

**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 4, 2020

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))

Securities registered pursuant to Section 12(b) of the Act:

<u>Title of Each Class</u>	<u>Trading Symbol(s)</u>	<u>Name of Each Exchange on Which Registered</u>
Common Stock, \$0.05 par value	SRDX	Nasdaq Global Select Market

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 4, 2020, Surmodics, Inc. (the “Company”) issued a press release (the “Press Release”) announcing the results for the quarter ended September 30, 2020. 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.

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Item 9.01 Financial Statements and Exhibits.

(d) *Exhibits.*

Exhibit Number	Description
99.1	Press Release dated November 4, 2020
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

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 4, 2020

By: /s/ Timothy J. Arens
Timothy J. Arens
Senior Vice President of Finance and Chief
Financial Officer

EXHIBIT INDEX

Exhibit Number	Description
99.1	Press Release dated November 4, 2020
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

Surmodics Reports Fourth Quarter Fiscal 2020 Results

EDEN PRAIRIE, Minn.--(BUSINESS WIRE)--November 4, 2020--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 2020 fourth quarter ended September 30, 2020.

Summary of Fourth Quarter and Recent Highlights

- Revenue of \$22.5 million, a decrease of 27% year-over-year
- GAAP EPS of (\$0.22), non-GAAP EPS of (\$0.18)
- FDA clearance received for Pounce™ Thrombus Retrieval System for non-surgical removal of clots from the peripheral arterial vasculature

“I am proud of the meaningful progress our team made in fiscal 2020 to advance our strategic objectives in spite of this year’s unprecedented challenges,” said Gary Maharaj, President and CEO of Surmodics, Inc. “Our team capped the year by achieving another milestone with the receipt of the 510(k) clearance for our Pounce™ Thrombus Retrieval System. As we look ahead to fiscal 2021, we remain confident in our long-term outlook and the ability to accomplish our strategic initiatives to deliver durable growth.”

Fourth Quarter Fiscal 2020 Financial Results

Total revenue for the fourth quarter of fiscal 2020 was \$22.5 million, compared to \$30.8 million in the prior-year period. Medical Device revenue was \$17.2 million in the fourth quarter of fiscal 2020, compared to \$24.8 million in the year-ago period, a decrease of 31%. Revenue in the fourth quarter includes \$1.6 million from our Development and Distribution Agreement with Abbott Vascular, Inc. (“Abbott”) for the SurVeil DCB™ drug coated balloon (DCB), compared to \$7.6 million in the prior-year quarter, which included the impact of the achievement of a milestone. In Vitro Diagnostics revenue was \$5.4 million for the fourth quarter of fiscal 2020, compared to \$6.0 million in the same prior-year quarter, a decrease of 10%.

GAAP loss per share in the fourth quarter of fiscal 2020 was (\$0.22), compared to earnings per share of \$0.26 in the year-ago period. On a non-GAAP basis, loss per share in the fourth quarter of fiscal 2020 was (\$0.18), compared to earnings per share of \$0.37 in the same prior-year quarter.

As of September 30, 2020, Surmodics reported cash and short-term investments totaling \$61.1 million and no debt. Surmodics generated \$1.3 million of cash from operating activities in the fourth quarter of fiscal 2020. Capital expenditures totaled \$1.0 million for the fourth quarter of fiscal 2020.

Fiscal 2021 Guidance

Due to the continued uncertainty surrounding the duration and magnitude of the COVID-19 pandemic, the Company will not provide financial guidance at this time.

Conference Call Today at 4 p.m. CT (5 p.m. ET)

Surmodics will host a webcast at 4 p.m. CT (5 p.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 4873909. The audio replay will be available beginning at 7 p.m. CT on Wednesday, November 4, 2020, until 7 p.m. CT on Wednesday, November 11, 2020.

About Surmodics, Inc.

Surmodics is a leading provider of surface modification technologies for intravascular medical devices and chemical components for in vitro diagnostic immunoassay tests and microarrays. Surmodics is pursuing development and commercialization of highly differentiated medical devices that are designed to address unmet clinical needs 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 Securities and Exchange Commission ("SEC").

