

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

July 28, 2016

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 July 28, 2016, Surmodics, Inc. (the “Company”) issued a press release (the “Press Release”) announcing the results for the quarter ended June 30, 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.*

<u>Exhibit Number</u>	<u>Description</u>
99.1	Press Release dated July 28, 2016.

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: July 28, 2016

/s/ Andrew D. C. LaFrence

Andrew D. C. LaFrence

Vice President Finance and Chief Financial Officer

EXHIBIT INDEX

Exhibit

Number

Description

99.1

Press Release dated July 28, 2016.

Surmodics Reports Third Quarter Fiscal 2016 Results

- **GAAP Revenue of \$20.0 Million, up 25%**
- **GAAP EPS of \$0.30, Non-GAAP EPS of \$0.37**
- **Core Business Performs Well as Key Strategic Growth Priorities Advance**
- **Raises Fiscal 2016 Revenue and EPS Guidance**

EDEN PRAIRIE, Minn.--(BUSINESS WIRE)--July 28, 2016--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 2016 third quarter, ended June 30, 2016.

“Surmodics continued to advance all key strategic growth priorities while delivering against our fiscal 2016 financial commitments,” said Gary Maharaj, president and chief executive officer. “We are pleased to say that the integration of the Creagh Medical and NorMedix acquisitions are on track. We have earned revenue from our first customer with fully integrated Surmodics coatings and Creagh Medical balloon technologies. We also continue to make excellent progress in enrollment for our investigational device exemption (IDE) study of our SurVeil™ drug-coated balloon platform with nine patients enrolled in the study.”

Third Quarter Revenue and Earnings Summary

GAAP revenue for the fiscal 2016 third quarter totaled \$20.0 million, compared with \$15.9 million a year earlier. Third quarter fiscal 2016 revenue included \$1.2 million from Surmodics’ fiscal 2016 acquisitions as well as a previously disclosed \$2.9 million, or \$0.14 per share, hydrophilic royalty catch-up payment, of which \$2.6 million related to periods prior to fiscal 2016.

Diluted GAAP earnings per share from continuing operations in the third quarter of fiscal 2016 were \$0.30, same as a year ago. On a non-GAAP basis, earnings per share increased 19% to \$0.37 in the third quarter of fiscal 2016 versus \$0.31 last year. Fiscal 2016 third quarter non-GAAP earnings exclude \$0.07 per share from acquisition-related transaction costs, including integration, contingent consideration accretion, amortization, foreign currency transaction and other expenses.

Medical Device Segment

This segment, which includes hydrophilic coatings, device drug delivery technologies and balloon catheter products, posted revenue of \$15.7 million in the third quarter of fiscal 2016, an increase of 35 percent compared to the year-ago period. The gain stems from higher hydrophilic coating royalties, reagent product sales and acquisition revenue. Fiscal third quarter 2016 hydrophilic coating royalty and license fee revenue included the \$2.9 million catch-up payment and aggregated \$10.5 million, an increase of 34 percent compared to the year-earlier period. The Medical Device business unit generated \$6.7 million of operating income in the third quarter compared to \$6.3 million in the prior-year quarter. Increased revenue offset by increased research and development expense as well as acquisition-related expenses accounted for the change in operating income.

In Vitro Diagnostics Segment

Revenue for the third quarter of fiscal 2016 grew one percent to \$4.3 million, as compared to an exceptionally strong year-ago period. The IVD business unit operating income in the third quarter of fiscal 2016 increased to \$1.7 million versus \$1.2 million in the prior-year quarter. Operating income benefited from lower legal costs.

Update on SurVeil Drug-Coated Balloon

As previously disclosed, Surmodics has enrolled the ninth patient in its IDE study of the SurVeil drug-coated balloon. This study is part of the Company's strategy of providing highly differentiated intravascular whole product solutions. Up to 15 patients can be enrolled. Surmodics plans to complete enrollment in this clinical study during the fourth quarter of fiscal 2016. "There is an opportunity with the next wave of DCB technology to continue to improve patient outcomes as the technology is advanced," said D. Christopher Metzger, M.D., at Wellmont Holston Valley Medical Center in Kingsport, Tennessee and National Principal Investigator for the PreVeil Study. "I am pleased to be part of Surmodics' U.S. early feasibility trial as we continue to evaluate this promising, next-generation technology available with the SurVeil DCB."

Balance Sheet and Cash Flow

As of June 30, 2016, the Company had \$44.2 million of cash and investments. Surmodics generated cash from operating activities of \$18.5 million in the first nine-months of fiscal 2016. Capital expenditures totaled \$4.9 million for the first nine-months of fiscal 2016. In addition, the Company used \$25.1 million of net cash to acquire Creagh Medical and NorMedix in the first nine-months of fiscal 2016.

