

SURMODICS INC
Form 10-Q
August 03, 2017

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D. C. 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended June 30, 2017

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

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 and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted 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 and post 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. 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 (Do not check if a smaller reporting company)	Smaller reporting company
	Emerging Growth Company

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

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

The number of shares of the registrant’s Common Stock, \$.05 par value per share, outstanding as of July 25, 2017 was 13,109,961.

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>	22
Item 3. <u>Quantitative and Qualitative Disclosures About Market Risk</u>	31
Item 4. <u>Controls and Procedures</u>	32

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>	34
Item 3. <u>Defaults Upon Senior Securities</u>	34
Item 4. <u>Mine Safety Disclosures</u>	34
Item 5. <u>Other Information</u>	34
Item 6. <u>Exhibits</u>	35

SIGNATURES 36

PART I. FINANCIAL INFORMATION

Item 1. Unaudited Condensed Financial Statements

Surmodics, Inc. and Subsidiaries

Condensed Consolidated Balance Sheets

	June 30, 2017	September 30, 2016
(in thousands, except share and per share data)		
	(Unaudited)	
ASSETS		
Current Assets:		
Cash and cash equivalents	\$ 11,350	\$ 24,987
Available-for-sale securities	32,360	21,954
Accounts receivable, net of allowance for doubtful accounts of \$149 and \$19 as of June 30, 2017 and September 30, 2016, respectively	6,994	6,869
Inventories, net	3,505	3,579
Income tax receivable	993	697
Prepays and other	2,467	472
Total Current Assets	57,669	58,558
Property and equipment, net	22,250	19,601
Deferred tax assets	3,073	5,027
Intangible assets, net	21,230	22,525
Goodwill	26,791	26,555
Other assets	877	628
Total Assets	\$ 131,890	\$ 132,894
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities:		
Accounts payable	\$ 1,916	\$ 1,622
Accrued liabilities:		
Compensation	3,182	5,418
Due to customers	156	881
Accrued other	1,210	1,109
Contingent consideration	925	925
Deferred revenue	155	180
Total Current Liabilities	7,544	10,135
Contingent consideration, less current portion	12,916	13,592
Deferred revenue, less current portion	245	188
Other long-term liabilities	1,836	2,146
Total Liabilities	22,541	26,061
Commitments and Contingencies (Note 15)		
Stockholders' Equity:		
Series A Preferred stock- \$.05 par value, 450,000 shares authorized; no shares issued and outstanding	—	—
Common stock- \$.05 par value, 45,000,000 shares authorized; 13,110,273 and 13,208,443 shares issued and outstanding as of June 30, 2017 and	656	660

Edgar Filing: SURMODICS INC - Form 10-Q

September 30, 2016, respectively

Additional paid-in capital	5,005	6,754
Accumulated other comprehensive income	2,016	1,273
Retained earnings	101,672	98,146
Total Stockholders' Equity	109,349	106,833
Total Liabilities and Stockholders' Equity	\$ 131,890	\$ 132,894

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

Surmodics, Inc. and Subsidiaries

Condensed Consolidated Statements of Income

(In thousands, except per share data)	Three Months		Nine Months	
	Ended June 30, 2017	2016	Ended June 30, 2017	2016
	(Unaudited)		(Unaudited)	
Revenue:				
Product sales	\$8,327	\$7,512	\$23,964	\$22,866
Royalties and license fees	7,244	10,556	22,564	25,207
Research, development and other	2,219	1,904	6,526	5,139
Total revenue	17,790	19,972	53,054	53,212
Operating costs and expenses:				
Product costs	2,914	2,777	8,104	8,069
Research and development	7,927	4,693	22,105	13,195
Selling, general and administrative	5,232	4,483	15,170	12,984
Acquired intangible asset amortization	603	806	1,790	1,940
Contingent consideration (gain) expense	(629)	555	(803)	1,056
Acquisition transaction, integration and other costs	—	61	—	3,192
Total operating costs and expenses	16,047	13,375	46,366	40,436
Operating income	1,743	6,597	6,688	12,776
Other (loss) income:				
Investment income, net	104	19	274	37
Foreign exchange (loss) gain	(594)	234	(121)	(336)
Gain on strategic investment and other	—	10	—	371
Other (loss) income, net	(490)	263	153	72
Income before income taxes	1,253	6,860	6,841	12,848
Income tax provision	(533)	(2,926)	(3,315)	(5,440)
Net income	\$720	\$3,934	\$3,526	\$7,408
Basic net income per share				
	\$0.05	\$0.30	\$0.27	\$0.57
Diluted net income per share				
	\$0.05	\$0.30	\$0.26	\$0.56
Weighted average number of shares outstanding:				
Basic	13,155	12,995	13,190	12,969
Diluted	13,385	13,284	13,404	13,203

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

Surmodics, Inc. and Subsidiaries

Condensed Consolidated Statements of Comprehensive Income

	Three Months		Nine Months	
	Ended		Ended	
	June 30,		June 30,	
	2017	2016	2017	2016
(In thousands)	(Unaudited)		(Unaudited)	
Net income	\$720	\$3,934	\$3,526	\$7,408
Other comprehensive income (loss):				
Unrealized holding (losses) gains on available-for-sale securities, net of tax	(8)	(34)	42	(36)
Foreign currency translation adjustments	2,295	(809)	701	919
Other comprehensive income (loss)	2,287	(843)	743	883
Comprehensive income	\$3,007	\$3,091	\$4,269	\$8,291

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

Surmodics, Inc. and Subsidiaries

Condensed Consolidated Statements of Cash Flows

(in thousands)	Nine Months Ended	
	2017	2016
	(Unaudited)	
Operating Activities:		
Net income	\$3,526	\$7,408
Adjustments to reconcile net income to net cash provided by operating activities:		
Depreciation and amortization	4,006	3,703
Stock-based compensation	2,620	2,729
Contingent consideration (gain) expense	(803)	1,033
Unrealized foreign exchange loss	127	336
Deferred taxes	1,954	(181)
Gain on sale of strategic investment	—	(377)
Provision for bad debts	128	—
Other	(1)	(15)
Change in operating assets and liabilities, net of acquisitions:		
Accounts receivable	(243)	1,999
Inventories	88	(112)
Prepays and other	(2,091)	45
Accounts payable and accrued liabilities	(1,129)	746
Income taxes	(558)	1,253
Deferred revenue	32	—
Net cash provided by operating activities	7,656	18,567
Investing Activities:		
Purchases of property and equipment	(4,881)	(4,869)
Purchases of available-for-sale securities	(54,935)	(9,562)
Maturities of available-for-sale securities	44,571	—
Cash proceeds from sales of property and equipment	—	15
Cash received from sale of strategic investment	—	377
Payments for acquisitions, net of cash acquired	—	(25,054)
Net cash used in investing activities	(15,245)	(39,093)
Financing Activities:		
Issuance of common stock	216	284
Payments for taxes related to net share settlement of equity awards	(2,128)	(371)
Repurchase of common stock	(4,046)	—
Payment of deferred financing costs	(96)	—
Payment of contingent consideration	—	(305)
Net cash used in financing activities	(6,054)	(392)
Effect of exchange rate changes on cash and cash equivalents	6	(14)
Net change in cash and cash equivalents	(13,637)	(20,932)
Cash and Cash Equivalents:		
Beginning of period	24,987	55,588
End of period	\$11,350	\$34,656
Supplemental Information:		
Cash paid for income taxes	\$1,889	\$4,313

Edgar Filing: SURMODICS INC - Form 10-Q

Noncash transactions from investing and financing activities:

Acquisition of property and equipment on account	\$112	\$133
Contingent consideration and debt assumed in Creagh Medical and NorMedix transactions	—	13,597
Issuance of performance shares, restricted and deferred stock units	2,414	1,390

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

Surmodics, Inc. and Subsidiaries

Notes to Condensed Consolidated Financial Statements

Period Ended June 30, 2017

(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 some amounts that are based on management’s best estimates and judgments. These estimates may be adjusted as more information becomes available, and any adjustment could be significant. The impact of any change in estimates is included in the determination of net income in the period in which the change in estimate is identified. The results of operations for the three and nine months ended June 30, 2017 are not necessarily indicative of the results that may be expected for the entire 2017 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, 2016, and footnotes thereto included in the Company’s Form 10-K as filed with the SEC on December 2, 2016.

2. New Accounting Pronouncements

Accounting Standards to be Implemented

In May 2014, the Financial Accounting Standards Board (“FASB”) issued Accounting Standards Codification (“ASC”) Update No. 2014-09, Revenue from Contracts with Customers (ASC Topic 606). Principles of this guidance require entities 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. Additionally, qualitative and quantitative disclosures are required about customer contracts, significant judgments and changes in judgments, and assets recognized from the costs to obtain or fulfill a contract. This accounting standard will be effective for the Company beginning in the first quarter of fiscal year 2019 (October 1, 2018) using one of two prescribed retrospective methods. The Company is currently evaluating the impact that the adoption of this standard will have on the Company’s business model and consolidated results of operations, cash flows and financial position. The Company currently plans to adopt the standard using the modified retrospective approach and expects the impact will be material to the consolidated financial statements due to an anticipated one-quarter acceleration of minimum license fees and royalty revenue earned under its hydrophilic license agreements, as well as several additional required disclosures.

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. Based on a preliminary assessment, the Company currently estimates the impact will not be material due to the fact that the leasing activities the Company engages in are not material to its operations.

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 2020 (October 1, 2019). 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. Based on a preliminary assessment, the Company currently estimates the impact will not be material as it historically has not had significant collectability concerns with its customers.

