

SURMODICS INC
Form 10-Q
February 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 December 31, 2016

or

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

For the transition period from _____ to _____

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

Edgar Filing: SURMODICS INC - Form 10-Q

(Address of principal executive offices) (Zip Code)

Registrant's telephone number, including area code: (952) 500-7000

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" and "smaller reporting 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

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 January 31, 2017 was 13,266,526.

TABLE OF CONTENTS

PART I. FINANCIAL INFORMATION

Item 1. <u>Unaudited Condensed Financial Statements</u>	Error! Bookmark not defined.
<u>Management's Discussion and Analysis of Financial Condition and Results of</u>	
Item 2. <u>Operations</u>	22
Item 3. <u>Quantitative and Qualitative Disclosures About Market Risk</u>	29
Item 4. <u>Controls and Procedures</u>	30

PART II. OTHER INFORMATION

Item 1. <u>Legal Proceedings</u>	32
Item	
1A. <u>Risk Factors</u>	32
Item 2. <u>Unregistered Sales of Equity Securities and Use of Proceeds</u>	32
Item 3. <u>Defaults Upon Senior Securities</u>	32
Item 4. <u>Mine Safety Disclosures</u>	32
Item 5. <u>Other Information</u>	32
Item 6. <u>Exhibits</u>	33

SIGNATURES

EX-12

EX-31.1

EX-31.2

EX-32.1

EX-32.2

EX-101 INSTANCE DOCUMENT

EX-101 SCHEMA DOCUMENT

EX-101 CALCULATION LINKBASE DOCUMENT

EX-101 DEFINITION LINKBASE DOCUMENT

EX-101 LABEL LINKBASE DOCUMENT

EX-101 PRESENTATION LINKBASE DOCUMENT

PART I. FINANCIAL INFORMATION

Item 1. Unaudited Condensed Financial Statements

Surmodics, Inc. and Subsidiaries

Condensed Consolidated Balance Sheets

	December 31, 2016	September 30, 2016
(in thousands, except share and per share data)		(Unaudited)
ASSETS		
Current Assets:		
Cash and cash equivalents	\$ 17,653	\$ 24,987
Available-for-sale securities	27,474	21,954
Accounts receivable, net of allowance for doubtful accounts of \$10 and \$19		
as of December 31, 2016 and September 30, 2016, respectively	6,504	6,869
Inventories	3,472	3,579
Income tax receivable	358	697
Prepays and other	1,183	472
Total Current Assets	56,644	58,558
Property and equipment, net	20,186	19,601
Deferred tax assets	4,286	5,027
Intangible assets, net	21,094	22,525
Goodwill	25,694	26,555
Other assets	721	628
Total Assets	\$ 128,625	\$ 132,894
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities:		
Accounts payable	\$ 1,611	\$ 1,622
Accrued liabilities:		
Compensation	1,364	5,418
Due to customers	340	881
Accrued other	1,563	1,109
Contingent consideration	925	925
Deferred revenue	131	180
Total Current Liabilities	5,934	10,135
Contingent consideration, less current portion	13,366	13,592
Deferred revenue, less current portion	258	188
Other long-term liabilities	1,884	2,146
Total Liabilities	21,442	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; 13,268,530 and	663	660

Edgar Filing: SURMODICS INC - Form 10-Q

13,208,443 shares issued and outstanding, respectively

Additional paid-in capital	7,009	6,754
Accumulated other comprehensive (loss) income	(935)	1,273
Retained earnings	100,446	98,146
Total Stockholders' Equity	107,183	106,833
Total Liabilities and Stockholders' Equity	\$128,625	\$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

	Three Months Ended December 31, 2016 2015	
(In thousands, except per share data)	(Unaudited)	
Revenue:		
Product sales	\$7,701	\$7,181
Royalties and license fees	8,001	7,954
Research, development and other	2,059	1,406
Total revenue	17,761	16,541
Operating costs and expenses:		
Product costs	2,628	2,366
Research and development	5,970	3,634
Selling, general and administrative	4,862	3,648
Acquisition transaction, integration and other costs	—	2,491
Acquired intangible asset amortization	596	354
Contingent consideration accretion expense	437	109
Total operating costs and expenses	14,493	12,602
Operating income	3,268	3,939
Other income (loss):		
Investment income, net	85	1
Foreign exchange gain (loss)	674	(135)
Other income (loss), net	759	(134)
Income before income taxes	4,027	3,805
Income tax provision	(1,727)	(1,152)
Net income	\$2,300	\$2,653
Basic net income per share	\$0.17	\$0.20
Diluted net income per share	\$0.17	\$0.20
Weighted average number of shares outstanding:		
Basic	13,200	12,966
Diluted	13,446	13,186

