

SURMODICS INC
Form 10-Q
February 08, 2018

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, 2017

or

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

Commission File Number: 0-23837

Surmodics, Inc.

(Exact name of registrant as specified in its charter)

MINNESOTA 41-1356149
(State of incorporation) (I.R.S. Employer

Identification No.)

9924 West 74th Street

Eden Prairie, Minnesota 55344

(Address of principal executive offices) (Zip Code)

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

Edgar Filing: SURMODICS INC - Form 10-Q

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

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

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

Large accelerated filer	Accelerated filer
Non-accelerated filer (Do not check if a smaller reporting company)	Smaller reporting company
	Emerging Growth Company

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

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

The number of shares of the registrant’s Common Stock, \$.05 par value per share, outstanding as of February 5, 2018 was 13,196,616.

TABLE OF CONTENTS

PART I. FINANCIAL INFORMATION

Item 1. <u>Unaudited Condensed Financial Statements</u>	3
Item 2. <u>Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	19
Item 3. <u>Quantitative and Qualitative Disclosures About Market Risk</u>	26
Item 4. <u>Controls and Procedures</u>	28

PART II. OTHER INFORMATION

Item 1. <u>Legal Proceedings</u>	29
Item 1A. <u>Risk Factors</u>	29
Item 2. <u>Unregistered Sales of Equity Securities and Use of Proceeds</u>	29
Item 3. <u>Defaults Upon Senior Securities</u>	29
Item 4. <u>Mine Safety Disclosures</u>	29
Item 5. <u>Other Information</u>	29
Item 6. <u>Exhibits</u>	30

SIGNATURES 31

PART I. FINANCIAL INFORMATION

Item 1. Unaudited Condensed Financial Statements

Surmodics, Inc. and Subsidiaries

Condensed Consolidated Balance Sheets

	December 31, 2017	September 30, 2017
	(Unaudited)	
(in thousands, except share and per share data)		
ASSETS		
Current Assets:		
Cash and cash equivalents	\$21,596	\$16,534
Restricted cash	350	—
Available-for-sale securities	24,756	31,802
Accounts receivable, net of allowance for doubtful accounts of \$204 and \$230 as of December 31, 2017 and September 30, 2017, respectively	6,695	7,211
Inventories	3,871	3,516
Income tax receivable	240	599
Prepays and other	2,488	1,221
Total Current Assets	59,996	60,883
Property and equipment, net	23,624	22,942
Deferred tax assets	2,313	4,027
Intangible assets, net	20,076	20,562
Goodwill	27,505	27,282
Other assets	1,039	897
Total Assets	\$134,553	\$136,593
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities:		
Accounts payable	\$2,309	\$2,396
Accrued liabilities:		
Compensation	1,683	3,822
Accrued other	1,790	1,835
Contingent consideration, current portion	13,752	1,750
Total Current Liabilities	19,534	9,803
Contingent consideration, less current portion	2,410	13,114
Other long-term liabilities	2,062	2,119
Total Liabilities	24,006	25,036
Commitments and Contingencies (Note 14)		
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; 13,195,616 and 13,094,988 shares issued and outstanding as of December 31, 2017 and September 30, 2017, respectively	660	655

Edgar Filing: SURMODICS INC - Form 10-Q

Additional paid-in capital	5,337	5,413
Accumulated other comprehensive income	4,034	3,417
Retained earnings	100,516	102,072
Total Stockholders' Equity	110,547	111,557
Total Liabilities and Stockholders' Equity	\$ 134,553	\$ 136,593

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

Surmodics, Inc. and Subsidiaries

Condensed Consolidated Statements of Operations

(In thousands, except per share data)	Three Months Ended December 31,	
	2017	2016
	(Unaudited)	
Revenue:		
Product sales	\$8,088	\$7,701
Royalties and license fees	7,076	8,001
Research, development and other	1,849	2,059
Total revenue	17,013	17,761
Operating costs and expenses:		
Product costs	2,891	2,628
Research and development	7,831	5,970
Selling, general and administrative	5,188	4,862
Acquired intangible asset amortization	618	596
Contingent consideration expense	1,118	437
Total operating costs and expenses	17,646	14,493
Operating (loss) income	(633)	3,268
Other income:		
Investment income, net	121	85
Foreign exchange (loss) gain	(186)	674
Gain on strategic investment	177	—
Other income, net	112	759
(Loss) income before income taxes	(521)	4,027
Income tax provision	(1,035)	(1,727)
Net (loss) income	\$(1,556)	\$2,300
Basic net (loss) income per share	\$(0.12)	\$0.17
Diluted net (loss) income per share	\$(0.12)	\$0.17
Weighted average number of shares outstanding:		
Basic	13,064	13,200
Diluted	13,064	13,446

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

Surmodics, Inc. and Subsidiaries

Condensed Consolidated Statements of Comprehensive (Loss) Income

	Three Months Ended December 31, 2017 2016 (Unaudited)	
(In thousands)		
Net (loss) income	\$ (1,556)	\$ 2,300
Other comprehensive income (loss) :		
Unrealized holding (losses) gains on available-for-sale securities, net of tax	(14)	46
Foreign currency translation adjustments	631	(2,254)
Other comprehensive income (loss)	617	(2,208)
Comprehensive (loss) income	\$ (939)	\$ 92

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

Surmodics, Inc. and Subsidiaries

Condensed Consolidated Statements of Cash Flows

(in thousands)	Three Months Ended December 31,	
	2017	2016
	(Unaudited)	
Operating Activities:		
Net (loss) income	\$(1,556)	\$2,300
Adjustments to reconcile net (loss) income to net cash provided by operating activities:		
Depreciation and amortization	1,520	1,282
Stock-based compensation	903	789
Contingent consideration expense	1,118	437
Unrealized foreign exchange loss (income)	180	(663)
Deferred taxes	1,714	742
Gain on strategic investment	(177)	—
Provision for bad debts	28	—
Other	(7)	(5)
Change in operating assets and liabilities:		
Accounts receivable	484	345
Inventories	(345)	73
Prepays and other	(1,188)	(746)
Accounts payable and accrued liabilities	(2,295)	(2,713)
Income taxes	190	82
Deferred revenue	45	28
Net cash provided by operating activities	614	1,951
Investing Activities:		
Purchases of property and equipment	(1,298)	(1,545)
Purchases of available-for-sale securities	(11,364)	(12,541)
Maturities of available-for-sale securities	18,400	7,071
Net cash provided by (used in) investing activities	5,738	(7,015)
Financing Activities:		
Issuance of common stock	155	13
Payments for taxes related to net share settlement of equity awards	(1,130)	(2,129)
Payment of deferred financing costs	—	(38)
Net cash used in financing activities	(975)	(2,154)
Effect of exchange rate changes on cash and cash equivalents	35	(116)
Net change in cash and cash equivalents	5,412	(7,334)
Cash and Cash Equivalents:		
Beginning of period	16,534	24,987
End of period	\$21,946	\$17,653
Supplemental Information:		
Cash paid for income taxes	\$12	\$897
Noncash transactions from investing and financing activities:		
Acquisition of property and equipment on account	\$187	\$227
Strategic investment gain receivable included in other current assets	177	—
Deferred financing costs in accounts payable	—	45

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, 2017

(Unaudited)

1. Basis of Presentation

The accompanying unaudited interim condensed consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America (“U.S.”) (“GAAP”) and, in the opinion of management, reflect all adjustments, consisting of normal recurring adjustments, needed to fairly present the financial results of Surmodics, Inc. and subsidiaries (“Surmodics” or the “Company”) for the periods presented. These financial statements include some amounts that are based on management’s best estimates and judgments. These estimates may be adjusted as more information becomes available, and any adjustment could be significant. The impact of any change in estimates is included in the determination of net (loss) income in the period in which the change in estimate is identified. The results of operations for the three months ended December 31, 2017 are not necessarily indicative of the results that may be expected for the entire 2018 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, 2017, and footnotes thereto included in the Company’s Form 10-K as filed with the SEC on December 1, 2017.