In August 2016, the FASB issued ASU No. 2016-15, Statement of Cash Flows (Topic 230): Classification of Certain Cash Receipts and Cash Payments. The new guidance clarifies requirements for presentation and classification of the following items within the statement of cash flows: debt prepayments, settlement of zero coupon debt instruments, contingent consideration payments, insurance proceeds, securitization transactions and distributions from equity method investees. The update also addresses classification of transactions that have characteristics of more than one class of cash flows. The accounting standard will be effective for the Company beginning in the first quarter of fiscal 2018. Early adoption is permitted, including adoption in an interim period, and the guidance will be applied retrospectively. The Company estimates the impact of this guidance will not be material to the Company's consolidated financial statements.

In January 2017, the FASB issued ASU No. 2017-04, Intangibles—Goodwill and Other (Topic 350): Simplifying the Test for Goodwill Impairment. The new guidance removes Step 2 of the goodwill impairment test, which requires a hypothetical purchase price allocation. A goodwill impairment will now be the amount by which a reporting unit's carrying value exceeds its fair value, not to exceed the carrying amount of goodwill. The accounting standard will be effective for the Company beginning in its fiscal 2020. Early adoption is permitted, and the guidance will be applied prospectively. The Company is currently evaluating the impact that the adoption of this standard will have on the Company's consolidated financial statements.

Accounting Standards Implemented

In March 2016, the FASB issued ASU No. 2016-09, Compensation – Stock Compensation (ASC Topic 718): Improvements to Employee Share-Based Payment Accounting. The accounting standard intends to simplify several areas of accounting for share-based compensation arrangements, including the income tax impact, classification of awards as either equity or liabilities, and classification on the statement of cash flows. The accounting standard is effective for the Company beginning in the first quarter of fiscal 2018 (October 1, 2017), and early adoption is permitted. The Company elected to early-adopt this accounting standard in the fourth quarter of fiscal 2016, for the fiscal year ended September 30, 2016. As a result of the adoption, the Company records excess tax benefits and certain tax deficiencies as income tax expense or benefit in the condensed consolidated statements of income, whereas such excess tax benefits or tax deficiencies were previously recorded in additional paid-in capital. As this guidance was applied retroactively to the beginning of the fiscal year ended September 30, 2016, previously reported quarterly income tax and net income for interim periods therein were adjusted for the effects of the adoption. This resulted in adjustments to increase the income tax provision and decrease net income by less than \$0.1 million for the three months ended June 30, 2016 and to reduce the income tax provision and increase net income by less than \$0.1 million for the nine months ended June 30, 2016. The adoption of this ASU also resulted in a (reduction) increase in net income per basic and diluted share of less than (\$0.01) per share and \$0.01 per share, respectively, for the three and nine-month periods ended June 30, 2016.

The newly adopted guidance also requires presentation of excess tax benefits as an operating activity on the statement of cash flows rather than as a financing activity. Prior to the adoption of ASU No. 2016-09, cash flows resulting from the tax benefits generated by tax deductions in excess of the compensation cost recognized for those options (excess tax benefits) were classified as financing cash flows. During the nine months ended June 30, 2016, the Company realized tax benefits from stock options resulting in approximately \$0.1 million of gross excess tax benefits, which are included as a component of cash flows from operating activities in the accompanying condensed consolidated statements of cash flows. This amount was previously reported as a component of cash flows from financing activities, but has been reclassified to conform to current accounting guidance.

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.

3. Business Combinations

For all business combinations, the Company records all assets and liabilities of the acquired business, including goodwill and other identified intangible assets, at their respective fair values as of the acquisition date. Contingent consideration, if any, is recognized at its fair value on the acquisition date and changes in fair value are recognized in earnings until settlement. Acquisition-related transaction costs are expensed as incurred.

Creagh Medical Ltd.

On November 20, 2015, the Company acquired 100% of the outstanding common shares and voting shares of Creagh Medical Ltd. (“Creagh Medical”) located in Ballinasloe, Ireland. The acquisition was financed with cash on hand and contingent seller financing. The Company acquired Creagh Medical for up to €30 million (approximately \$32 million as of the acquisition date), including an upfront payment of €18 million (approximately \$19.3 million as of the acquisition date), and up to €12 million (approximately \$12.8 million as of the acquisition date) based on achievement of revenue and value-creating operational milestones through September 30, 2018. The payment of the milestones, if any, will occur in the quarter ending December 31, 2018. Total transaction, integration and other costs associated with the Creagh Medical acquisition aggregated \$0.1 million and \$2.7 million for the three and nine months ended June 30, 2016, respectively. The operating results of Creagh Medical have been included in the Company’s Medical Device segment since the acquisition date. The Company realized \$2.2 million of revenue and a loss of \$2.2 million from Creagh Medical’s operations for the period from the acquisition date through June 30, 2016.

Creagh Medical designs and manufactures high-quality percutaneous transluminal angioplasty (“PTA”) balloon catheters. Since 2006, Creagh Medical has grown its technical and product capability with PTA products approved throughout the world, including Europe, the United States, and Japan. With these resources, the Company is uniquely positioned to offer a total solutions approach from product design and development through in-house extrusion, balloon forming, top-assembly and packaging and regulatory capabilities to approved products for exclusive distribution.

The purchase price of Creagh Medical consisted of the following:

(Dollars in thousands)	
Cash paid	\$18,449
Debt assumed	761
Contingent consideration	9,064
Total purchase price	28,274
Less cash and cash equivalents acquired	(251)
Total purchase price, net of cash acquired	\$28,023

The following table summarizes the final allocation of the purchase price to the fair values assigned to the assets acquired and the liabilities assumed at the date of the Creagh Medical acquisition:

	Fair Value	Estimated Useful Life
	(Dollars in thousands)	(In years)
Current assets	\$ 896	N/A
Property and equipment	634	1.0-10.0
Trade name	75	N/A
Developed technology	1,787	7.0

Edgar Filing: SURMODICS INC - Form 10-Q

In-process research and development	942	N/A
Customer relationships	11,119	7.0-10.0
Other noncurrent assets	81	N/A
Current liabilities	(942))N/A
Deferred tax liabilities	(9))N/A
Net assets acquired	14,583	
Goodwill	13,440	N/A
Total purchase price, net of cash acquired	\$ 28,023	

9

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

NorMedix, Inc.

On January 8, 2016, the Company acquired 100% of the shares of NorMedix, Inc. ("NorMedix"), a privately owned design and development company focused on ultra thin-walled, minimally invasive catheter technologies based in Plymouth, Minnesota. The acquisition was financed with cash on hand and contingent seller financing. The Company acquired NorMedix for up to \$14.0 million, including an upfront payment of \$7.0 million, and up to \$7.0 million based on achievement of revenue and value-creating operational milestones through September 30, 2019. Contingent consideration associated with the NorMedix transaction is payable as earned. This acquisition strengthened the Company's vascular device expertise and Research and Development ("R&D") capabilities and was a significant component of the Company's strategy to offer whole-product solutions to medical device customers, while continuing its commitment to consistently deliver innovation in coating technologies. Total transaction, integration and other costs associated with the NorMedix acquisition aggregated \$0.0 million and \$0.3 million for the three and nine-month periods ended June 30, 2016, respectively. The operating results for NorMedix have been included in the Medical Device segment since the acquisition date. The Company realized \$0.6 million of revenue and a loss of \$0.2 million from NorMedix's operations for the period from the acquisition date through June 30, 2016.

The purchase price of NorMedix consisted of the following:

(Dollars in thousands)	
Cash paid	\$6,905
Contingent consideration	3,520
Total purchase price	10,425
Less cash and cash equivalents acquired	(17)
Total purchase price, net of cash acquired	\$10,408

The following table summarizes the final allocation of the purchase price to the fair values assigned to the assets acquired and the liabilities assumed at the date of the NorMedix acquisition:

	Fair Value	Estimated Useful Life
	(Dollars in thousands)	(In years)
Net current assets	\$ 113	N/A
Property and equipment	60	7.0
Developed technology	6,850	10.0-14.0
Customer relationships	900	4.0
Deferred tax asset	690	N/A
Other noncurrent asset	13	N/A
Accounts payable	(187)	N/A
Deferred tax liabilities	(2,483)	N/A
Net assets acquired	5,956	
Goodwill	4,452	N/A
Total purchase price, net of cash acquired	\$ 10,408	

The NorMedix goodwill is a result of acquiring and retaining the NorMedix existing workforce and expected synergies from integrating their business into the Medical Device segment. The goodwill is not deductible for tax purposes.

On a pro forma basis, as if the Creagh Medical and NorMedix acquisitions had occurred as of the beginning of fiscal 2016, the Company's consolidated revenues would have been \$54.3 million and net income would have been \$6.9 million for the nine months ended June 30, 2016, with basic and diluted earnings per share of \$0.53 and \$0.52, respectively. All of the activity of NorMedix and Creagh Medical is included in the quarter ended June 30, 2016 condensed consolidated financial statements, therefore, pro forma activity for the third quarter of fiscal 2016 has not been presented. This fiscal 2016 unaudited pro forma financial information includes adjustments for additional amortization expense of \$0.4 million on identifiable intangible assets and contingent consideration accretion expense of \$0.3 million, eliminating non-recurring transactional professional fees of \$3.0 million, and tax effect impact of \$0.1 million. The tax impact of the adjustments in all periods reflects no tax benefit from contingent consideration accretion as well as a significant portion of our transaction-related costs in fiscal 2016 as they are not deductible for tax purposes. Further, Creagh Medical amortization expense does not reflect an Irish tax benefit as we acquired a net operating loss carryforward as of the acquisition date that was offset in the aggregate by deferred tax liabilities and a valuation allowance. Therefore, the amortization of Creagh Medical intangible assets results in a decrease in deferred tax liabilities with a corresponding increase to a deferred tax valuation allowance. NorMedix amortization expense reflects a tax benefit based on our incremental U.S. tax rate.

4. Fair Value Measurements

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

Fair Value Hierarchy

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

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

The Company did not have any Level 1 assets as of June 30, 2017 and September 30, 2016.

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

The Company's Level 2 assets as of June 30, 2017 and September 30, 2016 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.