Safe Harbor for Forward-looking Statements

This press release, and disclosures related to it, contain forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Statements that are not historical or current facts, including statements regarding the Company's ability to execute on its strategy, its potential to achieve consistent double-digit revenue growth in fiscal 2022 and beyond, initiatives to deliver durable growth, emerging FDA requirements for premarket approvals of new vascular devices that use Paclitaxel, expectations regarding conduct and timing of clinical studies, expectation regarding the presentations of clinical information regarding our products, target dates and the potential for delay related to regulatory clearances, target dates for regulatory filing, plans for product releases and clinical evaluations, potential future revenue amounts under our Distribution and Development Agreement with Abbott Vascular, expectations regarding the impact of patent expirations on future revenues, expectation regarding future operating expenses, and expectation regarding the Company's positioning for long-term growth, shareholder value creation, and the adequacy of cash and investments to provide capacity to support the Company's strategic growth initiatives, 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, without limitation: (1) our ability to successfully develop and commercialize our SurVeil™ DCB (including realization of the full potential benefits of our agreement with Abbott), A vess™ DCB, Sundance™ 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) possible adverse market conditions and possible adverse impacts on our cash flows; (4) the impacts, duration, and severity of the global COVID-19 pandemic and the effects of responses to it on healthcare systems, the general economy, our business partners, and our operations; 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, 2019, 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 operating (loss) income percentage, non-GAAP (loss) income before income taxes, non-GAAP net (loss) income, and non-GAAP diluted (loss) 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 payouts 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.

CONTACT:

Surmodics, Inc.

Tim Arens, 952-500-7000

ir@surmodics.com

Surmodics, Inc. and Subsidiaries
Condensed Consolidated Statements of Operations
(in thousands, except per share data)
(Unaudited)

	Three Months Ended		Fiscal Year Ended	
	September 30,		September 30,	
	2020	2019	2020	2019
Revenue:				
Product sales	\$ 10,586	\$ 10,711	\$ 44,317	\$ 40,219
Royalties and license fees	9,867	16,806	40,634	48,458
Research, development and other	2,090	3,299	9,913	11,400
Total revenue	<u>22,543</u>	<u>30,816</u>	<u>94,864</u>	<u>100,077</u>
Operating costs and expenses:				
Product costs	3,902	3,659	15,317	13,639
Research and development	12,787	14,523	50,188	52,885
Selling, general and administrative	7,300	7,186	28,392	23,950
Acquired in-process research and development	—	890	—	890
Acquired intangible asset amortization	547	596	2,218	2,405
Contingent consideration expense (gain)	—	87	—	(161)
Total operating costs and expenses	<u>24,536</u>	<u>26,941</u>	<u>96,115</u>	<u>93,608</u>
Operating (loss) income	(1,993)	3,875	(1,251)	6,469
Other (expense) income, net	(85)	243	(203)	1,089
(Loss) income before income taxes	(2,078)	4,118	(1,454)	7,558
Income tax (provision) benefit	(868)	(564)	2,577	34
Net (loss) income	<u>\$ (2,946)</u>	<u>\$ 3,554</u>	<u>\$ 1,123</u>	<u>\$ 7,592</u>
Basic (loss) income per share:	\$ (0.22)	\$ 0.27	\$ 0.08	\$ 0.57
Diluted (loss) income per share:	\$ (0.22)	\$ 0.26	\$ 0.08	\$ 0.55
Weighted average number of shares outstanding:				
Basic	13,639	13,400	13,552	13,389
Diluted	13,639	13,769	13,812	13,779

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

	September 30,	
	2020	2019
Assets		
Current Assets:		
Cash and cash equivalents	\$ 30,785	\$ 30,361
Available-for-sale securities	30,313	24,931
Accounts receivable, net	7,675	8,993
Contract assets — royalties and license fees	6,108	8,210
Inventories, net	5,966	4,501
Prepays and other	5,761	4,424
Total Current Assets	86,608	81,420
Property and equipment, net	30,103	29,748
Deferred income taxes	7,315	6,176
Intangible assets, net	13,283	14,226
Goodwill	27,185	26,171
Other assets	4,269	2,124
Total Assets	\$ 168,763	\$ 159,865
Liabilities and Stockholders' Equity		
Current Liabilities:		
Contingent consideration	—	3,200
Deferred revenue	5,200	5,553
Other current liabilities	13,692	11,456
Total Current Liabilities	18,892	20,209
Deferred revenue	10,796	11,628
Other long-term liabilities	8,020	5,512
Total Liabilities	37,708	37,349
Total Stockholders' Equity	131,055	122,516
Total Liabilities and Stockholders' Equity	\$ 168,763	\$ 159,865

