

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

November 9, 2018

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 November 9, 2018, Surmodics, Inc. (the “Company”) issued a press release (the “Press Release”) announcing the results for the quarter ended September 30, 2018. 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 November 9, 2018.

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: November 9, 2018

/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
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99.1	Press Release dated November 9, 2018.
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Surmodics Reports Fourth Quarter Fiscal 2018 Results and Issues Fiscal 2019 Guidance

EDEN PRAIRIE, Minn.--(BUSINESS WIRE)--November 9, 2018--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 2018 fourth quarter ended September 30, 2018, and provided its financial outlook for fiscal 2019.

Summary of Fourth Quarter Fiscal 2018 Highlights and Fiscal 2019 Guidance

- Revenue of \$23.0 million, an increase of 15% year-over-year
- GAAP EPS of (\$0.13), non-GAAP EPS of \$0.05
- Submitted application for first in-human study for arteriovenous (AV) access drug coated balloon (DCB)
- Fiscal 2019 revenue outlook of \$92.0 to \$97.0 million, GAAP EPS outlook of (\$0.32) to (\$0.02)

“We continue to drive strong revenue growth and solid operational performance as we execute on our strategic objectives,” said Gary Maharaj, President & CEO of Surmodics. “The positive twelve-month data recently presented from PREVEIL, the early feasibility study of our SurVeil[®] DCB and the recent submission for first in-human study for our AV access DCB, AVess[™], demonstrate meaningful progress towards our whole-products solutions initiatives.”

Fourth Quarter Fiscal 2018 Financial Results

Total revenue for the fourth quarter of fiscal 2018 was \$23.0 million, as compared with \$20.1 million in the prior-year period. Medical Device revenue was \$17.0 million in the fourth quarter of fiscal 2018, as compared with \$14.7 million in the year-ago period, an increase of 15.4%, and includes \$2.2 million from our *SurVeil* agreement with Abbott. In Vitro Diagnostics revenue was \$6.1 million for the fourth quarter of fiscal 2018 as compared with \$5.3 million in the same prior-year quarter, an increase of 13.4%.

Diluted GAAP loss per share in the fourth quarter of fiscal 2018 was \$(0.13) as compared with diluted GAAP earnings per share of \$0.03 in the year-ago period. On a non-GAAP basis, earnings per share were \$0.05 in the fourth quarter of fiscal 2018, as compared with \$0.18 in the year-ago period.

As of September 30, 2018, cash and investments were \$65.0 million. Surmodics generated cash from operating activities of \$34.1 million in fiscal 2018. Capital expenditures totaled \$9.0 million for fiscal 2018.

Fiscal 2019 Outlook

Surmodics expects fiscal year 2019 revenue to range from \$92 million to \$97 million. The Company expects diluted EPS in the range of (\$0.32) to (\$0.02) per share, which reflects the Company's continued investment in research and development to further its whole-product solutions strategy. Non-GAAP diluted EPS is expected to be in the range of (\$0.07) to \$0.23 per share.

Conference Call

Surmodics will host a webcast at 7:30 a.m. CT (8:30 a.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 1123199. The audio replay will be available beginning at 10:30 a.m. CT on Friday, November 9, 2018, until 10:30 a.m. CT on Friday, November 16, 2018.

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, and our *SurVeil* DCB and other proprietary products 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, obtain regulatory approval for, and 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, 2017, 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 (loss) 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,	
	2018	2017	2018	2017
	(Unaudited)		(Unaudited)	
Revenue:				
Product sales	\$ 10,704	\$ 8,826	\$ 37,953	\$ 32,790
Royalties and license fees	10,323	9,223	35,424	31,787
Research, development and other	2,011	2,009	7,959	8,535
Total revenue	<u>23,038</u>	<u>20,058</u>	<u>81,336</u>	<u>73,112</u>
Operating costs and expenses:				
Product costs	4,089	3,317	13,997	11,422
Research and development	12,591	9,713	40,973	31,817
Selling, general and administrative	6,505	5,307	24,111	20,478
Acquired in-process research and development	—	—	7,888	—
Acquired intangible asset amortization	613	629	2,491	2,419
Contingent consideration expense (gain)	1,681	676	675	(127)
Total operating costs and expenses	<u>25,479</u>	<u>19,642</u>	<u>90,135</u>	<u>66,009</u>
Operating (loss) income	(2,441)	416	(8,799)	7,103
Other income (loss), net	411	(224)	1,267	(70)
(Loss) income from operations before income taxes	(2,030)	192	(7,532)	7,033
Income tax benefit (provision)	277	208	3,075	(3,107)
Net (loss) income	<u>\$ (1,753)</u>	<u>\$ 400</u>	<u>\$ (4,457)</u>	<u>\$ 3,926</u>
Basic (loss) income per share:	\$ (0.13)	\$ 0.03	\$ (0.34)	\$ 0.30
Diluted (loss) income per share:	\$ (0.13)	\$ 0.03	\$ (0.34)	\$ 0.29
Weighted average number of shares outstanding:				
Basic	13,279	13,041	13,157	13,153
Diluted	13,279	13,365	13,157	13,389