Level 3 liabilities at June 30, 2017 and September 30, 2016 consist of contingent consideration obligations for the achievement of revenue and value-creating milestones related to the acquisitions of Creagh Medical and NorMedix discussed in Note 3.

In valuing 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 June 30, 2017:

(Dollars in thousands)	Quoted Prices in			Total Fair Value as of June 30, 2017
	Active Markets for Identical Instruments (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)	
Assets				
Cash equivalents	\$ —	\$ 5,953	\$ —	\$5,953
Available-for-sale securities	—	32,360	—	32,360
Total assets	\$ —	\$ 38,313	\$ —	\$38,313
Liabilities				
Contingent consideration	\$ —	\$ —	\$ (13,841)	\$(13,841)
Total liabilities	\$ —	\$ —	\$ (13,841)	\$(13,841)

The following table presents information about the Company's assets and liabilities measured at fair value on a recurring basis as of September 30, 2016:

(Dollars in thousands)	Quoted Prices in			Total Fair Value as of September 30, 2016
	Active Markets for Identical Instruments (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)	
Assets				
Cash equivalents	\$ —	\$ 22,160	\$ —	\$ 22,160
Available-for-sale securities	—	21,954	—	\$ 21,954
Total assets	\$ —	\$ 44,114	\$ —	\$ 44,114
Liabilities				
Contingent consideration	\$ —	\$ —	\$ (14,517)	\$(14,517)
Total liabilities	\$ —	\$ —	\$ (14,517)	\$(14,517)

Edgar Filing: SURMODICS INC - Form 10-Q

The following table summarizes the changes in the contingent consideration liabilities measured at fair value using Level 3 inputs for the three and nine months ended June 30, 2017 and 2016:

(Dollars in thousands)	Three Months Ended June 30,		Nine Months Ended June 30,	
	2017	2016	2017	2016
Beginning balance	\$13,870	\$13,646	\$14,517	\$—
Additions	—	—	—	12,581
Fair value adjustments	(1,192)	70	(2,350)	70
Settlements	—	—	—	—
Interest accretion	563	485	1,547	986
Foreign currency translation loss (gain)	600	(251)	127	313
Ending balance	\$13,841	\$13,950	\$13,841	\$13,950

12

There were no transfers of assets or liabilities between amounts measured using Level 1, Level 2, or Level 3 fair value measurements during fiscal 2017 to date or fiscal 2016.

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 — 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. During the three and nine months ended June 30, 2017, we recorded gains of \$1.2 million and \$2.4 million, respectively, related to downward adjustments to the estimated fair value of certain revenue and strategic milestones related to the Creagh Medical and NorMedix acquisitions as the probability of the milestones being achieved was reduced. For the Creagh Medical and NorMedix revenue-based milestones, the Company discounted forecasted revenue by 14.0% to 23.5%, respectively, which represents the Company's weighted average cost of capital for each transaction, adjusted for the short-term nature of the cash flows. The resulting present value of revenue was used as an input into an option pricing approach, which also considered the Company's risk of non-payment of the revenue-based milestones. Non-revenue milestones were projected to have a 25-95% probability of achievement and related payments were discounted using the Company's estimated cost of debt, or 2.7% to 3.0%. To the extent that actual results differ from these estimates, the fair value of the contingent consideration liabilities could change significantly. Accretion expense is recorded as an increase to the contingent consideration liabilities due to the passage of time. The contingent consideration liability related to the Creagh Medical acquisition is denominated in Euros and is not hedged. Foreign currency translation and losses are recorded as this obligation is marked to period-end exchange rates.

5. Investments

Investments consisted principally of commercial paper and corporate bond securities and are classified as available-for-sale as of June 30, 2017 and September 30, 2016. Available-for-sale securities are reported at fair value with unrealized gains and losses, net of tax, excluded from the condensed consolidated statements of income and reported in the condensed consolidated statements of comprehensive income as well as a separate component of stockholders' equity in the condensed consolidated balance sheets, except for other-than-temporary impairments, which are reported as a charge to current earnings. 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 (loss). This adjustment results in a new cost basis for the investment. Interest earned on debt securities, including amortization of premiums and accretion of discounts, is included in 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.

Edgar Filing: SURMODICS INC - Form 10-Q

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

	June 30, 2017			
(Dollars in thousands)	Amortized Cost	Unrealized Gains	Unrealized Losses	Fair Value
Commercial paper and corporate bonds	\$32,382	\$ —	\$ (22)	\$ 32,360
Total	\$32,382	\$ —	\$ (22)	\$ 32,360

	September 30, 2016			
(Dollars in thousands)	Amortized Cost	Unrealized Gains	Unrealized Losses	Fair Value
Commercial paper and corporate bonds	\$22,019	\$ —	\$ (65)	\$ 21,954
Total	\$22,019	\$ —	\$ (65)	\$ 21,954

The following table summarizes sales of available-for-sale debt securities:

	Three Months Ended June 30,		Nine Months Ended June 30,	
(Dollars in thousands)	2017	2016	2017	2016
Proceeds from maturities	\$ 17,500	\$ —	\$ 44,571	\$ —
Gross realized gains	—	—	—	—
Gross realized losses	—	—	—	—

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:

	June 30,	September 30,
(Dollars in thousands)	2017	2016
Raw materials	\$ 1,643	\$ 1,766
Work-in process	584	492
Finished products	1,278	1,321
Total	\$ 3,505	\$ 3,579

7. Other Assets

Other assets consist of the following:

	June 30,	September 30,
(Dollars in thousands)	2017	2016
ViaCyte, Inc.	\$ 479	\$ 479
Other noncurrent assets	398	149
Other assets, net	\$ 877	\$ 628

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 \$0.6 million and \$0.8 million for the three months ended June 30, 2017 and 2016, respectively. The Company recorded amortization expense of 1.9 million for the both nine-month periods ended June 30, 2017 and 2016.

Intangible assets consisted of the following:

(Dollars in thousands)	June 30, 2017			
	Weighted Average Original Life (Years)	Gross Carrying Amount	Accumulated Amortization	Net
Definite-lived intangible assets:				
Customer lists and relationships	8.9	\$ 17,888	\$ (7,349)) \$ 10,539
Core technology	8.0	530	(530)) —
Developed technology	10.8	9,216	(1,247)) 7,969
Non-compete	5.0	230	(92)) 138
Patents and other	16.5	2,321	(1,387)) 934
Subtotal		30,185	(10,605)) 19,580
Unamortized intangible assets:				
In-process research and development		1,004	—) 1,004
Trademarks and trade names		646	—) 646
Total		\$ 31,835	\$ (10,605)) \$ 21,230

(Dollars in thousands)	September 30, 2016			
	Weighted Average Original Life (Years)	Gross Carrying Amount	Accumulated Amortization	Net
Definite-lived intangible assets:				
Customer lists and relationships	8.9	\$ 17,692	\$ (6,123)) \$ 11,569
Core technology	8.0	530	(530)) —
Developed technology	11.8	8,724	(618)) 8,106
Non-compete	5.0	230	(58)) 172
Patents and other	16.5	2,321	(1,275)) 1,046
Subtotal		29,497	(8,604)) 20,893
Unamortized intangible assets:				
In-process research and development		987	—) 987
Trademarks and trade names		645	—) 645
Total		\$ 31,129	\$ (8,604)) \$ 22,525

Based on the intangible assets in service as of June 30, 2017, excluding any possible future amortization associated with acquired in-process research and development (“IPR&D”), which has not met technological feasibility as of June 30, 2017, estimated amortization expense for the remainder of fiscal 2017 and each of the next five fiscal years is as follows:

(Dollars in thousands)	
Remainder of 2017	\$ 699
2018	2,606
2019	2,606
2020	2,430
2021	2,291
2022	2,251

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, 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 June 30, 2017 and September 30, 2016 totaled \$26.8 million and \$26.6 million, respectively. Goodwill in the Medical Device reporting unit represents the gross value from the acquisitions of Creagh Medical and NorMedix in fiscal 2016. 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 2016 annual impairment test, and there have been no events or circumstances that have occurred in the first nine months of fiscal 2017 to indicate that goodwill has been impaired.

The change in the carrying amount of goodwill by segment for the nine months ended June 30, 2017 was as follows:

(Dollars in thousands)	In Vitro Diagnostics	Medical Device	Total
Balance as of September 30, 2016	\$ 8,010	\$ 18,545	\$ 26,555
Currency translation adjustment	—	236	236
Balance as of June 30, 2017	\$ 8,010	\$ 18,781	\$ 26,791

10. 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.

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

(Dollars in thousands)	Three Months Ended June 30,		Nine Months Ended June 30,	
	2017	2016	2017	2016
Product costs	\$19	\$4	\$69	\$12
Research and development	139	101	387	220
Selling, general and administrative	790	725	2,164	2,497
Total	\$948	\$830	\$2,620	\$2,729

As of June 30, 2017, approximately \$5.3 million of total unrecognized compensation costs related to non-vested awards is expected to be recognized over a weighted average period of approximately 2.2 years. The unrecognized compensation costs above include \$2.0 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 June 30, 2017 and 2016 were \$7.22 and \$6.49, respectively, and \$7.57 and \$6.85 during the nine months ended June 30, 2017 and 2016, respectively. The assumptions used as inputs in the model were as follows:

	Three Months Ended June 30, 2017		Nine Months Ended June 30, 2016	
Risk-free interest rates	1.8 %	1.3 %	1.7 %	1.9 %
Expected life (years)	4.7	4.7	4.6	4.6
Expected volatility	33.3 %	35.2 %	34.3 %	36.8 %
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 award. 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 to ten years or upon termination of employment or service as a Board member. With respect to members of our Board, non-qualified stock options generally become exercisable on a 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 \$0.3 million for both the three-month periods ended June 30, 2017 and 2016, and \$0.9 million for both the nine-month periods ended June 30, 2017 and 2016.

