

SURMODICS INC
Form 10-Q
February 01, 2019

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D. C. 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended December 31, 2018

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

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

Large accelerated filer	Accelerated filer
Non-accelerated filer	Smaller reporting company
	Emerging Growth Company

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

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

The number of shares of the registrant’s Common Stock, \$.05 par value per share, outstanding as of January 30, 2019 was 13,482,275.

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>	23
Item 3.	<u>Quantitative and Qualitative Disclosures About Market Risk</u>	30
Item 4.	<u>Controls and Procedures</u>	31

PART II. OTHER INFORMATION

Item 1.	<u>Legal Proceedings</u>	32
Item 1A.	<u>Risk Factors</u>	32
Item 2.	<u>Unregistered Sales of Equity Securities and Use of Proceeds</u>	33
Item 3.	<u>Defaults Upon Senior Securities</u>	33
Item 4.	<u>Mine Safety Disclosures</u>	33
Item 5.	<u>Other Information</u>	33
Item 6.	<u>Exhibits</u>	34
	<u>SIGNATURES</u>	35

PART I. FINANCIAL INFORMATION

Item 1. Unaudited Condensed Financial Statements

Surmodics, Inc. and Subsidiaries

Condensed Consolidated Balance Sheets

	December 31, 2018	September 30, 2018
(Unaudited)		
(in thousands, except share and per share data)		
ASSETS		
Current Assets:		
Cash and cash equivalents	\$ 14,402	\$ 23,318
Restricted cash	—	350
Available-for-sale securities	31,453	41,352
Accounts receivable, net of allowance for doubtful accounts of \$164 and \$147		
as of December 31, 2018 and September 30, 2018, respectively	9,761	8,877
Contract assets - royalties and license fees	6,707	—
Inventories, net	4,168	4,016
Income tax receivable	1,244	1,152
Prepays and other	2,941	2,462
Total Current Assets	70,676	81,527
Deferred tax assets	4,778	6,304
Property and equipment, net	29,898	30,143
Intangible assets, net	16,874	17,683
Goodwill	26,834	27,032
Other assets	1,602	1,446
Total Assets	\$ 150,662	\$ 164,135
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities:		
Accounts payable	\$ 2,754	\$ 2,546
Accrued liabilities:		
Compensation	1,892	5,635
Accrued other	5,053	6,265
Deferred revenue	7,391	9,646
Contingent consideration	3,326	11,041
Total Current Liabilities	20,416	35,133
Contingent consideration, less current portion	—	3,425
Deferred revenue, less current portion	10,913	11,247
Other long-term liabilities	5,712	5,720
Total Liabilities	37,041	55,525
Commitments and Contingencies (Note 15)		
Stockholders' Equity:		

Edgar Filing: SURMODICS INC - Form 10-Q

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; 13,482,139 and 13,397,647 shares issued and outstanding as of December 31, 2018 and September 30, 2018, respectively	674	670
Additional paid-in capital	6,340	7,607
Accumulated other comprehensive income	2,184	2,718
Retained earnings	104,423	97,615
Total Stockholders' Equity	113,621	108,610
Total Liabilities and Stockholders' Equity	\$ 150,662	\$ 164,135

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,	
	2018	2017
	(Unaudited)	
Revenue:		
Product sales	\$9,751	\$8,088
Royalties and license fees	10,096	7,076
Research, development and other	2,394	1,849
Total revenue	22,241	17,013
Operating costs and expenses:		
Product costs	3,523	2,891
Research and development	11,486	7,831
Selling, general and administrative	5,949	5,188
Acquired intangible asset amortization	606	618
Contingent consideration (gain) expense	(35)	1,118
Total operating costs and expenses	21,529	17,646
Operating income (loss)	712	(633)
Other income:		
Investment income, net	316	121
Interest expense	(37)	—
Foreign exchange gain (loss)	136	(186)
Gain on strategic investment and other	7	177
Other income, net	422	112
Income (loss) before income taxes	1,134	(521)
Income tax provision	176	(1,035)
Net income (loss)	\$1,310	\$(1,556)
Basic net income (loss) per share	\$0.10	\$(0.12)
Diluted net income (loss) per share	\$0.09	\$(0.12)
Weighted average number of shares outstanding:		
Basic	13,367	13,064
Diluted	13,827	13,064

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

Surmodics, Inc. and Subsidiaries

Condensed Consolidated Statements of Comprehensive Income (Loss)

(In thousands)	Three Months Ended December 31,	
	2018	2017
	(Unaudited)	
Net income (loss)	\$1,310	\$(1,556)
Other comprehensive (loss) income:		
Unrealized holding gains (losses) on available-for-sale securities, net of tax	4	(14)
Foreign currency translation adjustments	(538)	631
Other comprehensive (loss) income	(534)	617
Comprehensive income (loss)	\$776	\$(939)

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

Surmodics, Inc. and Subsidiaries

Condensed Consolidated Statements of Stockholders' Equity

(In thousands)	Common Stock		Additional Paid-In Capital	Accumulated Other Comprehensive Income	Retained Earnings	Total Stockholders' Equity
	Shares	Amount				
Balance at September 30, 2018	13,398	\$ 670	\$ 7,607	\$ 2,718	\$97,615	\$ 108,610
Net impact from adoption of ASC Topic 606						
(Note 2)	—	—	—	—	5,498	5,498
Net income	—	—	—	—	1,310	1,310
Other comprehensive loss, net of tax	—	—	—	(534)	—	(534)
Issuance of common stock	128	6	(6)	—	—	—
Common stock options exercised, net	1	0	36	—	—	36
Purchase of common stock to pay employee						
taxes	(44)	(2)	(2,528)	—	—	(2,530)
Stock-based compensation	—	—	1,231	—	—	1,231
Balance at December 31, 2018	13,483	\$ 674	\$ 6,340	\$ 2,184	\$104,423	\$ 113,621
(In thousands)	Common Stock		Additional Paid-In Capital	Accumulated Other Comprehensive Income	Retained Earnings	Total Stockholders' Equity
	Shares	Amount				
Balance at September 30, 2017	13,095	\$ 655	\$ 5,413	\$ 3,417	\$102,072	\$ 111,557
Net loss	—	—	—	—	(1,556)	(1,556)
Other comprehensive income, net of tax	—	—	—	617	—	617
Issuance of common stock	123	6	(6)	—	—	—
Common stock options exercised, net	13	1	154	—	—	155
Purchase of common stock to pay employee						
taxes	(35)	(2)	(1,127)	—	—	(1,129)
Stock-based compensation	—	—	903	—	—	903
Balance at December 31, 2017	13,196	\$ 660	\$ 5,337	\$ 4,034	\$100,516	\$ 110,547

Surmodics, Inc. and Subsidiaries

Condensed Consolidated Statements of Cash Flows

(in thousands)	Three Months Ended December 31,	
	2018	2017
	(Unaudited)	
Operating Activities:		
Net income (loss)	\$1,310	\$(1,556)
Adjustments to reconcile net income (loss) to net cash (used in) provided by operating activities:		
Depreciation and amortization	1,756	1,520
Stock-based compensation	1,231	903
Payment of contingent consideration obligations in excess of acquisition-date value	(2,041)	—
Contingent consideration (gain) expense	(35)	1,118
Unrealized foreign exchange (gain) loss	—	180
Deferred taxes (1)	310	1,714
Gain on strategic investment	(7)	(177)
Provision for bad debts	63	28
Other	12	(7)
Change in operating assets and liabilities:		
Accounts receivable and contract asset (1)	(762)	484
Inventories	(161)	(345)
Prepays and other	(649)	(1,188)
Accounts payable	190	(63)
Accrued liabilities	(3,737)	(2,232)
Income taxes (1)	(496)	190
Deferred revenue (1)	(2,389)	45
Net cash (used in) provided by operating activities	(5,405)	614
Investing Activities:		
Purchases of property and equipment	(2,066)	(1,298)
Purchases of available-for-sale securities	(10,098)	(11,364)
Maturities of available-for-sale securities	20,000	18,400
Cash received from sale of strategic investment	7	—
Net cash provided by investing activities	7,843	5,738
Financing Activities:		
Issuance of common stock	36	155
Payments for taxes related to net share settlement of equity awards	(2,661)	(1,130)
Payment of contingent consideration obligations	(9,064)	—
Net cash used in financing activities	(11,689)	(975)
Effect of exchange rate changes on cash, restricted cash and cash equivalents	(15)	35
Net change in cash, restricted cash and cash equivalents	(9,266)	5,412
Cash, Restricted Cash and Cash Equivalents:		
Beginning of period	23,668	16,534
End of period	\$14,402	\$21,946