Fiscal 2016 Outlook

According to Maharaj, "Through the first three quarters of fiscal 2016, our revenue increased 19 percent. As a result, we are raising our revenue and earnings guidance for fiscal 2016."

Surmodics is increasing full-year revenue guidance to be in the range of \$68.0 million to \$70.0 million as well as diluted GAAP earnings per share in the range of \$0.52 to \$0.59. Surmodics also is increasing non-GAAP earnings per share to a range of \$0.98 to \$1.08, up from a range of \$0.75 to \$0.85. Surmodics is reaffirming its anticipated capital expenditures in the range of \$8.0 million to \$9.0 million.

Live Webcast

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 www.surmodics.com and click on the webcast icon. A replay of the third quarter conference call will be available by dialing 888-203-1112 and entering conference call ID passcode 8648070. The audio replay will be available beginning at 10:30 a.m. CT today until 10:30 a.m. CT on Thursday, August 4, 2016. In addition, the conference call audio and transcript will be archived on the Company's website following the call.

About Surmodics SurVeil™ Drug-Coated Balloon

The *SurVeil* drug-coated balloon incorporates Surmodics' decades of experience as a leading supplier of surface modification technologies to the medical device industry. It includes a Surmodics-proprietary drug-excipient formulation for the balloon coating, and a new and proprietary manufacturing process for the coating applications. It also includes the Surmodics Serene™ low-friction, low-particulate hydrophilic coating on the catheter shaft. The SurVeil DCB is not available for sale in the US and is for investigational use only. We initiated a first-in-human clinical trial using Surmodics *SurVeil* drug-coated balloon on April 5, 2016.

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. 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 2016, our fiscal 2016 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* drug-coated balloon product, including progress in our IDE study; (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, 2015, 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. We believe that these non-GAAP measures 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		Nine Months Ended	
	June 30,		June 30,	
	2016	2015	2016	2015
	(Unaudited)		(Unaudited)	
Revenue:				
Royalties and license fees	\$ 10,556	\$ 7,908	\$ 25,207	\$ 22,566
Product sales	7,512	6,583	22,866	18,082
Research and development	1,904	1,423	5,139	3,887
Total revenue	<u>19,972</u>	<u>15,914</u>	<u>53,212</u>	<u>44,535</u>
Operating costs and expenses:				
Product costs	2,777	2,174	8,069	6,031
Research and development	4,693	3,860	13,195	11,839
Selling, general and administrative	4,483	3,872	12,984	11,387
Acquisition transaction, integration and other costs	61	—	3,192	—
Intangible asset amortization	806	151	1,940	454
Contingent consideration accretion expense	555	—	1,056	—
Total operating costs and expenses	<u>13,375</u>	<u>10,057</u>	<u>40,436</u>	<u>29,711</u>
Operating income	<u>6,597</u>	<u>5,857</u>	<u>12,776</u>	<u>14,824</u>
Other income (loss), net	<u>263</u>	<u>(4)</u>	<u>72</u>	<u>645</u>
Income before income taxes	<u>6,860</u>	<u>5,853</u>	<u>12,848</u>	<u>15,469</u>
Income tax provision	<u>(2,857)</u>	<u>(1,929)</u>	<u>(5,507)</u>	<u>(4,879)</u>
Net income	<u>\$ 4,003</u>	<u>\$ 3,924</u>	<u>\$ 7,341</u>	<u>\$ 10,590</u>
Basic net income per share	<u>\$ 0.31</u>	<u>\$ 0.30</u>	<u>\$ 0.57</u>	<u>\$ 0.81</u>
Diluted net income per share	<u>\$ 0.30</u>	<u>\$ 0.30</u>	<u>\$ 0.56</u>	<u>\$ 0.79</u>
Weighted average number of shares outstanding:				
Basic	12,995	13,002	12,969	13,057
Diluted	13,284	13,279	13,203	13,324

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

	June 30, 2016	September 30, 2015
		(Unaudited)
Assets		
Cash and short-term investments	\$ 34,656	\$ 55,588
Available-for-sale securities	9,523	—
Accounts receivable	5,859	7,478
Inventories	3,345	2,979
Other current assets	686	1,744
Total current assets	54,069	67,789
Property and equipment, net	17,183	12,968
Intangible assets, net	22,889	2,760
Goodwill	26,544	8,010
Other assets	6,229	7,183
Total assets	\$ 126,914	\$ 98,710
Liabilities and Stockholders' Equity		
Current liabilities	8,069	4,700
Total current liabilities	8,069	4,700
Contingent consideration	13,950	—
Other liabilities	2,089	2,137
Total stockholders' equity	102,806	91,873
Total liabilities and stockholders' equity	\$ 126,914	\$ 98,710