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

Surmodics, Inc. and Subsidiaries

Condensed Consolidated Statements of Comprehensive Income

	Three Months Ended December 31, 2016 2015 (Unaudited)	
(In thousands)		
Net income	\$2,300	\$2,653
Other comprehensive (loss) income:		
Unrealized holding gains (losses) on available-for-sale securities, net of tax	46	(2)
Foreign currency translation adjustments	(2,254)	408
Other comprehensive (loss) income	(2,208)	406
Comprehensive income	\$92	\$3,059

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

Surmodics, Inc. and Subsidiaries

Condensed Consolidated Statements of Cash Flows

	Three Months Ended December 31, 2016 2015 (Unaudited)	
(in thousands)		
Operating Activities:		
Net income	\$2,300	\$2,653
Adjustments to reconcile net income to net cash provided by operating activities:		
Depreciation and amortization	1,282	909
Stock-based compensation	789	684
Contingent consideration accretion	437	109
Unrealized foreign exchange (income) loss	(663)	135
Deferred taxes	742	753
Other	(5)	(3)
Change in operating assets and liabilities, net of acquisitions:		
Accounts receivable	345	2,194
Inventories	73	(83)
Prepays and other	(746)	(75)
Accounts payable and accrued liabilities	(2,713)	(1,354)
Income taxes	82	356
Deferred revenue	28	—
Net cash provided by operating activities	1,951	6,278
Investing Activities:		
Purchases of property and equipment	(1,545)	(384)
Purchases of available-for-sale securities	(12,541)	—
Maturities of available-for-sale securities	7,071	—
Payments for acquisition, net of cash acquired	—	(18,166)
Net cash used in investing activities	(7,015)	(18,550)
Financing Activities:		
Issuance of common stock	13	10
Payments for taxes related to net share settlement of equity awards	(2,129)	(353)
Payment of deferred financing costs	(38)	—
Payment of contingent consideration	—	(305)
Net cash used in financing activities	(2,154)	(648)
Effect of exchange rate changes on cash	(116)	—
Net change in cash and cash equivalents	(7,334)	(12,920)
Cash and Cash Equivalents:		
Beginning of period	24,987	55,588
End of period	\$17,653	\$42,668
Supplemental Information:		
Cash paid for income taxes	\$897	\$42
Noncash transactions from investing and financing activities:		
Acquisition of property and equipment on account	\$227	\$54
Deferred financing costs in accounts payable	45	—
Contingent consideration and debt assumed in Creagh Medical transaction	—	9,857

Issuance of performance shares, restricted and deferred stock units	2,414	1,073
---	-------	-------

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 December 31, 2016

(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 months ended December 31, 2016 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 expects to complete its evaluation during fiscal 2017. Based on a preliminary assessment, the Company currently estimates the impact may be material due to the potential acceleration of minimum license fees and a one quarter acceleration of royalty revenue pursuant to our hydrophilic license agreements.

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 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.

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.

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 is currently evaluating the impact that the adoption of this standard will have on the Company's condensed consolidated statements of cash flows.

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 condensed 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 an adjustment to reduce the income tax provision and increase net income by \$0.1 million in the three months ended December 31, 2015, with a corresponding increase in net income per basic and diluted share of \$0.01 per share.

The 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) are classified as financing cash flows. During the three months ended December 31, 2015, 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 for the three months ended December 31, 2015 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 \$2.4 million for the quarter ended December 31, 2015. The operating results of Creagh Medical have been included in the Company's Medical Device segment since the acquisition date. The Company realized \$0.5 million of revenue and a loss of \$0.3 million from the Creagh Medical operations for the three months ended December 31, 2015.

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
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	

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.

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 \$0.1 million for the three months ended December 31, 2015. The operating results for NorMedix have been included in the Medical Device segment since the acquisition date.

The purchase price of NorMedix consisted of the following:

9

Edgar Filing: SURMODICS INC - Form 10-Q

(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 (Dollars in thousands)	Estimated Useful Life (In years)
Net current assets	\$ 113	N/A
Property and equipment	60	N/A
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 and net income would have been \$17.6 million and \$4.2 million for the three months ended December 31, 2015, with basic and diluted earnings per share of \$0.32. This unaudited pro forma financial information includes adjustments for additional amortization expense on identifiable intangible assets of \$0.4 million and contingent consideration accretion expense of \$0.3 million, eliminating non-recurring transactional professional fees of \$2.5 million, and tax effect impact of \$0.3 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 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 December 31, 2016 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 December 31, 2016 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 December 31, 2016 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 December 31, 2016:

	Quoted Prices in			Total Fair Value as of December 31, 2016
	Active Markets for Identical Instruments (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)	
(Dollars in thousands)				
Assets				
Cash equivalents	\$ —	\$ 13,775	\$ —	\$ 13,775
Available-for-sale securities	—	27,474	—	27,474
Total assets	\$ —	\$ 41,249	\$ —	\$ 41,249
Liabilities				
Contingent consideration	\$ —	\$ —	\$ (14,291)	\$ (14,291)
Total liabilities	\$ —	\$ —	\$ (14,291)	\$ (14,291)