Supplemental Information:

Cash paid for income taxes	\$3	\$12
Noncash transactions from investing and financing activities:		
Acquisition of property and equipment, net of refundable credits in other current assets		
and liabilities	\$147	\$187
Strategic investment gain receivable included in other current assets	—	177

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

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

7

Surmodics, Inc. and Subsidiaries

Notes to Condensed Consolidated Financial Statements

Period Ended December 31, 2018

(Unaudited)

1. Basis of Presentation

The accompanying unaudited interim condensed consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America (“U.S.”) (“GAAP”) and, in the opinion of management, reflect all adjustments, consisting of normal recurring adjustments, needed to fairly present the financial results of Surmodics, Inc. and subsidiaries (“Surmodics” or the “Company”) for the periods presented. These financial statements include amounts that are based on management’s best estimates and judgments. These estimates may be adjusted as more information becomes available, and any adjustment could be significant. The impact of any change in estimates is included in the determination of net income (loss) in the period in which the change in estimate is identified. The results of operations for the three months ended December 31, 2018 are not necessarily indicative of the results that may be expected for the entire 2019 fiscal year.

In accordance with the rules and regulations of the U.S. Securities and Exchange Commission (“SEC”), the Company has omitted footnote disclosures that would substantially duplicate the disclosures contained in the audited consolidated financial statements of the Company. These unaudited condensed consolidated financial statements should be read together with the audited consolidated financial statements for the fiscal year ended September 30, 2018, and footnotes thereto included in the Company’s Form 10-K as filed with the SEC on November 30, 2018.

New Accounting Pronouncements

Recently Adopted

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

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

recognized at each renewal of the license contract, which generally occurs on the last day of the quarter for minimum royalties contractually due in the following quarter. The adoption of ASC Topic 606 resulted in cumulative-effect adjustments to opening retained earnings, contract assets, deferred tax assets and income tax receivable.

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

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

The impact of adoption of Topic 606 to the Company's condensed consolidated statements of operations for three months ended December 31, 2018 was a reduction of royalty and license fee revenue of \$0.2 million and reduced income tax benefit of less than \$0.1 million.

Not Yet Adopted

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

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

2. Revenue

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

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

(In thousands)	Three Months Ended December 31,	
	2018	2017
Medical Device	(Unaudited)	
Product sales	\$4,778	\$3,850
Royalties	7,685	7,042
Research, development and other	2,384	1,848
License fees	2,411	34
Total Revenue - Medical Device	17,258	12,774
IVD		
Product sales	4,973	4,237
Other	10	2
Total Revenue - IVD	4,983	4,239
Total Revenue	\$22,241	\$17,013

Performance Obligations

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

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

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

Royalties – Royalty revenue consists of sales-based and recurring minimum royalties earned under licenses of our surface modification technologies. Performance obligations under these licenses, which consist of the right to use the

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

License fees – For distinct license performance obligations, upfront license fees are recognized when the Company satisfies the underlying performance obligation. This generally occurs upon transfer of the right to use the Company's licensed technology to the customer, with the exception of the license of the Company's SurVeil® drug-coated balloon (the "SurVeil DCB") disclosed below and

in Note 3 to the condensed consolidated financial statements. Certain license arrangements include contingent milestone payments, which are due following achievement by our customers of specified sales or regulatory milestones. Contingent milestone payment terms vary by contract. The Company has generally fulfilled its performance obligation prior to achievement of these milestones. However, because of the uncertainty of the milestone achievement, and/or the dependence on sales of our customers, variable consideration for contingent milestones is fully constrained and excluded from the contract price until the milestone is achieved by our customer, to the extent collectability is reasonably certain.

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

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

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

Contract Assets, Deferred Revenue and Remaining Performance Obligations

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

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

Remaining performance obligations include deferred revenue and amounts the Company expects to receive for goods and services that have not yet been delivered or provided under existing, noncancellable contracts. For contracts that have an original duration of one year or less, the Company has elected the practical expedient applicable to such contracts and does not disclose the transaction price for remaining performance obligations at the end of each reporting period and when the Company expects to recognize this revenue. At December 31, 2018, the estimated revenue expected to be recognized in future periods related to performance obligations that are unsatisfied for executed contracts with an original duration of one year or more was approximately \$18.3 million. This revenue is entirely related to the R&D and Clinical Services performance obligation in the Abbott Agreement from

the upfront payment received in fiscal 2018 and does not include revenue from potential contingent milestone payments that may be received throughout the course of the agreement. The Company expects to recognize the remaining revenue from this performance obligation over the next six years as the services, which are primarily comprised of the TRANSCEND clinical study, are completed.

3. Collaborative Arrangement

Under the Abbott Agreement, Abbott will have exclusive worldwide commercialization rights for the SurVeil DCB to treat the superficial femoral artery, which is currently being evaluated in a U.S. pivotal clinical trial. Separately, Abbott also received options to negotiate agreements for Surmodics' below-the-knee and arteriovenous (AV) fistula DCB products, which are currently in pre-clinical development and a first-in human clinical study, respectively. Surmodics is responsible for conducting all necessary clinical trials and other activities required to achieve U.S. and European Union regulatory clearances for the SurVeil DCB, including completion of the ongoing TRANSCEND clinical trial. Abbott and Surmodics will participate on a joint development committee charged with providing guidance on the Company's clinical and regulatory activities with regard to the SurVeil product.

The Company has received a \$25 million upfront fee and may receive up to \$67 million of additional payments upon achievement of various clinical and regulatory milestones. For the three months ended December 31, 2018, the Company recognized revenue totaling \$2.4 million from the Abbott arrangement, all of which was previously included in deferred revenue. As of December 31, 2018, \$18.3 million remains in deferred revenue from the upfront payment received. Upon the commercialization of the SurVeil DCB, Surmodics will be responsible for the manufacture and supply of clinical and commercial quantities of the product. Revenue from these product sales, including a set transfer price and a share of net profits resulting from third-party sales by Abbott, will be recognized if and when these products are shipped and control is transferred to the customer.

4. Fair Value Measurements

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

Fair Value Hierarchy

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

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

The Company did not have any Level 1 assets as of December 31, 2018 and September 30, 2018.

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

The Company's Level 2 assets as of December 31, 2018 and September 30, 2018 consisted of money market funds, commercial paper instruments and corporate bonds.

Level 3 — Unobservable inputs to the valuation methodology that are supported by little or no market activity and that are significant to the measurement of the fair value of the assets or liabilities. Level 3 assets and liabilities include those whose fair value measurements are determined using pricing models, discounted cash flow methodologies or similar valuation techniques, as well as significant management judgment or estimation.

The Level 3 liability as of December 31, 2018 consisted of contingent consideration obligations related to the fiscal 2016 acquisition of NorMedix, Inc. ("NorMedix"). Level 3 liabilities as of September 30, 2018 consisted of contingent consideration obligations related

to the fiscal 2016 acquisitions of Creagh Medical Ltd. (“Creagh Medical”) and NorMedix. Consideration owed to the sellers of Creagh Medical upon achievement of revenue and value-creating milestones through September 30, 2018, was 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, if any, is due to be paid in first quarter of fiscal 2020. Contingent consideration included in current liabilities of \$3.3 million and \$11.0 million as of December 31, 2018 and September 30, 2018, respectively, represents the Company’s estimated fair value of amounts expected to be paid within one year of each respective balance sheet date. During the three months ended December 31, 2018, the Company paid contingent consideration obligations related to the Creagh Medical acquisition totaling \$11.0 million, including \$9.1 million included in cash flows used in financing activities on the condensed consolidated statement of cash flows. The financing portion of the contingent consideration payment is equal to the acquisition-date value of the contingent consideration obligation, in accordance with ASC 230 Statements of Cash Flows.

