

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

August 6, 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 August 6, 2018, Surmodics, Inc. (the “Company”) issued a press release (the “Press Release”) announcing the results for the quarter ended June 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*

<u>Exhibit Number</u>	<u>Description</u>
99.1	Press Release dated August 6, 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: August 6, 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 August 6, 2018.
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Surmodics Reports Third Quarter Fiscal 2018 Results

Raises Fiscal 2018 Revenue Guidance

EDEN PRAIRIE, Minn.--(BUSINESS WIRE)--August 6, 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 third quarter ended June 30, 2018, and updated its financial outlook for fiscal 2018.

Summary of Third Quarter Fiscal 2018 and Recent Highlights

- Revenue of \$22.2 million, up 24.9%
- Raising revenue guidance range to \$79.0 to \$81.0 million
- GAAP EPS of \$(0.20), Non-GAAP EPS of \$0.27
- Acquisition of thrombectomy platform strengthens product pipeline

“We are pleased to report strong operating performance and meaningful advances on our strategic objectives during the quarter,” said Gary Maharaj, President and CEO of Surmodics. “We are on track to complete enrollment in our TRANSCEND U.S. pivotal clinical trial in fiscal 2019. The acquisition of Embolitech’s promising thrombectomy technology platform leverages our unique capabilities and advances our focus on developing highly differentiated products.”

Third Quarter Fiscal 2018 Financial Results

Total revenue for the third quarter of fiscal 2018 was \$22.2 million, as compared with \$17.8 million in the prior-year period. Medical Device revenue was \$16.7 million in the third quarter of fiscal 2018, as compared with \$12.8 million in the year-ago period, an increase of 30.7%, and includes \$1.7 million from our SurVeil[®] agreement with Abbott. In Vitro Diagnostics revenue was \$5.5 million for the third quarter of fiscal 2018 as compared with \$5.0 million in the same prior-year quarter, an increase of 10.3%.

Diluted GAAP loss per share in the third quarter of fiscal 2018 was \$(0.20) as compared with diluted GAAP earnings per share of \$0.05 in the year-ago period. On a non-GAAP basis, earnings per share were \$0.27 in the third quarter of fiscal 2018, as compared with \$0.09 in the year-ago period. GAAP results were negatively affected by the current-quarter acquisition of in-process research and development assets from Embolitech, which resulted in a \$0.47 charge in the period, after tax.

As of June 30, 2018, cash and investments were \$62.4 million. Surmodics generated cash from operating activities of \$29.2 million in the first nine months of fiscal 2018. Capital expenditures totaled \$6.9 million for the first nine months of fiscal 2018.

Fiscal 2018 Guidance Revised

As a result of revenue performance in the first nine months of fiscal 2018 and to reflect the Embolitech technology acquisition, Surmodics is raising its fiscal 2018 revenue and non-GAAP earnings guidance, while narrowing its diluted GAAP earnings guidance. Surmodics expects fiscal year 2018 revenue to range from \$79.0 million to \$81.0 million, up from previous expectations in the range of \$75.0 million to \$79.0 million. The Company expects diluted loss in the range of (\$0.25) to (\$0.30) per share as compared with the prior guidance of (\$0.20) to (\$0.35) per share. Non-GAAP diluted earnings guidance now ranges from \$0.39 to \$0.44 per share as compared with prior guidance of (\$0.06) to \$0.09 per share.

Conference Call

Surmodics will host a webcast at 7:30 a.m. CT (8:30 a.m. ET) today to discuss third 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 third quarter conference call will be available by dialing 888-203-1112 and entering conference call ID passcode 8313933. The audio replay will be available beginning at 10:30 a.m. CT on Monday, August 6, 2018, until 10:30 a.m. CT on Monday, August 13, 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 2018, and our *SurVeil* DCB and other proprietary products, including the timing, impact and success of 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, 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 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		Nine Months Ended	
	June 30,		June 30,	
	2018	2017	2018	2017
	(Unaudited)		(Unaudited)	
Revenue:				
Product sales	\$ 10,475	\$ 8,327	\$ 27,249	\$ 23,964
Royalties and license fees	9,597	7,244	25,101	22,564
Research, development and other	2,155	2,219	5,948	6,526
Total revenue	<u>22,227</u>	<u>17,790</u>	<u>58,298</u>	<u>53,054</u>
Operating costs and expenses:				
Product costs	4,104	2,914	9,908	8,104
Research and development	9,778	7,927	28,383	22,105
Selling, general and administrative	5,977	5,232	17,606	15,170
Acquired in-process research and development	7,888	—	7,888	—
Acquired intangible asset amortization	624	603	1,878	1,790
Contingent consideration expense (gain)	106	(629)	(1,006)	(803)
Total operating costs and expenses	<u>28,477</u>	<u>16,047</u>	<u>64,657</u>	<u>46,366</u>
Operating (loss) income	(6,250)	1,743	(6,359)	6,688
Other income (loss), net	955	(490)	856	153
(Loss) Income before income taxes	(5,295)	1,253	(5,503)	6,841
Income tax benefit (provision)	2,613	(533)	2,799	(3,315)
Net (loss) income	<u>\$ (2,682)</u>	<u>\$ 720</u>	<u>\$ (2,704)</u>	<u>\$ 3,526</u>
Basic (loss) income per share:	\$ (0.20)	\$ 0.05	\$ (0.21)	\$ 0.27
Diluted (loss) income per share:	\$ (0.20)	\$ 0.05	\$ (0.21)	\$ 0.26
Weighted average number of shares outstanding:				
Basic	13,203	13,155	13,117	13,190
Diluted	13,203	13,385	13,117	13,404