Edgar Filing: SURMODICS INC - Form 10-Q

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

	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)	
(Dollars in thousands)	(Level 1)	(Level 2)	(Level 3)	2016
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)

The following table summarizes the changes in the contingent consideration liabilities measured at fair value using Level 3 inputs for the three months ended December 31, 2016 and 2015:

(Dollars in thousands)	Three Months Ended December 31,	
	2016	2015
Beginning balance	\$14,517	\$—
Additions	—	9,064
Fair value adjustments	—	—
Settlements	—	—
Interest accretion	437	109
Foreign currency translation (gain) loss	(663)	135
Ending balance	\$14,291	\$9,308

There were no transfers of assets or liabilities to or from amounts measured using Level 3 fair value measurements during fiscal 2017 or 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. For the revenue-based milestones, the Company discounted forecasted revenue by 14.1% to 22.8%, 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 65-95% probability of achievement and related payments were discounted using the Company's estimated cost of debt, or 5.6% to 6.7%. To the extent that actual results differ from these estimates, the fair value of the contingent consideration liabilities could change significantly. The contingent consideration liability related to the Creagh Medical acquisition is denominated in Euros and is not hedged. The Company recorded a foreign currency gain of \$0.7 million and a loss of \$0.1 million for the three months ended

December 31, 2016 and 2015, respectively, related to this contingent consideration as this obligation was marked to period-end exchange rates.

5. Investments

Investments consisted principally of commercial paper securities and are classified as available-for-sale as of December 31, 2016 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.

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:

December 31, 2016					
(Dollars in thousands)	Amortized Cost	Unrealized Gains	Unrealized Losses	Fair Value	
Commercial paper and corporate bonds	\$27,487	\$ —	\$ (13)	\$ 27,474	
Total	\$27,487	\$ —	\$ (13)	\$ 27,474	

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 December 31,		
(Dollars in thousands)	2016	2015
Proceeds from maturities	\$ 7,071	\$ —
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:

		September
(Dollars in thousands)	December 31, 2016	30, 2016
Raw materials	\$ 1,724	\$ 1,766
Work-in process	449	492
Finished products	1,299	1,321
Total	\$ 3,472	\$ 3,579

7. Other Assets

Other assets consist of the following:

	December 31,	September 30,
(Dollars in thousands)	2016	2016
ViaCyte, Inc.	\$ 479	\$ 479
Other noncurrent assets	242	149
Other assets, net	\$ 721	\$ 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 adverse 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 \$0.4 million for the three months ended December 31, 2016 and 2015, respectively.

Intangible assets consisted of the following:

	December 31, 2016			
	Weighted	Gross		
(Dollars in thousands)	Average	Carrying	Accumulated	
	Original	Amount	(Years)	Net
			Amortization	
Definite-lived intangible assets:				
Customer lists and relationships	8.9	\$ 16,979	\$ (6,434)	\$ 10,545
Core technology	8.0	530	(530)	—
Developed technology	11.8	8,610	(800)	7,810
Non-compete	5.0	230	(69)	161
Patents and other	16.5	2,322	(1,312)	1,010
Subtotal		28,671	(9,145)	19,526
Unamortized intangible assets:				
In-process research and development		927	—	927
Trademarks and trade names		641	—	641
Total		\$ 30,239	\$ (9,145)	\$ 21,094

	September 30, 2016			
	Weighted	Gross		
(Dollars in thousands)	Average	Carrying	Accumulated	
	Original	Amount	(Years)	Net
			Amortization	
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 December 31, 2016, excluding any possible future amortization associated with acquired in-process research and development (“IPR&D”), which has not met technological feasibility as of December 31, 2016, 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	\$ 1,864
2018	2,439
2019	2,439
2020	2,264
2021	2,125

2022	2,085
------	-------

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 December 31, 2016 and September 30, 2016 totaled \$25.7 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 quarter of fiscal 2017 to indicate that goodwill has been impaired.

The change in the carrying amount of goodwill by segment for the three months ended December 31, 2016 was as follows:

(Dollars in thousands)	In Vitro Diagnostics	Medical Device	Total
Balance as of September 30, 2016	\$ 8,010	\$18,545	\$26,555
Translation adjustment	—	(861)	(861)
Balance as of December 31, 2016	\$ 8,010	\$17,684	\$25,694

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 December 31,	
	2016	2015
Product costs	\$ 13	\$ 6
Research and development	125	59

Edgar Filing: SURMODICS INC - Form 10-Q

Selling, general and administrative	651	619
Total	\$ 789	\$ 684

As of December 31, 2016, approximately \$6.2 million of total unrecognized compensation costs related to non-vested awards is expected to be recognized over a weighted average period of approximately 2.5 years. The unrecognized compensation costs above include \$2.6 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 December 31, 2016 and 2015 were \$7.59 and \$6.87, respectively. The assumptions used as inputs in the model were as follows:

	Three Months Ended December 31, 2016		2015	
Risk-free interest rates	1.7	%	2.0	%
Expected life (years)	4.6		4.6	
Expected volatility	34.4	%	36.7	%
Dividend yield	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 and \$0.3 million during the three months ended December 31, 2016 and 2015, respectively.