The total pre-tax intrinsic value of options exercised during the three and nine months ended June 30, 2017 was less than \$0.1 million in each period. The total pre-tax intrinsic value of options exercised during the three and nine months ended June 30, 2016 was \$0.4 million and \$1.7 million, respectively. The intrinsic value represents the difference between the average exercise price and the fair market value of the Company's common stock on the last day of the respective fiscal period end.

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. Compensation expense has been recognized for the estimated fair value of the common shares and is being charged to income over the vesting term. The stock-based compensation expense table includes Restricted Stock expenses recognized related to these awards, which totaled \$0.1 million for both the three-month periods ended June 30, 2017 and 2016, and \$0.4 million and \$0.2 million for the nine-month periods ended June 30, 2017 and 2016, respectively.

Performance Share Awards

The Company has entered into performance share agreements with certain key employees and executives, 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 2015 (2015 – 2017), 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 2014 were finalized in the nine months ended June 30, 2017 and resulted in the issuance of 38,505 shares (maximum was 78,606 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 best 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 the Performance Shares expenses recognized related to these awards, which totaled \$0.4 million and \$0.3 million for the three-month periods ended June 30, 2017 and 2016, respectively, and \$1.0 million and \$1.3 million for the nine-month periods ended June 30, 2017 and 2016, respectively.

The fair values of the Performance Shares, at target, were \$1.2 million, \$1.3 million and \$0.9 million in each fiscal year for awards granted in fiscal 2017, 2016 and 2015, respectively.

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:

	Minimum	Target	
Performance Period	Shares	Shares	Maximum Shares
Fiscal 2015 – 2017	8,440	42,199	84,398
Fiscal 2016 – 2018	13,268	66,338	132,676
Fiscal 2017 – 2019	10,437	52,185	104,370

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 June 30, 2017 and September 30, 2016, there was less than \$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 nine-month periods ended June 30, 2017 and 2016 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 nine months ended June 30, 2017 and 2016, the Company awarded 16,004 and 18,877 restricted stock units (“RSUs”), respectively, under the 2009 Equity Incentive Plan to non-employee directors and certain key employees in foreign jurisdictions. Forfeiture of 446 RSUs occurred during the nine months ended June 30, 2017. As of June 30, 2017 and September 30, 2016, 44,440 and 32,101 RSUs were outstanding, respectively, with an estimated fair market value of \$1.3 million and \$0.9 million, respectively. RSU awards are not considered issued or outstanding common stock of the Company until they vest. The estimated fair value of the RSUs was calculated based on the closing market price of Surmodics’ common stock on the date of grant. Compensation expense has been recognized for the estimated fair value of the common shares and is being charged to income over the vesting term. The stock-based compensation table includes RSU expenses recognized related to these awards, which totaled less than \$0.1 million for both the three-month periods ended June 30, 2017 and 2016, and \$0.2 million and \$0.1 million for the respective nine-month periods ended June 30, 2017 and 2016.

Directors can also 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 deferral elections made annually. During the nine months ended June 30, 2017 and 2016, 2,953 and 6,646 units, respectively, were issued with a total fair value of less than \$0.1 million in each period. As of June 30, 2017 and September 30, 2016, outstanding DSUs totaled 24,030 and 21,077, respectively, with an estimated fair value of \$0.7 million and \$0.6 million, respectively. These DSUs are fully

vested. Stock-based compensation expense related to DSU awards totaled less than \$0.1 million for both the three-month periods ended June 30, 2017 and 2016, and \$0.1 million for both the nine-month periods ended June 30, 2017 and 2016.

11. Revolving Credit Facility

On November 2, 2016, the Company amended and restated its revolving credit facility. The new agreement increased the available principal to \$30.0 million and extended the maturity to November 2019. In addition, the agreement includes a \$5.0 million multi-currency overdraft facility in Ireland. Borrowings under the credit facility, if any, will bear interest at a benchmark rate plus a margin ranging from 1.00% to 1.75% based on the Company's leverage ratio, as defined in the loan agreement. A facility fee is payable quarterly on unused commitments at a rate of 0.15% per annum. The Company has the option to increase the credit facility in increments of \$5.0 million up to an additional \$20.0 million, subject to approval of the lender. The Company's obligations under

the credit facility are secured by substantially all of its assets, other than intellectual property and real estate, as well as the majority of its equity interest in its subsidiaries.

In connection with the credit facility, the Company is required to comply with certain financial and non-financial covenants. As of June 30, 2017, the Company has no debt outstanding and was in compliance with all financial covenants.

12. Net Income Per Share Data

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

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

	Three Months Ended June 30,		Nine Months Ended June 30,	
	2017	2016	2017	2016
Net income available to common shareholders	\$720	\$3,934	\$3,526	\$7,408
Basic weighted average shares outstanding	13,155	12,995	13,190	12,969
Dilutive effect of outstanding stock options, non-vested restricted stock, restricted stock units, deferred stock units and performance shares	230	289	214	234
Diluted weighted average shares outstanding	13,385	13,284	13,404	13,203

The calculation of weighted average diluted shares outstanding excludes outstanding stock options associated with the right to purchase 0.1 million and 0.3 million shares of common stock for the three months ended June 30, 2017 and 2016, respectively, and \$0.1 million and 0.2 million for the nine months ended June 30, 2017 and 2016, respectively, as their inclusion would have had an antidilutive effect on diluted net income per share.

The Company's Board of Directors has authorized the repurchase of up to \$30.0 million of the Company's outstanding common stock. This authorization does not have an expiration date. During the third quarter of fiscal 2017, the Company repurchased 169,868 shares of common stock at an average price of \$23.78 per share for a total of \$4.0 million. As of June 30, 2017, the Company has \$26.0 million available for future repurchases under the current authorization.

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, 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 provisions of \$0.5 million and \$2.9

million for the three months ended June 30, 2017 and 2016, respectively, representing effective tax rates, defined as income tax expense divided by income before taxes, of 42.5% and 42.8%, respectively. The Company recorded income tax provisions of \$3.3 million and \$5.4 million for the nine months ended June 30, 2017 and 2016, respectively, representing effective tax rates of 48.5% and 42.3%, respectively. The Company's effective tax reflects the impact of state income taxes, permanent tax items and discrete tax benefits. The effective income tax rate for the three and nine-month periods ended June 30, 2017 and 2016 differs from the U.S. federal statutory tax rate of 35.0% primarily due to operating losses in Ireland, where tax benefits are offset by a valuation allowance, as well as amortization, transaction costs (fiscal 2016 only) and contingent consideration accretion, including fair value adjustments, associated with the Creagh Medical and NorMedix acquisitions and foreign currency translation gains and losses on Euro-denominated contingent consideration liabilities, all of which are not deductible for income tax purposes. These increases to the effective income tax rate are partially offset by the domestic production manufacturing deduction and the U.S. federal research and development income tax credit. The effective income tax rate for the nine months ended June 30, 2017 is also impacted by discrete tax expense of \$0.3 million related to expiring stock option awards, partially offset by \$0.2 of state income tax reserve reversals related to the expiration of statutory filing requirements in each period.

The total amount of unrecognized tax benefits, excluding interest and penalties that, if recognized, would affect the effective tax rate is \$1.2 million as of June 30, 2017 and September 30, 2016. Currently, the Company does not expect the liability for unrecognized tax benefits to change significantly in the next 12 months with the above balances classified on the condensed consolidated balance sheets in other long-term liabilities. Interest and penalties related to unrecognized tax benefits are recorded in income tax 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 2014 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 the respective acquisition dates, pursuant to the terms of the related share purchase agreements. As of June 30, 2017 and September 30, 2016, there were no undistributed earnings in foreign subsidiaries.

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.

During fiscal 2016, the Company acquired Creagh Medical and NorMedix, which are included in the Medical Device segment subsequent to the respective acquisition dates, as further discussed in Note 3.

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

	Three Months Ended June 30,		Nine Months Ended June 30,	
(Dollars in thousands)	2017	2016	2017	2016
Revenue:				
Medical Device	\$12,778	\$15,654	\$39,260	\$39,500
In Vitro Diagnostics	5,012	4,318	13,794	13,712
Total revenue	\$17,790	\$19,972	\$53,054	\$53,212
Operating income:				
Medical Device	\$1,403	\$6,673	\$6,627	\$12,825
In Vitro Diagnostics	2,230	1,673	5,922	5,298

Edgar Filing: SURMODICS INC - Form 10-Q

Total segment operating income	3,633	8,346	12,549	18,123
Corporate	(1,890)	(1,749)	(5,861)	(5,347)
Total operating income	\$1,743	\$6,597	\$6,688	\$12,776

Depreciation and amortization:

Medical Device	\$1,132	\$982	\$3,180	\$2,440
In Vitro Diagnostics	103	222	309	647
Corporate	170	202	517	616
Total depreciation and amortization	\$1,405	\$1,406	\$4,006	\$3,703

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.

On February 22, 2017, the Company was sued by Merit Medical Systems, Inc. ("Merit") in the U.S. District Court for the District of Utah. NorMedix was added as a defendant on April 3, 2017. The lawsuit alleges breach of contract and seeks declaratory relief in connection with a services agreement entered into between Merit and NorMedix on March 3, 2015. In the lawsuit, Merit claims that certain technology and intellectual property related to thin-walled catheter technologies were developed by NorMedix under the services agreement and, pursuant to the terms of that agreement, should be owned by Merit. Pretrial proceedings are underway. The Company has not recorded an expense related to damages in connection with this matter because any potential loss is not currently probable or reasonably estimable. Additionally, the Company cannot reasonably estimate the range of loss, if any, that may result from this matter. Under the stock purchase agreement, pursuant to which the Company acquired NorMedix, the Company may have certain rights of indemnification against losses (including, without limitation, damages, expenses and costs) incurred as a result of the claims asserted in the litigation.