Surmodics, Inc. and Subsidiaries
Supplemental Segment Information

(in thousands)

(Unaudited)

	Three Months Ended September 30,				% Change
	2020		2019		
		% of Total		% of Total	
Revenue:					
Medical Device	\$ 17,179	76.2%	\$ 24,849	80.6%	(30.9)%
In Vitro Diagnostics	5,364	23.8%	5,967	19.4%	(10.1)%
Total revenue	<u>\$ 22,543</u>		<u>\$ 30,816</u>		(26.8)%

	Fiscal Year Ended September 30,				% Change
	2020		2019		
		% of Total		% of Total	
Revenue:					
Medical Device	\$ 71,401	75.3%	\$ 78,353	78.3%	(8.9)%
In Vitro Diagnostics	23,463	24.7%	21,724	21.7%	8.0%
Total revenue	<u>\$ 94,864</u>		<u>\$ 100,077</u>		(5.2)%

	Three Months Ended		Fiscal Year Ended	
	September 30,		September 30,	
	2020	2019	2020	2019
Operating (loss) income:				
Medical Device	\$ (1,902)	\$ 3,707	\$ (3,246)	\$ 4,794
In Vitro Diagnostics	2,456	2,774	11,771	10,620
Total segment operating (loss) income	554	6,481	8,525	15,414
Corporate	(2,547)	(2,606)	(9,776)	(8,945)
Total (loss) income from operations	<u>\$ (1,993)</u>	<u>\$ 3,875</u>	<u>\$ (1,251)</u>	<u>\$ 6,469</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		Fiscal Year Ended	
	September 30,		September 30,	
	2020	2019	2020	2019
Net (loss) income	\$ (2,946)	\$ 3,554	\$ 1,123	\$ 7,592
Income tax provision (benefit)	868	564	(2,577)	(34)
Depreciation and amortization	1,873	1,850	7,263	7,312
Investment income, net	(72)	(247)	(656)	(1,097)
Interest expense	34	40	133	152
EBITDA	(243)	5,761	5,286	13,925
Adjustments:				
Contingent consideration expense (gain) (2)	—	87	—	(161)
Foreign exchange loss (3)	—	—	—	(126)
Loss (gain) on strategic investment (4)	—	—	479	(7)
Acquired in-process research and development (5)	—	890	—	890
Claim settlement accrual (6)	—	—	—	(650)
Asset impairment (7)	—	256	—	256
Adjusted EBITDA	\$ (243)	\$ 6,994	\$ 5,765	\$ 14,127
Net Cash Provided by Operating Activities	\$ 1,314	\$ 12,520	\$ 14,010	\$ 8,038

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

Three Months Ended September 30, 2020

	<u>Total</u> <u>Revenue</u>	<u>Operating</u> <u>Loss</u>	<u>Operating</u> <u>Loss</u> <u>Percentage</u>	<u>Loss</u> <u>Before</u> <u>Income</u> <u>Taxes</u>	<u>Net</u> <u>Loss</u> <u>(9)</u>	<u>Diluted</u> <u>EPS</u>	<u>Effective</u> <u>tax rate</u>
GAAP	\$ 22,543	\$ (1,993)	(8.8)%	\$ (2,078)	\$ (2,946)	\$ (0.22)	(41.8)%
Adjustments:							
Amortization of acquired intangible assets (1)	—	547	2.4%	547	517	0.04	
Non-GAAP	<u>\$ 22,543</u>	<u>\$ (1,446)</u>	<u>(6.4)%</u>	<u>\$ (1,531)</u>	<u>\$ (2,429)</u>	<u>\$ (0.18)</u>	<u>(58.7)%</u>

Three Months Ended September 30, 2019

	<u>Total</u> <u>Revenue</u>	<u>Operating</u> <u>Income</u>	<u>Operating</u> <u>Income</u> <u>Percentage</u>	<u>Income</u> <u>Before</u> <u>Income</u> <u>Taxes</u>	<u>Net</u> <u>Income</u> <u>(9)</u>	<u>Diluted</u> <u>EPS</u>	<u>Effective</u> <u>tax rate</u>
GAAP	\$ 30,816	\$ 3,875	12.6%	\$ 4,118	\$ 3,554	\$ 0.26	13.7%
Adjustments:							
Amortization of acquired intangible assets (1)	—	596	1.9%	596	551	0.04	
Contingent consideration expense (2)	—	87	0.3%	87	87	0.01	
Acquired in-process research and development (5)	—	890	2.9%	890	703	0.05	
Asset impairment (7)	—	256	0.8%	256	256	0.02	
Non-GAAP	<u>\$ 30,816</u>	<u>\$ 5,704</u>	<u>18.5%</u>	<u>\$ 5,947</u>	<u>\$ 5,151</u>	<u>\$ 0.37</u>	<u>13.4%</u>