The total pre-tax intrinsic value of options exercised during the three months ended December 31, 2016 and 2015 was less than \$0.1 million in each period. 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 in each of the three months ended December 31, 2016 and 2015, 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). 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 three months ended December 31, 2016 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 \$0.2 million for both the three months ended December 31, 2016 and 2015.

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

1999 Employee Stock Purchase Plan

Under the 1999 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 December 31, 2016 and September 30, 2016, there was \$0.1 million of employee contributions included in accrued liabilities in the condensed consolidated balance sheets. Stock compensation expense recognized related to the Stock Purchase Plan for the three months ended December 31, 2016 and 2015 totaled less than \$0.1 million in each period. The stock-based compensation table includes the Stock Purchase Plan expenses.

Restricted Stock and Deferred Stock Units

During the three months ended December 31, 2016 and 2015, the Company awarded 6,570 and 8,916 restricted stock units (“RSUs”), respectively, under the 2009 Equity Incentive Plan to non-employee directors and certain key employees in foreign jurisdictions. Forfeiture of 74 RSUs occurred in the first quarter of fiscal 2017. As of December 31, 2016 and September 30, 2016, 35,378 and 32,101 RSUs were outstanding, respectively, with an estimated fair market value of \$0.9 million for both periods. 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 months ended December 31, 2016 and 2015.

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 three months ended December 31, 2016 and 2015, 1,971 and 1,842 units, respectively, were issued with a total fair value of less than \$0.1 million in each period. As of December 31, 2016 and September 30, 2016, outstanding DSUs totaled 23,048 and 21,077, respectively, with an estimated fair value of \$0.6 million for both periods. These DSUs are fully vested. Stock-based compensation expense related to DSU awards, totaled less than \$0.1 million for the three months ended December 31, 2016 and 2015, respectively.

11. Revolving Credit Facility

On November 2, 2016, the Company amended and restated the revolving credit facility. The new agreement increased the available principal to \$30.0 million and extended the maturity of the previous facility by three years 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 December 31, 2016, 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 December 31,	
	2016	2015
Net income available to common shareholders	\$2,300	\$2,653
Basic weighted average shares outstanding	13,200	12,966
Dilutive effect of outstanding stock options, non-vested restricted stock, restricted stock units, deferred stock units and performance shares	246	220
Diluted weighted average shares outstanding	13,446	13,186

The calculation of weighted average diluted shares outstanding excludes outstanding stock options associated with the right to purchase 0.3 million and 0.4 million shares of common stock for the three months ended December 31, 2016 and 2015, 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.

13. Income Taxes

The Company recorded income tax provisions of \$1.7 million and \$1.2 million for the three months ended December 31, 2016 and 2015, respectively, representing effective tax rates of 42.9% and 30.3%, 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 month periods ended December 31, 2016 and 2015 differs from the U.S. federal statutory tax rate of 35.0% primarily due to transaction costs and contingent consideration accretion associated with the Creagh Medical and NorMedix acquisitions, the domestic production manufacturing deduction and the U.S. federal research and development income tax credit, operating losses in a jurisdiction where tax benefits are offset by a valuation allowance, and discrete tax expense related to expiring stock option awards.

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 both December 31, 2016 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. The Internal Revenue Service ("IRS") completed an examination of the Company's U.S. income tax return for fiscal 2012 in the fourth quarter of fiscal 2014 with a payment made associated with a timing adjustment. U.S. income tax returns for years prior to fiscal 2013 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 2006. For tax returns for non-U.S. jurisdictions, the Company is no longer subject to income tax examination for years prior to 2011. 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 December 31, 2016 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, based on the criteria set forth in FASB ASC Topic 280, Segment Reporting, 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 December 31,	
(Dollars in thousands)	2016	2015
Revenue:		
Medical Device	\$13,757	\$12,247
In Vitro Diagnostics	4,004	4,294
Total revenue	\$17,761	\$16,541
Operating income:		
Medical Device	\$3,719	\$3,830
In Vitro Diagnostics	1,456	1,643
Total segment operating income	5,175	5,473
Corporate	(1,907)	(1,534)
Total operating income	\$3,268	\$3,939
Depreciation and amortization:		
Medical Device	\$1,004	\$487
In Vitro Diagnostics	103	222
Corporate	175	200
Total depreciation and amortization	\$1,282	\$909

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

estimated loss or range of loss is disclosed. In most cases, significant judgment is required to estimate the amount and timing of a loss to be recorded.