The Company believes that the claims in the lawsuit are without merit and plans to vigorously defend and prosecute this matter.

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 \$228,000 using a euro to US dollar exchange rate of 1.1409 to the Euro as of June 30, 2017) until the last patent expires which is currently estimated to be September 2027. The total minimum future payments associated with this license are approximately \$2.3 million. The license is currently utilized by one of the Company's drug delivery customers.

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, 2016. 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 2017, our revenue performance has been driven by our core Medical Device and In Vitro Diagnostics ("IVD") businesses as well incremental increases in product sales and contract research and development services from the fiscal 2016 acquisitions of Creagh Medical Ltd. ("Creagh Medical") and NorMedix, Inc. ("NorMedix") in our Medical Device segment (together the "Fiscal 2016 Acquisitions"). Revenue in the Medical Device business are composed of product sales, hydrophilic coatings royalties, and contract research and development services. Medical Device segment revenue decreased by 1% for the first nine months of fiscal 2017 as compared with the first nine months of fiscal 2016. The first nine-months of fiscal 2016 included two significant customer royalty revenue adjustments which resulted in \$1.5 million of incremental net revenue. Medical Device revenue declines in the nine months ended June 30, 2017 were largely due to declines in royalty and license fee revenue resulting from these prior-year catch-up adjustments, as well as previously disclosed patent expirations. However, product sales as well as research, development and other revenue have grown year-over-year. Our IVD business derives its revenue from product sales of diagnostic technology. Revenue from the IVD segment increased by 1% in the first nine months of fiscal year 2017 compared with the same prior-year period. During the nine months ended June 30, 2017, the IVD business was negatively affected by a decline from a significant microarray customer that was acquired by one of its competitors. However, in the third quarter of fiscal 2017, revenue increases across several product categories generated 16% growth in IVD sales from the same prior-year quarter.

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; the vast majority (typically in excess of 90%) of revenue in the "royalties and license fees" category is in the form of royalties; and (3) research and commercial development fees generated on customer projects. Revenue fluctuates from quarter to quarter depending on, among other factors: our customers' success in selling products incorporating our technologies; the timing of introductions of licensed products by our customers; the timing of introductions of products that compete with our customers' products; the number 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 and other products sold to customers.

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 third generation of PhotoLink hydrophilic technology was protected by a family of patents that expired in November 2015 (in the U.S.) and October 2016 (in certain other countries). The royalty revenue associated with our third generation

technology was approximately 17% of our fiscal 2016 revenue. Approximately 24% of our total revenue in fiscal 2016 was generated from fourth-generation hydrophilic coating technologies, which are protected by a family of patents that begin to expire in fiscal 2020. Of the license agreements using our early-generation technologies, most will continue to generate royalty revenue at a reduced royalty rate beyond patent expiration. The remainder of our hydrophilic royalty revenue is derived from other Surmodics coatings that are protected by a number of patents that extend to at least fiscal 2035. While we are actively seeking to convert our customers to one of our advanced generations 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

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. During fiscal 2016, we made significant progress on our whole-product solutions strategy with the Fiscal 2016 Acquisitions, as well as the initiation of an early feasibility clinical study of the Surmodics SurVeil® DCB (“SurVeil DCB”). The development of the SurVeil DCB is a major step forward in our strategy to offer whole-product solutions for the medical device industry. The SurVeil DCB early feasibility clinical study, conducted in the U.S., met its primary endpoint by demonstrating peak paclitaxel plasma concentrations post-index procedure. Consistent with pre-clinical data, systemic levels were low and cleared rapidly.

In July 2017, we received an investigational device exemption (“IDE”) from the U.S. Food and Drug Administration (“FDA”) to initiate a pivotal clinical trial of the SurVeil DCB. The randomized clinical trial, TRANSCEND, will evaluate the SurVeil DCB for treatment for peripheral artery disease (“PAD”) in the upper leg compared to 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 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 approximately 60 sites in the U.S. and 18 outside the U.S. Study participants will be randomized to receive either treatment with SurVeil DCB or IN.PACT Admiral DCB. The primary efficacy endpoint of the trial 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 expect to initiate enrollment in the TRANSCEND clinical trial in the fourth quarter of calendar 2017 and have engaged a clinical research organization to assist us with the administration of the clinical trial. 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 cost of the TRANSCEND clinical trial will range between \$32 million to \$40 million over the next several years.

In addition to our SurVeil DCB program, we are developing another DCB for treatment of PAD below-the-knee. During fiscal 2017, we completed a dosing study and are preparing to move the program into the next phase of clinical evaluation. We also are developing a number of interventional catheter and balloon-based products that incorporate Surmodics coatings, including a DCB for treatment of AV Fistulas. During the third quarter of fiscal 2017 we completed regulatory submission for a new balloon catheter product incorporating our Serene® hydrophilic coating technology, as well as a microcatheter incorporating our Pristyne® hydrophilic coating technology. We expect to receive regulatory clearance for each of these two products during calendar 2017.

We prioritize our internal R&D programs based on a number of factors, including a program’s strategic fit, commercial impact, potential competitive advantage, 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.

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 customer R&D and internal 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 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. For the quarter ended June 30, 2017, there were no significant changes in our critical accounting policies.

For a detailed description of our 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, 2016.

Results of Operations – Three and Nine Months Ended June 30

Revenue. Revenue for the third quarter of fiscal 2017 was \$17.8 million, a decrease of \$2.1 million, or 10.9%, compared with the third quarter of fiscal 2016. Revenue during the first nine months of fiscal 2017 was \$53.1 million, a decrease of \$0.1 million, or 0.3% compared with the same period in fiscal 2016. The change in revenue, as detailed in the table below, is further explained in the narrative below.

(Dollars in thousands)	Three Months			Nine Months		
	Ended June 30, 2017	2016	% Change	Ended June 30, 2017	2016	% Change
Revenue						
Medical Device	\$12,778	\$15,654	(18.4)%	\$39,260	\$39,500	(0.6)%
In Vitro Diagnostics	5,012	4,318	16.1%	13,794	13,712	0.6%
Total Revenue	\$17,790	\$19,972	(10.9)%	\$53,054	\$53,212	(0.3)%

Medical Device. Medical Device revenue was \$12.8 million in the third quarter of fiscal 2017, a decrease of 18.4% as compared with \$15.7 million for the third quarter of fiscal 2016. Medical Device revenue was \$39.3 million in the first nine months of fiscal 2017, a decrease of 0.6% as compared with \$39.5 million for the same prior-year period. The decrease in quarterly revenue was attributable to a catch-up payment of \$2.9 million received during the third quarter of fiscal 2016 for previously unreported royalties owed to the Company by one customer for the period from fiscal 2009 through fiscal 2016. This prior-year payment, along with previously disclosed patent expirations, resulted in a decrease in royalties and license fees of \$3.3 million in the current-year quarter as compared with the prior-year quarter. We also realized increases in product sales as well as research, development and other revenue of \$0.1 million and \$0.3 million, respectively, in the third quarter of fiscal 2017 as compared with third quarter of fiscal 2016.

The decrease in revenue for the nine months ended June 30, 2017 from the comparable prior-year period was attributable to the \$2.9 million catch-up payment discussed above, which was partially offset by a reduction in royalties and license fees revenue in the second quarter of fiscal 2016 resulting from a \$1.1 million out-of-period revenue adjustment to correct a cumulative overstatement of royalty revenue, of which \$1.0 million related to years prior to fiscal 2016. During the quarter ended June 30, 2016, the Company entered into an agreement to pay a customer \$1.4 million to settle this matter. The additional \$0.3 million was considered to be a change in estimate and was recorded as a reduction of royalty revenue during the quarter ended June 30, 2016. These two items, along with previously disclosed patent expirations, resulted in a decrease in royalties and license fees of \$2.6 million for the first nine months of fiscal 2017 as compared with the same prior-year period. Comparing the first nine months of fiscal 2017 with fiscal 2016, we recognized increases in product sales of \$1.0 million as well as an increase of \$1.4 million in research, development and other revenue.

Over the past several years, we have realized an increase in demand for coating and feasibility services, which are components of our research, development and other revenue, and we expect to continue to enhance our capabilities in this area over the next several quarters. Royalty and license fee revenue was stronger than expected in the fiscal 2017 periods as our customers reported a higher mix of revenue in royalty-bearing jurisdictions outside of the United States as well as products that have migrated to more advanced generations of hydrophilic coatings. As previously reported, the patent covering our third-generation hydrophilic coatings in countries outside of the U.S. expired on October 31, 2016. For fiscal 2017, we expect royalty and license fee revenue to decline between \$3.4 million to \$4.0 million as the result of the fiscal 2016 royalty revenue adjustments and the impact of patent expirations governing our third-generation patents.

In Vitro Diagnostics. In Vitro Diagnostics revenue was \$5.0 million in the third quarter of fiscal 2017, an increase of 16.1%, as compared with \$4.3 million for the third quarter of fiscal 2016. In Vitro Diagnostics revenue was \$13.8 million in the first nine months of fiscal 2017, an increase of 0.6%, as compared with \$13.7 million as compared with the same prior-year period. In the third quarter of fiscal 2017, sales volume increases across several product lines resulted in an increase in product revenue of \$0.7 million from the same prior-year quarter. The fiscal 2017 three and nine-month periods were also impacted by a decline in sales to a previously significant microarray customer that was acquired by one of its competitors. For fiscal 2017, we expect the loss of this microarray customer will negatively impact revenue by \$1.2 million. We expect total revenue from our In Vitro Diagnostics business to grow in the low single digits, percentage-wise, as compared with the prior year.