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

Assets and Liabilities Measured at Fair Value on a Recurring Basis

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

The following table presents information about the Company’s assets and liabilities measured at fair value on a recurring basis as of December 31, 2018:

(Dollars in thousands)	Quoted Prices in			Total Fair Value as of December 31, 2018
	Active Markets for Identical Instruments (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)	
Assets				
Cash equivalents	\$ —	\$ —	\$ —	\$ —
Available-for-sale securities	—	31,453	—	31,453
Total assets	\$ —	\$ 31,453	\$ —	\$ 31,453
Liabilities				
Contingent consideration	\$ —	\$ —	\$ (3,326)	\$ (3,326)
Total liabilities	\$ —	\$ —	\$ (3,326)	\$ (3,326)

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

Edgar Filing: SURMODICS INC - Form 10-Q

Quoted Prices in

Active Markets

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

The following table summarizes the changes in the contingent consideration liabilities measured at fair value using Level 3 inputs for the three months ended December 31, 2018 and 2017:

(Dollars in thousands)	Three Months Ended December 31,	
	2018	2017
Beginning balance	\$14,466	\$14,864
Additions	—	—
Fair value adjustments	(149)	1,019
Settlements	(10,979)	—
Interest accretion	114	99
Foreign currency translation (gain) loss	(126)	180
Ending balance	\$3,326	\$16,162

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

Valuation Techniques

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

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

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

Contingent consideration obligations — The values of the contingent consideration liabilities were determined based on discounted cash flow analyses that included revenue estimates, probability of strategic milestone achievement and a discount rate, which are considered significant unobservable inputs. For the NorMedix revenue-based milestones, the Company discounted forecasted revenue by 20.5%, which represents the Company's weighted average cost of capital for this transaction, adjusted for the short-term nature of the cash flows. The present value of forecasted revenue was used as an input into an option pricing approach, which also considered the Company's risk of non-payment of the NorMedix revenue-based milestones. Non-revenue milestones for the NorMedix acquisition that have not already been achieved were projected to have a 5%-95% probability of achievement and expected payments were discounted using the Company's estimated cost of debt of 6.0%. To the extent that actual results differ from these estimates, the fair value of the contingent consideration liabilities could change significantly during the contingency periods. Accretion expense is recorded as an increase to the contingent consideration liabilities due to the passage of time. Fair value adjustments represent changes in the value of the obligations related to adjustments to forecasted revenue and probability of strategic milestone completion. The contingent consideration liability related to the Creagh Medical acquisition was denominated in Euros. Foreign currency translation gains and losses are recorded as this obligation is marked to exchange rates at period-end and on the date of settlement.

5. Investments

Investments consisted principally of commercial paper and corporate bond securities and are classified as available-for-sale as of December 31, 2018 and September 30, 2018. These available-for-sale securities are reported at fair value with unrealized gains and losses, net of tax, excluded from the condensed consolidated statements of operations and reported in the condensed consolidated statements of comprehensive income (loss) as well as a separate component of stockholders' equity in the condensed consolidated balance sheets, except for other-than-temporary impairments, which are reported as a charge to current earnings as they occur. A loss would be recognized when there is an other-than-temporary impairment in the fair value of any individual security classified as available-for-sale, with the associated net unrealized loss reclassified out of accumulated other comprehensive income with a corresponding adjustment to other income. This adjustment would result in a new cost basis for the investment. Interest earned on debt securities, including amortization of premiums and accretion of discounts, is included in investment income, net within other income. Realized gains and losses from the sales of debt securities, which are included in other income, are determined using the

specific identification method. Investment purchases are accounted for on the date the trade is executed, which may not be the same as the date the transaction is cash settled.

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

(Dollars in thousands)	December 31, 2018			
	Amortized Cost	Unrealized Gains	Unrealized Losses	Fair Value
Short-term commercial paper and corporate bonds	\$31,501	\$ —	\$ (48)) \$ 31,453
Total	\$31,501	\$ —	\$ (48)) \$ 31,453

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

6. Inventories

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

(Dollars in thousands)	December 31,	September
	2018	30, 2018
Raw materials	\$ 1,961	\$ 1,890
Work-in process	753	780
Finished products	1,454	1,346
Total	\$ 4,168	\$ 4,016

7. Other Assets

Other assets consist of the following:

(Dollars in thousands)	December 31,	September
	2018	30, 2018
ViaCyte, Inc.	\$ 479	\$ 479
Other noncurrent assets	1,123	967

Other assets, net	\$ 1,602	\$ 1,446
-------------------	----------	----------

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

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

8. Intangible Assets

Intangible assets consist principally of acquired patents and technology, customer lists and relationships, licenses and trademarks. The Company recorded amortization expense of \$0.7 million for both the three-month periods ended December 31, 2018 and 2017.

Intangible assets consisted of the following:

(Dollars in thousands)	December 31, 2018			
	Weighted Average Original Amortization (Years)	Carrying Amount	Accumulated Amortization	Net
Definite-lived intangible assets:				
Customer lists and relationships	8.9	\$ 17,922	\$ (9,717)	\$ 8,205
Developed technology	11.5	9,618	(2,575)	7,043
Non-compete	5.0	230	(161)	69
Patents and other	16.5	2,321	(1,607)	714
Subtotal		30,091	(14,060)	16,031
Unamortized intangible assets:				
In-process research and development		263	—	263
Trademarks and trade names		580	—	580
Total		\$ 30,934	\$ (14,060)	\$ 16,874

(Dollars in thousands)	September 30, 2018			
	Weighted Average Original Amortization (Years)	Carrying Amount	Accumulated Amortization	Net
Definite-lived intangible assets:				
Customer lists and relationships	8.9	\$ 18,086	\$ (9,377)	\$ 8,709
Developed technology	11.5	9,656	(2,361)	7,295
Non-compete	5.0	230	(150)	80
Patents and other	16.5	2,321	(1,569)	752
Subtotal		30,293	(13,457)	16,836
Unamortized intangible assets:				
In-process research and development		267	—	267
Trademarks and trade names		580	—	580
Total		\$ 31,140	\$ (13,457)	\$ 17,683

Based on the intangible assets in service as of December 31, 2018, 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, 2018, estimated amortization expense for the remainder of fiscal 2019 and each of the next five fiscal years is as follows (in thousands):

Remainder of 2019	\$ 2,000
2020	2,491
2021	2,352
2022	2,313
2023	1,725
2024	1,631

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

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

9. Goodwill

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

Goodwill as of December 31, 2018 and September 30, 2018 totaled \$26.8 million and \$27.0 million, respectively. Goodwill in the Medical Device reporting unit represents the gross value from the fiscal 2016 acquisitions of Creagh Medical and NorMedix. Goodwill in the In Vitro Diagnostics reporting unit represents the gross value from the acquisition of BioFX Laboratories, Inc. (“BioFX”) in fiscal 2007.

Goodwill was not impaired in either reporting unit based on the outcome of the fiscal 2018 annual impairment test, and there have been no events or circumstances that have occurred in the first three months of fiscal 2019 to indicate that goodwill has been impaired.

The change in the carrying amount of goodwill by segment for the three months ended December 31, 2018 was as follows:

(Dollars in thousands)	In Vitro Diagnostics	Medical Device	Total
Balance as of September 30, 2018	\$ 8,010	\$ 19,022	\$ 27,032
Currency translation adjustment	—	(198)	(198)
Balance as of December 31, 2018	\$ 8,010	\$ 18,824	\$ 26,834

10. Accrued Liabilities

Accrued liabilities consisted of the following:

	December 31, 2018	September 30, 2018
Accrued professional fees	\$ 433	\$ 311
Accrued clinical study expense	2,460	2,839
Accrued purchases	782	533
Customer claim	1,000	1,000
Construction in progress	33	1,199
Deferred rent	123	121
Other	222	262
Total	\$ 5,053	\$ 6,265

11. Stock-based Compensation

Edgar Filing: SURMODICS INC - Form 10-Q

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

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

(Dollars in thousands)	Three Months Ended December 31,	
	2018	2017
Product costs	\$32	\$(6)
Research and development	213	158
Selling, general and administrative	986	751
Total	\$1,231	\$903

As of December 31, 2018, approximately \$9.8 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 \$0.5 million, remaining to be expensed over the life of the awards, based on payout levels associated with performance share awards that are currently anticipated to be fully expensed because the performance conditions are expected to exceed minimum threshold levels.

Stock Option Awards

The Company uses the Black-Scholes option pricing model to determine the weighted average grant date fair value of stock options granted. The weighted average per share fair values of stock options granted during the three months ended December 31, 2018 and 2017 were \$18.30 and \$10.57, respectively.