2. New Accounting Pronouncements

Accounting Standards to be Adopted

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

after the effective date, and, for contracts which have remaining obligations as of the effective date, the Company will adjust the beginning balance of retained earnings as of October 1, 2018.

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

In June 2016, the FASB issued ASU No 2016-13, Financial Instruments – Credit Losses (ASC Topic 326), Measurement of Credit Losses on Financial Statements. This ASU requires a financial asset (or a group of financial assets) measured at an amortized cost basis to be presented at the net amount expected to be collected. The allowance for credit losses is a valuation account that is deducted from the amortized cost basis of the financial asset(s) to present the net carrying value at the amount expected to be

collected on the financial asset. The accounting standard will be effective for the Company beginning in the first quarter of fiscal 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.

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. 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, 2017 and September 30, 2017.

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, 2017 and September 30, 2017 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 as of December 31, 2017 and September 30, 2017 consist of contingent consideration obligations related to the fiscal 2016 acquisitions of Creagh Medical Ltd. ("Creagh Medical") and NorMedix, Inc. ("NorMedix"). Consideration owed to the sellers of Creagh Medical upon achievement of revenue and value-creating milestones through September 30, 2018, is due to be paid during the quarter ending December 31, 2018. Consideration owed to the sellers of NorMedix upon achievement of revenue and value-creating milestones through September 30, 2019, is due to be paid within sixty days following the quarter in which each milestone is achieved. Contingent consideration included in current liabilities of \$13.8 million and \$1.8 million as of December 31, 2017 and September 30, 2017,

respectively, represents the Company's estimate of fair value of amounts expected to be paid within one year of each respective balance sheet date.

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.

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 December 31, 2017:

(Dollars in thousands)	Quoted Prices in			Total Fair Value as of December 31, 2017
	Active Markets for Identical Instruments (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)	
Assets				
Cash equivalents	\$ —	\$ 13,799	\$ —	\$ 13,799
Available-for-sale securities	—	24,756	—	24,756
Total assets	\$ —	\$ 38,555	\$ —	\$ 38,555
Liabilities				
Contingent consideration	\$ —	\$ —	\$ (16,162)	\$ (16,162)
Total liabilities	\$ —	\$ —	\$ (16,162)	\$ (16,162)

The following table presents information about the Company's assets and liabilities measured at fair value on a recurring basis as of September 30, 2017:

(Dollars in thousands)	Quoted Prices in			Total Fair Value as of September 30, 2017
	Active Markets for Identical Instruments (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)	
Assets				
Cash equivalents	\$ —	\$ 6,639	\$ —	\$ 6,639
Available-for-sale securities	—	31,802	—	\$ 31,802
Total assets	\$ —	\$ 38,441	\$ —	\$ 38,441
Liabilities				
Contingent consideration	\$ —	\$ —	\$ (14,864)	\$ (14,864)
Total liabilities	\$ —	\$ —	\$ (14,864)	\$ (14,864)

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, 2017 and 2016:

Three Months Ended

Edgar Filing: SURMODICS INC - Form 10-Q

(Dollars in thousands)	December 31,	
	2017	2016
Beginning balance	\$ 14,864	\$ 14,517
Additions	—	—
Fair value adjustments	1,019	—
Settlements	—	—
Interest accretion	99	437
Foreign currency translation loss (gain)	180	(663)
Ending balance	\$ 16,162	\$ 14,291

9

There were no transfers of assets or liabilities between amounts measured using Level 1, Level 2, or Level 3 fair value measurements during fiscal 2018 to date or fiscal 2017.

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 NorMedix revenue-based milestones, the Company discounted forecasted revenue by 23.5%, which represents the Company's weighted average cost of capital for this transaction, adjusted for the short-term nature of the cash flows. The present value of forecasted revenue was used as an input into an option pricing approach, which also considered the Company's risk of non-payment of the NorMedix revenue-based milestones. Expected payments of the Creagh Medical revenue milestones were discounted using the Company's estimated cost of debt at December 31, 2017. Non-revenue milestones for the Creagh Medical and NorMedix acquisitions that have not already been achieved were projected to have a 25-98% probability of achievement and expected payments were discounted using the Company's estimated cost of debt, or 2.7% to 3.0%. To the extent that actual results differ from these estimates, the fair value of the contingent consideration liabilities could change significantly. Accretion expense is recorded as an increase to the contingent consideration liabilities due to the passage of time. Fair value adjustments represent changes in the value of the obligations related to adjustments to forecasted revenue and probability of strategic milestone completion. The contingent consideration liability related to the Creagh Medical acquisition is denominated in Euros and is not hedged. Foreign currency translation and losses are recorded as this obligation is marked to period-end exchange rates.

4. Investments

Investments consisted principally of commercial paper and corporate bond securities and are classified as available-for-sale as of December 31, 2017 and September 30, 2017. Available-for-sale securities are reported at fair value with unrealized gains and losses, net of tax, excluded from the condensed consolidated statements of operations and reported in the condensed consolidated statements of comprehensive (loss) income as well as a separate component of stockholders' equity in the condensed consolidated balance sheets, except for other-than-temporary impairments, which are reported as a charge to current earnings. A loss would be recognized when there is an other-than-temporary impairment in the fair value of any individual security classified as available-for-sale, with the associated net unrealized loss reclassified out of accumulated other comprehensive income with a corresponding adjustment to other income (loss). This adjustment results in a new cost basis for the investment. Interest earned on debt securities, including amortization of premiums and accretion of discounts, is included in other income. Realized gains and losses from the sales of debt securities, which are included in other income, are determined using the specific identification method. Investment purchases are accounted for on the date the trade is executed, which may not be the same as the date the transaction is cash settled.

Edgar Filing: SURMODICS INC - Form 10-Q

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

	December 31, 2017			
(Dollars in thousands)	Amortized Cost	Unrealized Gains	Unrealized Losses	Fair Value
Commercial paper and corporate bonds	\$24,782	\$ —	\$ (26)	\$ 24,756
Total	\$24,782	\$ —	\$ (26)	\$ 24,756

Edgar Filing: SURMODICS INC - Form 10-Q

	September 30, 2017				
(Dollars in thousands)	Amortized Cost	Unrealized Gains	Unrealized Losses		Fair Value
Commercial paper and corporate bonds	\$31,817	\$ —	\$ (15))	\$ 31,802
Total	\$31,817	\$ —	\$ (15))	\$ 31,802

5. 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:

	December 31,	September 30,
(Dollars in thousands)	2017	2017
Raw materials	\$ 2,123	\$ 1,603
Work-in process	669	659
Finished products	1,079	1,254
Total	\$ 3,871	\$ 3,516

6. Other Assets

Other assets consist of the following:

	December 31,	September 30,
(Dollars in thousands)	2017	2017
ViaCyte, Inc.	\$ 479	\$ 479
Other noncurrent assets	560	418
Other assets, net	\$ 1,039	\$ 897

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

The carrying value of each cost method investment is reviewed quarterly for changes in circumstances or the occurrence of events that suggest the Company’s investment may not be recoverable. The fair value of cost method investments is not adjusted if there are no identified events or changes in circumstances that may have a material effect on the fair value of the investment.

7. Intangible Assets

Intangible assets consist principally of acquired patents and technology, customer lists and relationships, licenses and trademarks. The Company recorded amortization expense of \$0.7 million and \$0.6 million for the three-month periods ended December 31, 2017 and 2016, respectively.

