

**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549**

FORM 8-K

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

May 1, 2019

Date of report (Date of earliest event reported)

Surmodics, Inc.

(Exact Name of Registrant as Specified in its Charter)

Minnesota

(State of Incorporation)

0-23837

(Commission File Number)

41-1356149

(I.R.S. Employer
Identification No.)

**9924 West 74th Street
Eden Prairie, Minnesota**

(Address of Principal Executive Offices)

55344

(Zip Code)

(952) 500-7000

(Registrant's Telephone Number, Including Area Code)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instruction A.2):

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

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.

Item 2.02 Results of Operations And Financial Condition.

On May 1, 2019, Surmodics, Inc. (the “Company”) issued a press release (the “Press Release”) announcing the results for the quarter ended March 31, 2019. A copy of the full text of the Press Release is furnished as Exhibit 99.1 to this report.

The information contained in this Item 2.02, including Exhibit 99.1, shall not be deemed to be “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, nor shall they be deemed to be incorporated by reference into any filing under the Securities Act of 1933, as amended, except as shall be expressly set forth by specific reference in such a filing.

Item 9.01 Financial Statements and Exhibits.

(d) *Exhibits.*

Exhibit Number	Description
99.1	Press Release dated May 1, 2019.

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 hereunto duly authorized.

SURMODICS, INC.

Date: May 1, 2019

/s/ Timothy J. Arens

Timothy J. Arens

Vice President of Corporate Development and Strategy,

Interim Vice President of Finance and Chief Financial Officer

EXHIBIT INDEX

Exhibit Number	Description
<u>99.1</u>	<u>Press Release dated May 1, 2019.</u>

Surmodics Reports Second Quarter Fiscal 2019 Results

Updates Fiscal 2019 Guidance

EDEN PRAIRIE, Minn.--(BUSINESS WIRE)--May 1, 2019--Surmodics, Inc. (Nasdaq: SRDX), a leading provider of medical device and in vitro diagnostic technologies to the healthcare industry, today announced results for its fiscal 2019 second quarter ended March 31, 2019, and updated its financial outlook for fiscal 2019.

Summary of Second Quarter and Recent Highlights

- Revenue of \$22.7 million, an increase of 19% year-over-year
- GAAP EPS of \$0.09, non-GAAP EPS of \$0.07
- TRANSCEND clinical trial enrollment 75% complete
- FDA Clearance of Sublime™ guide sheath for radial access

“Our second quarter performance marked our fourth consecutive quarter of double-digit year-over-year revenue growth as both our Medical Device and IVD businesses continued to generate meaningful top-line gains,” said Gary Maharaj, President and CEO of Surmodics. “Despite the current uncertainty related to paclitaxel-coated devices, we have appropriately adjusted our TRANSCEND trial to respond to the FDA’s recommendations and are pleased to have many of our trial sites actively enrolling and randomizing patients. In addition, we continue to make progress on our key strategic initiatives including the recent FDA 510(k) clearance of our *Sublime* guide sheath for radial access to the peripheral arteries.”

Second Quarter Fiscal 2019 Financial Results

Total revenue for the second quarter of fiscal 2019 was \$22.7 million, as compared with \$19.1 million in the prior-year period. Medical Device revenue was \$17.3 million in the second quarter of fiscal 2019, as compared with \$14.1 million in the year-ago period, an increase of 23%, and includes \$1.6 million from our *SurVeil*™ agreement with Abbott, as compared with \$0.5 million in the prior-year quarter. In Vitro Diagnostics revenue was \$5.4 million for the second quarter of fiscal 2019 as compared with \$5.0 million in the same prior-year quarter, an increase of 7%.

Diluted GAAP earnings per share in the second quarter of fiscal 2019 was \$0.09 as compared with \$0.11 in the year-ago period. On a non-GAAP basis, earnings per share were \$0.07 in the second quarter of fiscal 2019, as compared with \$0.07 in the year-ago period.

As of March 31, 2019, cash and investments were \$46.5 million. Surmodics generated \$1.5 million of cash from operating activities in the second quarter of fiscal 2019. Capital expenditures totaled \$1.0 million for the second quarter of fiscal 2019.

