

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

January 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 January 28, 2016, the Company issued a press release (the "Press Release") announcing the results for the quarter ended December 31, 2015. 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 January 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: January 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 January 28, 2016.

SurModics Reports First Quarter Fiscal 2016 Results

- **GAAP Revenue of \$16.5 Million, up 16%**
- **GAAP EPS of \$0.19, Non-GAAP EPS of \$0.38**
- **Fiscal 2016 Guidance Reaffirmed**

EDEN PRAIRIE, Minn.--(BUSINESS WIRE)--January 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 first quarter, ended December 31, 2015.

“The SurModics team had an exceptional first quarter of fiscal 2016,” said Gary Maharaj, president and chief executive officer. “We delivered outstanding results from our core Medical Device and In Vitro Diagnostic businesses while completing both the November 2015 Creagh Medical and January 2016 NorMedix acquisitions. We are well-positioned to meet our fiscal 2016 financial commitments with our first quarter financial results as well as execute our future growth with our whole products solutions strategy with these acquisitions and our continued progress on the SurModics *SurVeil*TM drug-coated balloon platform. ”

First Quarter Revenue and Earnings Summary

GAAP revenue for the fiscal 2016 first quarter totaled \$16.5 million, compared with \$14.2 million a year earlier. First quarter fiscal 2016 revenue included \$0.5 million from Creagh Medical.

Diluted GAAP earnings per share from continuing operations in the first quarter of fiscal 2016 were \$0.19 compared with \$0.27 a year ago. Both the first quarter of fiscal 2016 and 2015 earnings include a \$0.02 per share discrete income tax benefit from the renewal of the federal research and development tax credit. As indicated by SurModics earlier this month, fiscal 2016 first quarter earnings also reflect a \$0.20 per share reduction from Creagh Medical acquisition-related transaction costs including investment banker fees, integration, contingent consideration accretion, foreign currency transaction and other expenses. On a non-GAAP comparative basis, earnings per share were \$0.38 in the first quarter of fiscal 2016 versus \$0.26 last year, an increase of 46%.

Medical Device Segment

This business, which includes hydrophilic coatings, device drug delivery technologies, and balloon catheter products, posted revenue of \$12.2 million in the first quarter of fiscal 2016, an increase of 15% compared to the year-ago period. The gain stems from higher hydrophilic royalties, reagent product sales, and research and development contract coating services as well as the Creagh Medical acquisition. Fiscal first quarter 2016 hydrophilic coating royalty revenue was \$7.5 million, an increase of 6% compared to the year-earlier period. The Medical Device business unit generated \$3.8 million of operating income in the first quarter compared to \$5.5 million in the prior-year quarter. Higher gross margin from revenue gains was more than offset by \$2.8 million of Creagh Medical transaction-related expenses, amortization, accretion and foreign currency transaction loss costs.

In Vitro Diagnostics Segment

Revenue for the first quarter of fiscal 2016 totaled \$4.3 million, an increase of 20% compared to the year-ago period. The IVD business unit generated \$1.6 million of operating income in the first quarter of fiscal 2016, which reflects a 50% increase from a year ago. Operating income benefited from improved operating leverage due to higher revenue and lower legal costs.

Balance Sheet and Cash Flow

As of December 31, 2015, the Company had \$42.7 million of cash and investments. SurModics generated cash from operating activities of \$6.1 million in the first quarter of fiscal 2016. Capital expenditures totaled \$0.4 million for the first quarter of fiscal 2016. In addition, the Company used \$18.2 million of net cash to acquire Creagh Medical in the first quarter.

Fiscal 2016 Outlook

SurModics is reaffirming its previously stated guidance for fiscal 2016. The Company expects revenue to range from \$62 million to \$66 million, with diluted GAAP earnings in the range of \$0.30 to \$0.35 per share and non-GAAP earnings of \$0.66 to \$0.75 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 167645. The audio replay will be available beginning at 10:30 a.m. CT on Thursday, January 28, 2016, until 10:30 a.m. CT on Thursday, February 4, 2016.

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 plan to initiate a first-in-human clinical trial using SurModics *SurVeil* drug-coated balloon by the end of the second quarter of fiscal 2016.

About SurModics, Inc.

SurModics partners with the world's leading and emerging medical device, diagnostic and life science companies to develop and commercialize innovative products designed to improve lives by enabling the detection and treatment of disease. Our mission is to be a trusted partner to our customers by providing the most advanced surface modification technologies and *in vitro* diagnostic chemical components that help enhance the well-being of patients. The Company's core offerings include surface modification coating technologies that impart lubricity, prohealing, and biocompatibility characteristics and components for *in vitro* diagnostic test kits and microarrays. SurModics' strategy is to build on the product and technical leadership within these fields, and expand the core offerings to generate opportunities for longer term sustained growth. 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 the timing associated with the initiation of our first-in-human clinical trial; (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 and acquire target companies or 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	
	December 31,	
	2015	2014
	(Unaudited)	
Revenue		
Royalties and license fees	\$ 7,954	\$ 7,275
Product sales	7,181	5,847
Research and development	1,406	1,083
Total revenue	16,541	14,205
Operating expenses		
Product costs	2,366	1,902
Research and development	3,634	3,576
Selling, general and administrative	3,608	3,542
Amortization, special and other charges	2,994	151
Total operating costs and expenses	12,602	9,171
Operating income	3,939	5,034
Other (loss) income, net	(134)	50
Income before income taxes	3,805	5,084
Income tax provision	(1,292)	(1,470)
Net income	\$ 2,513	\$ 3,614
Basic net income per share	\$ 0.19	\$ 0.27
Diluted net income per share	\$ 0.19	\$ 0.27
Weighted average shares outstanding		
Basic	12,966	13,225
Diluted	13,186	13,423

