

**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 4, 2021

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	The 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 August 4, 2021, Surmodics, Inc. (the “Company”) issued a press release (the “Press Release”) announcing the results for the quarter ended June 30, 2021. 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 August 4, 2021.
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: August 4, 2021

/s/ Timothy J. Arens

Timothy J. Arens

Senior Vice President of Finance and Chief Financial Officer

Surmodics Reports Third Quarter Fiscal 2021 Results and Updates Fiscal 2021 Revenue and EPS Guidance

EDEN PRAIRIE, Minn.--(BUSINESS WIRE)--August 4, 2021--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 2021 third quarter ended June 30, 2021 and updated its financial outlook for its fiscal 2021.

Summary of Third Quarter and Recent Highlights

- Revenue of \$23.9 million, a decrease of 11% year-over-year
- GAAP EPS of \$(0.24), non-GAAP EPS of \$(0.17)
- PMA submission completed for SurVeil™ drug-coated balloon
- FDA 510(k) clearance received for Sublime™ .018 RX PTA Dilatation Catheter
- Successful first patient use of Pounce™ Thrombectomy System for arterial clot removal
- FDA 510(k) clearance received on expanded indication for Pounce™ Thrombectomy System for use in vessels as small as 3.5 mm
- Acquisition of Vetex Medical Limited expands thrombectomy platform to include venous clot removal

“We made substantial progress in our third quarter to advance our product pipeline, including the final PMA submission for our *SurVeil* drug-coated balloon. We continue to receive valuable and encouraging physician feedback on their clinical experiences using our *Sublime* and *Pounce* products,” said Gary Maharaj, President and CEO of Surmodics, Inc. “In addition, with our recent acquisition of Vetex Medical, we have expanded our innovative thrombectomy platform to be capable of removing both arterial and venous clots.”

Third Quarter Fiscal 2021 Financial Results

Total revenue for the third quarter of fiscal 2021 was \$23.9 million, compared to \$26.9 million in the prior-year period. Medical Device revenue was \$16.8 million for the third quarter of fiscal 2021, compared to \$20.5 million for the prior-year period, a decrease of 18%. Medical Device revenue in the third quarter of fiscal 2021 includes \$1.0 million from our Development and Distribution Agreement with Abbott Vascular, Inc. (“Abbott”) for the *SurVeil* drug-coated balloon (“DCB”), compared to \$7.6 million in the prior-year quarter, which included the impact of the achievement of the CE Mark milestone. In Vitro Diagnostics revenue was \$7.1 million for the third quarter of fiscal 2021, compared to \$6.4 million in the same prior-year quarter, an increase of 12%.

Diluted GAAP loss per share in the third quarter of fiscal 2021 was \$(0.24), compared to earnings per share of \$0.18 in the prior-year period. On a non-GAAP basis, loss per share in the third quarter of fiscal 2021 was \$(0.17), compared to \$0.21 in the same prior-year quarter.

As of June 30, 2021, Surmodics reported cash and investments totaling \$72.0 million and no debt. Surmodics reported \$2.8 million of cash provided by operating activities in the third quarter of fiscal 2021. Capital expenditures totaled \$0.9 million for the third quarter of fiscal 2021. The acquisition of Vetex Medical Limited on July 2, 2021 was funded using \$30 million of cash on hand and \$10 million from the Company’s \$25 million revolving credit facility.

Updated Fiscal 2021 Guidance

As a result of our operating performance in the first nine months of fiscal 2021, we are raising our full-year revenue guidance for fiscal 2021. We are increasing our fiscal 2021 revenue expectations to a range of \$103.5 million to \$105.5 million, from our previous revenue range of \$101 million to \$105 million. Diluted GAAP EPS for fiscal 2021 is now expected to range from a loss per share of \$(0.10) to earnings per share of \$0.05, compared with our previous expectations of a loss per share of \$(0.05) to earnings per share of \$0.20. Diluted non-GAAP EPS for fiscal 2021 is now expected to range from \$0.16 to \$0.31 per share, compared with previous expectations of \$0.10 to \$0.35 per share.