InnoCore Technologies BV. In 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 \$211,000 using a euro to US dollar exchange rate of 1.0536 to the Euro as of December 31, 2016) until the last patent expires which is currently estimated to be September 2027. The total minimum future payments associated with this license are approximately \$2.7 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 business performance has been driven by growth in our core Medical Device business 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"). Revenues in the Medical Device business are driven by product sales, hydrophilic coatings royalties, and contract research development services. Medical Device segment revenue grew 12% in the first three months of fiscal 2017, stemming from higher product sales, royalties, research, development and other revenue. Our In Vitro Diagnostics ("IVD") business is driven by product sales of diagnostic technology. Revenue from the IVD segment decreased 7% in the first three months of fiscal year 2017 compared with the same prior-year period as the business was impacted by strong fourth quarter fiscal 2016 sales in several product categories as well as a decline from a significant microarray customer that had previously been acquired by one of its competitors.

We continue to derive our revenue from three primary sources: (1) product revenues from the sale of reagent chemicals to licensees, the sale of stabilization products, antigens, substrates and surface coatings to the diagnostic and biomedical research markets as well as the sale of medical devices and related products (such as balloons and catheters) to original equipment manufacturer (OEM) suppliers and distributors; (2) royalties and license fees from licensing our proprietary surface modification and device drug delivery technologies to customers; 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. Among these, our third generation of PhotoLink hydrophilic technology is 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 revenues are 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, and partner with them on successful commercialization. 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 in-

human early feasibility study of the Surmodics SurVeil® drug-coated balloon (“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. We received preliminary results from the feasibility study in December 2016 and, based on the findings to date, are expecting to launch the next phase of clinical study by the end of fiscal 2017. To facilitate this, in January 2017 we engaged a clinical research organization (“CRO”) to plan and manage the clinical trial.

We prioritize our internal R&D programs in our segments 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 based on the first-in-human program, and typically include many of the same factors discussed above with respect to our customer R&D programs. 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 primarily based on the level of customer program activity. 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 December 31, 2016, 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 Months Ended December 31

Revenue. Revenue during the first quarter of fiscal 2017 was \$17.8 million, an increase of \$1.2 million, or 7.4%, compared with the first quarter of fiscal 2016. The change in revenue, as detailed in the table below, is further explained in the narrative below.

	Three Months Ended December 31,		% Change	
(Dollars in thousands)	2016	2015		
Revenue				
Medical Device	\$13,757	\$12,247	12.3	%
In Vitro Diagnostics	4,004	4,294	(6.8)	%
Total Revenue	\$17,761	\$16,541	7.4	%

Medical Device. Medical Device revenue was \$13.8 million in the first quarter of fiscal 2017, an increase of 12.3% compared with \$12.2 million for the first quarter of fiscal 2016. The change in total revenue was attributable to increases in revenue of \$0.8 million from higher product sales and \$0.7 million from higher research and development

services. These increases include \$0.9 million of incremental revenue from the Fiscal 2016 Acquisitions. License and royalty revenue for the first quarter of fiscal 2017 was up slightly from the prior year. Royalty revenue was stronger than expected 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. 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 revenue to decline between \$4.0 million to \$5.0 million as the result of one-time items that occurred in fiscal 2016 and the impact of patent expirations governing our third-generation patents.

In Vitro Diagnostics. In Vitro Diagnostics revenue was \$4.0 million in the first quarter of fiscal 2017, a decrease of 6.8% compared with \$4.3 million for first quarter of fiscal 2016. The decrease in the first quarter of fiscal 2017 was primarily due to reduced sales to a significant microarray customer that had previously been acquired by one of its competitors. We expect a decline in revenue from the microarray customer to adversely impact our IVD business through our third quarter of fiscal 2017.

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 December 31,					
	2016			2015		
	% Total		Revenue	% Total		Revenue
	Amount			Amount		
Product costs	\$2,628	15	%	\$2,366	14	%
Research and development	5,970	34		3,634	22	
Selling, general and administrative	4,862	27		3,648	22	
Acquired intangible asset amortization	596	3		354	2	
Contingent consideration accretion expense	437	2		109	1	
Acquisition transaction, integration and other costs	—	—		2,491	15	

Product costs. Product costs were \$2.6 million and \$2.4 million for the three months ended December 31, 2016 and 2015, respectively, or 15% and 14% of total revenue in each respective period. Product gross margins (defined as product sales less related product costs) were 65.9% and 67.1% of product sales for the three months ended December 31, 2016 and 2015, respectively. The reduction in product gross margins was largely a result of a \$0.1 million loss from a damaged shipment from a vendor, which was partially offset by improved product mix in our Medical Device segment.

