million, as compared with cash provided by accrued liabilities of \$0.8 million for the first six months of fiscal 2019 and 2018, respectively. The increase in cash used by accrued liabilities the fiscal 2019 period, as compared with the fiscal 2018 period, is due to a \$1.2 million increase in incentive compensation payments and a reduction in the customer claim settlement accrual of \$1.0 million in the current fiscal year period, as well as a reduction of accrued clinical trial expenses of \$1.0 million.
- Cash used by accounts receivable totaled \$0.8 million in the first six months of fiscal 2019, as compared with less than \$0.1 million in the same fiscal 2018 period. This is primarily due to the increase in product sales and related accounts receivable in the fiscal 2019 period.
- Cash provided by accounts payable totaled \$1.3 million in the first six months of fiscal 2019, as compared with cash used in accounts payable of \$0.4 million in the same fiscal 2018 period. The increase in accounts payable in the fiscal 2019 period is due primarily to an increase in amounts owed for clinical trial expenses.

Investing Activities. We received cash from investing activities of \$14.3 million in the first six months of fiscal 2019, as compared with cash used in investing activities of \$14.4 million in the first six months of fiscal 2018. We invested \$3.1 million and \$4.0 million in property and equipment in the first six months of fiscal 2019 and fiscal 2018,

respectively. In the first six months of fiscal 2019 and 2018, we received \$17.4 million and used \$10.5 million, respectively, from maturities of available-for-sale debt securities, net of purchases of other investments.

Financing Activities. We used cash in financing activities of \$11.5 million and \$1.7 million in the first six months of fiscal 2019 and 2018, respectively. In the first six months of fiscal 2019 and 2018, we paid \$2.7 million and \$1.1 million, respectively, to purchase common stock to pay employee taxes resulting from the exercise of stock options and vesting of other stock awards. During the first six months of fiscal 2019, we paid contingent consideration of \$11.0 million related to the Creagh Medical acquisition, \$9.1 million of which was recorded as cash from financing activities.

We believe that our existing cash, and cash equivalents and investments, which totaled \$46.5 million as of March 31, 2019, 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 Surmodics' business will continue to generate cash flows at current levels, and disruptions in financial markets may negatively impact our ability to access capital in a timely manner and on attractive terms.

Customer Concentrations. Our licensed technologies provide royalty revenue, which represents the largest revenue stream to the Company. We have licenses with a diverse base of customers and certain customers have multiple products using our technology. Abbott and Medtronic plc ("Medtronic") are our largest customers, comprising 11% and 16%, respectively, of our consolidated revenue for fiscal 2018. These same customers each comprised 15% of our consolidated revenue for the first six months of fiscal 2019. Abbott has several separately licensed products, including the SurVeil license, which generate royalty revenue for Surmodics, none of which represented more than 9% of total revenue for the first six months of fiscal 2019. Medtronic has several separately licensed products that generate royalty revenue for Surmodics, none of which represented more than 3% of our total revenue. No other individual customer using licensed technology constitutes more than 10% of Surmodics' total fiscal 2019 to date or fiscal 2018 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 March 31, 2019 and September 30, 2018, 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 our growth strategy, including our ability to sign new license agreements, bring new products to market and broaden our hydrophilic coatings royalty revenue, the impact of patent expirations on our hydrophilic coatings royalty 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, short-term requirements, future property and equipment investment levels, the impact of potential lawsuits or claims, the impact of Abbott, Medtronic, as well as other significant customers, including new diagnostic kit 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, and our expectations related to our income tax expense for fiscal 2019. Without limiting the foregoing, words or phrases such as "anticipate," "believe," "could," "estimate," "expect," "forecast," "intend," "may," "plan," "possible," "project," "will" and 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 I, Item 1A of our Annual Report on Form 10-K for the fiscal year ended September 30, 2018. 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 could adversely affect our growth strategy and the royalty 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

31

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 AvestTM 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 and changes in consumer confidence;
- 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 PhotoLink[®] hydrophilic technology protected by a family of patents which will begin to expire in November 2019 (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 in "Risk Factors" and other sections of Surmodics' Annual Report on Form 10-K for the fiscal year ended September 30, 2018, 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 March 31, 2019, we held \$24.0 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 royalty revenue from the sale of customer products in foreign jurisdictions. Royalties generated in foreign jurisdictions by customers are converted and paid in U.S. dollars per contractual terms. Substantially all of our purchasing transactions are denominated in U.S. Dollars or Euros. To date, we have not entered into any

foreign currency forward exchange contracts or other derivative financial instruments to hedge the effects of adverse fluctuations in foreign currency exchange.

Item 4. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

The Company maintains disclosure controls and procedures as defined in Rules 13a-15(e) and 15d-15(e) of the Securities Exchange Act of 1934, as amended (the "Exchange Act"). The Company's management, under the supervision and with the participation of the Company's Chief Executive Officer and Chief Financial Officer, referred to collectively herein as the Certifying Officers, carried out an evaluation of the effectiveness of the design and operation of the Company's disclosure controls and procedures as of March 31, 2019. Based on that evaluation, the Company's Certifying Officers concluded that, as of the end of the period covered by this report, the Company's disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) of the Exchange Act) were effective to ensure that information required to be disclosed by the Company in reports that it files under the Exchange Act is recorded, processed, summarized and reported within the time period specified in the Securities and Exchange Commission rules and forms, and to ensure that information required to be disclosed by the Company in the reports the Company files or submits under the Exchange Act is accumulated and communicated to the Company's management, including its Certifying Officers, as appropriate, to allow timely decisions regarding required disclosures.