Conference Call Today at 7:30 a.m. CT (8:30 a.m. ET)

Surmodics is hosting 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 1161286. The audio replay will be available beginning at 10:30 a.m. CT on Wednesday, August 4, 2021, until 10:30 a.m. CT on Wednesday, August 11, 2021.

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 revenue and earnings expectations for fiscal 2021; expectations regarding design verification, process validation, and manufacturing validation related to the Company's products; expectations regarding expansion of the potential range of uses of the Company's products; the potential market position of the Company's products; the anticipated fiscal 2021 full-year license revenue associated with the Development and Distribution Agreement with Abbott; expectations regarding FDA premarket approval of our *SurVeil* DCB and the receipt of a related milestone payment from Abbott; the ability of the Company's portfolio of products to create significant long-term shareholder value; the Company's strategy; expectations regarding the conduct and timing of clinical studies and the Company's disclosures related to them; potential products in the Company's development pipeline; plans for clinical product evaluations; potential future revenue amounts under our Development and Distribution Agreement with Abbott; expectations regarding royalty revenue growth, operating expenses and full-year tax expense; expectations regarding the future financial impacts of the acquisition of Vetex Medical Limited; 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*TM DCB, *Sundance*TM 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; (5) our ability to integrate the acquisition of Vetex Medical Limited successfully and realize the anticipated benefits of the acquisition; and (6) 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, 2020 and subsequent SEC filings. 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, 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 also are providing guidance on a range of non-GAAP diluted earnings per share for fiscal 2021. 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.
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		Nine Months Ended	
	June 30,		June 30,	
	2021	2020	2021	2020
Revenue:				
Product sales	\$ 12,084	\$ 11,987	\$ 33,969	\$ 33,731
Royalties and license fees	8,796	12,398	38,182	30,767
Research, development and other	2,993	2,498	9,014	7,823
Total revenue	<u>23,873</u>	<u>26,883</u>	<u>81,165</u>	<u>72,321</u>
Operating costs and expenses:				
Product costs	5,105	4,443	13,018	11,415
Research and development	12,246	13,324	36,003	37,401
Selling, general and administrative	7,885	7,416	22,815	21,092
Acquired intangible asset amortization	560	536	1,676	1,671
Acquisition transaction, integration and other costs	461	—	461	—
Total operating costs and expenses	<u>26,257</u>	<u>25,719</u>	<u>73,973</u>	<u>71,579</u>
Operating (loss) income	(2,384)	1,164	7,192	742
Other (expense) income	(127)	47	(284)	(118)
(Loss) income before income taxes	(2,511)	1,211	6,908	624
Income tax (provision) benefit	(776)	1,248	(2,382)	3,445
Net (loss) income	<u>\$ (3,287)</u>	<u>\$ 2,459</u>	<u>\$ 4,526</u>	<u>\$ 4,069</u>
Basic net (loss) income per share	\$ (0.24)	\$ 0.18	\$ 0.33	\$ 0.30
Diluted net (loss) income per share	\$ (0.24)	\$ 0.18	\$ 0.32	\$ 0.30
Weighted average number of shares outstanding:				
Basic	13,837	13,601	13,740	13,577
Diluted	13,837	13,786	13,959	13,775