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

	June 30, 2018	September 30, 2017
Assets		(Unaudited)
Current Assets:		
Cash and cash equivalents	\$ 27,273	\$ 16,534
Restricted cash	350	—
Available-for-sale securities	34,760	31,802
Accounts receivable, net	8,312	7,211
Inventories, net	3,975	3,516
Prepays and other	4,176	1,820
Total Current Assets	78,846	60,883
Property and equipment, net	27,976	22,942
Deferred tax assets	5,981	4,027
Intangible assets, net	18,430	20,562
Goodwill	27,132	27,282
Other assets	1,622	897
Total Assets	\$ 159,987	\$ 136,593
Liabilities and Stockholders' Equity		
Current Liabilities:		
Contingent consideration, current portion	11,708	1,750
Deferred revenue	10,319	62
Other current liabilities	9,558	7,991
Total Current Liabilities	31,585	9,803
Contingent consideration, less current portion	1,151	13,114
Deferred revenue, less current portion	12,825	181
Other long-term liabilities	5,681	1,938
Total Liabilities	51,242	25,036
Total Stockholders' Equity	108,745	111,557
Total Liabilities and Stockholders' Equity	\$ 159,987	\$ 136,593

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

	Three Months Ended June 30,						% Change
	2018		2017		% of Total	% of Total	
	\$	% of Total	\$	% of Total			
Revenue:							
Medical Device	\$ 16,701	75.1%	\$ 12,778	71.8%		30.7%	
In Vitro Diagnostics	5,526	24.9%	5,012	28.2%		10.3%	
Total revenue	<u>\$ 22,227</u>		<u>\$ 17,790</u>			24.9%	
	Nine Months Ended June 30,						
	2018		2017		% of Total	% of Total	
	\$	% of Total	\$	% of Total			
Revenue:							
Medical Device	\$ 43,527	74.7%	\$ 39,260	74.0%		10.9%	
In Vitro Diagnostics	14,771	25.3%	13,794	26.0%		7.1%	
Total revenue	<u>\$ 58,298</u>		<u>\$ 53,054</u>			9.9%	
	Three Months Ended		Nine Months Ended				
	June 30,		June 30,				
	2018	2017	2018	2017			
Operating (loss) income:							
Medical Device	\$ (6,193)	\$ 1,403	\$ (6,351)	\$ 6,627			
In Vitro Diagnostics	2,176	2,230	6,269	5,922			
Total segment operating (loss) income	(4,017)	3,633	(82)	12,549			
Corporate	(2,233)	(1,890)	(6,277)	(5,861)			
Total operating (loss) income	<u>\$ (6,250)</u>	<u>\$ 1,743</u>	<u>\$ (6,359)</u>	<u>\$ 6,688</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		Nine Months Ended	
	June 30,		June 30,	
	2018	2017	2018	2017
Net (loss) income	\$ (2,682)	\$ 720	\$ (2,704)	\$ 3,526
Income tax (benefit) provision	(2,613)	533	(2,799)	3,315
Depreciation and amortization	1,605	1,405	4,711	4,006
Investment income, net	(303)	(104)	(566)	(274)
EBITDA	(3,993)	2,554	(1,358)	10,573
Adjustments:				
Contingent consideration expense (gain) (1)	106	(629)	(1,006)	(803)
Foreign exchange (gain) loss (2)	(592)	594	(74)	121
Gain on strategic investment (4)	—	—	(177)	—
Claim settlement accrual (6)	—	—	1,000	—
Acquired in-process research and development (7)	7,888	—	7,888	—
Adjusted EBITDA	\$ 3,409	\$ 2,519	\$ 6,273	\$ 9,891
Net Cash Provided by Operating Activities	\$ 1,791	\$ 3,393	\$ 29,222	\$ 7,656

Estimated Non-GAAP Net Earnings per Common Share Guidance Reconciliation
For the Fiscal Year Ended September 30, 2018
(Unaudited)