	Three Months Ended December 31,	
	2018	2017
Risk-free interest rates	2.9 %	2.0 %
Expected life (years)	4.5	4.8
Expected volatility	33.2 %	33.0 %
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 awards. The expected life of options granted was determined based on the Company's experience. Expected volatility was based on the Company's stock price movement over a period approximating the expected term. Based on management's judgment, dividend yields were expected to be 0.0% for the expected life of the options. The Company also estimated forfeitures of options granted, which were based on historical experience.

Non-qualified stock options are granted at fair market value on the date of grant. Non-qualified stock options expire in seven 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 \$0.5 million and \$0.4 million for the three months ended December 31, 2018 and 2017.

The total pre-tax intrinsic value of options exercised during the three months ended December 31, 2018 and 2017 was less than \$0.1 million and \$0.3 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,

2018 and 2017, the Company awarded 42,248 and 57,635 Restricted Stock shares, respectively, to certain key employees and officers. Forfeiture of 507 and 2,220 Restricted Stock shares occurred during the three months ended December 31, 2018 and 2017, respectively. As of December 31, 2018 and September 30, 2018, 94,624 and 85,424 Restricted Stock shares were outstanding, respectively. Compensation expense has been recognized for the estimated fair value of the common shares, net of estimated forfeitures, and is being charged to operating expenses over the vesting term. The stock-based compensation expense table includes Restricted Stock expenses recognized related to these awards, which totaled \$0.4 million and \$0.2 million for the three months ended December 31, 2018 and 2017, respectively.

Performance Share Awards

The Company has entered into performance share agreements with certain key employees covering the issuance of common stock (“Performance Shares”). Performance Shares vest upon the achievement of all or a portion of certain performance objectives (which may include financial or project objectives), which must be achieved during the performance period. The Organization and Compensation Committee of the Board of Directors (the “Committee”) approves the performance objectives used for our executive compensation programs, which objectives were cumulative revenue and cumulative earnings before interest, income taxes,

depreciation and amortization (“EBITDA”) for the three-year performance periods for awards granted in fiscal 2016 (2016 – 2018) and fiscal 2017 (2017 – 2019). The fiscal 2017 awards also include performance objectives related to achievement of the Company’s strategic initiatives. Assuming that the minimum performance level is attained, the number of shares that may actually vest will vary based on performance from 20% (minimum) to 200% (maximum) of the target number of shares. Shares will be issued to participants as soon as practicable following the end of each performance period, subject to Committee approval and verification of results. Awards granted in fiscal 2016 were finalized in the three months ended December 31, 2018 and resulted in the issuance of 76,396 shares (maximum was 132,676 shares) based on the performance objectives relative to actual results achieved during the performance period. The per share compensation cost for each award is fixed on the grant date. Compensation expense is recognized in each period based on management’s estimate of the achievement level of actual and forecasted results, as appropriate, compared with the specified performance objectives and the related impact on the number of Performance Shares expected to vest. The stock-based compensation expense table includes Performance Shares expenses recognized related to these awards, which totaled \$0.2 million in each of the three-month periods ended December 31, 2018 and 2017.

The fair values of the Performance Shares, at target, were \$1.2 million for awards granted in fiscal 2017. There were no Performance Share awards granted in fiscal 2018.

The aggregate number of shares that could be awarded to our executives if the minimum, target and maximum performance goals are met, based on the fair value at the date of grant is as follows as of December 31, 2018, taking into account the aforementioned forfeiture of Performance Shares:

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

Employee Stock Purchase Plan

Under the Employee Stock Purchase Plan (“Stock Purchase Plan”), the Company is authorized to issue up to 600,000 shares of common stock. All full-time and part-time U.S. employees can choose to have up to 10% of their annual compensation withheld, with a limit of \$25,000, to purchase the Company’s common stock at purchase prices defined within the provisions of the Stock Purchase Plan. As of December 31, 2018 and September 30, 2018, there was \$0.1 million of employee contributions included in accrued liabilities in the condensed consolidated balance sheets. Stock compensation expense recognized related to the Stock Purchase Plan for the three months ended December 31, 2018 and 2017 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, 2018 and 2017, the Company awarded 6,206 and 5,626 restricted stock units (“RSUs”), respectively, to non-employee directors and certain key employees in foreign jurisdictions. As of December 31, 2018 and September 30, 2018, 57,387 and 60,182 RSUs were outstanding, respectively. RSU awards are not considered issued or outstanding common stock of the Company until they vest. Compensation expense has been recognized for the estimated fair value of the common shares and is being charged to operating expenses over the vesting term. The estimated fair value of the RSUs was calculated based on the closing market price of Surmodics’ common stock on the grant date. The stock-based compensation table includes RSU expenses recognized related to

these awards, which totaled \$0.1 million for the both the three months ended December 31, 2018 and 2017.

Directors may elect to receive their annual fees for services to the Board in deferred stock units (“DSUs”). Certain directors elected this option beginning on January 1, 2013 with subsequent deferral elections updated quarterly. During the three months ended December 31, 2018 and 2017, 751 and 500 units, respectively, were issued with a total fair value of less than \$0.1 million in each period. As of December 31, 2018 and September 30, 2018, outstanding, fully vested DSUs totaled 27,742 and 26,991, respectively. Stock-based compensation expense related to DSU awards totaled less than \$0.1 million for both the three-month periods ended December 31, 2018 and 2017.

12. Net Income (Loss) Per Share Data

Basic net income (loss) per common share is calculated by dividing net income (loss) by the weighted average number of common shares outstanding during the period. Diluted net income 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 shares of common stock as well as unvested restricted stock and performance stock units are considered to be potentially dilutive common shares. However, these shares have been excluded from the calculation of diluted net loss per share as their effect is antidilutive for the three months ended December 31, 2017, as a result of the net losses incurred for the period. Therefore, diluted weighted average number of shares outstanding and diluted net loss per share were the same as basic weighted average number of shares outstanding and net loss per share for the three months ended December 31, 2017.

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

	Three Months Ended December 31,	
	2018	2017
Net income (loss) available to common shareholders	\$1,310	\$(1,556)
Basic weighted average shares outstanding	13,367	13,064
Dilutive effect of outstanding stock options, non-vested restricted stock, restricted stock units, deferred stock units and performance shares	460	—
Diluted weighted average shares outstanding	13,827	13,064

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

13. Income Taxes

For interim income tax reporting, the Company estimates its annual effective tax rate and applies it to year-to-date pretax income (loss), excluding unusual or infrequently occurring discrete items. Tax jurisdictions with losses for which tax benefits cannot be realized are excluded. The Company recorded income tax (benefit) provision of \$(0.2) million and \$1.0 million for the three months ended December 31, 2018 and 2017, 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 tax provision for the first three months of fiscal 2018 included discrete tax expense of \$1.2 million from the Company's net deferred tax assets revaluation based on the enacted tax rate of 21%, as compared with the previous rate of 35%.

The effective income tax rate for the three months ended December 31, 2018 differs from the U.S. federal statutory tax rate of 21% primarily due to the favorable impacts of stock award activity and increased U.S. federal research and development tax credits. These benefits were partly offset by non-deductible acquired intangible asset amortization, as well as operating losses incurred in Ireland, where tax benefits are offset by a valuation allowance. The effective income tax rate for the three months ended December 31, 2017 differs from the U.S. federal statutory tax rate of 24.5% primarily due to operating losses incurred in Ireland, where tax benefits are offset by a valuation allowance, and non-deductible acquired intangible asset amortization, contingent consideration accretion, including fair value adjustments, as well as unrealized foreign currency translation losses on Euro-denominated contingent consideration liabilities. These increases to the effective income tax rate were partially offset by the U.S. federal research and

development income tax credit. The effective income tax rate for the three months ended December 31, 2018 and 2017 was impacted by discrete tax benefits of \$0.5 million and \$0.2 million, respectively, related to share awards vested, expired, cancelled and exercised during the periods.

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

The Company files income tax returns, including returns for its subsidiaries, in the U.S. federal jurisdiction and in various state jurisdictions as well as several non-U.S. jurisdictions. Uncertain tax positions are related to tax years that remain subject to examination. U.S. income tax returns for years prior to fiscal 2015 are no longer subject to examination by federal tax authorities. For tax returns for state and local jurisdictions, the Company is no longer subject to examination for tax years generally before fiscal 2007. For tax returns for non-U.S. jurisdictions, the Company is no longer subject to income tax examination for years prior to 2012. Additionally, the Company has been indemnified of liability for any taxes relating to Creagh Medical and NorMedix for periods prior to their respective acquisition dates, pursuant to the terms of the related share purchase agreements. As of December 31, 2018 and September 30, 2018, there were no undistributed earnings in foreign subsidiaries. The Internal Revenue Service (“IRS”) completed

an examination of our fiscal 2016 U.S. federal income tax return in the third quarter of fiscal 2018, with a payment made associated primarily with timing adjustments.

