

**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**

October 31, 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 October 31, 2019, Surmodics, Inc. (the “Company”) issued a press release (the “Press Release”) announcing the results for the quarter ended September 30, 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.*

<u>Exhibit Number</u>	<u>Description</u>
99.1	Press Release dated October 31, 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: October 31, 2019

/s/ Timothy J. Arens

Timothy J. Arens
Vice President of Finance and Chief Financial
Officer

EXHIBIT INDEX

Exhibit Number	Description
99.1	Press Release dated October 31, 2019.

Surmodics Reports Fourth Quarter Fiscal 2019 Results and Issues Fiscal 2020 Revenue and EPS Guidance

EDEN PRAIRIE, Minn.--(BUSINESS WIRE)--October 31, 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 fourth quarter ended September 30, 2019, and provided its financial outlook for fiscal 2020.

Summary of Fourth Quarter and Recent Highlights

- Revenue of \$30.8 million, an increase of 33.8% year-over-year
- GAAP EPS of \$0.26, non-GAAP EPS of \$0.37
- Completed enrollment in TRANSCEND pivotal clinical trial for SurVeil™ drug-coated balloon (DCB)
- Completed enrollment in first in-human study for A vess™ arteriovenous (AV) access DCB
- Submitted application for first in-human study for Sundance™ below-the-knee DCB; granted “Breakthrough Device Designation” from the FDA
- Signed agreement with a leading multi-national medical device partner for worldwide distribution of Surmodics’ .014” and .018” low-profile PTA balloon catheters

“During fiscal 2019, we made important progress across our key strategic objectives while delivering strong organic revenue and solid operational results,” said Gary Maharaj, President and CEO of Surmodics, Inc. “In the face of unpredictability related to the Paclitaxel debate, our team has demonstrated impressive execution which included completing enrollment for our TRANSCEND clinical trial. I am excited by our achievements to date and look forward to continued progress in 2020.”

Fourth Quarter Fiscal 2019 Financial Results

Total revenue for the fourth quarter of fiscal 2019 was \$30.8 million, as compared with \$23.0 million in the prior-year period. Medical Device revenue was \$24.8 million in the fourth quarter of fiscal 2019, as compared with \$17.0 million in the year-ago period, an increase of 46%. Revenue in the fourth quarter includes \$7.6 million from our *SurVeil* agreement with Abbott, as compared with \$2.2 million in the prior-year quarter. In Vitro Diagnostics revenue was \$6.0 million for the fourth quarter of fiscal 2019 as compared with \$6.1 million in the same prior-year quarter, a decrease of 1%.

Diluted GAAP earnings per share in the fourth quarter of fiscal 2019 were \$0.26 as compared with a loss per share of \$(0.13) in the year-ago period. On a non-GAAP basis, earnings per share were \$0.37 in the fourth quarter of fiscal 2019, as compared with \$0.05 in the year-ago period.

As of September 30, 2019, cash and investments were \$55.3 million. Surmodics generated \$12.5 million of cash from operating activities in the fourth quarter of fiscal 2019. Capital expenditures totaled \$1.9 million for the fourth quarter of fiscal 2019.

Fiscal 2020 Guidance

Surmodics expects fiscal year 2020 revenue to range from \$87 million to \$91 million. The Company expects diluted EPS in the range of (\$0.60) to (\$0.30) per share, which reflects the Company's continued investment to advance its whole-product solutions strategy. Non-GAAP diluted EPS is expected to be in the range of (\$0.44) to (\$0.14) per share.