Research and development (R&D) expenses. R&D expenses were \$5.9 million and \$3.6 million for the first quarter of fiscal 2016 and 2015, respectively, or 33.6% and 22.0% of total revenue in each respective period. The fiscal 2017 increase in total R&D expenses from fiscal 2016 was primarily the result of higher spending for our DCB and proprietary product development activities. Fiscal 2017 included \$1.1 million of incremental R&D expenses from our Fiscal 2016 Acquisitions. We expect R&D expense to increase in the remainder of fiscal 2017 compared with fiscal 2016 as we invest in our whole-products solutions strategy and continue to invest in our DCB development activities, including the commencement of a clinical study. We anticipate fiscal 2017 R&D expense will be approximately high-thirty to low-forty percent of revenue.

Selling, general and administrative (SG&A) expenses. SG&A expenses were \$4.9 million and \$3.6 million for the first quarter of fiscal 2016 and 2015, respectively, or 27.7% and 22.1% of total revenue for each respective period. The increase in SG&A expenses as a percent of total revenue reflects \$0.4 million of incremental expenses attributable to our Fiscal 2016 Acquisitions as well as additional infrastructure needed to support our whole-products solutions strategy. We expect fiscal 2017 SG&A expenses as a percent of revenue will be approximately high twenty percent of revenue.

Acquisition transaction, integration and other costs. In the first quarter of fiscal 2016, we incurred \$2.5 million in 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 four to 14 years. In addition, we own certain intangible assets related to the BioFx acquisition in fiscal 2007. We recorded \$0.6 million in amortization expense related to these acquisitions in the first quarter of fiscal 2017 as compared to \$0.4 million in the prior-year quarter. The increase is the result of the Fiscal 2016 Acquisitions. Acquired intangible asset amortization, is estimated to total \$2.5 million in fiscal 2017.

Contingent consideration accretion expense. For the first quarter of fiscal 2017, we recorded \$0.4 million of contingent consideration expense related to our contingent consideration liabilities from the Fiscal 2016 Acquisitions, due to the passage of time (i.e. accretion). Accretion expense increased \$0.3 million from the prior-year quarter, as

Creagh Medical was acquired in the middle of the first quarter of fiscal 2016 and NorMedix was acquired in the second quarter of fiscal 2016. Based on the most recent projections related to the Fiscal 2016 Acquisitions, we estimate contingent consideration accretion expense to be approximately \$2.0 million in fiscal 2017. In addition, if there are 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.

Edgar Filing: SURMODICS INC - Form 10-Q

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

	Three Months Ended December 31,	
(Dollars in thousands)	2016	2015
Investment income, net	\$85	\$1
Foreign exchange gain (loss)	674	(135)
Other (loss) income, net	\$759	\$(134)

Other income (loss) was \$0.8 million and \$(0.1) million in the three months ended December 31, 2016 and 2015, respectively. The foreign exchange gain (loss) in the quarters ended December 31, 2016 and 2015 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.

Income tax provision. The income tax provision was \$1.7 million and \$1.3 million for the three months ended December 31, 2016 and 2015, respectively, representing an effective tax rate of 42.9% and 30.3%, respectively. The difference between the U.S. federal statutory tax rate of 35.0% and our effective tax rate for the three months ended December 31, 2016 and 2015 is primarily due to transaction costs and contingent consideration accretion associated with the Fiscal 2016 Acquisitions, the domestic production manufacturing deduction and the US federal research and development tax credit. 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. The effective income tax rate for the three months ended December 31, 2016 differs from the three months ended December 31, 2015 primarily due to contingent consideration accretion and foreign currency gains (losses) associated with the Fiscal 2016 Acquisitions, as well as operating losses in Ireland, where tax benefits are offset by a valuation allowance.

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 \$0.3 million and (\$0.1 million) for the three months ended December 31, 2016 and 2015, respectively. 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 to incur between \$2.5 million and \$3.5 million in income tax expense for fiscal 2017. Amortization expense from the Creagh Medical acquisition does not reflect an Irish income tax benefit as we acquired a net operating loss carryforward as of the acquisition date that was offset in the aggregate with deferred tax liabilities and a valuation allowance. Therefore, taxable income or losses in Ireland will result in no reported tax impacts in fiscal 2017.

Segment Operating Results

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

	Three Months Ended December 31,		
(Dollars in thousands)	2016	2015	%

			Change	
Operating income:				
Medical Device	\$3,719	\$3,830	(3)	)%
In Vitro Diagnostics	1,456	1,643	(11)	)%
Total segment operating income	5,175	5,473		
Corporate	(1,907)	(1,534)	24	%
Total operating income	\$3,268	\$3,939	(17)	)%

Medical Device. Operating income was \$3.7 million in the first quarter of fiscal 2017, compared with \$3.8 million in the first quarter of fiscal 2016. Operating income decreased as higher revenues were offset by \$1.0 million of amortization and contingent consideration accretion expenses associated with the Fiscal 2016 Acquisitions, as well as an increase in R&D expenses of \$2.3 million related to our investment in our drug-coated balloon and proprietary medical device product development programs. Operating income as a percentage of revenue was 27.0% and 31.2% in the first quarter of fiscal 2017 and 2016, respectively.