	Full Fiscal Year Estimate	
	Low	High
GAAP results	\$ (0.30)	\$ (0.25)
Contingent consideration gain (1)	(0.08)	(0.08)
Foreign exchange gain (2)	(0.01)	(0.01)
Amortization of acquired intangibles (3)	0.18	0.18
Gain on strategic investment (4)	(0.01)	(0.01)
Tax reform impact (5)	0.09	0.09
Claim settlement accrual (6)	0.06	0.06
Acquired in-process research and development (7)	0.47	0.47
Dilutive effect of outstanding stock awards (8)	(0.01)	(0.01)
Non-GAAP results	\$ 0.39	\$ 0.44

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 June 30, 2018

	Total Revenue	Operating (Loss) Income	Operating (Loss) Income Percentage	(Loss) Income Before Income Taxes	Net (Loss) Income (9)	Diluted EPS	Effective tax rate
GAAP	\$ 22,227	\$ (6,250)	(28.1%)	\$ (5,295)	\$ (2,682)	\$ (0.20)	49.3%
Adjustments:							
Contingent consideration expense (1)	—	106	0.5	106	106	0.01	
Foreign exchange gain (2)	—	—	—	(592)	(592)	(0.04)	
Amortization of acquired intangible assets (3)	—	624	2.8	624	584	0.04	
Acquired in-process research and development (7)	—	7,888	35.5	7,888	6,232	0.47	
Dilutive effect of outstanding stock awards (8)	—	—	—	—	—	(0.01)	
Non-GAAP	<u>\$ 22,227</u>	<u>\$ 2,368</u>	<u>10.7%</u>	<u>\$ 2,731</u>	<u>\$ 3,648</u>	<u>\$ 0.27</u>	<u>(33.6%)</u>

For the Three Months Ended June 30, 2017

	Total Revenue	Operating Income	Operating Income Percentage	Income Before Income Taxes	Net Income (9)	Diluted EPS	Effective tax rate
GAAP	\$ 17,790	\$ 1,743	9.8%	\$ 1,253	\$ 720	\$ 0.05	42.5%
Adjustments:							
Contingent consideration accretion gain (1)	—	(629)	(3.5)	(629)	(629)	(0.05)	
Foreign exchange loss (2)	—	—	—	594	594	0.05	
Amortization of acquired intangible assets (3)	—	603	3.4	603	524	0.04	
Non-GAAP	<u>\$ 17,790</u>	<u>\$ 1,717</u>	<u>9.7%</u>	<u>\$ 1,821</u>	<u>\$ 1,209</u>	<u>\$ 0.09</u>	<u>33.6%</u>

For the Nine Months Ended June 30, 2018

	Total Revenue	Operating (Loss) Income	Operating (Loss) Income Percentage	(Loss) Income Before Income Taxes	Net (Loss) Income (9)	Diluted EPS	Effective tax rate
GAAP	\$ 58,298	\$ (6,359)	(10.9%)	\$ (5,503)	\$ (2,704)	\$ (0.21)	50.9%
Adjustments:							
Contingent consideration gain (1)	—	(1,006)	(1.7)	(1,006)	(1,006)	(0.08)	
Foreign exchange gain (2)	—	—	—	(74)	(74)	(0.01)	
Amortization of acquired intangible assets (3)	—	1,878	3.2	1,878	1,721	0.13	
Gain on strategic investment (4)	—	—	—	(177)	(177)	(0.01)	
Tax reform impact (5)	—	—	—	—	1,246	0.09	
Claim settlement accrual (6)	—	1,000	1.7	1,000	755	0.06	
Acquired in-process research and development (7)	—	7,888	13.5	7,888	6,232	0.47	
Dilutive effect of outstanding stock awards (8)	—	—	—	—	—	(0.01)	
Non-GAAP	<u>\$ 58,298</u>	<u>\$ 3,401</u>	<u>5.8%</u>	<u>\$ 4,006</u>	<u>\$ 5,993</u>	<u>\$ 0.44</u>	<u>(49.6%)</u>

For the Nine Months Ended June 30, 2017

	Total Revenue	Operating Income	Operating Income Percentage	Income Before Income Taxes	Net Income (9)	Diluted EPS	Effective tax rate
GAAP	\$ 53,054	\$ 6,688	12.6%	\$ 6,841	\$ 3,526	\$ 0.26	48.5%
Adjustments:							
Contingent consideration gain (1)	—	(803)	(1.5)	(803)	(803)	(0.06)	
Foreign exchange loss (2)	—	—	—	121	121	0.01	
Amortization of acquired intangible assets (3)	—	1,790	3.4	1,790	1,554	0.12	
Non-GAAP	<u>\$ 53,054</u>	<u>\$ 7,675</u>	<u>14.5%</u>	<u>\$ 7,949</u>	<u>\$ 4,398</u>	<u>\$ 0.33</u>	<u>44.7%</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.
- (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 as of June 30, 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) 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 nine months ended June 30, 2018 and in our guidance for the year 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, 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.
- (9) 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 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 is calculated using a 21% effective tax rate.

CONTACT:

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