Fiscal 2019 Guidance Revised

Although we continue to enroll patients in our TRANSCEND trial, the current uncertainty related to utilization of paclitaxel-coated devices has and is expected to continue to impact our recognition of *SurVeil* revenue and TRANSCEND clinical trial expense. We are updating our full-year revenue and earnings guidance for fiscal 2019 to account for this impact, as well as our strong operating performance in the first half of our fiscal year. We are lowering our fiscal 2019 revenue expectations by \$5.5 million to a range of \$88.5 million to \$91.5 million, from our previous revenue range of \$94 million to \$97 million. We are increasing our fiscal 2019 diluted GAAP EPS to a range of \$0.14 to \$0.24 per share compared with our previous expectations of a diluted loss in the range of (\$0.22) to a loss of (\$0.02) per share. Diluted non-GAAP EPS is now expected to be in the range of \$0.26 to \$0.36 per share compared with previous expectations of \$0.02 to \$0.22 per share.

Conference Call

Surmodics will host a webcast at 4 p.m. CT (5 p.m. ET) today to discuss second quarter results. To access the webcast, go to the investor relations portion of the Company's website at <https://surmodics.gcs-web.com> and click on the webcast icon. The webcast will be archived on the Company's website for 90 days. A replay of the second quarter conference call will be available by dialing 888-203-1112 and entering conference call ID passcode 7350230. The audio replay will be available beginning at 7 p.m. CT on Wednesday, May 1, 2019, until 7 p.m. CT on Wednesday, May 8, 2019.

About Surmodics, Inc.

Surmodics is the global leader in surface modification technologies for intravascular medical devices and a leading provider of chemical components for in vitro diagnostic (IVD) immunoassay tests and microarrays. Surmodics is pursuing highly differentiated whole-product solutions that are designed to address unmet clinical needs for its medical device customers and engineered to the most demanding requirements. This key growth strategy leverages the combination of the Company's expertise in proprietary surface technologies, along with enhanced device design, development and manufacturing capabilities. The Company mission remains to improve the detection and treatment of disease. Surmodics is headquartered in Eden Prairie, Minnesota. For more information, visit www.surmodics.com. The content of Surmodics' website is not part of this press release or part of any filings that the company makes with the SEC.

Safe Harbor for Forward-Looking Statements

This press release contains forward-looking statements. Statements that are not historical or current facts, including statements about beliefs and expectations regarding the Company's performance in the near- and long-term, including our revenue and earnings expectations for fiscal 2019, our *SurVeil* DCB and other proprietary products, and the TRANSCEND clinical trial are forward-looking statements. Forward-looking statements involve inherent risks and uncertainties, and important factors could cause actual results to differ materially from those anticipated, including (1) our ability to successfully develop, timely complete clinical trials for, obtain regulatory approval for and, if approved, commercialize our *SurVeil* DCB (including realization of the full potential benefits of our agreement with Abbott), and other proprietary products; (2) our reliance on third parties (including our customers and licensees) and their failure to successfully develop, obtain regulatory approval for, market and sell products incorporating our technologies; (3) possible adverse market conditions and possible adverse impacts on our cash flows, and (4) the factors identified under "Risk Factors" in Part I, Item 1A of our Annual Report on Form 10-K for the fiscal year ended September 30, 2018, and updated in our subsequent reports filed with the SEC. These reports are available in the Investors section of our website at <https://surmodics.gcs-web.com> and at the SEC website at www.sec.gov. Forward-looking statements speak only as of the date they are made, and we undertake no obligation to update them in light of new information or future events.

Use of Non-GAAP Financial Information

In addition to reporting financial results in accordance with U.S. generally accepted accounting principles, or GAAP, Surmodics is reporting non-GAAP financial results including EBITDA and Adjusted EBITDA, non-GAAP operating income, non-GAAP income before income taxes, non-GAAP net income, and non-GAAP diluted earnings per share, and the non-GAAP effective income tax rate. We believe that these non-GAAP measures, when read in conjunction with the Company's GAAP financial statements, provide meaningful insight into our operating performance excluding certain event-specific matters, and provide an alternative perspective of our results of operations. We use non-GAAP measures, including those set forth in this release, to assess our operating performance and to determine payout under our executive compensation programs. We believe that presentation of certain non-GAAP measures allows investors to review our results of operations from the same perspective as management and our board of directors and facilitates comparisons of our current results of operations. The method we use to produce non-GAAP results is not in accordance with GAAP and may differ from the methods used by other companies. Non-GAAP results should not be regarded as a substitute for corresponding GAAP measures but instead should be utilized as a supplemental measure of operating performance in evaluating our business. Non-GAAP measures do have limitations in that they do not reflect certain items that may have a material impact on our reported financial results. As such, these non-GAAP measures should be viewed in conjunction with both our financial statements prepared in accordance with GAAP and the reconciliation of the supplemental non-GAAP financial measures to the comparable GAAP results provided for the specific periods presented, which are attached to this release.