Surmodics, Inc. and Subsidiaries
Condensed Consolidated Statements of Cash Flows
(in thousands)

	Nine Months Ended	
	June 30,	
	2016	2015
	(Unaudited)	
Operating Activities:		
Net income	\$ 7,341	\$ 10,590
Depreciation and amortization	3,703	2,083
Stock-based compensation	2,729	1,841
Contingent consideration accretion and foreign currency transaction loss expenses	1,369	—
Deferred taxes	2	450
Gain on sales of available-for-sale securities and strategic investments	(377)	(496)
Net other operating activities	(82)	(478)
Change in operating assets and liabilities:		
Accounts receivable	1,999	(1,244)
Accounts payable and accrued liabilities	746	132
Income taxes	1,137	(221)
Net change in other operating assets and liabilities	(67)	(581)
Net cash provided by operating activities from continuing operations	<u>18,500</u>	<u>12,076</u>
Investing Activities:		
Payments for acquisitions, net of cash acquired	(25,054)	—
Net purchases of property and equipment	(4,854)	(354)
Cash received from sale of strategic assets	377	21
Cash transferred to discontinued operations	—	(45)
Net other investing activities	(9,562)	18,822
Net cash (used in) provided by investing activities from continuing operations	<u>(39,093)</u>	<u>18,444</u>
Financing Activities:		
Purchase of common stock to fund employee taxes	(371)	(810)
Repurchase of common stock	—	(20,000)
Net other financing activities	46	887
Net cash used in financing activities from continuing operations	<u>(325)</u>	<u>(19,923)</u>
Net cash (used in) provided by continuing operations	<u>(20,918)</u>	<u>10,597</u>
Discontinued operations:		
Net cash used in operating activities	—	(45)
Net cash provided by financing activities	—	45
Net cash provided by discontinued operations	<u>—</u>	<u>—</u>
Effect of exchange rate changes on cash	(14)	—
Net change in cash and cash equivalents	(20,932)	10,597
Cash and Cash Equivalents:		
Beginning of period	55,588	43,511
End of period	<u>\$ 34,656</u>	<u>\$ 54,108</u>

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

(Unaudited)

	Three Months Ended June 30,				% Change
	2016		2015		
	% of Total	% of Total	% of Total	% of Total	
Revenue					
Medical Device	\$ 15,654	78.4%	\$ 11,629	73.1%	34.6%
In Vitro Diagnostics	4,318	21.6	4,285	26.9	0.8
Total revenue	<u>\$ 19,972</u>	<u>100.0%</u>	<u>\$ 15,914</u>	<u>100.0%</u>	25.5%
	Nine Months Ended June 30,				% Change
	2016		2015		
	% of Total	% of Total	% of Total	% of Total	
Revenue					
Medical Device	\$ 39,500	74.2%	\$ 32,827	73.7%	20.3%
In Vitro Diagnostics	13,712	25.8	11,708	26.3	17.1
Total revenue	<u>\$ 53,212</u>	<u>100.0%</u>	<u>\$ 44,535</u>	<u>100.0%</u>	19.5%
	Three Months Ended June 30,		Nine Months Ended June 30,		
	2016	2015	2016	2015	
Operating Income					
Medical Device	\$ 6,673	\$ 6,295	\$ 12,825	\$ 16,507	
In Vitro Diagnostics	1,673	1,191	5,298	3,220	
Corporate	(1,749)	(1,629)	(5,347)	(4,903)	
Total operating income	<u>\$ 6,597</u>	<u>\$ 5,857</u>	<u>\$ 12,776</u>	<u>\$ 14,824</u>	

Surmodics, Inc., and Subsidiaries
Net Income and Diluted EPS GAAP to Non-GAAP Reconciliation
For the Three Months Ended June 30, 2016
(in thousands, except per share data)
(Unaudited)

	<u>Total Revenue</u>	<u>Operating Income</u>	<u>Operating Income Percentage</u>	<u>Income Before Income Taxes</u>	<u>Net Income</u>	<u>Diluted EPS</u>
GAAP	\$ 19,972	\$ 6,597	33.0%	\$ 6,860	\$ 4,003	\$ 0.30
Adjustments:						
Contingent consideration expense (1)	—	555	2.8	555	555	0.04
Foreign exchange gain (2)	—	—	—	(250)	(250)	(0.02)
Amortization of intangible assets (3)	—	806	4.0	806	688	0.05
Non-GAAP	<u>\$ 19,972</u>	<u>\$ 7,958</u>	<u>39.8%</u>	<u>\$ 7,971</u>	<u>\$ 4,996</u>	<u>\$ 0.37</u>

(1) The contingent consideration adjustment represents accounting adjustments to state contingent consideration liabilities at their estimated fair value.