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 June 30,				Nine Months Ended June 30,			
	2017		2016		2017		2016	
	Amount	% Total Revenue	Amount	% Total Revenue	Amount	% Total Revenue	Amount	% Total Revenue
Product costs	\$2,914	16 %	\$2,777	14 %	\$8,104	15 %	\$8,069	15 %
Research and development	7,927	45	4,693	23	22,105	42	13,195	25
Selling, general and administrative	5,232	29	4,483	22	15,170	29	12,984	24
Acquired intangible asset amortization	603	3	806	4	1,790	3	1,940	4
Contingent consideration (gain) accretion expense	(629)	(4)	555	3	(803)	—	1,056	2
Acquisition transaction, integration and other costs	—	—	61	0	—	—	3,192	6

Product costs. Product costs were \$2.9 million and \$8.1 million for the three and nine months ended June 30, 2017, respectively, or 16% and 15% of total revenue in each respective period. Product costs were \$2.8 million and \$8.1 million for the three and nine months ended June 30, 2016, or 14% and 15% of total revenue in the respective periods in fiscal 2016. Product gross margins (defined as product sales less related product costs) were 65.0% and 66.2%, respectively, of product sales for the three and nine months ended June 30, 2017 as compared with 63.0% and 64.7%, respectively, of product sales for the three and nine months ended June 30, 2016. The improvement in product gross margins was due to favorable product mix and overhead absorption due to manufacturing volume increases in both our Medical Device and IVD segments.

Research and development (R&D) expenses. R&D expenses were \$7.9 million and \$22.1 million for the three and nine months ended June 30, 2017, respectively, or 44.6% and 41.7% of total revenue in each respective period, as compared with \$4.7 million and \$13.2 million, or 23.5% and 24.8% of total revenue for the respective periods in fiscal 2016. The increases in R&D expenses in the fiscal 2017 periods were primarily the result of planned higher spending for our DCB and proprietary product development activities and, to a lesser extent, increases in costs for our commercial research and development projects as the result of higher research, development and other revenue. Due to accelerations in spending on DCB and proprietary product development, we anticipate fiscal 2017 R&D expense will be approximately forty to forty-four percent of revenue.

Selling, general and administrative (SG&A) expenses. SG&A expenses were \$5.2 million and \$15.2 million for the three and nine months ended June 30, 2017, respectively, or 29.4% and 28.6% of total revenue for each respective period. SG&A expenses were \$4.5 million and \$13.0 million for the three and nine months ended June 30, 2016, respectively, or 22.4% and 24.4% of total revenue for each respective period. The increase in SG&A expenses reflects \$0.2 million and \$0.7 million of incremental expenses for the three and nine months ended June 30, 2017, respectively, as compared with the same fiscal 2016 periods attributable to our Fiscal 2016 Acquisitions as well as infrastructure investments to support our whole-products solutions strategy. We expect fiscal 2017 SG&A expenses will be in the high twenties, as a percent of revenue.

Acquisition transaction, integration and other costs. In the third quarter and first nine months of fiscal 2016, we incurred \$0.1 million and \$3.2 million, respectively, of acquisition transaction, integration and other costs related to our Fiscal 2016 Acquisitions.

Intangible asset amortization. As part of our Fiscal 2016 Acquisitions, 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 and \$1.8 million in amortization expense related to acquisitions in the three and nine months ended June 30, 2017, respectively, as compared with \$0.8 million and \$1.9 million in the respective prior-year periods. The decrease in amortization in the fiscal 2017 periods as compared with the 2016 periods is primarily from a lower average U.S. Dollar to Euro exchange rate in the current-year periods. Acquired intangible asset amortization, is estimated to total \$2.5 million in fiscal 2017.

Contingent consideration (gain) accretion expense. For the three and nine months ended June 30, 2017, we recorded a net gain of \$0.6 million and \$0.8 million, respectively, related to our contingent consideration liabilities from the Fiscal 2016 Acquisitions. For the three and nine months ended June 30, 2017, we recognized gains of \$1.2 and \$2.4 million from changes in the estimated fair value of our contingent consideration obligations. These gains are the result of changes in the amount and expected timing of revenue milestones as well as the probability and timing of achieving non-revenue milestones. These gains were partially offset by expense for the passage of time (i.e. accretion), which aggregated \$0.6 million and \$1.5 million, respectively, for the three and nine months ended June 30, 2017 and \$0.6 million and \$1.5 million in the respective prior-year periods. We expect to recognize a net gain of \$0.4 million for fiscal 2017 related to our contingent consideration liabilities from the Fiscal 2016 Acquisitions. If there are any changes in the amount, probability or timing of achievement of contingent consideration milestones, there may be adjustments, which could be material, in the statement of income to reflect changes in the fair value of contingent consideration liabilities.

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

	Three Months Ended June 30,		Nine Months Ended June 30,	
(Dollars in thousands)	2017	2016	2017	2016
Investment income, net	\$104	\$19	\$274	\$37
Foreign exchange (loss) gain	(594)	234	(121)	(336)
Gains on strategic investments and other	—	10	—	371
Other (loss) income, net	\$(490)	\$263	\$153	\$72

Other (loss) income was \$(0.5) million and \$0.1 million, respectively, for the three and nine months ended June 30, 2017, compared with \$0.3 million and \$0.1 million in the respective prior-year periods. The increase in investment income in the fiscal 2017 periods is the result of higher interest rates on debt investments, as well as an increase in investment principal. The foreign exchange (loss) gain in the periods ended June 30, 2017 and 2016 is related to the change in exchange rates associated with the Euro-denominated contingent consideration liability from the fiscal 2016 Creagh Medical acquisition, which is scheduled to be paid in the first quarter of fiscal 2019. During the three and nine-month periods ended June 30, 2017, the Euro strengthened against the U.S. Dollar, resulting in losses for the periods.

Income tax provision. The income tax provision was \$0.5 million and \$3.3 million, respectively, for the three and nine months ended June 30, 2017, representing an effective tax rate, defined as income tax expense divided by income before taxes, of 42.5% and 48.5% in each respective period. The income tax provision was \$2.9 million and \$5.4 million, respectively, for the three and nine months ended June 30, 2016, representing an effective tax rate of 42.8% and 42.3% in each respective period. The difference between the U.S. federal statutory tax rate of 35.0% and our effective tax rate for the three months ended June 30, 2017 and 2016 is primarily due to increased operating losses in Ireland, where tax benefits are offset by a valuation allowance, non-deductible amortization and contingent consideration accretion, including fair value adjustments, associated with the Fiscal 2016 Acquisitions, foreign currency translation gains and losses on Euro-denominated contingent consideration liabilities, and a benefit from an increased fiscal 2017 domestic production manufacturing deduction and federal R&D tax credit. The effective income tax rate for the nine months ended June 30, 2017 differs from the nine months ended June 30, 2016 primarily due to increases in the aforementioned operating losses in Ireland, changes in the expected fiscal 2017 domestic production manufacturing deduction and federal R&D tax credits as well as non-deductible adjustments to the contingent consideration liabilities. The fiscal 2016 periods were also affected by non-deductible transaction costs. Discrete items largely consist of state income tax reserve reversals related to the expiration of statutory filing requirements in each period, as well as the effects of expirations and cancellations of stock option awards, as further discussed below.

Additionally, new guidance related to accounting for excess tax benefits (ASU No. 2016-09, Compensation – Stock Compensation (ASC Topic 718): Improvements to Employee Share-Based Payment Accounting) was adopted in fiscal 2016, resulting in recognition of a tax expense (benefit) from tax deficiencies (excess tax benefits) realized from share awards vested, expired, cancelled and exercised of less than \$(0.1) and \$0.2 million for the respective three and nine-month periods ended June 30, 2017 and \$0.1 million and \$(0.1) million for the respective three and nine-month periods ended June 30, 2016. Prior to adoption of the guidance, excess tax benefits and tax deficiencies were recorded within additional paid-in capital on the condensed consolidated balance sheets. The adoption of ASU-2016-09 will increase volatility in the Company's effective tax rate.

We expect income tax expense for fiscal 2017 to be in the range of \$3.5 million to \$4.0 million. 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 will result in no reported tax benefit or expense in fiscal 2017.

Segment Operating Results

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

(Dollars in thousands)	Three Months Ended June 30,			Nine Months Ended June 30,		
	2017	2016	Change	2017	2016	Change
Operating income:						
Medical Device	\$1,403	\$6,673	(79)%	\$6,627	\$12,825	(48)%
In Vitro Diagnostics	2,230	1,673	33 %	5,922	5,298	12 %
Total segment operating income	3,633	8,346		12,549	18,123	
Corporate	(1,890)	(1,749)	8 %	(5,861)	(5,347)	10 %
Total operating income	\$1,743	\$6,597	(74)%	\$6,688	\$12,776	(48)%

Medical Device. Operating income was \$1.4 million in the third quarter of fiscal 2017, as compared with \$6.7 million in the third quarter of fiscal 2016. Operating income was \$6.6 million in the first nine months of fiscal 2017, as compared with \$12.8 million in the first nine months of fiscal 2016. Operating income decreased in the three and nine months ended June 30, 2017 from the comparable fiscal 2016 periods as higher revenue was offset by increases of \$3.2 million and \$8.9 million, respectively, in R&D expenses related to our planned investment in our drug-coated balloon and proprietary medical device product development programs. Additionally, as previously discussed, the fiscal 2016 periods were positively impacted by the fiscal 2016 royalty revenue adjustments, which resulted in \$2.6 million and \$1.5 million of incremental net revenue in the three and nine-month periods ended June 30, 2016, respectively. The net decrease in current-year revenue resulting from these adjustments was partially offset by a net gain on the contingent consideration obligations of \$0.6 million and \$0.8 million, respectively, for the three and nine months ended June 30, 2017, as compared with a net expense of \$0.6 million and \$1.1 million in the respective prior-year periods. Operating income as a percentage of revenue was 11.0% and 42.6% in the third quarter of fiscal 2017 and 2016, respectively, and 16.9% and 32.5% in the first nine months of fiscal 2017 and 2016, respectively.