11

Intangible assets consisted of the following:

(Dollars in thousands)	December 31, 2017			
	Weighted Average Original Life (Years)	Gross Carrying Amount	Accumulated Amortization	Net
Definite-lived intangible assets:				
Customer lists and relationships	8.9	\$ 18,478	\$ (8,279)) \$ 10,199
Developed technology	11.7	9,334	(1,702)) 7,632
Non-compete	5.0	230	(115)) 115
Patents and other	16.5	2,321	(1,459)) 862
Subtotal		30,363	(11,555)) 18,808
Unamortized intangible assets:				
In-process research and development		688	—) 688
Trademarks and trade names		580	—) 580
Total		\$ 31,631	\$ (11,555)) \$ 20,076

(Dollars in thousands)	September 30, 2017			
	Weighted Average Original Life (Years)	Gross Carrying Amount	Accumulated Amortization	Net
Definite-lived intangible assets:				
Customer lists and relationships	8.9	\$ 18,293	\$ (7,834)) \$ 10,459
Developed technology	11.7	9,297	(1,478)) 7,819
Non-compete	5.0	230	(103)) 127
Patents and other	16.5	2,321	(1,423)) 898
Subtotal		30,141	(10,838)) 19,303
Unamortized intangible assets:				
In-process research and development		679	—) 679
Trademarks and trade names		580	—) 580
Total		\$ 31,400	\$ (10,838)) \$ 20,562

Based on the intangible assets in service as of December 31, 2017, 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, 2017, estimated amortization expense for the remainder of fiscal 2018 and each of the next five fiscal years is as follows (in thousands):

Remainder of 2018	\$ 2,015
2019	2,686
2020	2,511
2021	2,372
2022	2,332
2023	1,715

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.

8. 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, 2017 and September 30, 2017 totaled \$27.5 million and \$27.3 million, respectively. Goodwill in the Medical Device reporting unit represents the gross value from the fiscal 2016 acquisitions of Creagh Medical and NorMedix. Goodwill in the In Vitro Diagnostics reporting unit represents the gross value from the acquisition of BioFX Laboratories, Inc. (“BioFX”) in fiscal 2007.

Goodwill was not impaired in either reporting unit based on the outcome of the fiscal 2017 annual impairment test, and there have been no events or circumstances that have occurred in the first three months of fiscal 2018 to indicate that goodwill has been impaired.

The change in the carrying amount of goodwill by segment for the three months ended December 31, 2017 was as follows:

(Dollars in thousands)	In Vitro Diagnostics	Medical Device	Total
Balance as of September 30, 2017	\$ 8,010	\$ 19,272	\$ 27,282
Currency translation adjustment	—	223	223
Balance as of December 31, 2017	\$ 8,010	\$ 19,495	\$ 27,505

9. 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 (benefit) were allocated to the following expense categories:

(Dollars in thousands)	Three Months Ended December 31,	
	2017	2016
Product costs	\$(6)	\$ 13
Research and development	158	125
Selling, general and administrative	751	651
Total	\$ 903	\$ 789

As of December 31, 2017, approximately \$8.0 million of total unrecognized compensation costs related to non-vested awards is expected to be recognized over a weighted average period of approximately 2.7 years. The unrecognized compensation costs above include \$1.3 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-month periods ended December 31, 2017 and 2016 were \$10.57 and \$7.59, respectively. The assumptions used as inputs in the model were as follows:

	Three Months Ended December 31,	
	2017	2016
Risk-free interest rates	2.0 %	1.7 %
Expected life (years)	4.8	4.6
Expected volatility	33.0%	34.4%
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 \$0.4 million and \$0.3 million for the three-month periods ended December 31, 2017 and 2016, respectively.

The total pre-tax intrinsic value of options exercised during the three months ended December 31, 2017 and 2016 was \$0.3 million and less than \$0.1 million, respectively. The intrinsic value represents the difference between the Company's common stock fair market value on the date of exercise and the option's exercise price.

Restricted Stock Awards

The Company has entered into restricted stock agreements with certain key employees, covering the issuance of common stock ("Restricted Stock"). Under accounting guidance, these shares are considered to be non-vested shares. The Restricted Stock is released to the key employees if they are employed by the Company at the end of the vesting period. Restricted Stock vesting periods range from one to three years. During the three months ended December 31, 2017 and 2016, the Company awarded 57,635 and 39,958 Restricted Stock shares, respectively, to certain key employees and officers. Forfeiture of 2,220 Restricted Stock shares occurred during the three months ended December 31, 2017. As of December 31, 2017 and September 30, 2017, 100,557 and 67,917 Restricted Stock shares were outstanding, respectively. Compensation expense has been recognized for the estimated fair value of the common shares, net of estimated forfeitures, and is being charged to operating expenses over the vesting term. The stock-based compensation expense table includes Restricted Stock expenses recognized related to these awards, which totaled \$0.2 million and \$0.1 million for the three-month periods ended December 31, 2017 and 2016, respectively.

Performance Share Awards

The Company has entered into performance share agreements with certain key employees and executives, covering the issuance of common stock (“Performance Shares”). Performance Shares vest upon the achievement of all or a portion of certain performance objectives (which may include financial or project objectives), which must be achieved during the performance period. The Organization and Compensation Committee of the Board of Directors (the “Committee”) approves the performance objectives used for our executive compensation programs, which objectives were cumulative revenue and cumulative earnings before interest, income taxes, depreciation and amortization (“EBITDA”) for the three-year performance periods for awards granted in fiscal 2015 (2015 – 2017), fiscal 2016 (2016 – 2018) and fiscal 2017 (2017 – 2019). The fiscal 2017 awards also include performance objectives related to achievement of the Company’s strategic initiatives. Assuming that the minimum performance level is attained, the number of shares that may actually vest will vary based on performance from 20% (minimum) to 200% (maximum) of the target number of shares. Shares will be issued to participants as soon as practicable following the end of each performance period, subject to Committee approval and verification of results. Awards granted in fiscal 2015 were finalized in the three months ended December

31, 2017 and resulted in the issuance of 51,478 shares (maximum was 84,398 shares) based on the performance objectives relative to actual results achieved during the performance period. The per share compensation cost for each award is fixed on the grant date. Compensation expense is recognized in each period based on management’s estimate of the achievement level of actual and forecasted results, as appropriate, compared with the specified performance objectives and the related impact on the number of Performance Shares expected to vest. The stock-based compensation expense table includes the Performance Shares expenses recognized related to these awards, which totaled \$0.2 million for both the three-month periods ended December 31, 2017 and 2016.

The fair values of the Performance Shares, at target, were \$1.2 million, and \$1.3 million for awards granted in fiscal 2017 and 2016, 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 2016 – 2018	13,268	66,338	132,676
Fiscal 2017 – 2019	10,437	52,185	104,370

Employee Stock Purchase Plan

Under the Employee Stock Purchase Plan (“Stock Purchase Plan”), the Company is authorized to issue up to 600,000 shares of common stock. All full-time and part-time U.S. employees can choose to have up to 10% of their annual compensation withheld, with a limit of \$25,000, to purchase the Company’s common stock at purchase prices defined within the provisions of the Stock Purchase Plan. As of December 31, 2017 and September 30, 2017, there was less than \$0.1 million of employee contributions included in accrued liabilities in the condensed consolidated balance sheets. Stock compensation expense recognized related to the Stock Purchase Plan for the three months ended December 31, 2017 and 2016 totaled less than \$0.1 million in each respective period. The stock-based compensation table includes the Stock Purchase Plan expenses.

Restricted Stock and Deferred Stock Units

During the three months ended December 31, 2017 and 2016, the Company awarded 5,626 and 6,570 restricted stock units (“RSUs”), respectively, to non-employee directors and certain key employees in foreign jurisdictions. As of December 31, 2017 and September 30, 2017, 28,444 and 44,391 RSUs were outstanding. 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 grant date. Compensation expense has been recognized for the estimated fair value of the common shares and is being charged to income over the vesting term. The stock-based compensation table includes RSU expenses recognized related to these awards, which totaled less than \$0.1 million for both the three-month periods ended December 31, 2017 and 2016.

Directors can also elect to receive their annual fees for services to the Board in deferred stock units (“DSUs”). Certain directors elected this option beginning on January 1, 2013 with deferral elections made annually. During the three months ended December 31, 2017 and 2016, 500 and 1,971 units, respectively, were issued with a total fair value of less than \$0.1 million in each period. As of December 31, 2017 and September 30, 2017, outstanding DSUs totaled 24,941 and 24,441, respectively. These DSUs are fully vested. Stock-based compensation expense related to DSU awards totaled less than \$0.1 million for both the three-month periods ended December 31, 2017 and 2016.