(2) Foreign exchange gain related to marking contingent consideration to market.

(3) To exclude amortization of acquisition related intangible assets and associated tax impact.

The above table is a summary of the pro forma adjustments to GAAP earnings and EPS, columns may not foot due to rounding.

Surmodics, Inc., and Subsidiaries
Net Income and Diluted EPS GAAP to Non-GAAP Reconciliation
For the Three Months Ended June 30, 2015
(in thousands, except per share data)
(Unaudited)

	<u>Total Revenue</u>	<u>Operating Income</u>	<u>Operating Income Percentage</u>	<u>Income Before Income Taxes</u>	<u>Net Income</u>	<u>Diluted EPS</u>
GAAP	\$ 15,914	\$ 5,857	36.8%	\$ 5,853	\$ 3,924	\$ 0.30
Adjustments:						
Amortization of intangible assets (1)	—	151	0.9	151	100	0.01
Non-GAAP	<u>\$ 15,914</u>	<u>\$ 6,008</u>	<u>37.8%</u>	<u>\$ 6,004</u>	<u>\$ 4,024</u>	<u>\$ 0.31</u>

(1) To exclude amortization of acquisition related intangible assets and associated tax impact.

The above table is a summary of the pro forma adjustments to GAAP earnings and EPS; columns may not foot due to rounding.

Surmodics, Inc., and Subsidiaries
Net Income and Diluted EPS GAAP to Non-GAAP Reconciliation
For the Nine Months Ended June 30, 2016
(in thousands, except per share data)
(Unaudited)

	<u>Total Revenue</u>	<u>Operating Income</u>	<u>Operating Income Percentage</u>	<u>Income Before Income Taxes</u>	<u>Net Income</u>	<u>Diluted EPS</u>
GAAP	\$ 53,212	\$ 12,776	24.0%	\$ 12,848	\$ 7,341	\$ 0.56
Adjustments:						
Acquisition transaction, integration and other costs (1)	—	3,192	6.0	3,192	2,865	0.22
Contingent consideration expense (2)	—	1,056	2.0	1,056	1,056	0.08
Foreign exchange loss (3)	—	—	—	316	316	0.02
Research and development tax credit (4)	—	—	—	—	(222)	(0.02)
Amortization of intangible assets (5)	—	1,940	3.6	1,940	1,655	0.13
Gain on strategic investment (6)	—	—	—	(361)	(361)	(0.03)
Non-GAAP	<u>\$ 53,212</u>	<u>\$ 18,964</u>	<u>35.6%</u>	<u>\$ 18,991</u>	<u>\$ 12,650</u>	<u>\$ 0.96</u>

- (1) 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.
- (2) The contingent consideration adjustment represents accounting adjustments to state contingent consideration liabilities at their estimated fair value.
- (3) Foreign exchange loss related to marking contingent consideration to market.
- (4) Represents the estimated 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 and the discrete fiscal 2015 provision to tax return true-up.
- (5) To exclude amortization of acquisition related intangible assets and associated tax impact.
- (6) Represents the gain recognized on the sale of a strategic investment.

The above table is a summary of the pro forma adjustments to GAAP earnings and EPS, columns may not foot due to rounding.

Surmodics, Inc., and Subsidiaries
Net Income and Diluted EPS GAAP to Non-GAAP Reconciliation
For the Nine Months Ended June 30, 2015
(in thousands, except per share data)
(Unaudited)

	<u>Total Revenue</u>	<u>Operating Income</u>	<u>Operating Income Percentage</u>	<u>Income Before Income Taxes</u>	<u>Net Income</u>	<u>Diluted EPS</u>
GAAP	\$ 44,535	\$ 14,824	33.3%	\$ 15,469	\$ 10,590	\$ 0.79
Adjustments:						
Research and development tax credit (1)	—	—	—	—	(201)	(0.01)
Gain on strategic investment (2)	—	—	—	(523)	(523)	(0.04)
Amortization of intangible assets (3)	—	454	1.0	454	300	0.02
Non-GAAP	<u>\$ 44,535</u>	<u>\$ 15,278</u>	<u>34.3%</u>	<u>\$ 15,400</u>	<u>\$ 10,166</u>	<u>\$ 0.76</u>

- (1) Represents a discrete income tax benefit associated with the December 2014 signing of the Tax Increase Prevention Act of 2014 which retroactively reinstated federal R&D income tax credits for calendar 2014.
- (2) Represents the gain recognized on the sale of a strategic investment.
- (3) To exclude amortization of acquisition related intangible assets and associated tax impact.

The above table is a summary of the pro forma adjustments to GAAP earnings and EPS, columns may not foot due to rounding.

CONTACT:

Surmodics, Inc.

Andy LaFrence, 952-500-7000

Vice President of Finance and Chief Financial Officer