Surmodics, Inc. and Subsidiaries
Condensed Consolidated Statements of Operations
(in thousands, except per share data)
(Unaudited)

	Three Months Ended		Six Months Ended	
	March 31,		March 31,	
	2019	2018	2019	2018
	(Unaudited)		(Unaudited)	
Revenue:				
Product sales	\$ 9,887	\$ 8,686	\$ 19,638	\$ 16,774
Royalties and license fees	9,932	8,428	20,028	15,504
Research, development and other	2,857	1,944	5,251	3,793
Total revenue	<u>22,676</u>	<u>19,058</u>	<u>44,917</u>	<u>36,071</u>
Operating costs and expenses:				
Product costs	3,093	2,913	6,616	5,804
Research and development	13,555	10,774	25,041	18,605
Selling, general and administrative	4,876	6,440	10,825	11,628
Acquired intangible asset amortization	604	636	1,210	1,254
Contingent consideration gain	(317)	(2,230)	(352)	(1,112)
Total operating costs and expenses	<u>21,811</u>	<u>18,533</u>	<u>43,340</u>	<u>36,179</u>
Operating income (loss)	865	525	1,577	(108)
Other income (loss), net	235	(211)	657	(99)
Income (loss) before income taxes	1,100	314	2,234	(207)
Income tax benefit	162	1,220	338	185
Net income (loss)	<u>\$ 1,262</u>	<u>\$ 1,534</u>	<u>\$ 2,572</u>	<u>\$ (22)</u>
Basic income (loss) per share:	\$ 0.09	\$ 0.12	\$ 0.19	\$ (0.00)
Diluted income (loss) per share:	\$ 0.09	\$ 0.11	\$ 0.19	\$ (0.00)
Weighted average number of shares outstanding:				
Basic	13,390	13,102	13,379	13,078
Diluted	13,785	13,465	13,816	13,078

Surmodics, Inc. and Subsidiaries
Condensed Consolidated Balance Sheets
(in thousands)
(Unaudited)

	March 31, 2019	September 30, 2018
	(Unaudited)	
Assets		
Current Assets:		
Cash and cash equivalents	\$ 22,470	\$ 23,318
Restricted cash	—	350
Available-for-sale securities	24,023	41,352
Accounts receivable, net	9,312	8,877
Contract assets - royalties and license fees	7,065	—
Inventories, net	4,345	4,016
Prepays and other	4,302	3,614
Total Current Assets	71,517	81,527
Property and equipment, net	29,512	30,143
Deferred tax assets	5,301	6,304
Intangible assets, net	16,020	17,683
Goodwill	26,549	27,032
Other assets	2,081	1,446
Total Assets	\$ 150,980	\$ 164,135
Liabilities and Stockholders' Equity		
Current Liabilities:		
Contingent consideration, current portion	3,009	11,041
Deferred revenue	6,385	9,646
Other current liabilities	10,950	14,446
Total Current Liabilities	20,344	35,133
Contingent consideration, less current portion	—	3,425
Deferred revenue, less current portion	10,470	11,247
Other long-term liabilities	4,853	5,720
Total Liabilities	35,667	55,525
Total Stockholders' Equity	115,313	108,610
Total Liabilities and Stockholders' Equity	\$ 150,980	\$ 164,135

Surmodics, Inc. and Subsidiaries
Supplemental Segment Information
(in thousands)
(Unaudited)

	Three Months Ended March 31,				% Change
	2019		2018		
	\$	% of Total	\$	% of Total	
Revenue:					
Medical Device	\$ 17,301	76.3%	\$ 14,052	73.7%	23.1%
In Vitro Diagnostics	5,375	23.7%	5,006	26.3%	7.4%
Total revenue	<u>\$ 22,676</u>		<u>\$ 19,058</u>		19.0%

	Six Months Ended March 31,				% Change
	2019		2018		
	\$	% of Total	\$	% of Total	
Revenue:					
Medical Device	\$ 34,559	76.9%	\$ 26,826	74.4%	28.8%
In Vitro Diagnostics	10,358	23.1%	9,245	25.6%	12.0%
Total revenue	<u>\$ 44,917</u>		<u>\$ 36,071</u>		24.5%