10. Revolving Credit Facility

The Company has a revolving credit facility with available principal totaling \$30.0 million, which terminates on November 2019. In addition, the agreement has 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 maintain certain financial covenants related to a maximum leverage ratio and a minimum EBITDA amount and to comply with nonfinancial covenants. As of December 31, 2017, the Company had no borrowings outstanding on the line of credit and was in compliance with all financial covenants under the credit facility.

11. Net (Loss) Income Per Share Data

Basic net (loss) income per common share is calculated by dividing net (loss) income by the weighted average number of common shares outstanding during the period. Diluted net income per common share is computed by dividing net income by the weighted average number of common and dilutive common equivalent shares outstanding during the period. The Company's potentially dilutive common shares are those that result from dilutive common stock options, non-vested stock relating to restricted stock awards, restricted stock units, deferred stock units and performance shares. Options to purchase common stock as well as unvested restricted stock and performance stock units are considered to be potentially dilutive common shares, but have been excluded from the calculation of diluted net loss per share as their effect is anti-dilutive for the three months ended December 31, 2017 as a result of the net loss incurred for that period. Therefore, diluted net loss per share was the same as basic net loss per share for the three months ended December 31, 2017. The calculation of weighted average diluted shares outstanding excludes outstanding stock options associated with the right to purchase 0.3 million shares of common stock for the three months ended December 31, 2016, as their inclusion would have had an antidilutive effect on diluted net income per share.

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,	
	2017	2016
Net (loss) income available to common shareholders	\$(1,556)	\$2,300
Basic weighted average shares outstanding	13,064	13,200
Dilutive effect of outstanding stock options, non-vested restricted stock, restricted stock units, deferred stock units and performance shares	—	246
Diluted weighted average shares outstanding	13,064	13,446

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

12. Income Taxes

For interim income tax reporting, the Company estimates its annual effective tax rate and applies it to year-to-date pretax income, excluding unusual or infrequently occurring discrete items. Tax jurisdictions with losses for which tax

benefits cannot be realized are excluded. The Company recorded income tax provisions of \$1.0 million and \$1.7 million for the three months ended December 31, 2017 and 2016, respectively. In December 2017, the Tax Cuts and Jobs Act tax legislation was signed into law, which reduced the U.S. Federal statutory tax rate from 35% to 21%, among other changes. As a result of the enactment of this legislation, the Company's fiscal 2018 first quarter net loss includes discrete tax expense of \$1.2 million from the Company's net deferred tax assets revaluation based on the enacted tax rate of 21%, as compared with the previous rate of 35%. U.S. tax law requires that taxpayers with a fiscal year beginning before and ending after the effective date of a rate change calculate a blended tax rate for the year based on the pro rata number of days in the year before and after such effective date. As a result, for the fiscal year ending September 30, 2018, our U.S. federal statutory income tax rate is expected to be 24.5%. The effective income tax rate for the three months ended December 31, 2017 and 2016 differs from the U.S. federal statutory tax rate of 24.5% and 35%, respectively, primarily due to operating losses incurred in Ireland, where tax benefits are offset by a valuation allowance, and non-deductible acquired intangible asset amortization, contingent consideration accretion, including fair value adjustments, as well as unrealized foreign currency translation gains and losses on Euro-denominated contingent consideration liabilities. These increases to the effective income tax rate were partially offset by the U.S. federal research and development income tax credit and, in fiscal 2017, the domestic production manufacturing deduction. The effective income tax rate for the three months ended December 31, 2017 and 2016 is also impacted by discrete tax (benefit) expense of \$(0.2) million and \$0.3 million, respectively, related to expiring stock option awards, and \$0.1 million and \$0.2 million of state income tax reserve reversals related to the expiration of statutory filing requirements in each respective period.

The total amount of unrecognized tax benefits, excluding interest and penalties that, if recognized, would affect the effective tax rate is \$1.4 million and \$1.2 million as of December 31, 2017 and September 30, 2017, respectively. 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 the income tax provision.

The Company files income tax returns, including returns for its subsidiaries, in the U.S. federal jurisdiction and in various state jurisdictions as well as several non-U.S. jurisdictions. Uncertain tax positions are related to tax years that remain subject to examination. U.S. income tax returns for years prior to fiscal 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 2007. For tax returns for non-U.S. jurisdictions, the Company is no longer subject to income tax examination for years prior to 2012. Additionally, the Company has been indemnified of liability for any taxes relating to Creagh Medical and NorMedix for periods prior to their respective acquisition dates, pursuant to the terms of the related share purchase agreements. As of December 31, 2017 and September 30, 2017 there were no undistributed earnings in foreign subsidiaries. The Internal Revenue Service (“IRS”) commenced an examination of our fiscal 2016 U.S. federal income tax return in the fourth quarter of fiscal 2017. The examination has not been completed.

13. Segment and Geographical Information

The Company’s management evaluates performance and allocates resources based on reported results for two reportable segments, as follows: (1) the Medical Device unit, which is comprised of manufacturing balloons and catheters used for a variety of interventional cardiology, peripheral and other applications, surface modification coating technologies to improve access, deliverability, and predictable deployment of medical devices, as well as drug delivery coating technologies to provide site-specific drug delivery from the surface of a medical device, with end markets that include coronary, peripheral, and neurovascular, and urology, among others, and (2) the In Vitro Diagnostics unit, which consists of component products and technologies for diagnostic immunoassay as well as molecular tests and biomedical research applications, with products that include protein stabilization reagents, substrates, antigens and surface coatings.

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

(Dollars in thousands)	Three Months Ended	
	December 31, 2017	2016
Revenue:		
Medical Device	\$12,774	\$13,757
In Vitro Diagnostics	4,239	4,004
Total revenue	\$17,013	\$17,761
Operating (loss) income:		
Medical Device	\$(389)	\$3,719
In Vitro Diagnostics	1,670	1,456
Total segment operating income	1,281	5,175
Corporate	(1,914)	(1,907)
Total operating (loss) income	\$(633)	\$3,268

Depreciation and amortization:		
Medical Device	\$1,272	\$1,004
In Vitro Diagnostics	90	103
Corporate	158	175
Total depreciation and amortization	\$1,520	\$1,282

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.

14. Commitments and Contingencies

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

On January 17, 2018, we entered into a settlement agreement fully resolving the previously disclosed litigation involving Merit Medical Systems, Inc. (“Merit”) and NorMedix. The Company believes that the settlement will not have a material impact on its business, financial condition or results of operations.

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 \$240,000 using a euro to US dollar exchange rate of \$1.1979 to the Euro as of December 31, 2017) until the last patent expires which is currently estimated to be September 2027. The total minimum future payments associated with this license are approximately \$2.4 million. The license is currently utilized by one of the Company’s drug delivery customers.

Operating Leases. The Company leases certain facilities under noncancelable operating lease agreements. Rent expense for the three months ended December 31, 2017 and 2016 was \$0.1 million for each period. In November 2017, the Company executed a lease for a 36,000 square feet facility in Eden Prairie, Minnesota. This facility will consolidate substantially all of our whole products solutions research and development operations into one location. Contractual obligations under the lease agreement total \$4.0 million over the ten-year lease term, which is expected to commence in May 2018. In connection with this lease, the Company deposited \$0.4 million into a restricted cash account, to be held until the leased facility is occupied, at which point the cash will be returned to the Company. Annual commitments pursuant to operating lease agreements in place as of December 31, 2017 for the remainder of fiscal 2018 and each of the next five fiscal years is as follows (in thousands):

Remainder of 2018	\$280
2019	441
2020	450

Edgar Filing: SURMODICS INC - Form 10-Q

2021	396
2022	391
2023	399
Thereafter	1,933
Total minimum lease payments	\$4,290

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, 2017. 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 2018, our revenue performance continues to be driven by our core Medical Device and In Vitro Diagnostics ("IVD") businesses. Revenue in the Medical Device business is composed of product sales, hydrophilic coatings royalties, and contract research and development services. Medical Device segment revenue decreased by 7% for the first quarter of fiscal 2018 as compared with the first quarter of fiscal 2017. Medical Device revenue declines were largely due to declines in royalty and license fee revenue resulting from previously disclosed patent expirations as well as declines in research, development and other revenue. Product sales in our Medical Device segment grew 3% year-over-year as a result of higher reagent shipments. Our IVD business derives its revenue from diagnostic technology product sales. Revenue from the IVD segment increased by 6% in the first three months of fiscal year 2018 as compared with the same prior-year period.