In Vitro Diagnostics. Operating income was \$2.2 million in the third quarter of fiscal 2017, as compared with \$1.7 million in the comparable prior-year quarter. Operating income was \$5.9 million in the first nine months of fiscal 2017, as compared with \$5.3 million in the first nine months of fiscal 2016. Operating income as a percentage of revenue was 44.5% and 42.9% in the three and nine months ended June 30, 2017, respectively. Operating income as a percentage of revenue was 38.8% and 38.7% in the three and nine months ended June 30, 2016, respectively. Operating income in the three and nine months ended June 30, 2017 benefited from favorable product gross margins and operating expense reductions of \$0.1 million and \$0.3 million, respectively. Product gross margins increased to 65.4% and 65.7% in the respective three and nine-month periods ended June 30, 2017 from 63.5% and 64.1% in the comparable fiscal 2016 periods. These improvements were due to a favorable product mix and overhead absorption due to manufacturing volume increases.

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. The unallocated Corporate operating loss was \$1.9 million and \$5.9 million in the three and nine-month periods ended June 30, 2017, respectively. The unallocated Corporate operating loss was \$1.7 million and \$5.3 million in the three and nine-month periods ended June 30, 2016, respectively.

Liquidity and Capital Resources

As of June 30, 2017, we had working capital of \$50.1 million, an increase of \$1.7 million from September 30, 2016. Working capital is defined by us as current assets minus current liabilities. The increase from the prior-year end is primarily a result of cash generated from operating activities and an increase in prepaid costs. Our cash and cash equivalents and available-for-sale investments totaled \$43.7 million at June 30, 2017, a decrease of \$3.2 million from \$46.9 million at September 30, 2016. This change was primarily driven by \$4.9 million of investments in capital equipment, \$4.0 million paid for repurchases of common stock and \$2.1 million of cash payments for taxes related to net share settlement of equity awards, partially offset by \$7.7 million of cash provided by operations during the first nine months of fiscal 2017.

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 (“Merrill Lynch 1-3 Year Government-Corporate 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.

On November 2, 2016, entered into an Amended and Restated Credit Agreement (the "Credit Agreement") with Wells Fargo Bank, National Association. The Credit Agreement provides for a secured revolving line of credit of \$30.0 million until November 2019. The Company's obligations under the Credit Agreement are secured by substantially all of its and its subsidiaries' assets, other than intellectual property and real estate. The Company has also pledged the majority of the stock of its subsidiaries to secure such obligations. Interest under the Credit Agreement and accrues at a benchmark rate, plus an applicable margin ranging from 1.00% to 1.75% based on the Company's ratio of total funded debt to EBITDA (as defined in the Credit Agreement). A facility fee is payable quarterly on unused commitments at a rate of 0.15% per annum. As of June 30, 2017, we had no debt outstanding and were in compliance with all financial covenants under the Credit Agreement.

We generated cash flows from operating activities of approximately \$7.7 million and \$18.6 million in the nine months ended June 30, 2017 and 2016, respectively. The following table depicts our cash flows provided by operating activities:

(Dollars in thousands)	Nine Months Ended June 30,	
	2017	2016
Net income	\$3,526	\$7,408
Depreciation and amortization	4,006	3,703
Stock-based compensation	2,620	2,729
Contingent consideration (gain) expense	(803)	1,033
Unrealized foreign exchange loss	127	336
Deferred taxes	1,954	(181)
Net other operating activities	127	(392)
Net change in other operating assets and liabilities	(3,901)	3,931
Net cash provided by operating activities	\$7,656	\$18,567

Operating Activities. Net cash flow from operating activities has provided us with significant sources of liquidity. During the first nine months of fiscal 2017, operating cash flow was primarily generated by net income as adjusted for non-cash expenses (benefits) for depreciation and amortization, contingent consideration gain, unrealized foreign exchange loss, stock-based compensation and deferred taxes. Deferred tax asset reductions during the fiscal 2017 period were primarily related to changes in tax depreciation methods for certain long-lived assets and positively impacted cash flows by \$2.0 million, compared to a negative impact of \$0.2 million in the prior-year period. Net changes in operating assets and liabilities for the first nine months of fiscal 2017 had a negative impact on cash flows of \$3.9 million compared with a positive impact of \$3.9 million in fiscal 2016. Significant changes in operating assets and liabilities during these periods included:

- Cash (used) provided by accounts receivable was (\$0.2) million in the fiscal 2017 period, compared with \$2.0 million in the fiscal 2016 period, which benefited from a \$2.4 million customer payment due in the fourth quarter of fiscal 2015 and paid in the first quarter of fiscal 2016. Fiscal 2017 cash flows were negatively impacted by increased accounts receivable balances due from increased product sales during the third quarter.

Cash used for prepaids and other current assets totaled \$2.0 million in the fiscal 2017 period as compared with cash provided of \$0.1 million in the prior-year period. This change included cash used for increased prepaid clinical trial expenses of \$1.0 million as well as research and development tax credit assets and other reimbursable R&D expenses of \$1.1 million.

• Cash provided by amounts due to customers for overpaid royalties and license fees totaled \$0.2 million during the fiscal 2017 period, compared with \$1.7 million in the fiscal 2016 period. These overpayments primarily relate to the previously disclosed patent expirations. The reduction in these amounts reflects improved customer royalty reporting and settlements of customer overpayments.

28

☛ Cash used for payments of accrued incentive compensation increased by \$0.5 million from the fiscal 2016 period to \$1.3 million during the fiscal 2017 period as the result of payments of incentive compensation obligations related to the achievement of performance objectives in fiscal 2016 versus fiscal 2015.

☛ Cash used by income taxes payable and receivable totaled in a \$0.6 million in the fiscal 2017 period in the fiscal 2017 period, as compared with a \$1.3 million increase in the fiscal 2016 period. These changes were the result of timing differences in tax over/under payments relative to actual tax expense for the periods.

Investing Activities. We used cash in investing activities of \$15.2 million in the first nine months of fiscal 2017 as compared with cash used in investing activities of \$39.1 million in the first nine months of fiscal 2016. We invested \$4.9 million in property and equipment in the first nine months of both fiscal 2017 and fiscal 2016. In the first nine months of fiscal 2017, we invested \$10.3 million in available-for-sale debt securities, net of maturities of other investments, as compared with \$9.6 million in the same prior-year period. We acquired Creagh Medical and NorMedix in the first nine months of fiscal 2016 for net upfront cash payments of \$25.1 million.

Financing Activities. We used cash in financing activities of \$6.1 million and \$0.4 million in the first nine months of fiscal 2017 and 2016, respectively. In the first nine months of fiscal 2017, we paid \$2.1 million to purchase common stock to pay employee taxes resulting from the exercise of stock options in the fourth quarter of 2016 as well as the issuance of common shares associated with our fiscal 2014-2016 performance share program. Additionally, in the third quarter of fiscal 2017, we paid \$4.0 million to repurchase 169,868 common shares in open market purchases. In the first nine months of fiscal 2016, we paid contingent consideration of \$0.3 million related to a prior-year acquisition and used cash of \$0.4 million to purchase common stock to pay employee taxes resulting primarily from the issuance of common shares associated with our fiscal 2013-2015 performance share program. Cash paid for financing activities was partially offset by cash received from the issuance of shares related to exercises of employee stock options totaling \$0.2 million and \$0.3 million for the respective nine-month periods ended June 30, 2017 and 2016.

We believe that our existing cash, and cash equivalents and investments, which totaled \$43.7 million as of June 30, 2017, together with cash flow from operations and our \$30.0 million credit facility, 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. In the event Creagh Medical begins to generate taxable income in future years, repatriation of its earnings may result in substantial U.S. tax cost. Our current plans do not foresee a need to repatriate funds that are designated as permanently reinvested in order to fund our operations or meet currently anticipated liquidity and capital investment needs.

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. Medtronic plc ("Medtronic") is our largest customer comprising 25% of our consolidated revenue for fiscal 2016 and 19% of our consolidated revenue for the first nine months of fiscal 2017. Medtronic has several separately licensed products that generate royalty revenue for Surmodics, none of which represented more than 7% of Surmodics' total revenue. No other individual customer using licensed technology constitutes more than 5% of Surmodics' total revenue.

Share Purchase Activity

As of the beginning of our third quarter of fiscal 2017, the Company's Board of Directors had authorized the repurchase of up to \$30.0 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. During the third quarter of fiscal 2017, the Company

repurchased 169,868 shares of common stock at an average price of \$23.78 per share for a total of approximately \$4.0 million. As of June 30, 2017, the Company has \$26.0 million available for future repurchases under the current authorization.

Off-Balance Sheet Arrangements

As of June 30, 2017 and September 30, 2016, the Company 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, revenues 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 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 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 Medtronic, as well as other significant customers, including new diagnostic kit customers, our ability to recognize the expected benefits of our recent acquisitions and the Company’s strategy to transform to a provider of whole-product solutions, and the timing, impact and success of the clinical evaluation of the SurVeil DCB. Without limiting the foregoing, words or phrases such as “anticipate,” “believe,” “could,” “estimate,” “expect,” “forecast,” “intend,” “may,” “plan,” “possible,” “project,” “will” 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, 2016. 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 customer, 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;
- 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 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 U.S. Food and Drug Administration 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 successfully develop, obtain regulatory approval for, and commercialize our SurVeil DCB product, including our reliance on a clinical research organization to manage the TRANSCEND clinical trial, other DCB products and other catheter and balloon-based products;
- our ability to perform successfully 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 third generation of our PhotoLink® hydrophilic technology protected by a family of patents which expired in November 2015 (in the U.S.) and October 2016 (in certain other countries) to one of our advanced generation technologies and to offset any decline in revenues from customers that

we are unlikely 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

30

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; and other factors described in "Risk Factors" and other sections of Surmodics' Annual Report on Form 10-K for the fiscal year ended September 30, 2016, which you are encouraged to read carefully.