Changes in Internal Controls over Financial Reporting

There were no changes in our internal control over financial reporting (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act) during the three months ended March 31, 2019 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II — OTHER INFORMATION

Item 1. Legal Proceedings

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

Item 1A. Risk Factors

In our report on Form 10-K for the fiscal year ended September 30, 2018, filed with the SEC on November 30, 2018, we identify under “Part 1, Item 1A. Risk Factors.” important factors which could affect our financial performance and could cause our actual results for future periods to differ materially from our anticipated results or other expectations, including those expressed in any forward-looking statements made in this Form 10-Q.

There have been no material changes in our risk factors subsequent to the filing of our Form 10-K for the fiscal year ended September 30, 2018, other than a risk factor related to delays in our ongoing and planned clinical studies, further discussed below.

Delays in clinical studies are common and have many causes, and any significant delay in clinical studies being conducted by us could result in delays in obtaining regulatory approvals and jeopardize the ability to proceed to commercialization of our SurVeil DCB and other products.

We began enrollment in the TRANSCEND clinical study for our SurVeil DCB in the first quarter of fiscal 2018 and, in December 2018, we commenced a first-in-human clinical study of our Avesc DCB. There are risks involved in these and other clinical studies, including that they may fail to enroll a sufficient number of patients for a variety of reasons or be completed on schedule, if at all. In the second quarter of fiscal year 2019, we temporarily paused patient enrollment in TRANSCEND, the pivotal clinical trial of our SurVeil DCB following the March 15, 2019 publication of a FDA letter to physicians relating to the FDA's preliminary analysis of a potentially concerning signal of increased long-term mortality related to paclitaxel-coated devices. While we resumed patient enrollment in TRANSCEND shortly after making updates to informed consent forms, providing updates to investigator communications related to the FDA communication and taking certain other steps, there can be no assurance that we will not experience future similar delays in this or any other clinical trial. Clinical trials for any of our products could be delayed for a variety of reasons, including, but not limited to:

- delays in reaching agreement with applicable regulatory authorities on a clinical study design;
- issuance of publications or communications relating to the safety of certain medical devices, including recent studies and communications regarding the evaluation of risks associated with paclitaxel-coated products including the FDA notice mentioned above;
- suspension or termination of a clinical study by us, the FDA or foreign regulatory authorities due to adverse events or safety concerns relating to our product; and
- delays in recruiting suitable patients willing to participate in a trial, or delays in having patients complete participation or return for post-treatment follow-up.

If the initiation or completion of any of the ongoing or planned clinical studies for our products is delayed for any of the above or other reasons, the regulatory approval process would be delayed and the ability to commercialize and commence sales of our products could be materially harmed. Additionally, clinical study delays may allow our competitors to bring products to market before we do, which could impair our ability to successfully commercialize our product candidates. Any of these events could have a material adverse effect on our business, financial condition and results of operations.

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

(c) Issuer Purchases of Equity Securities

The following table presents information with respect to purchases of common stock of the Company made during the three months ended March 31, 2019, by the Company or on behalf of the Company or any “affiliated purchaser” of the Company, as defined in Rule 10b-18(a)(3) under the Exchange Act.

Period	Total Number of Shares Purchased as Part of Publicly Announced Plans or Programs	Average Price Paid per Share	Plans or Programs	Approximate Dollar Value of Shares That May Yet Be Purchased Under the Plans or Programs (1)
1/1/19 — 1/31/19	—	N/A	—	\$ 25,298,238
2/1/19 — 2/28/19	—	N/A	—	\$ 25,298,238
3/1/19 — 3/31/19	—	N/A	—	\$ 25,298,238
Total	—	N/A	—	\$ 25,298,238

(1)As of March 31, 2019, the Company has an aggregate of \$25.3 million available for future common stock repurchase 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 for 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 Description

- 2.1 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.
- 2.2 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.
- 2.3 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.
- 3.1 Restated Articles of Incorporation, as amended — incorporated by reference to Exhibit 3.1 of the Company’s Quarterly Report on Form 10-Q filed on July 29, 2016, SEC File No. 0-23837.
- 3.2 Restated Bylaws of Surmodics, Inc., as amended December 18, 2015 — incorporated by reference to Exhibit 3.2 of the Company’s Current Report on Form 8-K filed on December 23, 2015.
- 10.1 Surmodics, Inc. 2019 Equity Incentive Plan — incorporated by reference to Exhibit 2.2 to the Company’s Schedule 14A filed on December 21, 2018, SEC File No. 0-23837.
- 31.1* Certification of Chief Executive Officer pursuant to 18 U.S.C. Sec. 1350 as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
- 31.2* Certification of Chief Financial Officer pursuant to 18 U.S.C. Sec. 1350 as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
- 32.1* Certification of Chief Executive Officer pursuant to 18 U.S.C. Sec. 1350 as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
- 32.2* Certification of Chief Financial Officer pursuant to 18 U.S.C. Sec. 1350 as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
- 101* Financial statements from the Quarterly Report on Form 10-Q for Surmodics, Inc. for the quarterly period ended March 31, 2019, filed on May 3, 2019, formatted in Extensible Business Reporting Language (XBRL): (i) Condensed Consolidated Balance Sheets, (ii) Condensed Consolidated Statements of Operations, (iii) Condensed Consolidated Statements of Comprehensive Income, (iv) Condensed Consolidated Statements of Stockholders’ Equity, (v) Condensed Consolidated Statements of Cash Flows, and (vi) Notes to Condensed Consolidated Financial Statements.

* 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.

May 3, 2019 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)