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

	September 30,	
	2018	2017
	(Unaudited)	
Assets		
Current Assets:		
Cash and cash equivalents	\$ 23,318	\$ 16,534
Restricted cash	350	—
Available-for-sale securities	41,352	31,802
Accounts receivable, net	8,877	7,211
Inventories, net	4,016	3,516
Prepays and other	3,614	1,820
Total Current Assets	81,527	60,883
Property and equipment, net	30,143	22,942
Deferred tax assets	6,304	4,027
Intangible assets, net	17,683	20,562
Goodwill	27,032	27,282
Other assets	1,446	897
Total Assets	\$ 164,135	\$ 136,593
Liabilities and Stockholders' Equity		
Current Liabilities:		
Contingent consideration, current portion	11,041	1,750
Deferred revenue	9,646	62
Other current liabilities	14,446	7,991
Total Current Liabilities	35,133	9,803
Contingent consideration, less current portion	3,425	13,114
Deferred revenue	11,247	181
Other long-term liabilities	5,720	1,938
Total Liabilities	55,525	25,036
Total Stockholders' Equity	108,610	111,557
Total Liabilities and Stockholders' Equity	\$ 164,135	\$ 136,593

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

	Three Months Ended September 30				% Change
	2018		2017		
Revenue:	% of Total		% of Total		
Medical Device	\$ 16,986	73.7%	\$ 14,723	73.4%	15.4%
In Vitro Diagnostics	6,052	26.3%	5,335	26.6%	13.4%
Total revenue	<u>\$ 23,038</u>		<u>\$ 20,058</u>		14.9%
	Years Ended September 30,				
	2018		2017		
Revenue:	% of Total		% of Total		% Change
Medical Device	\$ 60,513	74.4%	\$ 53,983	73.8%	12.1%
In Vitro Diagnostics	20,823	25.6%	19,129	26.2%	8.9%
Total revenue	<u>\$ 81,336</u>		<u>\$ 73,112</u>		11.2%
	Three Months Ended September 30,		Years Ended September 30,		
	2018	2017	2018	2017	
Operating (loss) income:					
Medical Device	\$ (2,127)	\$ 276	\$ (8,478)	\$ 6,902	
In Vitro Diagnostics	2,350	2,371	8,619	8,293	
Total segment operating income	223	2,647	141	15,195	
Corporate	(2,664)	(2,231)	(8,940)	(8,092)	
Total (loss) income from operations	<u>\$ (2,441)</u>	<u>\$ 416</u>	<u>\$ (8,799)</u>	<u>\$ 7,103</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,	
	2018	2017	2018	2017
Net (loss) income	\$ (1,753)	\$ 400	\$ (4,457)	\$ 3,926
Income tax (benefit) provision	(277)	(208)	(3,075)	3,107
Depreciation and amortization	1,720	1,549	6,431	5,555
Investment income, net	(285)	(116)	(851)	(390)
EBITDA	(595)	1,625	(1,952)	12,198
Adjustments:				
Contingent consideration expense (gain) (1)	1,681	676	675	(127)
Foreign exchange (gain) loss (2)	(74)	347	(148)	474
Gain on strategic investment (4)	—	(43)	(177)	(43)
Claim settlement accrual (6)	—	—	1,000	—
Acquired in-process research and development (7)	—	—	7,888	—
Asset impairment (8)	—	427	—	427
Adjusted EBITDA	\$ 1,012	\$ 3,032	\$ 7,286	\$ 12,929
 Net Cash Provided by Operating Activities	 \$ 4,830	 \$ 6,397	 \$ 34,052	 \$ 14,053