Many of these factors are outside the control and knowledge of us, and could result in increased volatility in period-to-period results. Investors are advised not to place undue reliance upon our forward-looking statements and to consult any further disclosures by us on this subject in our filings with the SEC.

Item 3. Quantitative and Qualitative Disclosures About Market Risk

Our investment policy requires investments with high credit quality issuers and limits the amount of credit exposure to any one issuer. Our investments consist principally of interest-bearing corporate debt securities with varying maturity dates, which are less than one year. Because of the credit criteria of our investment policies, the primary market risk associated with these investments is interest rate risk. We do not use derivative financial instruments to manage interest rate risk or to speculate on future changes in interest rates. As of June 30, 2017, we held \$32.4 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 the 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.

With the Creagh Medical acquisition in November 2015, 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 revenues and expenses denominated in Euro's 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. Further, we are subject to foreign currency risk associated with the payment of up to €12 million of Creagh Medical contingent consideration in approximately December 2018. For the first nine months of fiscal 2017, we have recorded a foreign currency exchange loss of \$0.1 million related to this future payment. A 10% increase or decrease in the U.S. Dollar to Euro exchange rate could have a \$1.0 million impact on this payment based on the exchange rate as of June 30, 2017. 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, carried out an evaluation of the effectiveness of the design and operation of the Company's disclosure controls and procedures as of June 30, 2017. Based on that evaluation, the Company's Chief Executive Officer and Chief Financial Officer concluded that the Company's disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) of the Exchange Act) were not effective as of June 30, 2017 due to the material weakness in internal control over financial reporting described below.

Material Weakness in Internal Control over Financial Reporting

In April 2016, the Company concluded its internal control over financial reporting was not effective due to a material weakness in the design and operating effectiveness of its transactional and review controls related to the recognition of royalty revenue. The ineffectiveness of these internal controls did not result in a restatement of previously issued interim or annual consolidated financial statements. This material weakness has not been remediated as of June 30, 2017, and could result in a misstatement of royalty revenue and related accounts and disclosures that could be material to the condensed consolidated financial statements. Accordingly, management concluded that the Company's internal control over financial reporting was not effective as of June 30, 2017. Although the Company has already made progress in remediation of this issue, as indicated below, sufficient time needs to pass before management can conclude that newly implemented controls are operating effectively and that the material weaknesses has been adequately remediated.

Notwithstanding the material weakness in our internal control over financial reporting, we have concluded that the interim condensed consolidated financial statements and other financial information included in this Quarterly Report on Form 10-Q, fairly present in all material respects our financial condition, results of operations and cash flows as of, and for, the periods presented.

The foregoing has been approved by our management, including our Chief Executive Officer and Chief Financial Officer, who have been involved with the reassessment and analysis of our internal control over financial reporting.

Changes in Internal Controls over Financial Reporting

There were no changes in our internal control over financial reporting (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act) during the three months ended June 30, 2017 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Status of Material Weakness Remediation

With oversight from the Audit Committee, the Company's management designed and implemented certain changes in processes and controls in fiscal 2016 and 2017 for the purpose of remediating the material weakness described above and to enhance the Company's internal control over financial reporting as follows:

- Enhanced the evaluation and analysis of royalties reported and/or paid by customers to determine the proper amount of revenue to be recognized based on terms of the relevant license agreement, including comparison of amounts reported by customers to management's expectations.
- Established quarterly meetings of a cross-functional team from our Medical Device business development, accounting and legal departments to review and evaluate license agreements and royalty revenue in order to identify

circumstances that could impact recognition of royalty revenue with an emphasis on the review of the analysis generated from the preceding control, new or amended licenses, licenses impacted by expired or expiring patents, non-routine royalty revenue as well as the status of current customer inquiries related to reported and unpaid royalty revenue.

• Augmented proactive communications with customers and internal departments related to patent expirations, license terms and license utilization.

• Established a process for ongoing monitoring, review and conclusion of customer investigations or inquiries. These matters are identified from a review of customer license agreements, customer utilization of the Company's technology, royalty revenue reporting and discussions with customers, among other things.

We believe these remediation measures have strengthened our internal control over financial reporting and will result in remediation of the material weakness identified. These additional controls were designed and implemented in the third and fourth quarters of fiscal 2016, but have not operated for an appropriate amount of time for management to determine their operational effectiveness. Accordingly, management has determined that the material weakness has not been remediated as of June 30, 2017. During the remainder of fiscal 2017, management will test and evaluate the effectiveness of these new processes and procedures to ascertain whether they are designed and operating effectively to provide reasonable assurance that they will prevent or detect a material error in the financial statements. Management may deem it necessary to enhance other existing controls and/or implement additional controls as the evaluation progresses.

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. See footnote 15 to the condensed, consolidated financial statements, which describes a matter which arose during the nine months ended June 30, 2017.

Item 1A. Risk Factors

In our report on Form 10-K for the fiscal year ended September 30, 2016, filed with the SEC on December 2, 2016, 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, 2016.

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 June 30, 2017, 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	Total Number of Shares Purchased as Part of Publicly Announced Plans or Programs	Approximate Dollar Value of Shares That May Yet Be Purchased Under the Plans or Programs (1)
4/1/17 — 4/30/17—		N/A	—	\$ 30,000,000
5/1/17 — 5/31/17	120,333	23.33	—	\$ 27,188,346
6/1/17 — 6/30/17	1749,535	24.88	—	\$ 25,954,107
Total	169,868	23.78	—	\$ 25,954,107

(1) As of June 30, 2017, the Company has an aggregate of \$26.0 million available for future common stock repurchase under an authorization approved by the Board of Directors for up to \$20 million on November 6, 2015 and an authorization approved by the Board of Directors on November 5, 2014 for which \$6.0 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. named therein dated as of November 20, 2015 (excluding certain schedules and exhibits, which Surmodics, Inc. agrees to furnish to the Securities and Exchange Commission upon request) – incorporated by reference to Exhibit 2.1 of the Company’s Current Report on Form 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. named therein dated as of November 20, 2015 (excluding schedules and exhibits, which Surmodics, Inc. agrees to furnish to the Securities and Exchange Commission upon request) – incorporated by reference to Exhibit 2.2 of the Company’s Current Report on Form 8-K filed on November 27, 2015, SEC File No. 0-23837.

- 2.3 Stock Purchase Agreement by and among Surmodics, Inc., the shareholders of NorMedix, Inc. and Gregg Sutton, as Seller’s Agent dated as of January 8, 2016 (excluding schedules and exhibits, which Surmodics, Inc. agrees to furnish to the Securities and Exchange Commission upon request) – incorporated by reference to Exhibit 2.1 of the Company’s Current Report on 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* Letter Amendment to Amended and Restated Credit Agreement dated November 2, 2016 by and between Surmodics, Inc. and Wells Fargo Bank, National Association.

- 31.1* Certification of Chief Executive Officer Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.

- 31.2* Certification of Chief Financial Officer Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.

- 32.1* Certification of Chief Executive Officer Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.

- 32.2* Certification of Chief Financial Officer 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 June 30, 2017, filed on August 3, 2017, formatted in Extensible Business Reporting Language (XBRL): (i) Condensed Consolidated Balance Sheets, (ii) Condensed Consolidated Statements of Income,

(iii) Condensed Consolidated Statements of Comprehensive Income, (iv) Condensed Consolidated Statements of Cash Flows, and (v) Notes to Condensed Consolidated Financial Statements.

* Filed herewith

35

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

August 3, 2017 Surmodics, Inc.

By: /s/ Andrew D.C. LaFrence
Andrew D.C. LaFrence
Vice President of Finance, Information Systems and
Chief Financial Officer
(duly authorized signatory, principal financial officer, and principal accounting officer)

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

EXHIBIT INDEX TO FORM 10-Q

For the Quarter Ended June 30, 2017

SURMODICS, INC.

Exhibit	Description
2.1	Share Purchase Agreement by and among Surmodics, Inc. and the shareholders of Creagh Medical Ltd. named therein dated as of November 20, 2015 (excluding certain schedules and exhibits, which Surmodics, Inc. agrees to furnish to the Securities and Exchange Commission upon request) – incorporated by reference to Exhibit 2.1 of the Company’s Current Report on Form 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. named therein dated as of November 20, 2015 (excluding schedules and exhibits, which Surmodics, Inc. agrees to furnish to the Securities and Exchange Commission upon request) – incorporated by reference to Exhibit 2.2 of the Company’s Current Report on Form 8-K filed on November 27, 2015, SEC File No. 0-23837.
2.3	Stock Purchase Agreement by and among Surmodics, Inc., the shareholders of NorMedix, Inc. and Gregg Sutton, as Seller’s Agent dated as of January 8, 2016 (excluding schedules and exhibits, which Surmodics, Inc. agrees to furnish to the Securities and Exchange Commission upon request) – incorporated by reference to Exhibit 2.1 of the Company’s Current Report on 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 on December 18, 2015— incorporated by reference to Exhibit 3.2 to the Company’s Current Report on Form 8-K filed on December 23, 2015, SEC File No. 0-23837.
10.1*	Letter Amendment to Amended and Restated Credit Agreement dated November 2, 2016 by and between Surmodics, Inc. and Wells Fargo Bank, National Association.
31.1*	Certification of Chief Executive Officer Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2*	Certification of Chief Financial Officer Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1*	Certification of Chief Executive Officer Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2*	Certification of Chief Financial Officer Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.

Edgar Filing: SURMODICS INC - Form 10-Q

101.INS* XBRL Instance Document

101.SCH* XBRL Taxonomy Extension Schema Document

101.CAL* XBRL Taxonomy Extension Calculation Linkbase Document

101.DEF* XBRL Taxonomy Extension Definition Linkbase Document

101.LAB* XBRL Taxonomy Extension Label Linkbase Document

101.PRE* XBRL Taxonomy Extension Presentation Linkbase Document

*Filed herewith

37