In Vitro Diagnostics. Operating income was \$1.5 million in the first quarter of fiscal 2017, compared with \$1.6 million in the first quarter of fiscal 2016. Product sales decreased \$0.3 million and the related product gross margins of 61.0% in the first quarter of fiscal 2017 were down from 65.4% in the first quarter of fiscal 2016. Product gross margins decreased as a result of sales mix, as well as a \$0.1 million cost associated with a casualty loss incurred in the first quarter of fiscal 2017 related to a damaged shipment. Allocated corporate expenses decreased by \$0.1 million in the first quarter of fiscal 2017 compared with the first quarter of fiscal 2016, as the Medical Device segment absorbed more overhead costs due to increased operating activities in fiscal 2017. The operating income as a percentage of revenue was 36.3% and 38.3% in the first quarter of fiscal 2017 and 2016, respectively.

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 \$1.5 million in the three months ended December 31, 2016 and 2015, respectively.

Liquidity and Capital Resources

As of December 31, 2016, we had working capital of \$50.7 million, an increase of \$2.3 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 reductions in current liabilities. Our cash and cash equivalents and available-for-sale investments totaled \$45.1 million at December 31, 2016, a decrease of \$1.8 million from \$46.9 million at September 30, 2016. This change was principally associated with \$2.0 million of cash flow from operations was offset by \$2.1 million of stock purchases to pay employee taxes and \$1.5 million of investments in capital equipment during the first quarter 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 and commercial paper investments. 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 4, 2013, we entered into a three year, \$20.0 million secured revolving credit facility. On November 2, 2016, we amended and restated the secured revolving credit facility pursuant to an Amended and Restated Credit Agreement (the "Credit Agreement") with Wells Fargo Bank, National Association (the "Bank"). The Credit Agreement increases availability under the secured revolving line of credit from \$20.0 million to \$30.0 million and extends the maturity of the previous facility by three years. 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 expense under the Credit Agreement is reduced as compared to the Company's prior secured revolving credit facility and accrues at a benchmark rate, plus an applicable margin ranging from 1.00% to 1.75%. A facility fee is payable quarterly on unused commitments at a rate of 0.15% per annum. The interest rate margins are determined based on the Company's ratio of total funded debt to EBITDA (as defined in the Credit Agreement).

Edgar Filing: SURMODICS INC - Form 10-Q

We generated cash flows from operating activities of approximately \$2.0 million and \$6.3 million in the first quarter ended December 31, 2016 and 2015, respectively. The following table depicts our cash flows provided by operating activities:

	Three Months Ended December 31,	
(Dollars in thousands)	2016	2015
Net income	\$2,300	\$2,653
Depreciation and amortization	1,282	909
Stock-based compensation	789	684
Contingent consideration accretion	437	109
Unrealized foreign exchange (income) loss	(663)	135
Deferred taxes	742	753
Net other operating activities	(5)	(3)
Net change in other operating assets and liabilities	(2,931)	1,038
Net cash provided by operating activities	\$1,951	\$6,278

Operating Activities. Net cash flow from operating activities has provided us with significant sources of liquidity. During the first three months of fiscal 2017, operating cash flow was primarily generated by net income as adjusted for non-cash expenses (benefits) for depreciation and amortization, unrealized foreign exchange income, stock-based compensation and deferred taxes; reduced by net other operating activities, which includes the excess tax benefit from stock-based compensation. Net income in the first quarter of fiscal 2017 was negatively impacted by increased depreciation, intangible amortization and contingent consideration expenses associated with the Fiscal 2016 Acquisitions. Additionally, net changes in operating assets and liabilities for the first quarter of fiscal 2017 had a negative impact on cash flows of \$2.9 million compared to \$1.0 million positive impact in fiscal 2016. Fiscal 2016 benefited from \$2.1 million of customer collections in excess of billings, compared to \$0.3 million in fiscal 2017, due to a \$2.4 million customer payment due in the fourth quarter of fiscal 2015 that was paid in October 2015. Additionally, payments of incentive compensation and operating expenses increased by \$1.3 million in fiscal 2017 from fiscal 2016 and increases in other current assets reduced cash by \$0.7 million in fiscal 2017 compared to \$0.1 million in fiscal 2016.

Investing Activities. We used cash in investing activities of \$7.0 million in the first quarter of fiscal 2017 compared with cash used in investing activities of \$18.6 million in the first quarter of fiscal 2016. We acquired Creagh Medical in the first quarter of fiscal 2016 with an initial payment, net of cash acquired, of \$18.2 million. We invested \$1.5 million in property and equipment in the first quarter of fiscal 2017, compared with \$0.4 million in the prior-year period. In the first quarter of fiscal 2017, we invested \$5.5 million in available-for-sale debt securities, net of maturities of other investments.