We continue to derive our revenue from three primary sources: (1) product sales revenue from the sale of reagent chemicals to licensees, the sale of stabilization products, antigens, substrates and surface coatings to the diagnostic and biomedical research markets as well as the sale of medical devices and related products (such as balloons and catheters) to original equipment manufacturer (OEM) suppliers and distributors; (2) royalties and license fees from licensing our proprietary surface modification and device drug delivery technologies to customers; the vast majority (typically in excess of 90%) of revenue in the "royalties and license fees" category is in the form of royalties; and (3) research and commercial development fees generated on customer projects. Revenue fluctuates from quarter to quarter depending on, among other factors: our customers' success in selling products incorporating our technologies; the timing of introductions of licensed products by our customers; the timing of introductions of products that compete with our customers' products; the number and activity level associated with customer development projects; the number and terms of new license agreements that are finalized each quarter; and the value of reagent chemicals and other products sold to customers.

We have several U.S. and international issued patents and pending international patent applications protecting various aspects of proprietary surface modification technologies, including compositions, methods of manufacture and methods of coating devices. The expiration dates for these patents and the anticipated expiration dates of patent applications that cover our hydrophilic coating technologies range from fiscal 2020 to fiscal 2035. Our third-generation PhotoLink technology was protected by a family of patents that expired in November 2015 (in the U.S.) and October 2016 (in certain other countries). The royalty revenue associated with our third-generation technology was approximately 12% of our fiscal 2017 revenue. Approximately 21% of our total revenue in fiscal 2017 was generated from our fourth-generation PhotoLink technology, which is 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. Our remaining hydrophilic royalty revenue is primarily derived from other Surmodics coating technologies that are protected by a number of patents extending to fiscal 2035. While we are actively seeking to convert our customers to 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. To that end, we will continue to invest in our whole-product solutions strategy throughout fiscal 2018. Tangible results of these investments in fiscal 2018 include U.S. Food and Drug Administration (“FDA”) clearance for our Telemark™ coronary/peripheral support microcatheter (“Telemark Microcatheter”) and initializing the TRANSCEND

Surveil pivotal clinical trial in the U.S. Additionally, in late fiscal 2017 we received FDA and Conformité Européenne (“CE Mark”) clearances for our .014” low-profile percutaneous transluminal angioplasty balloon dilation catheter (“.014” PTA balloon catheter”), designed for peripheral angioplasty procedures.

The development of these products, as well as the SurVeil DCB, is a major step forward in our strategy to offer whole-product solutions for the medical device industry. The SurVeil DCB early feasibility clinical study, conducted in the U.S., met its primary endpoint by demonstrating peak paclitaxel plasma concentrations post-index procedure. Consistent with pre-clinical data, systemic levels were low and cleared rapidly.

In July 2017, we received an investigational device exemption (“IDE”) from the FDA to initiate a pivotal clinical trial of the SurVeil DCB. The randomized clinical trial, TRANSCEND, will evaluate the SurVeil DCB for treatment for PAD in the upper leg compared with the Medtronic IN.PACT® Admiral® DCB. The objective of the TRANSCEND clinical trial is to evaluate the safety and effectiveness of the SurVeil DCB device for treatment of subjects with symptomatic PAD due to stenosis of the femoral and/or popliteal arteries. If successful, the TRANSCEND clinical trial will be used to support regulatory approvals and reimbursement in the U.S. and Europe. The trial will enroll up to 446 subjects at up to 60 sites in the U.S. and 18 outside the U.S. Study participants will be randomized to receive either treatment with SurVeil DCB or IN.PACT Admiral DCB. The trial’s primary efficacy endpoint is primary patency, defined as a composite of freedom from restenosis and clinically-driven target lesion revascularization through 12 months post-index procedure. All randomized subjects will be followed through 60 months post-index procedure. We initiated enrollment in the TRANSCEND clinical trial in October 2017 and have engaged a clinical research organization to assist us with the administration of the clinical trial. There is no assurance that the TRANSCEND clinical trial will support regulatory approval, or that any anticipated time frame will be met. We estimate that the cost of the TRANSCEND clinical trial will range between \$32 million to \$40 million over the next several years.

We are executing on our plan to develop and commercialize 12-15 medical device products over the next 5 years. Additional planned activities include initiation of surface modification experiments that improve medical device performance, as well as incorporation of our catheter technology platform into various other devices intended for the emerging peripheral vascular treatment market. Additionally, we are developing other products that utilize our DCB platform, including DCB’s for treatment of PAD below-the-knee (“BTK”) and arteriovenous (“AV”) fistulae, commonly associated with hemodialysis.

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

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

Critical Accounting Policies

Critical accounting policies are those policies that require the application of management’s most challenging, subjective or complex judgment, often as a result of the need to make estimates about the effect of matters that are inherently uncertain and may change in subsequent periods. Critical accounting policies involve judgments and

uncertainties that are sufficiently likely to result in materially different results under different assumptions and conditions. For the quarter ended December 31, 2017, there were no significant changes in our critical accounting policies.

For a detailed description of our critical accounting policies, see Management's Discussion and Analysis of Financial Condition and Results of Operations under Item 7 in our Annual Report on Form 10-K for the fiscal year ended September 30, 2017.

Results of Operations – Three Months Ended December 31

Revenue. Revenue for the first quarter of fiscal 2018 was \$17.0 million, a decrease of \$0.8 million, or 4.3%, compared with the first quarter of fiscal 2017. The change in revenue, as detailed in the table below, is further explained in the narrative below.

(Dollars in thousands)	Three Months Ended		% Change
	December 31, 2017	December 31, 2016	
Revenue			
Medical Device	\$12,774	\$13,757	(7.1)%
In Vitro Diagnostics	4,239	4,004	5.9%
Total Revenue	\$17,013	\$17,761	(4.2)%

Medical Device. Medical Device revenue was \$12.8 million in the first quarter of fiscal 2018, a decrease of 7.1% as compared with \$13.8 million for the first quarter of fiscal 2017. The decrease in quarterly revenue was attributable to previously disclosed patent expirations, which resulted in a decrease in royalties and license fees of \$0.9 million in the current-year quarter as compared with the prior-year quarter. We also realized decreases in research, development and other revenue of \$0.2 million in the first quarter of fiscal 2018 as compared with first quarter of fiscal 2017 due to delays in customer-sponsored R&D programs. Product sales increased \$0.1 million, or 3.4%, as compared with the prior-year quarter as the result of increased reagent volumes.

As previously reported, the family of patents covering our third-generation PhotoLink technology expired in November 2015 (in the U.S.) and October 2016 (in certain other countries). There is a royalty rate step down for licensed customers at the time these patents expire. For fiscal 2018, we expect royalty and license fee revenue to decline between \$2.5 million to \$3.5 million as the result of these patent expirations.

In Vitro Diagnostics. In Vitro Diagnostics revenue was \$4.2 million in the first quarter of fiscal 2018, an increase of 5.9%, as compared with \$4.0 million for the first quarter of fiscal 2017, primarily due to an increase in microarray slide sales. We expect total revenue from our In Vitro Diagnostics business to grow in the mid-single digits, percentage-wise, in fiscal 2018 as compared with the prior fiscal year.