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

	December 31, 2015	September 30, 2015
	(Unaudited)	
Assets		
Cash and short-term investments	\$ 42,668	\$ 55,588
Restricted cash	786	—
Accounts receivable	5,522	7,478
Inventories	3,301	2,979
Other current assets	961	1,744
Total current assets	53,238	67,789
Property and equipment, net	13,506	12,968
Intangible assets, net	16,502	2,760
Goodwill	21,822	8,010
Other assets	7,147	7,183
Total assets	\$ 112,215	\$ 98,710
Liabilities and Stockholders' Equity		
Current liabilities	\$ 5,608	\$ 4,700
Total current liabilities	5,608	4,700
Contingent consideration	9,308	—
Other liabilities	2,026	2,137
Total stockholders' equity	95,273	91,873
Total liabilities and stockholders' equity	\$ 112,215	\$ 98,710

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

	Three Months Ended	
	December 31,	
	2015	2014
	(Unaudited)	
Operating Activities:		
Net income	\$ 2,513	\$ 3,614
Depreciation and amortization	909	683
Stock-based compensation	684	525
Contingent consideration accretion and foreign currency transaction loss expenses	244	—
Deferred taxes	741	1,025
Net other operating activities	(143)	(492)
Change in operating assets and liabilities:		
Accounts receivable	2,194	309
Accounts payable and accrued liabilities	(1,248)	(508)
Income taxes	508	413
Net change in other operating assets and liabilities	(274)	(39)
Net cash provided by operating activities from continuing operations	<u>6,128</u>	<u>5,530</u>
Investing Activities:		
Payments for acquisitions, net of cash acquired	(18,156)	—
Net purchases of property and equipment	(384)	(41)
Cash transferred to discontinued operations	—	(45)
Net other investing activities	—	(2,238)
Net cash used in investing activities from continuing operations	<u>(18,540)</u>	<u>(2,324)</u>
Financing Activities:		
Purchase of common stock to fund employee taxes	(353)	(725)
Repurchase of common stock	—	(20,000)
Net other financing activities	(155)	568
Net cash used in financing activities from continuing operations	<u>(508)</u>	<u>(20,157)</u>
Net cash used in continuing operations	<u>(12,920)</u>	<u>(16,951)</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>
Net change in cash and cash equivalents	(12,920)	(16,951)
Cash and Cash Equivalents:		
Beginning of period	55,588	43,511
End of period	<u>\$ 42,668</u>	<u>\$ 26,560</u>

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

(Unaudited)

Revenue	Three Months Ended December 31,				% Change
	2015		2014		
		% of Total		% of Total	
Medical Device	\$ 12,247	74.0%	\$ 10,635	74.9%	15.2%
In Vitro Diagnostics	4,294	26.0	3,570	25.1	20.3
Total revenue	\$ 16,541	100.0%	\$ 14,205	100.0%	16.4%

Operating Income	Three Months Ended December 31,			
	2015		2014	
Medical Device	\$	3,830	\$	5,515
In Vitro Diagnostics		1,643		1,098
Corporate		(1,534)		(1,579)
Total operating income	\$	3,939	\$	5,034

SurModics, Inc., and Subsidiaries
Net Income and Diluted EPS GAAP to Non-GAAP Reconciliation
For the Three Months Ended December 31, 2015
(in thousands, except per share data)
(Unaudited)

	Total Revenue	Operating Income	Operating Income Percentage	Income Before Income Taxes	Net Income	Diluted EPS
GAAP	\$ 16,541	\$ 3,939	23.8%	\$ 3,805	\$ 2,513	\$ 0.19
Adjustments:						
Acquisition transaction, integration and other costs (1)	—	2,531	15.3	2,531	2,225	0.17
Contingent consideration accretion expense (2)	—	109	0.7	109	109	0.01
Research and development tax credit (3)	—	—	—	—	135	(0.02)
Foreign exchange loss (4)	—	—	—	135	(222)	0.01
Amortization of intangible assets (5)	—	354	2.1	354	298	0.02
Non-GAAP	<u>\$ 16,541</u>	<u>\$ 6,933</u>	<u>41.9%</u>	<u>\$ 6,934</u>	<u>\$ 5,058</u>	<u>\$ 0.38</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 accretion adjustment represents accounting adjustments to state contingent consideration liabilities at their estimated fair value.
- (3) 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.
- (4) Foreign exchange loss related to marking contingent consideration to market.
- (5) To exclude amortization of acquisition related intangible assets and associated tax impact.

SurModics, Inc., and Subsidiaries
Net Income and Diluted EPS GAAP to Non-GAAP Reconciliation
For the Three Months Ended December 31, 2014
(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	\$ 14,205	\$ 5,034	35.4%	\$ 5,084	\$ 3,614	\$ 0.27
Adjustments:						
Research and development tax credit (1)	—	—	—	—	(201)	(0.02)
Amortization of intangible assets (2)	—	151	1.1	151	96	0.01
Non-GAAP	<u>\$ 14,205</u>	<u>\$ 5,185</u>	<u>36.5%</u>	<u>\$ 5,235</u>	<u>\$ 3,509</u>	<u>\$ 0.26</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) To exclude amortization of acquisition related intangible assets and associated tax impact.

CONTACT:

SurModics, Inc.
Andy LaFrence, 952-500-7000
Vice President of Finance and Chief Financial Officer