	Three Months Ended		Six Months Ended	
	March 31,		March 31,	
	2019	2018	2019	2018
Operating income (loss):				
Medical Device	\$ (23)	\$ 232	\$ 334	\$ (157)
In Vitro Diagnostics	2,915	2,423	5,370	4,093
Total segment operating income	2,892	2,655	5,704	3,936
Corporate	(2,027)	(2,130)	(4,127)	(4,044)
Total operating income (loss)	<u>\$ 865</u>	<u>\$ 525</u>	<u>\$ 1,577</u>	<u>\$ (108)</u>

Surmodics, Inc. and Subsidiaries
Reconciliation of GAAP Measures to Non-GAAP Amounts
Schedule of EBITDA, Adjusted EBITDA and Cash Flows from Operations
(in thousands)
(Unaudited)

	Three Months Ended		Six Months Ended	
	March 31,		March 31,	
	2019	2018	2019	2018
Net income (loss)	\$ 1,262	\$ 1,534	\$ 2,572	\$ (22)
Income tax benefit	(162)	(1,220)	(338)	(185)
Depreciation and amortization	1,819	1,586	3,575	3,106
Investment income, net	(265)	(142)	(581)	(263)
Interest expense	37	—	74	—
EBITDA	2,691	1,758	5,302	2,636
Adjustments:				
Contingent consideration gain (1)	(317)	(2,230)	(352)	(1,112)
Foreign exchange loss (gain) (2)	—	353	(126)	539
Gain on strategic investment (4)	—	—	(7)	(177)
Claim settlement (6)	(650)	1,000	(650)	1,000
Adjusted EBITDA	\$ 1,724	\$ 881	\$ 4,167	\$ 2,886
Net Cash Provided by (Used In) Operating Activities	\$ 1,467	\$ 26,817	\$ (3,938)	\$ 27,431

Estimated Non-GAAP Net Earnings per Common Share Guidance Reconciliation
For the Fiscal Year Ended September 30, 2019
(Unaudited)

	Full Fiscal Year Estimate	
	Low	High
GAAP results	\$ 0.14	\$ 0.24
Contingent consideration adjustments (1)	0.01	0.01
Foreign exchange gain on contingent consideration (2)	(0.01)	(0.01)
Amortization of acquired intangibles (3)	0.16	0.16
Claim settlement (6)	(0.04)	(0.04)
Non-GAAP results	\$ 0.26	\$ 0.36

Surmodics, Inc., and Subsidiaries
Net Income (Loss) and Diluted EPS GAAP to Non-GAAP Reconciliation
(in thousands, except per share data)
(Unaudited)

For the Three Months Ended March 31, 2019

	Total Revenue	Operating Income	Operating Income Percentage	Income Before Income Taxes	Net Income (7)	Diluted EPS	Effective tax rate
GAAP	\$ 22,676	\$ 865	3.8%	\$ 1,100	\$ 1,262	\$ 0.09	(14.7%)
Adjustments:							
Contingent consideration gain (1)	—	(317)	(1.4)	(317)	(317)	(0.02)	
Amortization of acquired intangible assets (3)	—	604	2.7	604	559	0.04	
Gain on strategic investment (4)	—	—	—	—	—	—	
Claim settlement (6)	—	(650)	(2.9)	(650)	(514)	(0.04)	
Non-GAAP	<u>\$ 22,676</u>	<u>\$ 502</u>	<u>2.2%</u>	<u>\$ 737</u>	<u>\$ 990</u>	<u>\$ 0.07</u>	<u>(34.3%)</u>

For the Three Months Ended March 31, 2018

	Total Revenue	Operating Income (Loss)	Operating Income Percentage	Income Before Income Taxes	Net Income (7)	Diluted EPS	Effective tax rate
GAAP	\$ 19,058	\$ 525	2.8%	\$ 314	\$ 1,534	\$ 0.11	(388.5%)
Adjustments:							
Contingent consideration gain (1)	—	(2,230)	(11.7)	(2,230)	(2,230)	(0.17)	
Foreign exchange loss on contingent consideration (2)	—	—	—	338	338	0.03	
Amortization of acquired intangible assets (3)	—	636	3.3	636	584	0.04	
Claim settlement (6)	—	1,000	5.2	1,000	755	0.06	
Non-GAAP	<u>\$ 19,058</u>	<u>\$ (69)</u>	<u>(0.4%)</u>	<u>\$ 58</u>	<u>\$ 981</u>	<u>\$ 0.07</u>	<u>(1591.4%)</u>