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

Fiscal Year Ended September 30, 2020							
	Total	Operating	Operating	Loss	Net	Diluted	Effective
	Revenue	Loss	Loss	Before	Income	EPS	tax rate
	GAAP	(Income)	(Income)	Income	(9)	GAAP	GAAP
	\$	\$	Percentage	Taxes	\$	\$	%
GAAP	\$ 94,864	\$ (1,251)	(1.3)%	\$ (1,454)	\$ 1,123	\$ 0.08	177.2%
Adjustments:							
Amortization of acquired intangible assets (1)	—	2,218	2.3%	2,218	2,076	0.15	
Loss on strategic investment (4)	—	—	—	479	378	0.03	
Tax impact of CARES Act (8)	—	—	—	—	(1,768)	(0.13)	
Non-GAAP	<u>\$ 94,864</u>	<u>\$ 967</u>	<u>1.0%</u>	<u>\$ 1,243</u>	<u>\$ 1,809</u>	<u>\$ 0.13</u>	<u>(45.5)%</u>
Fiscal Year Ended September 30, 2019							
	Total	Operating	Operating	Income	Net	Diluted	Effective
	Revenue	Income	Income	Before	Income	EPS	tax rate
	GAAP	GAAP	Percentage	Income	(9)	GAAP	GAAP
	\$	\$	GAAP	Taxes	\$	\$	%
GAAP	\$ 100,077	\$ 6,469	6.5%	\$ 7,558	\$ 7,592	\$ 0.55	(0.4)%
Adjustments:							
Amortization of acquired intangible assets (1)	—	2,405	2.4%	2,405	2,226	0.16	
Contingent consideration gain (2)	—	(161)	(0.2)%	(161)	(161)	(0.01)	
Foreign exchange gain (3)	—	—	—	(126)	(126)	(0.01)	
Gain on strategic investment (4)	—	—	—	(7)	(7)	—	
Acquired in-process research and development (5)	—	890	0.9%	890	703	0.05	
Claim settlement (6)	—	(650)	(0.6)%	(650)	(514)	(0.04)	
Asset impairment (7)	—	256	0.2%	256	256	0.02	
Non-GAAP	<u>\$ 100,077</u>	<u>\$ 9,209</u>	<u>9.2%</u>	<u>\$ 10,165</u>	<u>\$ 9,969</u>	<u>\$ 0.72</u>	<u>1.9%</u>

- (1) Amortization of business acquisition-related intangible assets and associated tax impact. A significant portion of the business acquisition-related amortization is not tax deductible.
- (2) 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. These amounts are not taxable or tax deductible.
- (3) Foreign exchange gains and losses are related to marking non-U.S. dollar contingent consideration to period-end or settlement date exchange rates. These gains and losses are not taxable or tax deductible.
- (4) In fiscal 2020, represents the loss recognized on the impairment of a strategic investment for which an effective rate of 21% was used to estimate the income tax impact. In fiscal 2019, represents the gain recognized on the sale of a strategic investment which was not tax-effected as it was offset by previously recognized capital losses.
- (5) Represents acquisition of in-process research and development assets, net of the associated tax impact.
- (6) Represents a royalty-related customer claim accrued at \$1.0 million in the second quarter of fiscal 2018, settled in the second quarter of fiscal 2019 for \$0.4 million.
- (7) Impairment of indefinite-lived intangible assets which were not tax deductible.
- (8) Represents the income tax benefit recognized from the carryback of net operating losses under the Coronavirus Aid, Relief, and Economic Security Act (the "CARES Act") enacted in March 2020.
- (9) Net (loss) income includes the effect of the above adjustments on the income tax provision (benefit), taking into account deferred taxes and non-deductible items. In both fiscal 2020 and fiscal 2019, an effective rate of 21% was used to estimate the income tax impact of the adjustments, except that expenses occurring in Ireland have not been tax-effected as all tax benefits are offset by a full valuation allowance.

Contacts

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