

SURMODICS INC  
Form 10-Q  
May 04, 2018

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D. C. 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended March 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

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

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

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company 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	(Do not check if a 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 May 2, 2018 was 13,257,956.

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## PART I. FINANCIAL INFORMATION

## Item 1. Unaudited Condensed Financial Statements

## Surmodics, Inc. and Subsidiaries

## Condensed Consolidated Balance Sheets

	March 31, 2018	September 30, 2017
(in thousands, except share and per share data)		
	(Unaudited)	
<b>ASSETS</b>		
Current Assets:		
Cash and cash equivalents	\$27,712	\$ 16,534
Restricted cash	350	—
Available-for-sale securities	38,330	31,802
Accounts receivable, net of allowance for doubtful accounts of \$160 and \$230		
as of March 31, 2018 and September 30, 2017, respectively	7,216	7,211
Inventories, net	4,046	3,516
Income tax receivable	1,345	599
Prepays and other	2,342	1,221
Total Current Assets	81,341	60,883
Available-for-sale securities	3,953	—
Deferred tax assets	3,326	4,027
Property and equipment, net	25,844	22,942
Intangible assets, net	19,725	20,562
Goodwill	27,933	27,282
Other assets	1,197	897
Total Assets	\$163,319	\$ 136,593
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
Current Liabilities:		
Accounts payable	\$2,012	\$ 2,396
Accrued liabilities:		
Compensation	3,859	3,822
Accrued other	4,022	1,773
Deferred revenue	12,097	62
Contingent consideration	12,235	1,750
Total Current Liabilities	34,225	9,803
Contingent consideration, less current portion	1,110	13,114
Deferred revenue, less current portion	12,710	181
Other long-term liabilities	1,918	1,938
Total Liabilities	49,963	25,036
Commitments and Contingencies (Note 16)		
Stockholders' Equity:		
Series A Preferred stock- \$.05 par value, 450,000 shares authorized; no shares issued and outstanding	—	—

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Common stock- \$.05 par value, 45,000,000 shares authorized; 13,247,068 and

13,094,988 shares issued and outstanding as of March 31, 2018 and

September 30, 2017, respectively	662	655
Additional paid-in capital	5,431	5,413
Accumulated other comprehensive income	5,213	3,417
Retained earnings	102,050	102,072
Total Stockholders' Equity	113,356	111,557
Total Liabilities and Stockholders' Equity	\$ 163,319	\$ 136,593

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

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## Surmodics, Inc. and Subsidiaries

## Condensed Consolidated Statements of Operations

(In thousands, except per share data)	Three Months		Six Months Ended	
	Ended March 31, 2018 (Unaudited)	2017	March 31, 2018 (Unaudited)	2017
<b>Revenue:</b>				
Product sales	\$8,686	\$7,936	\$16,774	\$15,637
Royalties and license fees	8,428	7,319	15,504	15,320
Research, development and other	1,944	2,248	3,793	4,307
<b>Total revenue</b>	<b>19,058</b>	<b>17,503</b>	<b>36,071</b>	<b>35,264</b>
<b>Operating costs and expenses:</b>				
Product costs	2,913	2,562	5,804	5,190
Research and development	10,774	8,208	18,605	14,178
Selling, general and administrative	6,440	5,076	11,628	9,938
Acquired intangible asset amortization	636	591	1,254	1,187
Contingent consideration gain	(2,230 )	(611 )	(1,112 )	(174 )
<b>Total operating costs and expenses</b>	<b>18,533</b>	<b>15,826</b>	<b>36,179</b>	<b>30,319</b>
<b>Operating income (loss)</b>	<b>525</b>	<b>1,677</b>	<b>(108 )</b>	<b>4,945</b>
<b>Other (loss) income:</b>				
Investment income, net	142	85	263	170
Foreign exchange (loss) gain	(353 )	(201 )	(539 )	473
Gain on strategic investment	—	—	177	—
Other (loss) income, net	(211 )	(116 )	(99 )	643
<b>Income (loss) before income taxes</b>	<b>314</b>	<b>1,561</b>	<b>(207 )</b>	<b>5,588</b>
Income tax benefit (provision)	1,220	(1,055 )	185	(2,782 )
<b>Net income (loss)</b>	<b>\$1,534</b>	<b>\$506</b>	<b>\$(22 )</b>	<b>\$2,806</b>
<b>Basic net income (loss) per share</b>				
	<b>\$0.12</b>	<b>\$0.04</b>	<b>\$(0.00 )</b>	<b>\$0.21</b>
<b>Diluted net income (loss) per share</b>				
	<b>\$0.11</b>	<b>\$0.04</b>	<b>\$(0.00 )</b>	<b>\$0.21</b>
<b>Weighted average number of shares outstanding:</b>				
Basic	13,102	13,220	13,078	13,207
Diluted	13,465	13,428	13,078	13,415