14. Segment and Geographical Information

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

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

(Dollars in thousands)	Three Months Ended December 31,	
	2018	2017
Revenue:		
Medical Device	\$17,258	\$12,774
In Vitro Diagnostics	4,983	4,239
Total revenue	\$22,241	\$17,013
Operating income (loss):		
Medical Device	\$357	\$(389)
In Vitro Diagnostics	2,455	1,670
Total segment operating income	2,812	1,281
Corporate	(2,100)	(1,914)
Total operating income (loss)	\$712	\$(633)
Depreciation and amortization:		
Medical Device	\$1,388	\$1,272
In Vitro Diagnostics	116	90
Corporate	252	158
Total depreciation and amortization	\$1,756	\$1,520

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

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

process.

15. Commitments and Contingencies

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

21

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

In April 2018, a customer notified the Company that it believes it overpaid hydrophilic coating royalties to the Company from January 2009 through December 2017. During fiscal 2018, the Company recorded \$1.0 million in selling, general and administrative expenses related to this claim. These amounts are included in other accrued liabilities on the condensed consolidated balance sheet as of December 31, 2018 and September 30, 2018.

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 \$229,000 using a euro to US dollar exchange rate of \$1.1444 to the Euro as of December 31, 2018) until the last patent expires which is currently estimated to be September 2027. The total minimum future payments associated with this license are approximately \$2.1 million as of December 31, 2018. 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, 2018 and 2017 was \$0.1 million for both periods. In November 2017, the Company executed a lease for a 36,000 square feet facility in Eden Prairie, Minnesota. This facility will consolidate substantially all of our whole products solutions research and development operations into one location. Payments under the lease agreement over the ten-year lease term commenced in May 2018. In connection with this lease, the Company deposited \$0.4 million into a restricted cash account, which was returned to the Company during the three months ended December 31, 2018. Annual commitments pursuant to operating lease agreements in place as of December 31, 2018 for the remainder of fiscal 2019 and each of the next five fiscal years are as follows (in thousands):

Remainder of 2019	\$ 337
2020	458
2021	396
2022	391
2023	399
2024	407
Thereafter	1,526
Total minimum lease payments	\$3,914

Asset Acquisition. In May 2018, the Company entered into an asset purchase agreement with Embolitech, LLC to acquire certain intellectual property assets (the "Embolitech Transaction"). As part of the Embolitech Transaction, the Company paid the sellers \$5.0 million during fiscal 2018. Additionally, the Company is obligated to pay \$3.5 million in several installments beginning December 2019 and ending December 2023. These payments may be accelerated upon the occurrence of certain sales and regulatory milestones. An additional \$2.0 million payment is contingent upon the achievement of certain regulatory milestones within a contingency period ending in 2033. As of December 31, 2018 and September 30, 2018, \$3.0 million and \$2.9 million, respectively, is included in other long-term liabilities on the condensed consolidated balance sheets related to the Embolitech Transaction.

Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations

The following discussion and analysis provides information management believes is useful in understanding the operating results, cash flows and financial condition of Surmodics, Inc. and subsidiaries (referred to as "Surmodics," the "Company," "we," "us," "our" and other like terms). The discussion should be read in conjunction with both the unaudited condensed consolidated financial statements and related notes included in this Form 10-Q and our audited consolidated financial statements and related notes and Management's Discussion and Analysis of Financial Condition and Results of Operations, each included in our Annual Report on Form 10-K for the fiscal year ended September 30, 2018. This discussion contains various "Forward-Looking Statements" within the meaning of the Private Securities Litigation Reform Act of 1995. We refer readers to the statement entitled "Forward-Looking Statements" located at the end of this Item 2.

Overview

Surmodics is a leading provider of medical device and in vitro diagnostic technologies to the healthcare industry. In fiscal 2019, our revenue performance continues to be driven by our core Medical Device and In Vitro Diagnostics ("IVD") businesses. Revenue in the Medical Device business is comprised of product sales, hydrophilic coatings royalties and license fees, and contract research and development services. Medical Device segment revenue increased 35% for the first quarter of fiscal 2019 as compared with the same prior-year period. Medical Device revenue was favorably impacted by increased medical device product sales and license fee revenue from our Abbott Vascular, Inc. ("Abbott") agreement described below. Our IVD business derives its revenue from diagnostic technology product sales. Revenue from the IVD segment increased 18% in the first quarter of fiscal 2019 as compared with the same prior-year period, driven by growth across several product categories.

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

Since fiscal 2013, with our investment in our drug-coated balloon ("DCB") platform, we have been focused on a strategy to develop and manufacture proprietary medical device products that combine our surface modification coatings with medical devices or delivery systems ("whole-product solutions"). Our aim is to provide customers earlier access to highly differentiated whole-product solutions that address unmet clinical needs. On February 26, 2018, we entered into an agreement with Abbott (the "Abbott Agreement") whereby Abbott will have exclusive worldwide commercialization rights for Surmodics' SurVeil® DCB to treat the superficial femoral artery (the "SurVeil DCB"), which is currently being evaluated in a U.S. pivotal clinical trial. Separately, Abbott also received options to negotiate agreements for Surmodics' below-the-knee and arteriovenous (AV) fistula DCB products, which are currently in pre-clinical development and a first-in human clinical study, respectively. Upon the regulatory approval of the SurVeil DCB, Surmodics will be responsible for the manufacture and supply of clinical and commercial quantities of the product and will realize revenue from product sales to Abbott, which will include a share of profits resulting from third-party sales. In the quarter ended December 31, 2018, we recognized revenue of \$2.4 million related to the Abbott

Agreement which is included in royalties and license fees in our medical device segment. Revenue from the upfront fee is recognized as regulatory and clinical activities, primarily the TRANSCEND clinical trial, are performed. Variable consideration from the contingent milestones is excluded from revenue until the underlying contingencies are resolved, at which point the milestone will be recognized as the promised regulatory and clinical activities are performed. In December 2018, we commenced a first in-human clinical study of our A vess™ DCB for treatment of AV fistulae, commonly associated with hemodialysis. We expect to complete enrollment in this study during fiscal 2019.

We have several U.S. and international issued patents and pending international patent applications protecting various aspects of proprietary surface modification technologies, including compositions, methods of manufacture and methods of coating devices. The expiration dates for these patents and the anticipated expiration dates of patent applications that cover our hydrophilic coating technologies range from fiscal 2020 to fiscal 2035. Our fourth-generation PhotoLink technology is protected by a family of patents that begin to expire in November 2019. The royalty revenue associated with our fourth-generation technology was approximately

21% of our consolidated fiscal 2018 revenue. Of the license agreements using our fourth-generation technology, most continue to generate royalty revenue at a reduced royalty rate beyond patent expiration. We also continue to generate significant royalty revenue from license agreements leveraging our third-generation coating technology that continue to provide royalties for our “know-how” or other proprietary rights. Our remaining hydrophilic royalty revenue is primarily derived from other Surmodics coating technologies that are protected by a number of patents extending to fiscal 2035. While we are actively seeking to convert our customers to an advanced generation of our hydrophilic coating technology, there can be no assurance that we will be successful in doing so, or that those customers that have converted, or will convert, will sell products utilizing our technology which will generate earned royalty revenue for us.

Overview of Research and Development Activities

We continue to invest in our whole-product solutions strategy through research and development (“R&D”) activities in our proprietary products pipeline, including clinical and regulatory activities necessary to bring these products to market. The continued development of new products is critical to our strategy to offer whole-product solutions for the medical device industry. We expect to submit for regulatory approval for additional medical device products in fiscal 2019.

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

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

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

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

Critical Accounting Policies

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

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

For a detailed description of our other critical accounting policies, see Management's Discussion and Analysis of Financial Condition and Results of Operations under Item 7 in our Annual Report on Form 10-K for the fiscal year ended September 30, 2018.