Conference Call

Surmodics will host a webcast at 4 p.m. CT (5 p.m. ET) today to discuss fourth 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 fourth quarter conference call will be available by dialing 888-203-1112 and entering conference call ID passcode 5795202. The audio replay will be available beginning at 7 p.m. CT on Thursday, October 31, 2019, until 7 p.m. CT on Thursday, November 7, 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 2020, 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		Years Ended	
	September 30,		September 30,	
	2019	2018	2019	2018
	(Unaudited)		(Unaudited)	
Revenue:				
Product sales	\$ 10,711	\$ 10,704	\$ 40,219	\$ 37,953
Royalties and license fees	16,806	10,323	48,458	35,424
Research, development and other	3,299	2,011	11,400	7,959
Total revenue	<u>30,816</u>	<u>23,038</u>	<u>100,077</u>	<u>81,336</u>
Operating costs and expenses:				
Product costs	3,659	4,089	13,639	13,997
Research and development	14,523	12,591	52,885	40,973
Selling, general and administrative	7,186	6,505	23,950	24,111
Acquired in-process research and development	890	—	890	7,888
Acquired intangible asset amortization	596	613	2,405	2,491
Contingent consideration expense (gain)	87	1,681	(161)	675
Total operating costs and expenses	<u>26,941</u>	<u>25,479</u>	<u>93,608</u>	<u>90,135</u>
Operating income (loss)	3,875	(2,441)	6,469	(8,799)
Other income, net	243	411	1,089	1,267
Income from operations before income taxes	4,118	(2,030)	7,558	(7,532)
Income tax benefit (provision)	(564)	277	34	3,075
Net income (loss)	<u>\$ 3,554</u>	<u>\$ (1,753)</u>	<u>\$ 7,592</u>	<u>\$ (4,457)</u>
Basic income (loss) per share:	\$ 0.27	\$ (0.13)	\$ 0.57	\$ (0.34)
Diluted income (loss) per share:	\$ 0.26	\$ (0.13)	\$ 0.55	\$ (0.34)
Weighted average number of shares outstanding:				
Basic	13,400	13,279	13,389	13,157
Diluted	13,769	13,279	13,779	13,157

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

	September 30,	
	2019	2018
	(Unaudited)	
Assets		
Current Assets:		
Cash and cash equivalents	\$ 30,361	\$ 23,318
Restricted cash	—	350
Available-for-sale securities	24,931	41,352
Accounts receivable, net	8,993	8,877
Contract assets - royalties and license fees	8,210	—
Inventories, net	4,501	4,016
Prepays and other	4,424	3,614
Total Current Assets	81,420	81,527
Property and equipment, net	29,748	30,143
Deferred tax assets	6,176	6,304
Intangible assets, net	14,226	17,683
Goodwill	26,171	27,032
Other assets	2,124	1,446
Total Assets	\$ 159,865	\$ 164,135
Liabilities and Stockholders' Equity		
Current Liabilities:		
Contingent consideration, current portion	3,200	11,041
Deferred revenue	5,553	9,646
Other current liabilities	11,456	14,446
Total Current Liabilities	20,209	35,133
Contingent consideration, less current portion	—	3,425
Deferred revenue	11,628	11,247
Other long-term liabilities	5,512	5,720
Total Liabilities	37,349	55,525
Total Stockholders' Equity	122,516	108,610
Total Liabilities and Stockholders' Equity	\$ 159,865	\$ 164,135