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

## Surmodics, Inc. and Subsidiaries

## Condensed Consolidated Statements of Comprehensive Income

	Three Months		Six Months	
	Ended		Ended	
	March 31,		March 31,	
	2018	2017	2018	2017
(In thousands)	(Unaudited)		(Unaudited)	
Net income (loss)	\$1,534	\$506	\$(22 )	\$2,806
Other comprehensive income (loss):				
Unrealized holding (losses) gains on available-for-sale securities, net of tax	(28 )	4	(41 )	50
Foreign currency translation adjustments	1,207	660	1,837	(1,594)
Other comprehensive income (loss)	1,179	664	1,796	(1,544)
Comprehensive income	\$2,713	\$1,170	\$1,774	\$1,262

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

## Surmodics, Inc. and Subsidiaries

## Condensed Consolidated Statements of Cash Flows

(in thousands)	Six Months Ended	
	2018	2017
	(Unaudited)	
<b>Operating Activities:</b>		
Net (loss) income	\$(22 )	\$2,806
<b>Adjustments to reconcile net (loss) income to net cash provided by operating activities:</b>		
Depreciation and amortization	3,106	2,610
Stock-based compensation	2,003	1,671
Contingent consideration gain	(1,112 )	(174 )
Unrealized foreign exchange loss (income)	518	(473 )
Deferred taxes	701	525
Gain on strategic investment	(177 )	—
Provision for bad debts	25	—
Other	92	(25 )
<b>Change in operating assets and liabilities:</b>		
Accounts receivable	(15 )	(223 )
Inventories	(500 )	132
Prepays and other	(1,366 )	(1,006 )
Accounts payable and accrued liabilities	392	(1,959 )
Income taxes	(776 )	358
Deferred revenue	24,562	21
<b>Net cash provided by operating activities</b>	<b>27,431</b>	<b>4,263</b>
<b>Investing Activities:</b>		
Purchases of property and equipment	(4,020 )	(2,866 )
Purchases of available-for-sale securities	(43,517)	(40,051)
Maturities of available-for-sale securities	33,000	27,071
Cash proceeds from sales of property and equipment	4	—
Cash received from sale of strategic investment	177	—
<b>Net cash used in investing activities</b>	<b>(14,356)</b>	<b>(15,846)</b>
<b>Financing Activities:</b>		
Issuance of common stock	377	188
Payments for taxes related to net share settlement of equity awards	(1,132 )	(2,127 )
Payment of contingent consideration obligations	(925 )	—
Payment of deferred financing costs	—	(97 )
<b>Net cash used in financing activities</b>	<b>(1,680 )</b>	<b>(2,036 )</b>
Effect of exchange rate changes on cash and cash equivalents	133	(109 )
<b>Net change in cash and cash equivalents</b>	<b>11,528</b>	<b>(13,728)</b>
<b>Cash and Cash Equivalents:</b>		
Beginning of period	16,534	24,987
End of period	\$28,062	\$11,259
<b>Supplemental Information:</b>		
Cash paid for income taxes	\$782	\$1,881
<b>Noncash transactions from investing and financing activities:</b>		
Acquisition of property and equipment on account	\$329	\$303



Accrued taxes related to net share settlement of equity awards	1,222	—
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The accompanying notes are an integral part of these unaudited condensed consolidated financial statements.

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Surmodics, Inc. and Subsidiaries

Notes to Condensed Consolidated Financial Statements

Period Ended March 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 and six months ended March 31, 2018 are not necessarily indicative of the results that may be expected for the entire 2018 fiscal year.

In accordance with the rules and regulations of the U.S. Securities and Exchange Commission (“SEC”), the Company has omitted footnote disclosures that would substantially duplicate the disclosures contained in the audited consolidated financial statements of the Company. These unaudited condensed consolidated financial statements should be read together with the audited consolidated financial statements for the fiscal year ended September 30, 2017, and footnotes thereto included in the Company’s Form 10-K as filed with the SEC on December 1, 2017.

