

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

February 2, 2017

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))

Item 2.02 Results of Operations And Financial Condition.

On February 2, 2017, Surmodics, Inc. (the “Company”) issued a press release (the “Press Release”) announcing the results for the quarter ended December 31, 2016. 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 February 2, 2017.

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: February 2, 2017

/s/ Andrew D. C. LaFrence

Andrew D. C. LaFrence

Vice President, Finance and Information Systems,
and Chief Financial Officer

EXHIBIT INDEX

**Exhibit
Number**

Description

99.1

Press Release dated February 2, 2017.

Surmodics Reports First Quarter Fiscal 2017 Results

- **GAAP Revenue of \$17.8 Million, up 7%; Medical Device increase 12%**
- **GAAP EPS of \$0.17, Non-GAAP EPS of \$0.19**
- **Raises Revenue and EPS Guidance**

EDEN PRAIRIE, Minn.--(BUSINESS WIRE)--February 2, 2017--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 2017 first quarter, ended December 31, 2016.

“The Surmodics team made meaningful investments in our whole-product strategy while delivering top-line growth in the first quarter of fiscal 2017,” said Gary Maharaj, president and chief executive officer. “We believe that we are well-positioned for future growth as we remain on track to continue the clinical evaluation of our SurVeil™ drug-coated balloon (“DCB”) and prepare for regulatory submission of several proprietary products in the next few months.”

First Quarter Revenue and Earnings Summary

GAAP revenue for the fiscal 2017 first quarter totaled \$17.8 million, compared with \$16.5 million a year earlier, driven by strength in the Medical Device segment.

Diluted GAAP earnings per share in the first quarter of fiscal 2017 were \$0.17 compared with \$0.20 a year ago. On a non-GAAP comparative basis, earnings per share were \$0.19 in the first quarter of fiscal 2017 versus \$0.39 last year. Fiscal 2017 results included planned increased investments in research, development and other operating expenses to support the company’s whole-product strategy, including the *SurVeil* DCB.

Medical Device Segment

This segment, which includes hydrophilic coatings, device drug delivery technologies and balloon catheter products, posted revenue of \$13.8 million in the first quarter of fiscal 2017, an increase of 12.3% compared to the year-ago period. The growth stems from higher product sales, royalties, and research, development and other revenue. First quarter of fiscal 2017 included \$0.9 million of incremental revenue from our fiscal 2016 acquisitions. Fiscal first quarter 2017 hydrophilic coating royalty revenue was \$7.4 million, down slightly from the year-earlier period. The Medical Device business unit generated \$3.7 million of operating income in the first quarter compared to \$3.8 million in the prior-year quarter. Operating income was impacted by increases in planned investments related to our whole-product strategy as well as acquisition related amortization and accretion expense partially offset by increased margin from higher revenue and reduced acquisition-related costs.

Update on *SurVeil* Drug-Coated Balloon

Surmodics is performing its assessment of the data from the early feasibility study in order to submit these data to the relevant regulatory agencies for review and to determine the next clinical phase for the device.

"I'm pleased with the progress we have made advancing our *SurVeil* DCB. We are currently on plan with our discussions with regulatory agencies to continue its clinical development," said Maharaj.

In Vitro Diagnostics Segment

Revenue for the first quarter of fiscal 2017 totaled \$4.0 million, a decrease of 6.8% from the year-ago period. First quarter fiscal 2017 revenue was impacted by strong fourth quarter fiscal 2016 sales in several product categories as well as a decline from a significant microarray customer that had previously been acquired by one of its competitors. We expect a decline in revenue from this customer to continue through the third quarter of our fiscal 2017. The IVD business unit generated \$1.5 million of operating income in the first quarter of fiscal 2017, which reflects an 11.4% decrease from the year-ago period. Operating income also was impacted by lower revenue.

Balance Sheet and Cash Flow

As of December 31, 2016, the Company continued to have a strong cash position, with \$45.1 million of cash and investments. Surmodics generated cash from operating activities of \$2.0 million in the first quarter of fiscal 2017. Capital expenditures totaled \$1.5 million for the first quarter of fiscal 2017.

Fiscal 2017 Outlook

"We continue to build on our platform to accelerate future growth, achieving solid financial performance, delivering innovation and service in our core businesses, and executing according to plan. We have a number of initiatives we are pursuing in fiscal 2017 centered on making Surmodics more relevant to our medical device customers by developing complete product solutions for them. This, we believe, will drive long-term shareholder value," concluded Maharaj.

As the result of the strong first quarter Medical Device revenue and increasing clarity on DCB clinical trial plans for the remainder of fiscal 2017, Surmodics updated revenue and EPS guidance for fiscal 2017. The Company now expects GAAP revenue to range from \$64.0 million to \$68.0 million, up from a previous range of \$63.0 million to \$67.0 million. The Company now expects diluted earnings (loss) in the range of \$(0.07) to \$0.08 per share, up from a previous range of \$(0.15) to \$0.05 per share and non-GAAP earnings of \$0.18 to \$0.33 per share as compared with prior guidance of \$0.15 to \$0.35 per share.