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

	Fiscal 2019 Full-Year Estimate	
	Low	High
GAAP results	\$ (0.32)	\$ (0.02)
Contingent consideration adjustments (1)	0.08	0.08
Amortization of acquired intangibles (3)	0.17	0.17
Non-GAAP results	\$ (0.07)	\$ 0.23

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

For the Three Months Ended September 30, 2018

	Total Revenue	Operating (Loss) Income	Operating (Loss) Income Percentage	(Loss) Income Before Income Taxes	Net (Loss) Income (10)	Diluted EPS	Effective tax rate
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 (5)	—	—	—	—	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>

For the Three Months Ended September 30, 2017

	Total Revenue	Operating Income	Operating Income Percentage	Income Before Income Taxes	Net Income (10)	Diluted EPS	Effective tax rate
GAAP	\$ 20,058	\$ 416	2.1%	\$ 192	\$ 400	\$ 0.03	(108.3)%
Adjustments:							
Contingent consideration expense (1)	—	676	3.4	676	676	0.05	
Foreign exchange loss (2)	—	—	—	347	347	0.03	
Amortization of acquired intangible assets (3)	—	629	3.1	629	550	0.04	
Gain on strategic investment (4)	—	—	—	(43)	(43)	(0.00)	
Asset impairment (8)	—	427	2.1	427	427	0.03	
Non-GAAP	<u>\$ 20,058</u>	<u>\$ 2,148</u>	<u>10.7%</u>	<u>\$ 2,228</u>	<u>\$ 2,357</u>	<u>\$ 0.18</u>	<u>(5.8)%</u>

For the Year Ended September 30, 2018

	Total Revenue	Operating (Loss) Income	Operating (Loss) Income Percentage	(Loss) Income Before Income Taxes	Net (Loss) Income (10)	Diluted EPS	Effective tax rate
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 (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)	
Tax reform impact (5)	—	—	—	—	1,573	0.12	
Claim settlement accrual (6)	—	1,000	1.2	1,000	755	0.06	
Acquired in-process research and development (7)	—	7,888	9.7	7,888	6,232	0.47	
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>

For the Year Ended September 30, 2017

	Total Revenue	Operating Income	Operating Income Percentage	Income Before Income Taxes	Net Income (10)	Diluted EPS	Effective tax rate
GAAP	\$ 73,112	\$ 7,103	9.7%	\$ 7,033	\$ 3,926	\$ 0.29	44.2%
Adjustments:							
Contingent consideration gain (1)	—	(127)	(0.2)	(127)	(127)	(0.01)	
Foreign exchange loss (2)	—	—	—	474	474	0.04	
Amortization of acquired intangible assets (3)	—	2,419	3.3	2,419	2,105	0.16	
Gain on strategic investment (4)	—	—	—	(43)	(43)	(0.00)	
Asset impairment (8)	—	427	0.6	427	427	0.03	
Non-GAAP	<u>\$ 73,112</u>	<u>\$ 9,822</u>	<u>13.4%</u>	<u>\$ 10,183</u>	<u>\$ 6,762</u>	<u>\$ 0.51</u>	<u>33.6%</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 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 an estimated royalty-related customer claim settlement accrued in the second quarter of fiscal 2018 and associated tax impact.
- (7) Represents the acquisition of the Embolitech in-process research and development assets during the third quarter of fiscal 2018 and associated tax impact.
- (8) Impairment of indefinite-lived intangible assets which were not tax deductible.
- (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 three months and year ended September 30, 2018 as a result of the net loss for those periods on a GAAP basis. However, as the Non-GAAP adjustments result in Non-GAAP net income, 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 EPS includes these adjustments.
- (10) Net (loss) income includes the effect of the above adjustments on the income tax provision, taking into account deferred taxes and non-deductible items. Effective rates of 24.5% (fiscal 2018) and between 34-35% (fiscal 2017) 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 and acquired in-process research and development, which will be deductible at a 21% statutory tax rate.

CONTACT:

Surmodics, Inc.

Tim Arens, 952-500-7000

ir@surmodics.com