## 2. New Accounting Pronouncements

### Accounting Standards to be Adopted

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

earn under its agreement related to the Company's SurVeil® drug-coated balloon with Abbott Vascular, Inc. ("Abbott") entered into in fiscal 2018, which is disclosed in Note 3 to the condensed consolidated financial statements. Under the modified retrospective approach, the Company will apply the new revenue standard to all new revenue contracts initiated on or after the effective date, and, for contracts which have remaining obligations as of the effective date, the Company will adjust the beginning balance of retained earnings as of October 1, 2018.

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

In June 2016, the FASB issued ASU No 2016-13, Financial Instruments – Credit Losses (ASC Topic 326), Measurement of Credit Losses on Financial Statements. This ASU requires a financial asset (or a group of financial assets) measured at an amortized cost

basis to be presented at the net amount expected to be collected. The allowance for credit losses is a valuation account that is deducted from the amortized cost basis of the financial asset(s) to present the net carrying value at the amount expected to be collected on the financial asset. The accounting standard will be effective for the Company beginning in the first quarter of fiscal 2020 (October 1, 2019). Early adoption is permitted and the guidance will be applied using a modified retrospective approach. The Company is currently evaluating the impact that the adoption of this standard will have on the Company's results of operations, cash flows and financial position.

No other new accounting pronouncement issued or effective has had, or is expected to have, a material impact on the Company's condensed consolidated financial statements.

### 3. Collaborative Arrangement

On February 26, 2018, the Company entered into an agreement with Abbott whereby Abbott will have exclusive worldwide commercialization rights for Surmodics' SurVeil® drug-coated balloon 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 drug-coated balloon products, which are currently in pre-clinical development. Surmodics is responsible for conducting all necessary clinical trials and other activities required to achieve U.S. and European Union regulatory clearances for SurVeil, 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. The upfront fee and potential milestone payments will be recognized as royalty and license fee revenue as the clinical and regulatory activities are performed on a proportional performance basis, relative to the expected total cost of each underlying unit of account. For the three and six-month periods ended March 31, 2018, the Company recognized revenue totaling \$0.5 million from the Abbott arrangement. The remainder of the \$25 million upfront payment received is included in deferred revenue as of March 31, 2018. Upon the regulatory approval of the SurVeil® drug-coated balloon, Surmodics will be responsible for the manufacture and supply of clinical and commercial quantities of the product and will realize revenue based on initial product sales to Abbott as well as a share of net profits resulting from third-party sales by Abbott.

### 4. Fair Value Measurements

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

#### Fair Value Hierarchy

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

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

The Company did not have any Level 1 assets as of March 31, 2018 and September 30, 2017.

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

The Company's Level 2 assets as of March 31, 2018 and September 30, 2017 consisted of money market funds, commercial paper instruments and corporate bonds.

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

Level 3 liabilities as of March 31, 2018 and September 30, 2017 consist of contingent consideration obligations related to the fiscal 2016 acquisitions of Creagh Medical Ltd. (“Creagh Medical”) and NorMedix, Inc. (“NorMedix”). Consideration owed to the sellers of Creagh Medical upon achievement of revenue and value-creating milestones through September 30, 2018, is due to be paid during the quarter ending December 31, 2018. Consideration owed to the sellers of NorMedix upon achievement of revenue and value-creating milestones through September 30, 2019, is due to be paid within sixty days following the quarter in which each milestone is achieved. Contingent consideration included in current liabilities of \$12.2 million and \$1.8 million as of March 31, 2018 and September 30, 2017, 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 March 31, 2018, the Company paid contingent consideration obligations related to the NorMedix acquisition totaling \$0.9 million, which are included in cash flows used in financing activities on the condensed consolidated statement 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 March 31, 2018:

	Quoted Prices in			Total Fair Value as of March 31, 2018
	Active Markets for Identical Instruments (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)	
(Dollars in thousands)				
<b>Assets</b>				
Cash equivalents	\$ —	\$ 21,432	\$ —	\$21,432
Available-for-sale securities	—	42,283	—	42,283
Total assets	\$ —	\$ 63,715	\$ —	\$63,715