Results of Operations – Three Months Ended December 31

Revenue. Revenue for the first quarter of fiscal 2019 was \$22.2 million, an increase of \$5.2 million, or 30.7%, as compared with the first quarter of fiscal 2018. The following is a summary of revenue by segment.

(Dollars in thousands)	Three Months Ended		% Change
	2018	2017	
Revenue			
Medical Device	\$17,258	\$12,774	35.1 %
In Vitro Diagnostics	4,983	4,239	17.6 %
Total Revenue	\$22,241	\$17,013	30.7 %

Medical Device. Medical Device revenue was \$17.3 million in the first quarter of fiscal 2019, an increase of 35.1% as compared with \$12.8 million for the first quarter of fiscal 2018.

Product sales increased 24.1%, or \$0.9 million, in the current quarter as compared with the prior-year quarter, due primarily to a \$1.1 million increase in balloon catheter sales. Additionally, royalties and license fee revenue increased 42.7%, or \$3.0 million, in the current-year first quarter as compared with the prior-year first quarter, as a result of \$2.4 million of license fee revenue from the Abbott Agreement, as well as broad growth in royalties from our hydrophilic coatings customers. Additionally, a \$0.5 million increase in research, development and other revenue in the fiscal 2019 first quarter as compared with the prior year period resulted from increases in several customer projects.

In Vitro Diagnostics. In Vitro Diagnostics revenue increased 17.6% to \$5.0 million in the first quarter of fiscal 2019 as compared with \$4.2 million for the first quarter of fiscal 2018, primarily due to an increase in sales of our chemical components used in diagnostics tests and microarray slides.

Costs and Operating Expenses

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

Three Months Ended December 31,

Edgar Filing: SURMODICS INC - Form 10-Q

(Dollars in thousands)	2018		2017	
	Amount	% Total Revenue	Amount	% Total Revenue
Product costs	\$3,523	16 %	\$2,891	17 %
Research and development	11,486	52	7,831	46
Selling, general and administrative	5,949	27	5,188	30
Acquired intangible asset amortization	606	3	618	4
Contingent consideration (gain) expense	(35)	(0)	1,118	7

Product costs. Product gross margin (defined as product sales less related product costs) was 63.9% and 64.3% of product sales for the first quarter of fiscal 2019 and 2018, respectively. The decline in product gross margin percentage in the three months ended December 31, 2018, as compared with the prior-year period, was due to product mix changes. Product gross margin on IVD sales increased from the prior-year quarter, however these increases were more than offset by incremental balloon catheter medical device sales, which pushed product gross margins lower as a percent of revenue for the first quarter of fiscal 2019 as compared with the same quarter in the prior year. As previously disclosed, the scale-up of our Irish manufacturing facility and growth in sales from that facility are expected to negatively impact product gross margins in our Medical Device business in fiscal 2019.

Research and development (R&D) expenses. R&D expenses increased \$3.7 million in the three months ended December 31, 2018, from the same prior-year period. This increase was primarily the result of higher planned spending for our DCB and proprietary product development and clinical activities, including our TRANSCEND clinical trial. We plan to continue current levels of R&D spending throughout the remainder of fiscal 2019 to support our whole-product solutions strategy, including continued increases in clinical and regulatory expenses as we complete enrollment in the TRANSCEND clinical trial for our SurVeil DCB and enroll patients in a first in-human trial for our A vess DCB. We anticipate fiscal 2019 R&D expense will be in the low-to-mid fifties as a percent of fiscal 2019 revenue.

Selling, general and administrative (SG&A) expenses. SG&A expenses increased \$0.7 million in the three months ended December 31, 2018, respectively, from the same prior-year period, although they declined as a percent of revenue from 30% in fiscal 2018 to 27% in the first quarter of fiscal 2019. The increase in SG&A expenses from the prior-year period is due to compensation and benefit expenses associated with staffing to support our strategic initiatives. We expect fiscal 2019 SG&A expenses will range between 27% and 29%, as a percent of revenue.

Intangible asset amortization. As part of our fiscal 2016 acquisitions in our Medical Device business, we acquired certain intangible assets which are being amortized over periods ranging from 4 to 14 years. In addition, we own certain intangible assets related to the BioFx acquisition in fiscal 2007. We recognized \$0.6 million in amortization expense related to these acquisitions in the three months ended December 31, 2018 and 2017. Acquired intangible asset amortization is estimated to total \$2.5 million in fiscal 2019.

Contingent consideration accretion expense. For the three months ended December 31, 2018 and 2017, we recorded a net gain of less than \$(0.1) million and a net expense of \$1.1 million, respectively, related to our contingent consideration liabilities from prior-year acquisitions. The changes in contingent consideration gain and expense is related to normally scheduled accretion expense related to the passage of time offset by changes in estimated probabilities of achievement of certain revenue and strategic milestones. In fiscal 2019, if there are changes in the amount, probability or timing of achievement of contingent consideration milestones, there may be material adjustments in the consolidated statements of operations to reflect changes in the fair value of contingent consideration liabilities.

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

	Three Months Ended December 31,	
(Dollars in thousands)	2018	2017
Investment income, net	\$ 316	\$ 121
Interest expense	(37)	—
Foreign exchange gain (loss)	136	(186)
Gains on strategic investment and other	7	177
Other income, net	\$ 422	\$ 112

The increase in investment income in the first quarter of fiscal 2019, as compared with the prior-year periods, is the result of higher interest rates on debt investments as well as an increase in investment principal from the \$25 million Abbott payment. The foreign exchange gain (loss) in the three months ended December 31, 2018 and 2017 is primarily related to the change in exchange rates associated with the Euro-denominated contingent consideration

liability from the Creagh Medical acquisition, which was paid in the first quarter of fiscal 2019. In the three months ended December 31, 2018, the Euro weakened against the U.S. Dollar, resulting in gains for the period. The Euro strengthened against the U.S. Dollar in the three months ended December 31, 2017, resulting in losses for that period. We recognized a gain on a previously sold strategic investment in the first three months of fiscal 2018 as additional consideration was released from escrow.

Income tax provision. The income tax (benefit) provision was \$(0.2) million and \$1.0 million for the three months ended December 31, 2018 and 2017, respectively. In December 2017, the Tax Cuts and Jobs Act tax legislation was signed into law, which reduced the U.S. Federal statutory tax rate from 35% to 21%, among other changes. As a result of the enactment of this legislation, the Company's net loss for the three months ended December 31, 2017 included discrete tax expense of \$1.2 million from our net deferred tax assets revaluation based on the change in the statutory tax rate. The Company's effective tax rate reflects the impact of state income taxes, permanent tax items and discrete tax benefits, as well as operating losses in Ireland, where tax benefits are offset by a valuation allowance.

The tax benefits recognized in the three months ended December 31, 2018 as compared with tax expense in the same prior-year period, reflect expected pre-tax net income, offset by excess tax benefits related to stock-based compensation due to significant award exercise activity during the current-year quarter and estimated U.S. federal R&D tax credit. In the prior year, the tax expense was primarily driven by the aforementioned revaluation of deferred tax assets as a result of the tax rate change.

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

We expect income tax benefit to be in the range of \$1.4 million to \$0.6 million for fiscal 2019. Currently, income and losses generated in Ireland from our Creagh Medical acquisition do not reflect an Irish income tax expense (benefit) as they are offset by a valuation allowance. Therefore, taxable income or losses in Ireland, where the statutory tax rate is 12.5%, will result in no reported tax benefit or expense in fiscal 2019. Certain provisions of the Tax Cuts and Jobs Act significantly change the treatment of accumulated and future earnings of foreign subsidiaries. While we do not have accumulated earnings subject to a repatriation tax under the law, we may be subject to additional U.S. tax on our foreign subsidiary's income in future years.

Segment Operating Results

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

(Dollars in thousands)	Three Months Ended December 31,		
	2018	2017	Change
Operating income (loss):			
Medical Device	\$357	\$(389)	NM
In Vitro Diagnostics	2,455	1,670	47 %
Total segment operating income	2,812	1,281	
Corporate	(2,100)	(1,914)	10 %
Total operating income (loss)	\$712	\$(633)	NM

Medical Device. Operating income improved by \$0.7 million in the three months ended December 31, 2018, from an operating loss of \$0.4 million in the prior-year quarter. Operating income (loss) as a percentage of revenue was 2.1% and (3.0)% in the first quarter of fiscal 2019 and 2018, respectively. Operating results improved in the current-year quarter from the comparable prior-year quarter as a result of a \$4.5 million increase in revenue, partly offset by a \$3.7 million increase in R&D expenses related to our planned investment in our DCB and proprietary medical device product development and clinical programs. Additionally, we recognized a gain of \$0.1 million related to our contingent consideration obligations in the current-year quarter, as compared with expense of \$1.1 million in the prior-year quarter.