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

	June 30,	September 30,
	2021	2020
	(Unaudited)	(See note)
Assets		
Current Assets:		
Cash and cash equivalents	\$ 62,177	\$ 30,785
Available-for-sale securities	5,741	30,313
Accounts receivable, net	8,601	7,675
Contract assets - royalties and license fees	7,043	6,108
Inventories, net	6,316	5,966
Prepays and other	4,234	5,761
Total Current Assets	94,112	86,608
Property and equipment, net	29,112	30,103
Available-for-sale securities	4,050	—
Deferred tax assets	6,368	7,315
Intangible assets, net	11,482	13,283
Goodwill	27,379	27,185
Other assets	4,696	4,269
Total Assets	\$ 177,199	\$ 168,763
Liabilities and Stockholders' Equity		
Current Liabilities:		
Deferred revenue	5,151	5,200
Other current liabilities	12,511	13,692
Total Current Liabilities	17,662	18,892
Deferred revenue	11,035	10,796
Other long-term liabilities	7,670	8,020
Total Liabilities	36,367	37,708
Total Stockholders' Equity	140,832	131,055
Total Liabilities and Stockholders' Equity	\$ 177,199	\$ 168,763

Note: Derived from audited financial statements as of the date indicated.

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

	Three Months Ended June 30,				% Change
	2021		2020		
		% of Total		% of Total	
Revenue:					
Medical Device	\$ 16,755	70.2%	\$ 20,514	76.3%	(18.3)%
In Vitro Diagnostics	7,118	29.8%	6,369	23.7%	11.8%
Total revenue	<u>\$ 23,873</u>		<u>\$ 26,883</u>		(11.2)%
	Nine Months Ended June 30,				% Change
	2021		2020		
		% of Total		% of Total	
Revenue:					
Medical Device	\$ 60,858	75.0%	\$ 54,222	75.0%	12.2%
In Vitro Diagnostics	20,307	25.0%	18,099	25.0%	12.2%
Total revenue	<u>\$ 81,165</u>		<u>\$ 72,321</u>		12.2%
	Three Months Ended June 30,		Nine Months Ended June 30,		
	2021	2020	2021	2020	
Operating (loss) income:					
Medical Device	\$ (2,491)	\$ 532	\$ 5,480	\$ (1,344)	
In Vitro Diagnostics	3,378	3,254	10,407	9,315	
Total segment operating income	887	3,786	15,887	7,971	
Corporate	(3,271)	(2,622)	(8,695)	(7,229)	
Total operating (loss) income	<u>\$ (2,384)</u>	<u>\$ 1,164</u>	<u>\$ 7,192</u>	<u>\$ 742</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,	
	2021	2020	2021	2020
EBITDA and Adjusted EBITDA				
Net (loss) income	\$ (3,287)	\$ 2,459	\$ 4,526	\$ 4,069
Income tax provision (benefit)	776	(1,248)	2,382	(3,445)
Depreciation and amortization	1,844	1,790	5,610	5,390
Investment income, net	(26)	(124)	(95)	(584)
Interest expense	59	29	178	99
EBITDA	<u>(634)</u>	<u>2,906</u>	<u>12,601</u>	<u>5,529</u>
Adjustments:				
Acquisition transaction, integration and other costs (1)	461	—	461	—
Loss on strategic investment (2)	—	—	—	479
Adjusted EBITDA	<u>\$ (173)</u>	<u>\$ 2,906</u>	<u>\$ 13,062</u>	<u>\$ 6,008</u>
Cash Flows from Operations				
Net cash provided by operating activities	<u>\$ 2,755</u>	<u>\$ 11,439</u>	<u>\$ 14,500</u>	<u>\$ 12,696</u>

Guidance Reconciliation: Estimated Non-GAAP Diluted Earnings Per Share
For the Fiscal Year Ending September 30, 2021
(Unaudited)

	Fiscal 2021 Full-Year Estimate	
	Low	High
GAAP diluted EPS	\$ (0.10)	\$ 0.05
Amortization of acquired intangibles per diluted share (3)	0.19	0.19
Acquisition transaction, integration and other costs per diluted share (1)	0.07	0.07
Non-GAAP diluted EPS	<u>\$ 0.16</u>	<u>\$ 0.31</u>