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

	Three Months Ended September 30				% Change
	2019		2018		
		% of Total		% of Total	
Revenue:					
Medical Device	\$ 24,849	80.6%	\$ 16,986	73.7%	46.3%
In Vitro Diagnostics	5,967	19.4%	6,052	26.3%	(1.4)%
Total revenue	<u>\$ 30,816</u>		<u>\$ 23,038</u>		33.8%
	Years Ended September 30,				% Change
	2019		2018		
		% of Total		% of Total	
Revenue:					
Medical Device	\$ 78,353	78.3%	\$ 60,513	74.4%	29.5%
In Vitro Diagnostics	21,724	21.7%	20,823	25.6%	4.3%
Total revenue	<u>\$ 100,077</u>		<u>\$ 81,336</u>		23.0%
	Three Months Ended September 30,		Years Ended September 30,		
	2019	2018	2019	2018	
Operating income (loss):					
Medical Device	\$ 3,707	\$ (2,127)	\$ 4,794	\$ (8,478)	
In Vitro Diagnostics	2,774	2,350	10,620	8,619	
Total segment operating income	<u>6,481</u>	<u>223</u>	<u>15,414</u>	<u>141</u>	
Corporate	(2,606)	(2,664)	(8,945)	(8,940)	
Total income (loss) from operations	<u>\$ 3,875</u>	<u>\$ (2,441)</u>	<u>\$ 6,469</u>	<u>\$ (8,799)</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		Years Ended	
	September 30,		September 30,	
	2019	2018	2019	2018
Net income (loss)	\$ 3,554	\$ (1,753)	\$ 7,592	\$ (4,457)
Income tax provision (benefit)	564	(277)	(34)	(3,075)
Depreciation and amortization	1,850	1,720	7,312	6,431
Investment income, net	(247)	(285)	(1,097)	(851)
Interest expense	40	—	152	—
EBITDA	<u>5,761</u>	<u>(595)</u>	<u>13,925</u>	<u>(1,952)</u>
Adjustments:				
Contingent consideration expense (gain) (1)	87	1,681	(161)	675
Foreign exchange loss (2)	—	(74)	(126)	(148)
Gain on strategic investment (4)	—	—	(7)	(177)
Acquired in-process research and development (5)	890	—	890	7,888
Claim settlement accrual (6)	—	—	(650)	1,000
Asset impairment (7)	256	—	256	—
Adjusted EBITDA	<u>\$ 6,994</u>	<u>\$ 1,012</u>	<u>\$ 14,127</u>	<u>\$ 7,286</u>
Net Cash Provided by Operating Activities	<u>\$ 12,520</u>	<u>\$ 4,830</u>	<u>\$ 8,038</u>	<u>\$ 34,052</u>

Estimated Non-GAAP Net Earnings per Common Share Guidance Reconciliation
For the Fiscal Year Ended September 30, 2020
(Unaudited)

	Fiscal 2020 Full-Year Estimate	
	Low	High
GAAP results	\$ (0.60)	\$ (0.30)
Amortization of acquired intangibles (3)	0.16	0.16
Non-GAAP results	<u>\$ (0.44)</u>	<u>\$ (0.14)</u>

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 September 30, 2019

	<u>Total Revenue</u>	<u>Operating Income</u>	<u>Operating Income Percentage</u>	<u>Income Before Income Taxes</u>	<u>Net Income (10)</u>	<u>Diluted EPS</u>	<u>Effective tax rate</u>
GAAP	\$ 30,816	\$ 3,875	12.6%	\$ 4,118	\$ 3,554	\$ 0.26	13.7%
Adjustments:							
Contingent consideration expense (1)	—	87	0.3	87	87	0.01	
Amortization of acquired intangible assets (3)	—	596	1.9	596	551	0.04	
Acquired in-process research and development (5)	—	890	2.9	890	703	0.05	
Asset impairment (7)	—	256	0.8	256	256	0.02	
Non-GAAP	<u>\$ 30,816</u>	<u>\$ 5,704</u>	<u>18.5%</u>	<u>\$ 5,947</u>	<u>\$ 5,151</u>	<u>\$ 0.37</u>	<u>13.4%</u>

For the Three Months Ended September 30, 2018

	<u>Total Revenue</u>	<u>Operating (Loss) Income</u>	<u>Operating (Loss) Income Percentage</u>	<u>(Loss) Income Before Income Taxes</u>	<u>Net (Loss) Income (10)</u>	<u>Diluted EPS</u>	<u>Effective tax rate</u>
GAAP	\$ 23,038	\$ (2,441)	(10.6)%	\$ (2,030)	\$ (1,753)	\$ (0.13)	13.6%
Adjustments:							
Contingent consideration expense (1)	—	1,681	7.3	1,681	1,681	0.13	
Foreign exchange gain (2)	—	—	—	(74)	(74)	(0.01)	
Amortization of acquired intangible assets (3)	—	613	2.7	613	561	0.04	
Tax reform impact (8)	—	—	—	—	327	0.02	
Dilutive effect of outstanding stock awards (9)	—	—	—	—	—	(0.01)	
Non-GAAP	<u>\$ 23,038</u>	<u>\$ (147)</u>	<u>(0.6)%</u>	<u>\$ 190</u>	<u>\$ 742</u>	<u>\$ 0.05</u>	<u>(290.5)%</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 Year Ended September 30, 2019