In Vitro Diagnostics. Operating income increased by \$0.8 million in the three months ended December 31, 2018, as compared with the same prior-year period. Operating income as a percentage of revenue was 49.3% and 39.4% in the three months ended December 31, 2018, and 2017 respectively. Product gross margin as a percent of sales was 70.2% and 64.2% in the three months ended December 31, 2018, and 2017. Product gross margins and operating income in

the three months ended December 31, 2018 increased due to better product mix and manufacturing leverage.

Corporate. The Corporate category includes expenses for administrative corporate functions, such as executive, corporate accounting, legal, human resources and Board of Directors related fees and expenses, which have not been fully allocated to the Medical Device and In Vitro Diagnostics segments. Corporate also includes expenses, such as litigation, which are not specific to a segment and thus not allocated to our operating segments.

Liquidity and Capital Resources

As of December 31, 2018, we had working capital of \$50.3 million, an increase of \$3.9 million from September 30, 2018. Working capital is defined by us as current assets minus current liabilities. The increase from the prior year-end is a result of contract assets totaling \$6.7 million recorded during the quarter as a result of the adoption of ASC Topic 606, partly offset by payments for capital expenditures totaling \$2.1 million. Our cash and cash equivalents and available-for-sale investments totaled \$45.9 million at December 31, 2018, a decrease of \$19.1 million from \$65.0 million at September 30, 2018. This change was primarily driven by the

\$11.0 million payment of the contingent consideration owed related to the Creagh Medical acquisition, as well as payment of accrued compensation liabilities totaling \$4.1 million, capital expenditures of \$2.1 million and \$2.7 million of cash payments for taxes related to net share settlement of equity awards.

The Company's investment policy excludes ownership of collateralized mortgage obligations, mortgage-backed derivatives and other derivative securities without prior written approval of the Board of Directors. Our investments primarily consist of money market, corporate bond and commercial paper securities. Our investment policy requires that no more than 5% of investments be held in any one credit or issue, excluding U.S. government and government agency obligations. The primary investment objective of the portfolio is to provide for the safety of principal and appropriate liquidity while generating an above-benchmark ("Barclays Short Treasury 1-3 Month Index") total rate of return on a pre-tax basis. Management plans to continue to direct its investment advisors to manage the Company's securities investments primarily for the safety of principal for the foreseeable future as it continues to assess other investment opportunities and uses of its cash and securities investments, including those described below.

Summary of Cash Flows

(Dollars in thousands)	Three Months Ended	
	December 31, 2018	2017
Cash provided by (used in):		
Operating activities	(5,405)	614
Investing activities	7,843	5,738
Financing activities	(11,689)	(975)
Effect of exchange rates on changes in cash and cash equivalents	(15)	35
Net change in cash and cash equivalents	\$(9,266)	\$5,412

Operating Activities. We used cash for operating activities of approximately \$5.4 million in the three months ended December 31, 2018 as compared with cash generated from operating activities of \$0.6 million in the same prior-year period. During the first three months of fiscal 2019 and 2018, we had net income (loss) of \$1.3 million and \$(1.6) million, respectively. Additionally, \$2.0 million of the \$11.0 million payment of contingent consideration obligations related to the Creagh Medical acquisition is recorded as a reduction of cash flows from operations as it relates to accretion expense which increased these obligations from the acquisition date through final settlement. Net changes in operating assets and liabilities had a negative impact on cash flows of \$8.0 million in the three months ended December 31, 2018 as compared with a negative impact of \$3.1 million in the three months ended December 31, 2017. Significant changes in operating assets and liabilities during these periods included:

- Cash used by deferred revenue was \$2.4 million in the fiscal 2019 period, as compared with cash from deferred revenue of less than \$0.1 million in the fiscal 2018 period, due to recognition of a portion of the \$25.0 million upfront fee received from Abbott in the second quarter of fiscal 2018.
- Cash used by accounts receivable totaled \$0.8 million in the first quarter of fiscal 2019, as compared with cash from accounts receivable of \$0.5 million in the same fiscal 2018 period. This was primarily due to a \$1.7 million customer payment due in the first quarter of fiscal 2019, for which payment was received in January 2019.
- Cash used by accrued liabilities was \$3.7 million and \$2.3 million for the first quarter of fiscal 2019 and 2018, respectively. The increase in cash used by accrued liabilities the fiscal 2019 period, as compared with the fiscal 2018 period is due to a \$1.2 million increase in incentive compensation payments in the current fiscal year as well as a

reduction of accrued clinical trial expenses of \$0.4 million.

Investing Activities. We received cash from investing activities of \$7.8 million in the first quarter of fiscal 2019 as compared with \$5.7 million in the first quarter of fiscal 2018. We invested \$2.1 million and \$1.3 million in property and equipment in the first quarter of fiscal 2019 and fiscal 2018, respectively. In the first quarter of fiscal 2019 and 2018, we received \$9.9 million and \$7.0 million, respectively, from maturities of available-for-sale debt securities, net of purchases of other investments.

Financing Activities. We used cash in financing activities of \$11.7 million and \$1.0 million in the first three months of fiscal 2019 and 2018, respectively. In the first quarter of fiscal 2019 and 2018, we paid \$2.7 million and \$1.1 million, respectively, to purchase common stock to pay employee taxes resulting from the exercise of stock options and vesting of other stock awards. In the first quarter of fiscal 2019, we paid contingent consideration of \$11.0 million related to the Creagh Medical acquisition, \$9.1 million of which was recorded as cash from financing activities.

We believe that our existing cash, and cash equivalents and investments, which totaled \$45.9 million as of December 31, 2018, together with cash flow from operations, will provide liquidity sufficient to meet our cash needs and fund our operations and planned capital expenditures for the next twelve months. There can be no assurance, however, that Surmodics' business will continue to generate cash flows at current levels, and disruptions in financial markets may negatively impact our ability to access capital in a timely manner and on attractive terms.

Customer Concentrations. Our licensed technologies provide royalty revenue, which represents the largest revenue stream to the Company. We have licenses with a diverse base of customers and certain customers have multiple products using our technology. Abbott and Medtronic plc ("Medtronic") are our largest customers, comprising 11% and 16%, respectively, of our consolidated revenue for fiscal 2018. These same customers comprised 17% and 14%, respectively, of our consolidated revenue for the first quarter of fiscal 2019. Medtronic has several separately licensed products that generate royalty revenue for Surmodics, none of which represented more than 3% of our total revenue. No other individual customer using licensed technology constitutes more than 10% of Surmodics' total fiscal 2019 to date or fiscal 2018 revenue.

Share Purchase Activity

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

Off-Balance Sheet Arrangements

As of December 31, 2018 and September 30, 2018, we did not have any off-balance sheet arrangements that have, or are reasonably likely to have, a current or future effect on our financial condition, changes in financial condition, revenue or expenses, results of operations, liquidity, capital expenditures or capital resources that is material to investors.

Forward-Looking Statements

This Quarterly Report on Form 10-Q, including "Management's Discussion and Analysis of Financial Condition and Results of Operations" in Item 2, contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. These statements include expectations concerning our growth strategy, including our ability to sign new license agreements, bring new products to market and broaden our hydrophilic coatings royalty revenue, the impact of patent expirations on our hydrophilic coatings royalty revenue, product development programs, various milestone achievements, research and development plans and expenses, including the estimated cost associated with the TRANSCEND clinical trial, future cash flow and sources of funding, short-term requirements, future property and equipment investment levels, the impact of potential lawsuits or claims, the impact of Abbott, Medtronic, as well as other significant customers, including new diagnostic kit customers, our ability to recognize the expected benefits of our acquisitions and the Company's strategy to transform to a provider of whole-product solutions, the timing, impact and success of the clinical evaluation of the SurVeil DCB, and our expectations related to our income tax expense for fiscal 2019. Without limiting the foregoing, words or phrases such as "anticipate," "believe," "could," "estimate," "expect," "forecast," "intend," "may," "plan," "possible," "project," "will" and similar terminology, generate forward-looking statements. Forward-looking statements may also represent challenging goals for us. These statements, which represent the Company's expectations or beliefs concerning various future events, are based on current expectations that involve a number of risks and uncertainties that could cause actual results to differ materially from those of such forward-looking statements. We caution that undue reliance should not be placed on such forward-looking statements, which speak only as of the date made. Some of the factors which could cause results to

differ from those expressed in any forward-looking statement are set forth under “Risk Factors” in Part I, Item 1A of our Annual Report on Form 10-K for the fiscal year ended September 30, 2018. We disclaim any intent or obligation to update publicly these forward-looking statements, whether because of new information, future events or otherwise.