Financing Activities. We used cash in financing activities of \$2.2 million and \$0.5 million in the first quarter of fiscal 2017 and 2016, respectively. In the first quarter 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. In the first quarter 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.

We believe that our existing cash, and cash equivalents and investments, which totaled \$45.1 million as of December 31, 2016, 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 22% of our consolidated revenue for the first quarter of fiscal 2017. Medtronic has several separately licensed products that generate royalty revenue for Surmodics, none of which represented more than 4% of Surmodics' total revenue. No other individual customer using licensed technology constitutes more than 6% of Surmodics' total revenue.

Share Purchase Activity

The Company's Board of Directors has authorized the repurchase of up to an additional \$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.

Off-Balance Sheet Arrangements

As of December 31, 2016 and September 30, 2016, the Company did not have any off-balance sheet arrangements with any unconsolidated entities.

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 and broaden our hydrophilic coatings royalty revenue, product development programs, various milestone achievements, research and development expenses, future cash flow and sources of funding, short-term liquidity 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 our ability to implement a PMA Clinical trial of the Surmodics SurVeil® Drug Coated Balloon on any particular time frame. Without limiting the foregoing, words or phrases such as "anticipate," "believe," "could," "estimate," "expect," "forecast," "intend," "may," "possibly," "project," "will" and similar terminology, generally identify forward-looking statements. Forward-looking statements may also represent challenging goals for us. These statements, which represent the Company's expectations or beliefs concerning various future events, are based on current expectations that involve a number of risks and uncertainties that could cause actual results to differ materially from those of such forward-looking statements. We caution that undue reliance should not be placed on such forward-looking statements, which speak only as of the date made. Some of the factors which could cause results to differ from those expressed in any forward-looking statement are set forth under "Risk Factors" in Part 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 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 Surmodics SurVeil Drug Coated Balloon product, including our reliance on a clinical research organization to manage the PMA clinical trial; 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;

28

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 assimilate acquired operations, personnel, technology, information systems, and internal control systems and products; a lack of understanding of tax, legal and cultural differences; diversion of management's attention; difficulties and uncertainties in transitioning the customers or other business relationships from the acquired entity to us; the loss of key employees of acquired companies; 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 December 31, 2016, we held \$27.5 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 to 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 three months of fiscal 2017, we have recorded a foreign currency exchange gain of \$0.7 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 December 31, 2016. 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 December 31, 2016. 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 December 31, 2016 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 December 31, 2016, 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 December 31, 2016. 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 December 31, 2016 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 has designed and implemented certain changes in processes and controls 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 will strengthen our internal control over financial reporting and remediate 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 December 31, 2016. 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

There have been no material developments in the legal proceedings previously disclosed in the Company's Form 10-K for the fiscal year ended September 30, 2016.

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 December 31, 2015, 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)
10/1/16 — 10/31/16	—	N/A	—	\$ 30,000,000
11/1/16 — 11/30/16	—	N/A	—	\$ 30,000,000
12/1/16 — 12/31/16	—	N/A	—	\$ 30,000,000
Total	—	N/A	—	\$ 30,000,000

(1) As of December 31, 2016, the Company has an aggregate of \$30 million available for future common stock repurchases under authorizations previously issued by the Board of Directors.

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 Amended and Restated Credit Agreement dated November 2, 2016, by and between Surmodics, Inc., and Wells Fargo Bank, National Association — incorporated by reference to Exhibit 10.1 to the Company’s Current Report on Form 8-K filed on November 7, 2016, SEC File No. 0 23837.
- 10.2 Amended and Restated Revolving Line of Credit Note dated November 2, 2016 — incorporated by reference to Exhibit 10.2 to the Company’s Current Report on Form 8-K filed on November 7, 2016, SEC File No. 0 23837.

- 12* Computation of Ratio of Earnings to Fixed Charges.

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

Edgar Filing: SURMODICS INC - Form 10-Q

- 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 December 31, 2016, filed on February 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

33

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.

February 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 and principal financial officer)

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

EXHIBIT INDEX TO FORM 10-Q

For the Quarter Ended December 31, 2016

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	Amended and Restated Credit Agreement dated November 2, 2016, by and between Surmodics, Inc., and Wells Fargo Bank, National Association — incorporated by reference to Exhibit 10.1 to the Company’s Current Report on Form 8-K filed on November 7, 2016, SEC File No. 0 23837.
10.2	Amended and Restated Revolving Line of Credit Note dated November 2, 2016 — incorporated by reference to Exhibit 10.2 to the Company’s Current Report on Form 8-K filed on November 7, 2016, SEC File No. 0 23837.
12*	Computation of Ratio of Earnings to Fixed Charges.
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.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