Costs and Operating Expenses

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

(Dollars in thousands)	Three Months Ended December 31, 2017		Three Months Ended December 31, 2016	
	Amount	% Total Revenue	Amount	% Total Revenue
Product costs	\$2,891	17.0%	\$2,628	14.8%

Edgar Filing: SURMODICS INC - Form 10-Q

Research and development	7,831	46.0	5,970	33.6
Selling, general and administrative	5,188	30.5	4,862	27.4
Acquired intangible asset amortization	618	3.6	596	3.4
Contingent consideration (gain) accretion expense	1,118	6.6	437	2.5

Product costs. Product gross margins (defined as product sales less related product costs) were 64.3% and 65.9%, respectively, of product sales for the three months ended December 31, 2017 and 2016. In the first quarter of fiscal 2018, the scale-up of our Irish manufacturing facility and non-proprietary medical device product mix negatively impacted gross margins by 8.0%. This was partially offset by increases in reagent and IVD product sales, which positively affected product gross margins by 4.8%. In the first quarter of fiscal 2017, product gross margins were negatively affect by \$0.1 million, or 1.6%, from a damaged shipment to a vendor.

Research and development (R&D) expenses. The \$1.9 million increase in R&D expenses in the first quarter of fiscal 2018 period was primarily the result of planned higher spending for our DCB and proprietary product development and clinical activities. We plan to accelerate R&D spending throughout fiscal 2018 to support our whole-product solutions strategy. We anticipate fiscal 2018 R&D expense will range between 55% and 60% of revenue.

Selling, general and administrative (SG&A) expenses. The \$0.3 million increase in SG&A expenses reflects continued infrastructure investments to support our whole-products solutions strategy. We expect fiscal 2018 SG&A expenses will be in the high twenties, as a percent of revenue.

Intangible asset amortization. As part of our prior year acquisitions, we acquired certain intangible assets which are being amortized over periods ranging from 4 to 14 years. In addition, we own certain intangible assets related to the BioFx acquisition in fiscal 2007. We recognized \$0.6 million in amortization expense related to these acquisitions in the first quarter of both fiscal 2018 and 2017. Acquired intangible asset amortization is estimated to total \$2.5 million in fiscal 2018.

Contingent consideration accretion expense. For the three months ended December 31, 2017 and 2016, we recorded a net expense of \$1.1 million and \$0.4 million, respectively, related to our contingent consideration liabilities from prior year acquisitions. The increase in expense from the prior year is due to achievement of a revenue milestone. We expect to recognize a net expense of \$3.0 million for fiscal 2018 related to our contingent consideration liabilities. If there are any changes in the amount, probability or timing of contingent consideration milestone achievement, there may be adjustments, which could be material, in the statements of operations to reflect changes in the fair value of contingent consideration liabilities.

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

	Three Months Ended December 31,	
(Dollars in thousands)	2017	2016
Investment income, net	\$ 121	\$ 85
Foreign exchange (loss) gain	(186)	674
Gains on strategic investment and other	177	—
Other income, net	\$ 112	\$ 759

The increase in investment income in the first quarter of fiscal 2018 is the result of higher interest rates on debt investments. The foreign exchange (loss) gain in the three months ended December 31, 2017 and 2016 is related to the change in exchange rates associated with the Euro-denominated contingent consideration liability from the Creagh Medical acquisition, which is scheduled to be paid in the first quarter of fiscal 2019. During the three-month period ended December 31, 2017, the Euro strengthened against the U.S. Dollar, resulting in a loss for the quarter. During the three-month period ended December 31, 2016, the Euro weakened against the U.S. Dollar, resulting in a gain for the quarter. We recognized a gain on a previously sold strategic investment in the first quarter of fiscal 2018 as additional consideration was released from escrow.

Income tax provision. The income tax provision was \$1.0 million and \$1.7 million, respectively, for the three months ended December 31, 2017 and 2016. In December 2017, the Tax Cuts and Jobs Act tax legislation was signed into law, which reduced the U.S. Federal statutory tax rate from 35% to 21%, among other changes. As a result of the enactment of this legislation, the Company's fiscal 2018 first quarter net loss includes discrete tax expense of \$1.2 million from our net deferred tax assets revaluation based on the change in the statutory tax rate. U.S. tax law requires that taxpayers with a fiscal year beginning before and ending after the effective date of a rate change calculate a blended tax rate for the year based on the pro rata number of days in the year before and after such effective date. As a result, for fiscal 2018, our statutory income tax rate is expected to be 24.5%. The Company's effective tax reflects the impact of state income taxes, permanent tax items and discrete tax benefits. The difference between the U.S. federal statutory tax rates of 24.5% and 35.0% for the three months ended December 31, 2017 and 2016, respectively, and our effective tax rates for the same periods is primarily due to operating losses in Ireland, where tax benefits are offset by a valuation allowance, non-deductible amortization and contingent consideration accretion, including fair value adjustments, associated with prior-year acquisitions, as well as foreign currency translation gains and losses on Euro-denominated contingent consideration liabilities. Offsetting these items are benefits from an increased federal

R&D tax credit and, in the 2017 period, the domestic production manufacturing deduction.

Discrete items, other than the revaluation of deferred tax assets discussed above, 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. Discrete tax (benefit) expense from (excess tax benefits) tax deficiencies realized from share awards vested, expired, cancelled and exercised totaled less than \$(0.2) million and \$0.3 million for the respective three-month periods ended December 31, 2017 and 2016.

We expect income tax expense, including the impact of tax reform, for fiscal 2018 to be in the range of \$0.3 million to \$0.8 million. Currently, income and losses generated in Ireland from our Creagh Medical acquisition do not reflect an Irish income tax

expense (benefit) as they are offset by a valuation allowance. Therefore, taxable income or losses in Ireland will result in no reported tax benefit or expense in fiscal 2018. Certain provisions of the Tax Cuts and Jobs Act significantly change the treatment of accumulated and future earnings of foreign subsidiaries. While we do not have accumulated earnings subject to a repatriation tax under the law, we may be subject to additional U.S. tax on our foreign subsidiary's income in future years. Additionally, we may be subject to limitations on deductibility of officer and executive compensation under the new legislation. We are currently evaluating the impact of these tax law changes on our fiscal 2018 tax provision.

Segment Operating Results

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

(Dollars in thousands)	Three Months Ended December 31,		
	2017	2016	Change
Operating (loss) income:			
Medical Device	\$(389)	\$3,719	(110)%
In Vitro Diagnostics	1,670	1,456	15 %
Total segment operating income	1,281	5,175	
Corporate	(1,914)	(1,907)	0 %
Total operating (loss) income	\$(633)	\$3,268	(119)%

Medical Device. Operating loss was \$0.4 million in the first quarter of fiscal 2018, as compared with operating income of \$3.7 million in the first quarter of fiscal 2017. Operating (loss) income as a percentage of revenue was (3.0)% and 27.0% in the first quarter of fiscal 2018 and 2017, respectively. Operating income decreased in the current-year quarter from the comparable prior-year quarter as a result of anticipated lower royalty revenue and license fees of \$0.9 million and a \$1.8 million increase in R&D expenses related to our planned investment in our DCB and proprietary medical device product development and clinical programs. Additionally, accretion expense on the contingent consideration obligations increased to \$1.1 million in the first quarter of fiscal 2018 from \$0.4 million in the first quarter of fiscal 2017 due to the achievement of a revenue milestone.

In Vitro Diagnostics. Operating income was \$1.7 million in the first quarter of fiscal 2018, as compared with \$1.5 million in the first quarter of 2017. Operating income as a percentage of revenue was 39.4% and 36.3% in the three months ended December 31, 2017 and 2016, respectively. Operating income in the three months ended December 31, 2017 benefited from favorable product gross margins. Product gross margins increased to 64.2% in the three months ended December 31, 2017 from 61.0%, in the prior-year period. These improvements were primarily due to a casualty loss incurred in the first quarter of fiscal 2017 related to a damaged shipment from a vendor, which reduced product gross margins in the prior-year quarter.