Although it is not possible to create a comprehensive list of all factors that may cause actual results to differ from our forward-looking statements, such factors include, among others:

- our reliance on a small number of significant customers, including our largest customers, Abbott and Medtronic, which causes our financial results and stock price to be subject to factors affecting those significant customers and their products, the timing of market introduction of their or competing products, product safety or efficacy concerns and intellectual property litigation could adversely affect our growth strategy and the royalty revenue we derive;
- 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;

29

- 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;
- clinical and regulatory developments relating to the evaluation of risks associated with paclitaxel-coated products, which developments may adversely impact our ability to obtain marketing approval (or the timing of any such approval) for our SurVeil DCB and other paclitaxel-coated products, to treat PAD in the femoral and/or popliteal arteries;
- our ability to successfully develop, obtain regulatory approval for, and commercialize our SurVeil DCB product, including our reliance on clinical research organizations to manage the TRANSCEND clinical trial and uncertainty related to the impacts of any clinical research relative to drug-coated balloons, including our Avest™ DCB, other DCB products and other catheter and balloon-based products, which will impact our ability to receive additional milestone payments under our agreement with Abbott;
- our ability to perform successfully with respect to certain product development activities, the related R&D expense impact and governmental and regulatory compliance activities which we have not previously undertaken in any significant manner;
- our ability to successfully convert our customers from the fourth generation of our PhotoLink® hydrophilic technology protected by a family of patents which will begin to expire in November 2019 (in the U.S.) to one of our advanced generation technologies or extend the royalty-bearing term of the customer license agreements, and to offset any decline in revenue from customers that we are unable to convert;
- our ability to identify and execute new acquisition opportunities as well as the process of integrating acquired businesses poses numerous risks, including an inability to integrate acquired operations, personnel, technology, information systems, and internal control systems and products; a lack of understanding of tax, legal and cultural differences; diversion of management's attention; difficulties and uncertainties in transitioning the customers or other business relationships from the acquired entity to us; the loss of key employees of acquired companies;
- other factors described in "Risk Factors" and other sections of Surmodics' Annual Report on Form 10-K for the fiscal year ended September 30, 2018, which you are encouraged to read carefully.

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

Item 3. Quantitative and Qualitative Disclosures About Market Risk

Our investment policy requires investments with high credit quality issuers and limits the amount of credit exposure to any one issuer. Our investments consist principally of interest-bearing corporate debt securities with varying maturity dates, which are less than one year. Because of the credit criteria of our investment policies, the primary market risk associated with these investments is interest rate risk. We do not use derivative financial instruments to manage interest rate risk or to speculate on future changes in interest rates. As of December 31, 2018, we held \$31.5 million in available-for-sale debt securities, all with maturity dates of less than one year, therefore interest rate fluctuations would have an insignificant impact on our results of operations or cash flows. Our policy also allows the Company to hold a substantial portion of funds in cash and cash equivalents, which are defined as financial instruments with original maturities of three months or less and may include money market instruments, certificates of deposit, repurchase agreements, corporate bonds and commercial paper instruments.

Management believes that a reasonable change in raw material prices would not have a material impact on future earnings or cash flows because the Company's inventory exposure is not material.

We are exposed to increasing Euro currency risk with respect to our manufacturing operations in Ireland. In a period where the U.S. dollar is strengthening or weakening as compared with the Euro, our revenue and expenses denominated in Euro currency are translated into U.S. dollars at a lower or higher value than they would be in an otherwise constant currency exchange rate environment. All sales transactions are denominated in U.S. dollars or Euros. We generate royalty revenue from the sale of customer products in foreign jurisdictions. Royalties generated in foreign jurisdictions by customers are converted and paid in U.S. dollars per contractual terms. Substantially all of our purchasing transactions are denominated in U.S. Dollars or Euros. To date, we have not entered into any

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

Item 4. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

The Company maintains disclosure controls and procedures as defined in Rules 13a-15(e) and 15d-15(e) of the Securities Exchange Act of 1934, as amended (the "Exchange Act"). The Company's management, under the supervision and with the participation of the Company's Chief Executive Officer and Chief Financial Officer, referred to collectively herein as the Certifying Officers, carried out an evaluation of the effectiveness of the design and operation of the Company's disclosure controls and procedures as of December 31, 2018. Based on that evaluation, the Company's Certifying Officers concluded that, as of the end of the period covered by this report, the Company's disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) of the Exchange Act) were effective to ensure that information required to be disclosed by the Company in reports that it files under the Exchange Act is recorded, processed, summarized and reported within the time period specified in the Securities and Exchange Commission rules and forms, and to ensure that information required to be disclosed by the Company in the reports the Company files or submits under the Exchange Act is accumulated and communicated to the Company's management, including its Certifying Officers, as appropriate, to allow timely decisions regarding required disclosures.

Changes in Internal Controls over Financial Reporting

There were no changes in our internal control over financial reporting (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act) during the three months ended December 31, 2018 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II — OTHER INFORMATION

Item 1. Legal Proceedings

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

Item 1A. Risk Factors

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

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

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

We began enrollment in the TRANSCEND clinical study for our SurVeil DCB in the first quarter of fiscal 2018 and, in December 2018, we commenced a first-in-human clinical study of our Avesc DCB. There are risks involved in these and other clinical studies, including that they may fail to enroll a sufficient number of patients for a variety of reasons or be completed on schedule, if at all. Clinical trials for any of our products could be delayed for a variety of reasons, including, but not limited to:

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

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

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

(c) Issuer Purchases of Equity Securities

The following table presents information with respect to purchases of common stock of the Company made during the three months ended December 31, 2018, by the Company or on behalf of the Company or any “affiliated purchaser” of the Company, as defined in Rule 10b-18(a)(3) under the Exchange Act.

Period	Total Number of Shares Purchased as Part of Publicly Announced Plans or Programs	Average Price Paid per Share	Total Number of Shares Purchased as Part of Publicly Announced Plans or Programs	Approximate Dollar Value of Shares That May Yet Be Purchased Under the Plans or Programs (1)
10/1/18 — 10/31/18	—	N/A	—	\$ 25,298,238
11/1/18 — 11/30/18	—	N/A	—	\$ 25,298,238
12/1/18 — 12/31/18	—	N/A	—	\$ 25,298,238
Total	—	N/A	—	\$ 25,298,238

(1) As of December 31, 2018, the Company has an aggregate of \$25.3 million available for future common stock repurchase under an authorization approved by the Board of Directors for up to \$20.0 million on November 6, 2015, all of which is remaining, and an authorization approved by the Board of Directors on November 5, 2014 for which \$5.3 million is remaining. These authorizations for share repurchases do not have a fixed expiration date.

Item 3. Defaults Upon Senior Securities

None.

Item 4. Mine Safety Disclosures

Not Applicable.

Item 5. Other Information

None.

Item 6. Exhibits

Exhibit Description

- 2.1 Share Purchase Agreement by and among Surmodics, Inc. and the shareholders of Creagh Medical Ltd. dated as of November 20, 2015 — incorporated by reference to Exhibit 2.1 to the Company’s 8-K 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, 2018, filed on February 1, 2019, formatted in Extensible Business Reporting Language (XBRL): (i) Condensed Consolidated Balance Sheets, (ii) Condensed Consolidated Statements of Operations, (iii) Condensed Consolidated Statements of Comprehensive Income, (iv) Condensed Consolidated Statements of Stockholders’ Equity, (v) Condensed Consolidated Statements of Cash Flows, and (vi) Notes to Condensed Consolidated Financial Statements.

*Filed herewith

SIGNATURES

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

February 1, 2019 Surmodics, Inc.

By: /s/ Timothy J. Arens
Timothy J. Arens
Vice President of Corporate Development and Strategy, Interim Vice President of Finance and
Chief Financial Officer

(duly authorized signatory and principal financial officer)