Live Webcast

Surmodics will host a webcast at 7:30 a.m. CT (8:30 a.m. ET) today to discuss first quarter results. To access the webcast, go to the investor relations portion of the Company's website at www.surmodics.com and click on the webcast icon. A replay of the first quarter conference call will be available by dialing 888-203-1112 and entering conference call ID passcode 8582113. The audio replay will be available beginning at 10:30 a.m. CT on Thursday, February 2, 2017, until 10:30 a.m. CT on Thursday, February 9, 2017.

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) tests and microarrays. Following two recent acquisitions of Creagh Medical and NorMedix, the Company is executing a key growth strategy for its medical device business by expanding to offer total intravascular product solutions to its medical device customers. The combination of proprietary surface technologies, along with enhanced device design, development and manufacturing capabilities, enables Surmodics to significantly increase the value it offers with highly differentiated intravascular solutions designed and engineered to meet the most demanding requirements. With this focus on offering total product solutions, Surmodics' mission remains to improve the detection and treatment of disease by using its technology to provide solutions to difficult medical device and diagnostic challenges. Surmodics is headquartered in Eden Prairie, Minnesota. For more information about the Company, 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, earnings and cash flow expectations for fiscal 2017, our fiscal 2017 priorities, and our *SurVeil* drug-coated balloon, 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, 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) our ability to successfully identify, acquire, and integrate target companies, and achieve expected benefits from acquisitions that are consummated; (4) possible adverse market conditions and possible adverse impacts on our cash flows, and (5) 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, 2016, and updated in our subsequent reports filed with the SEC. These reports are available in the Investors section of our website at www.surmodics.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 generally accepted accounting principles, or GAAP, Surmodics is reporting non-GAAP financial results including non-GAAP operating income, non-GAAP income before income taxes, non-GAAP net income, and non-GAAP diluted net income per share, and the non-GAAP effective 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 Income
(in thousands, except per share data)

	Three Months Ended	
	December 31,	
	2016	2015
	(Unaudited)	
Revenue:		
Product sales	\$ 7,701	\$ 7,181
Royalties and license fees	8,001	7,954
Research, development and other	2,059	1,406
Total revenue	17,761	16,541
Operating costs and expenses:		
Product costs	2,628	2,366
Research and development	5,970	3,634
Selling, general and administrative	4,862	3,648
Acquired intangible asset amortization	596	354
Contingent consideration accretion expense	437	109
Acquisition transaction, integration and other costs	—	2,491
Total operating costs and expenses	14,493	12,602
Operating income	3,268	3,939
Other income (loss), net	759	(134)
Income from operations before income taxes	4,027	3,805
Income tax provision	(1,727)	(1,152)
Net income	\$ 2,300	\$ 2,653
Basic income per share:	\$ 0.17	\$ 0.20
Diluted income per share:	\$ 0.17	\$ 0.20
Weighted average number of shares outstanding:		
Basic	13,200	12,966
Diluted	13,446	13,186

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

	December 31, 2016	September 30, 2016
	(Unaudited)	
Assets		
Current Assets:		
Cash and cash equivalents	\$ 17,653	\$ 24,987
Available-for-sale securities	27,474	21,954
Accounts receivable, net	6,504	6,869
Inventories	3,472	3,579
Prepays and other	1,541	1,169
Total Current Assets	56,644	58,558
Property and equipment, net	20,186	19,601
Deferred tax assets	4,286	5,027
Intangible assets, net	21,094	22,525
Goodwill	25,694	26,555
Other assets	721	628
Total Assets	\$ 128,625	\$ 132,894
Liabilities and Stockholders' Equity		
Current Liabilities	5,934	10,135
Contingent consideration, less current portion	13,366	13,592
Other long-term liabilities	2,142	2,334
Total Liabilities	21,442	26,061
Total Stockholders' Equity	107,183	106,833
Total Liabilities and Stockholders' Equity	\$ 128,625	\$ 132,894

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

	Three Months Ended December 31,				% Change
	2016		2015		
		% of Total		% of Total	
Revenue:					
Medical Device	\$ 13,757	77.5%	\$ 12,247	74.0%	12.3%
In Vitro Diagnostics	4,004	22.5%	4,294	26.0%	-6.8%
Total revenue	\$ 17,761		\$ 16,541		7.4%

	Three Months Ended December 31,	
	2016	2015
Operating income:		
Medical Device	\$ 3,719	\$ 3,830
In Vitro Diagnostics	1,456	1,643
Total segment operating income	5,175	5,473
Corporate	(1,907)	(1,534)
Total income from operations	\$ 3,268	\$ 3,939