	<u>Total Revenue</u>	<u>Operating Income</u>	<u>Operating Income Percentage</u>	<u>Income Before Income Taxes</u>	<u>Net Income (10)</u>	<u>Diluted EPS</u>	<u>Effective tax rate</u>
GAAP	\$ 100,077	\$ 6,469	6.5%	\$ 7,558	\$ 7,592	\$ 0.55	(0.4)%
Adjustments:							
Contingent consideration gain (1)	—	(161)	(0.2)	(161)	(161)	(0.01)	
Foreign exchange gain on contingent consideration (2)	—	—	—	(126)	(126)	(0.01)	
Amortization of acquired intangible assets (3)	—	2,405	2.4	2,405	2,226	0.16	
Gain on strategic investment (4)	—	—	—	(7)	(7)	(0.00)	
Acquired in-process research and development (5)	—	890	0.9	890	703	0.05	
Claim settlement (6)	—	(650)	(0.6)	(650)	(514)	(0.04)	
Asset impairment (7)	—	256	0.2	256	256	0.02	
Non-GAAP	<u>\$ 100,077</u>	<u>\$ 9,209</u>	<u>9.2%</u>	<u>\$ 10,165</u>	<u>\$ 9,969</u>	<u>\$ 0.72</u>	<u>1.9%</u>

For the Year Ended September 30, 2018

	<u>Total Revenue</u>	<u>Operating (Loss) Income</u>	<u>Operating (Loss) Income Percentage</u>	<u>(Loss) Income Before Income Taxes</u>	<u>Net (Loss) Income (10)</u>	<u>Diluted EPS</u>	<u>Effective tax rate</u>
GAAP	\$ 81,336	\$ (8,799)	(10.8)%	\$ (7,532)	\$ (4,457)	\$ (0.34)	40.8%
Adjustments:							
Contingent consideration expense (1)	—	675	0.8	675	675	0.05	
Foreign exchange gain on contingent consideration (2)	—	—	—	(148)	(148)	(0.01)	
Amortization of acquired intangible assets (3)	—	2,491	3.1	2,491	2,282	0.17	
Gain on strategic investment (4)	—	—	—	(177)	(177)	(0.01)	
Acquired in-process research and development (5)	—	7,888	9.7	7,888	6,232	0.47	
Claim settlement accrual (6)	—	1,000	1.2	1,000	755	0.06	
Tax reform impact (8)	—	—	—	—	1,573	0.12	
Dilutive effect of outstanding stock awards (9)	—	—	—	—	—	(0.02)	
Non-GAAP	<u>\$ 81,336</u>	<u>\$ 3,255</u>	<u>4.0%</u>	<u>\$ 4,197</u>	<u>\$ 6,735</u>	<u>\$ 0.49</u>	<u>(60.5)%</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) Represents acquisitions of in-process research and development assets during the fourth quarter of fiscal 2019 and the third quarter of fiscal 2018, net of the associated tax impact
- (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) Impairment of indefinite-lived intangible assets which were not tax deductible.
- (8) 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.
- (9) Options to purchase common stock as well as unvested restricted stock and performance stock units are considered to be potentially dilutive common shares but have been excluded from the calculation of GAAP net loss per share as their effect is anti-dilutive for the three and twelve months ended September 30, 2018 as a result of the net loss for these periods on a GAAP basis. However, as the Non-GAAP adjustments result in Non-GAAP net income for both periods, the dilutive effect of these options and other outstanding stock awards have been included in the calculation of Non-GAAP earnings per share. Accordingly, Diluted Non-GAAP EPS includes these adjustments.
- (10) 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.

Contacts

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