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 for both the three month ended December 31, 2017 and 2016.

Liquidity and Capital Resources

As of December 31, 2017, we had working capital of \$40.5 million, a decrease of \$10.6 million from September 30, 2017. Working capital is defined by us as current assets minus current liabilities. The decrease from the prior year-end is primarily a result of contingent consideration obligations totaling \$12.0 million related to the fiscal 2016 Creagh

Medical acquisition being classified as current liabilities as of December 31, 2017. Contingent consideration earned for this acquisition is scheduled to be paid in December 2018. Our cash and cash equivalents and available-for-sale investments totaled \$46.7 million at December 31, 2017, a decrease of \$1.6 million from \$48.3 million at September 30, 2017. This change was primarily driven by \$1.3 million of investments in capital equipment and \$1.1 million of cash payments for taxes related to net share settlement of equity awards, partially offset by \$0.6 million of cash provided by operations during the first three months of fiscal 2018.

The Company's investment policy excludes ownership of collateralized mortgage obligations, mortgage-backed derivatives and other derivative securities without prior written approval of the Board of Directors. Our investments primarily consist of money market, corporate bond and commercial paper securities. Our investment policy requires that no more than 5% of investments be

held in any one credit or issue, excluding U.S. government and government agency obligations. The primary investment objective of the portfolio is to provide for the safety of principal and appropriate liquidity while generating an above-benchmark (“Barclays Short Treasury 1-3 Month Index”) total rate of return on a pre-tax basis. Management plans to continue to direct its investment advisors to manage the Company’s securities investments primarily for the safety of principal for the foreseeable future as it continues to assess other investment opportunities and uses of its cash and securities investments, including those described below.

On November 2, 2016, we entered into an Amended and Restated Credit Agreement (the "Credit Agreement") with Wells Fargo Bank, National Association. The Credit Agreement provides for a secured revolving line of credit of \$30.0 million until November 2019. The Company's obligations under the Credit Agreement are secured by substantially all of its and its subsidiaries' assets, other than intellectual property and real estate. The Company has also pledged the majority of the stock of its subsidiaries to secure such obligations. Interest under the Credit Agreement and accrues at a benchmark rate, plus an applicable margin ranging from 1.00% to 1.75% based on the Company's ratio of total funded debt to EBITDA (as defined in the Credit Agreement). A facility fee is payable quarterly on unused commitments at a rate of 0.15% per annum. As of December 31, 2017, we had no debt outstanding and were in compliance with all financial covenants under the Credit Agreement.

We generated cash flows from operating activities of approximately \$0.6 million and \$2.0 million in the three months ended December 31, 2017 and 2016, respectively. The following table depicts our cash flows provided by operating activities:

(Dollars in thousands)	Three Months Ended	
	December 31, 2017	2016
Net (loss) income	\$(1,556)	\$2,300
Depreciation and amortization	1,520	1,282
Stock-based compensation	903	789
Contingent consideration expense	1,118	437
Unrealized foreign exchange loss (income)	180	(663)
Deferred taxes	1,714	742
Gain on strategic investment	(177)	—
Net other operating activities	21	(5)
Net change in other operating assets and liabilities	(3,109)	(2,931)
Net cash provided by operating activities	\$614	\$1,951

Operating Activities. During the first three months of fiscal 2018, operating cash flow was primarily generated by net loss as adjusted for non-cash expenses for depreciation and amortization, stock-based compensation, contingent consideration expense, unrealized foreign exchange loss (income), and deferred taxes, partially offset by a gain on a strategic investment. Deferred tax asset reductions during the fiscal 2018 period were primarily related to changes in statutory tax rates from the enactment of the Tax Cuts and Jobs Act, resulting in a reduction of deferred tax assets totaling \$1.2 million. Net changes in operating assets and liabilities for the first three months of fiscal 2018 had a negative impact on cash flows of \$3.1 and \$2.9 million in both the three-month periods ended December 31, 2017 and 2016, respectively. Significant changes in operating assets and liabilities during these periods included:

- Cash provided by accounts receivable was \$0.4 million in the fiscal 2018 period, as compared with \$0.5 million in the fiscal 2017 period due to lower revenue in each period as compared with the immediately preceding quarters.
- Cash used for inventory was \$0.3 million in the fiscal 2018 period as compared with cash provided by inventory of \$0.1 million in the fiscal 2017 period. In the fiscal 2018 period, we purchased more inventory to support increased reagent sales.

• Cash used for prepaids and other current assets totaled \$1.2 million in the fiscal 2018 period as compared with \$0.7 million in the prior-year period. This change is primarily due to cash used for prepaid clinical trial expenses of \$0.5 million in the first quarter of fiscal 2018.

• Cash used for payments of accrued incentive compensation, net of incentive compensation accrued during the periods, decreased by \$0.2 million from the fiscal 2017 period to \$2.1 million during the fiscal 2018 period as incentive compensation payments were lower in fiscal 2017 versus fiscal 2016 as the result of performance achievement in prior

24

years. These payments were partially offset by incentive compensation totaling \$0.7 million accrued in both the fiscal 2018 and 2017 periods.

Investing Activities. We generated cash from investing activities of \$5.7 million in the first three months of fiscal 2018 as compared with cash used in investing activities of \$7.0 million in the first three months of fiscal 2017. We invested \$1.3 million and \$1.5 million in property and equipment in the first three months of fiscal 2018 and fiscal 2017, respectively. In the first three months of fiscal 2018, we received \$7.0 million of proceeds from maturities of available-for-sale debt securities, net of re-invested proceeds, as compared with net cash used to purchase available-for-sale debt securities of \$5.5 million in the same prior-year period.

Financing Activities. We used cash in financing activities of \$1.0 million and \$2.2 million in the first three months of fiscal 2018 and 2017, respectively. Cash used in financing activities was lower by \$1.0 million in fiscal 2018 as we repurchased less common stock to pay employee taxes resulting from the exercise of stock options in the fourth quarter of fiscal 2016. Cash paid for financing activities was partially offset by cash received from the issuance of shares related to exercises of employee stock options totaling \$0.2 million and \$0.1 million for the respective three-month periods ended December 31, 2017 and 2016.

We believe that our existing cash, and cash equivalents and investments, which totaled \$46.7 million as of December 31, 2017, together with cash flow from operations will provide liquidity sufficient to meet our cash needs and fund our operations and planned capital expenditures for the next twelve months. There can be no assurance, however, that Surmodics' business will continue to generate cash flows at current levels, and disruptions in financial markets may negatively impact our ability to access capital in a timely manner and on attractive terms.

Customer Concentrations. Our licensed technologies provide royalty revenue, which represents the largest revenue stream to the Company. We have licenses with a diverse base of customers and certain customers have multiple products using our technology. Medtronic plc ("Medtronic") is our largest customer comprising 18% of our consolidated revenue for fiscal 2017 and 17% of our consolidated revenue for the first three months of fiscal 2018. Medtronic has several separately licensed products that generate royalty revenue for Surmodics, none of which represented more than 4% of our total revenue. No other individual customer using licensed technology constitutes more than 7% of Surmodics' total fiscal 2018 or 2017 revenue.

Share Purchase Activity

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

Off-Balance Sheet Arrangements

As of December 31, 2017 and September 30, 2017, we did not have any off-balance sheet arrangements that have, or are reasonably likely to have, a current or future effect on our financial condition, changes in financial condition, revenue or expenses, results of operations, liquidity, capital expenditures or capital resources that is material to investors.