Surmodics, Inc., and Subsidiaries
Net Income (Loss) and Diluted EPS GAAP to Non-GAAP Reconciliation - Continued
(in thousands, except per share data)
(Unaudited)

For the Six Months Ended March 31, 2019

	Total Revenue	Operating Income	Operating Income Percentage	Income Before Income Taxes	Net Income (7)	Diluted EPS	Effective tax rate
GAAP	\$ 44,917	\$ 1,577	3.5%	\$ 2,234	\$ 2,572	\$ 0.19	(15.1%)
Adjustments:							
Contingent consideration gain (1)	—	(352)	(0.8)	(352)	(352)	(0.03)	
Foreign exchange gain (2)	—	—	—	(126)	(126)	(0.01)	
Amortization of acquired intangible assets (3)	—	1,210	2.7	1,210	1,121	0.08	
Gain on strategic investment (4)	—	—	—	(7)	(7)	(0.00)	
Claim settlement (6)	—	(650)	(1.4)	(650)	(514)	(0.04)	
Non-GAAP	<u>\$ 44,917</u>	<u>\$ 1,785</u>	<u>4.0%</u>	<u>\$ 2,309</u>	<u>\$ 2,694</u>	<u>\$ 0.19</u>	<u>(16.7%)</u>

For the Six Months Ended March 31, 2018

	Total Revenue	Operating (Loss) Income	Operating (Loss) Income Percentage	(Loss) Income Before Income Taxes	Net (Loss) Income (7)	Diluted EPS	Effective tax rate
GAAP	\$ 36,071	\$ (108)	(0.3%)	\$ (207)	\$ (22)	\$ (0.00)	89.4%
Adjustments:							
Contingent consideration gain (1)	—	(1,112)	(3.1)	(1,112)	(1,112)	(0.08)	
Foreign exchange loss (2)	—	—	—	518	518	0.04	
Amortization of acquired intangible assets (3)	—	1,254	3.5	1,254	1,150	0.09	
Gain on strategic investment (4)	—	—	—	(177)	(177)	(0.01)	
Tax reform impact (5)	—	—	—	—	1,246	0.09	
Claim settlement accrual (6)	—	1,000	2.8	1,000	755	0.06	
Non-GAAP	<u>\$ 36,071</u>	<u>\$ 1,034</u>	<u>2.9%</u>	<u>\$ 1,276</u>	<u>\$ 2,358</u>	<u>\$ 0.18</u>	<u>(84.8%)</u>

- (1) Represents accounting adjustments to state acquisition-related contingent consideration liabilities at their estimated fair value, including accretion for the passage of time as well as adjustments to the liabilities' fair values related to changes in the timing and/or probability of achieving milestones. The tables include contingent consideration liability adjustments in each respective historical period and do not include in future-period fair value changes, other than estimated accretion expense as determined at the end of the current quarter. These amounts are not taxable or tax deductible.
- (2) Foreign exchange gains and losses are related to marking non-U.S. dollar contingent consideration to period-end or settlement date exchange rates. The tables include foreign currency exchange loss or gain recorded in each respective historical period and do not include forecasted currency fluctuations in future periods. These gains and losses are not taxable or tax deductible.
- (3) Amortization of acquisition-related intangible assets and associated tax impact. A significant portion of the acquisition-related amortization is not tax deductible.
- (4) Represents the gain recognized on the sale of a strategic investment which was not tax-affected as it was offset by previously recognized capital losses.
- (5) Income tax expense from the re-measurement of net deferred tax assets recognized after the enactment of the Tax Cuts and Jobs Act in December 2017.
- (6) Represents a royalty-related customer claim accrued at \$1.0 million in the second quarter of fiscal 2018, settled in the second quarter of 2019 for \$0.4 million.
- (7) Net income (loss) includes the effect of the above adjustments on the income tax provision, taking into account deferred taxes and non-deductible items. Effective rates of 21% (fiscal 2019) and 24.5% (fiscal 2018) were used to estimate the income tax impact of the adjustments, except that expenses occurring in Ireland have not been tax-affected as all tax benefits are offset by a full valuation allowance.

CONTACT:

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