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

	Three Months Ended	
	December 31,	
	2016	2015
	(Unaudited)	
Net Income	\$ 2,300	\$ 2,653
Income tax provision	1,727	1,152
Depreciation and amortization	1,282	909
EBITDA	<u>5,309</u>	<u>4,714</u>
Adjustments:		
Contingent consideration accretion expense (1)	437	109
Foreign exchange (gain) loss (2)	(674)	135
Acquisition transaction, integration and other costs (3)	—	2,491
Adjusted EBITDA	<u>\$ 5,072</u>	<u>\$ 7,449</u>
Net Cash Provided by Operating Activities	<u>\$ 1,951</u>	<u>\$ 6,278</u>

Estimated Non-GAAP Net Income per Common Share Reconciliation
For the Fiscal Year Ended September 30, 2017

	Full Fiscal Year Estimate	
	Low	High
GAAP results - (loss) income per share	\$ (0.07)	\$ 0.08
Contingent consideration accretion expense (1)	0.15	0.15
Foreign exchange gain (2)	(0.05)	(0.05)
Amortization of acquired intangibles (4)	0.15	0.15
Non-GAAP results - income per share	<u>\$ 0.18</u>	<u>\$ 0.33</u>

- (1) Contingent consideration accretion expense represents accounting adjustments to state acquisition-related contingent consideration liabilities at their estimated fair value.
- (2) Foreign exchange gain and loss 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 period and do not include forecasted currency fluctuations in future periods.
- (3) Represents acquisition-related costs, including due diligence and integration expenses. Due diligence and other fees include legal, tax, investment banker and other expenses associated with acquisitions that can be highly variable and not representative of on-going operations.
- (4) Amortization of acquisition-related intangible assets and associated tax impact.

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

For the Three Months Ended December 31, 2016

	<u>Total Revenue</u>	<u>Operating Income</u>	<u>Operating Income Percentage</u>	<u>Income Before Income Taxes</u>	<u>Net Income (6)</u>	<u>Diluted EPS</u>	<u>Effective tax rate</u>
GAAP	\$ 17,761	\$ 3,268	18.4%	\$ 4,027	\$ 2,300	\$ 0.17	42.9%
Adjustments:							
Contingent consideration accretion expense (1)	—	437	2.5	437	437	0.03	(4.2)
Foreign exchange gain (2)	—	—	—	(674)	(674)	(0.05)	6.9
Amortization of acquired intangible assets (3)	—	596	3.3	596	517	0.04	(4.4)
Non-GAAP	<u>\$ 17,761</u>	<u>\$ 4,301</u>	<u>24.2%</u>	<u>\$ 4,386</u>	<u>\$ 2,580</u>	<u>\$ 0.19</u>	<u>41.2%</u>

For the Three Months Ended December 31, 2015

	<u>Total Revenue</u>	<u>Operating Income</u>	<u>Operating Income Percentage</u>	<u>Income Before Income Taxes</u>	<u>Net Income (6)</u>	<u>Diluted EPS</u>	<u>Effective tax rate</u>
GAAP	\$ 16,541	\$ 3,939	23.8%	\$ 3,805	\$ 2,653	\$ 0.20	30.3%
Adjustments:							
Contingent consideration accretion expense (1)	—	109	0.7	109	109	0.01	(0.8)
Foreign exchange loss (2)	—	—	—	135	135	0.01	(1.0)
Amortization of acquired intangible assets (3)	—	354	2.1	354	298	0.02	(1.0)
Acquisition transaction, integration and other costs (4)	—	2,491	15.1	2,491	2,185	0.17	(5.5)
Research and development tax credit (5)	—	—	—	—	(222)	(0.02)	3.2
Non-GAAP	<u>\$ 16,541</u>	<u>\$ 6,893</u>	<u>41.7%</u>	<u>\$ 6,894</u>	<u>\$ 5,158</u>	<u>\$ 0.39</u>	<u>25.2%</u>

(1) Represents accounting adjustments to state acquisition-related contingent consideration liabilities at their estimated fair value.

(2) Foreign exchange loss related to marking non-U.S. dollar contingent consideration liabilities to period-end exchange rates.

(3) Amortization of acquisition-related intangible assets and associated tax impact.

(4) Represents acquisition-related costs, including due diligence and integration expenses. Due diligence and other fees include legal, tax, investment banker and other expenses associated with acquisitions that can be highly variable and not representative of on-going operations. The majority of these costs were not deductible for income tax purposes.

(5) Represents a discrete income tax benefit associated with the December 2015 signing of the Protecting Americans from Tax Hikes Act of 2015, which retroactively reinstated federal R&D income tax credits for calendar 2015.

(6) Net income includes the effect of the above adjustments on the income tax provision, taking into account deferred taxes and non-deductible items. An effective rate between 34-35% was used to estimate the income tax impact of the adjustments.

CONTACT:

Surmodics, Inc.

Andy LaFrence, 952-500-7000

Vice President of Finance, Information Systems and Chief Financial Officer