Forward-Looking Statements

This Quarterly Report on Form 10-Q, including "Management's Discussion and Analysis of Financial Condition and Results of Operations" in Item 2, contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. These statements include expectations concerning our growth strategy, including our

ability to sign new license agreements, bring new products to market and broaden our hydrophilic coatings royalty revenue, the impact of patent expirations on our hydrophilic coatings royalty revenue, product development programs, various milestone achievements, research and development expenses, including the estimated cost associated with the TRANSCEND clinical trial, future cash flow and sources of funding, short-term requirements, future property and equipment investment levels, the impact of potential lawsuits or claims, the impact of Medtronic, as well as other significant customers, including new diagnostic kit customers, our ability to recognize the expected benefits of our acquisitions and the Company's strategy to transform to a provider of whole-product solutions, the timing, impact and success of the clinical evaluation of the SurVeil DCB, and our expectations related to our income tax expense for fiscal 2018. Without limiting the foregoing, words or phrases such as "anticipate," "believe," "could," "estimate," "expect," "forecast," "intend," "may," "plan," "possible," "project," "will" and similar terminology, generally identify forward-looking statements. Forward-looking statements may also represent challenging goals for us. These statements, which represent the Company's expectations or beliefs concerning various future events, are based on current expectations that involve a number of risks and uncertainties that could cause actual results to differ materially from those of such forward-looking statements. We caution that undue reliance should not

be placed on such forward-looking statements, which speak only as of the date made. Some of the factors which could cause results to differ from those expressed in any forward-looking statement are set forth under “Risk Factors” in Part I, Item 1A of our Annual Report on Form 10-K for the fiscal year ended September 30, 2017. 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 or failure to generate cash flows from operations could impact short-term liquidity requirements and expected capital and other expenditures;
- the difficulties and uncertainties associated with the lengthy and costly new product development and foreign and domestic regulatory approval processes, such as delays, difficulties or failures in achieving acceptable clinical results or obtaining foreign or U.S. Food and Drug Administration marketing clearances or approvals, which may result in lost market opportunities, failure to bring new products to market or postpone or preclude product commercialization by licensees or ourselves;
- the development of new products or technologies by competitors, technological obsolescence and other changes in competitive factors;
- our ability to successfully develop, obtain regulatory approval for, and commercialize our SurVeil DCB product, including our reliance on a clinical research organization to manage the TRANSCEND clinical trial, other DCB products and other catheter and balloon-based products;
- our ability to perform successfully certain product development activities, the related R&D expense impact and governmental and regulatory compliance activities which we have not previously undertaken in any significant manner;
- our ability to successfully convert our customers from the third generation of our PhotoLink® hydrophilic technology protected by a family of patents which expired in November 2015 (in the U.S.) and October 2016 (in certain other countries) to one of our advanced generation technologies and to offset any decline in revenue from customers that we are unlikely to convert;
- our ability to identify and execute new acquisition opportunities as well as the process of integrating acquired businesses poses numerous risks, including an inability to integrate acquired operations, personnel, technology, information systems, and internal control systems and products; a lack of understanding of tax, legal and cultural 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;
- there may be certain aspects of the recently enacted Tax Cuts and Jobs Act tax legislation that may adversely impact our expectations about our income tax expense for fiscal 2018; 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, 2017, 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

26

future changes in interest rates. As of December 31, 2017, we held \$38.6 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.

We are exposed to increasing Euro currency risk with respect to our manufacturing operations in Ireland. In a period where the U.S. dollar is strengthening or weakening as compared with the Euro, our revenue and expenses denominated in Euro'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 €12.0 million of Creagh Medical contingent consideration in approximately December 2018. For the first three months of fiscal 2018, we have recorded a foreign currency exchange loss of \$0.2 million related to this future payment. A 10% increase or decrease in the U.S. Dollar to Euro exchange rate could have a \$1.2 million impact on this payment based on the exchange rate as of December 31, 2017. To date, we have not entered into any foreign currency forward exchange contracts or other derivative financial instruments to hedge the effects of adverse fluctuations in foreign currency exchange.

Item 4. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

The Company maintains disclosure controls and procedures as defined in Rules 13a-15(e) and 15d-15(e) of the Securities Exchange Act of 1934, as amended (the "Exchange Act"). The Company's management, under the supervision and with the participation of the Company's Chief Executive Officer and Chief Financial Officer, referred to collectively herein as the Certifying Officers, carried out an evaluation of the effectiveness of the design and operation of the Company's disclosure controls and procedures as of December 31, 2017. Based on that evaluation, the Company's Certifying Officers concluded that, as of the end of the period covered by this report, the Company's disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) of the Exchange Act) were effective to ensure that information required to be disclosed by the Company in reports that it files under the Exchange Act is recorded, processed, summarized and reported within the time period specified in the Securities Exchange Commission rules and forms, and to ensure that information required to be disclosed by the Company in the reports the Company files or submits under the Exchange Act is accumulated and communicated to the Company's management, including its Certifying Officers, as appropriate, to allow timely decisions regarding required disclosures.

Changes in Internal Controls over Financial Reporting

There were no changes in our internal control over financial reporting (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act) during the three months ended December 31, 2017 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II — OTHER INFORMATION

Item 1. Legal Proceedings

From time to time, the Company has been involved in various legal actions involving its operations, products and technologies, including intellectual property and employment disputes. See footnote 14 to the condensed, consolidated financial statements, which describes a matter with Merit which arose during fiscal 2017. We entered into a settlement agreement full resolving the matter in January 2018, which was after our first quarter.

Item 1A. Risk Factors

In our report on Form 10-K for the fiscal year ended September 30, 2017, filed with the SEC on December 1, 2017, 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, 2017.

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, 2017, by the Company or on behalf of the Company or any “affiliated purchaser” of the Company, as defined in Rule 10b-18(a)(3) under the Exchange Act.

Period	Total Number of Shares Purchased as Part of Publicly Announced Plans or Programs	Average Price Paid per Share	Total Approximate Dollar Value of Shares That May Yet Be Purchased Under the Plans or Programs (1)
10/1/17 — 10/31/17	—	N/A	\$ 25,298,238
11/1/17 — 11/30/17	—	N/A	\$ 25,298,238
12/1/17 — 12/31/17	—	N/A	\$ 25,298,238
Total	—	N/A	\$ 25,298,238

(1) As of December 31, 2017, the Company has an aggregate of \$25.3 million available for future common stock repurchase under an authorization approved by the Board of Directors for up to \$20.0 million on November 6,

Edgar Filing: SURMODICS INC - Form 10-Q

2015 and an authorization approved by the Board of Directors on November 5, 2014 for which \$5.3 million is remaining. These authorizations for share repurchases do not have a fixed expiration date.

Item 3. Defaults Upon Senior Securities

None.

Item 4. Mine Safety Disclosures

Not Applicable.

Item 5. Other Information

None.

Item 6. Exhibits

Exhibit Description

- 2.1 Share Purchase Agreement by and among Surmodics, Inc. and the shareholders of Creagh Medical Ltd. dated as of November 20, 2015 — incorporated by reference to Exhibit 2.1 to the Company’s 8-K dated November 27, 2015, SEC File No. 0-23837.
- 2.2 Put and Call Option Agreement by and among Surmodics, Inc. and the shareholders of Creagh Medical Ltd. dated as of November 20, 2015 — incorporated by reference to Exhibit 2.2 to the Company’s 8-K filed on, SEC File No. 0-23837.
- 2.3 Stock Purchase Agreement, dated January 8, 2016, among Surmodics, Inc. and the shareholders of NorMedix, Inc. and Gregg Sutton as Seller’s Agent — incorporated by reference to Exhibit 2.1 to the Company’s Form 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.
- 31.1* Certification of Chief Executive Officer Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
- 31.2* Certification of Chief Financial Officer Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
- 32.1* Certification of Chief Executive Officer Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
- 32.2* Certification of Chief Financial Officer Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
- 101* Financial statements from the Quarterly Report on Form 10-Q for Surmodics, Inc. for the quarterly period ended December 31, 2017, filed on February 8, 2018, formatted in Extensible Business Reporting Language (XBRL): (i) Condensed Consolidated Balance Sheets, (ii) Condensed Consolidated Statements of Operations, (iii) Condensed Consolidated Statements of Comprehensive (Loss) Income, (iv) Condensed Consolidated Statements of Cash Flows, and (v) Notes to Condensed Consolidated Financial Statements.

*Filed herewith

30

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 8, 2018 Surmodics, Inc.

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