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

For the Three Months Ended June 30, 2021

	<u>Total Revenue</u>	<u>Operating Loss</u>	<u>Operating Loss Percentage</u>	<u>Loss Before Income Taxes</u>	<u>Net Loss (5)</u>	<u>Diluted EPS (6)</u>	<u>Effective tax rate</u>
GAAP	\$ 23,873	\$ (2,384)	(10.0)%	\$ (2,511)	\$ (3,287)	\$ (0.24)	(30.9)%
Adjustments:							
Amortization of acquired intangible assets (3)	—	560	2.4%	560	530	0.04	
Acquisition transaction, integration and other costs (1)	—	461	1.9%	461	461	0.03	
Non-GAAP	<u>\$ 23,873</u>	<u>\$ (1,363)</u>	<u>(5.7)%</u>	<u>\$ (1,490)</u>	<u>\$ (2,296)</u>	<u>\$ (0.17)</u>	<u>(54.1)%</u>

For the Three Months Ended June 30, 2020

	<u>Total Revenue</u>	<u>Operating Income</u>	<u>Operating Income Percentage</u>	<u>Income Before Income Taxes</u>	<u>Net Income (5)</u>	<u>Diluted EPS</u>	<u>Effective tax rate</u>
GAAP	\$ 26,883	\$ 1,164	4.3%	\$ 1,211	\$ 2,459	\$ 0.18	(103.1)%
Adjustments:							
Amortization of acquired intangible assets (3)	—	536	2.0%	536	503	0.03	
Non-GAAP	<u>\$ 26,883</u>	<u>\$ 1,700</u>	<u>6.3%</u>	<u>\$ 1,747</u>	<u>\$ 2,962</u>	<u>\$ 0.21</u>	<u>(69.5)%</u>

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

For the Nine Months Ended June 30, 2021

	Total Revenue	Operating Income	Operating Income Percentage	Income Before Income Taxes	Net Income (5)	Diluted EPS	Effective tax rate
GAAP	\$ 81,165	\$ 7,192	8.9%	\$ 6,908	\$ 4,526	\$ 0.32	34.5%
Adjustments:							
Amortization of acquired intangible assets (3)	—	1,676	2.1%	1,676	1,586	0.12	
Acquisition transaction, integration and other costs (1)	—	461	0.5%	461	461	0.03	
Non-GAAP	<u>\$ 81,165</u>	<u>\$ 9,329</u>	<u>11.5%</u>	<u>\$ 9,045</u>	<u>\$ 6,573</u>	<u>\$ 0.47</u>	<u>27.3%</u>

For the Nine Months Ended June 30, 2020

	Total Revenue	Operating Income	Operating Income Percentage	Income Before Income Taxes	Net Income (5)	Diluted EPS	Effective tax rate
GAAP	\$ 72,321	\$ 742	1.0%	\$ 624	\$ 4,069	\$ 0.30	(552.1)%
Adjustments:							
Amortization of acquired intangible assets (3)	—	1,671	2.3%	1,671	1,559	0.11	
Loss on strategic investment (2)	—	—	—	479	378	0.03	
Tax impact of CARES Act (4)	—	—	—	—	(1,768)	(0.13)	
Non-GAAP	<u>\$ 72,321</u>	<u>\$ 2,413</u>	<u>3.3%</u>	<u>\$ 2,774</u>	<u>\$ 4,238</u>	<u>\$ 0.31</u>	<u>(52.8)%</u>

- (1) Represents expenses specifically associated with the business acquisition of Vetex Medical Limited; these expenses are not tax deductible.
- (2) 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.
- (3) Amortization of business acquisition-related intangible assets and associated tax impact. A significant portion of the business acquisition-related amortization is not tax deductible.
- (4) 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.
- (5) 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 2021 and fiscal 2020, 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.
- (6) Potentially dilutive common shares resulting from dilutive common stock options and non-vested stock relating to restricted stock awards and restricted stock units have been excluded from the calculation of GAAP net loss per share as their effect was antidilutive for three months ended June 30, 2021 as a result of the GAAP net loss for the period.

Contacts

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ir@surmodics.com