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 10, 2	2021	
	Date of report (Date of earlies	st event reported)	
	Surmodics,	Inc.	
	(Exact Name of Registrant as Spe		_
Minnesota	0-23837	41-1356149	
(State of Incorporation)	(Commission File Nu	Tumber) (I.R.S. Employed Identification No.	
9924 West 74th Street Eden Prairie, Minnesota		55344	
(Address of Principal Executive C	Offices)	(Zip Code)	
	(952) 500-700	00	
(1	Registrant's Telephone Number, I		
☐ Pre-commencement communications pu	-12 under the Exchange Actursuant to Rule 14d-2(b) undursuant to Rule 13e-4(c) und	tt (17 CFR 240.14a-12) der the Exchange Act (17 CFR 240.14d-2(b)) der the Exchange Act (17 CFR 240.13e-4(c))	
Securiti	es registered pursuant to S	Section 12(b) of the Act:	
<u>Title of Each Class</u> Common Stock, \$0.05 par value	<u>Trading Symbol(s)</u> SRDX	Name of Each Exchange on Which Regist The Nasdaq Global Select Market	<u>ered</u>
		h company as defined in Rule 405 of the Senge Act of 1934 (§240.12b-2 of this chapter).	curities Act of
		Emerging growt	h company □
If an emerging growth company, indicate by check new or revised financial accounting standards provi		l not to use the extended transition period for complying the Exchange Act.	g with any \Box

Item 2.02 Results of Operations and Financial Condition.

On November 10, 2021, Surmodics, Inc. (the "<u>Company</u>") issued a press release (the "<u>Press Release</u>") announcing the Company's financial results for the quarter ended September 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
<u>99.1</u>	Press Release dated November 10, 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: November 10, 2021 /s/Timothy J. Arens

Timothy J. Arens

Senior Vice President of Finance and Chief Financial Officer

Surmodics Reports Fourth Quarter Fiscal 2021 Results and Issues Fiscal 2022 Revenue and EPS Guidance

EDEN PRAIRIE, Minn.--(BUSINESS WIRE)--November 10, 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 fourth quarter ended September 30, 2021 and provided its financial outlook for its fiscal 2022.

Summary of Fourth Quarter and Recent Highlights

- Revenue of \$24.0 million, an increase of 6% year-over-year
- GAAP EPS of \$(0.02), non-GAAP EPS of \$(0.10)
- Successful first patient use Sublime™ .018 RX PTA Dilatation Catheter

"We're extremely pleased to share that the Sublime™ and Pounce™ clinical product evaluations are confirming the meaningful advantages of our radial access and arterial thrombectomy products," said Gary Maharaj, President and CEO of Surmodics, Inc. "Our fiscal 2022 promises to be an exciting year as we accelerate the commercialization of our innovative radial access, thrombectomy and drug-coated balloon platforms."

Fourth Quarter Fiscal 2021 Financial Results

Total revenue for the fourth quarter of fiscal 2021 was \$24.0 million, compared to \$22.5 million in the prior-year period. Medical Device revenue was \$17.4 million for the fourth quarter of fiscal 2021, compared to \$17.2 million for the prior-year period, an increase of 1%. Medical Device revenue in the fourth quarter of fiscal 2021 includes \$1.2 million from our Development and Distribution Agreement with Abbott Vascular, Inc. ("Abbott") for the SurVeil™ drug-coated balloon, compared to \$1.6 million in the prior-year quarter. In Vitro Diagnostics revenue was \$6.6 million for the fourth quarter of fiscal 2021, compared to \$5.4 million in the same prior-year quarter, an increase of 23%.

Diluted GAAP earnings per share in the fourth quarter of fiscal 2021 was a loss per share of \$(0.02), compared to a loss per share of \$(0.22) in the prior-year period. On a non-GAAP basis, loss per share in the fourth quarter of fiscal 2021 was \$(0.10), compared to a loss per share of \$(0.18) in the same prior-year quarter. On a non-GAAP basis, adjusted net loss and adjusted EPS exclude a \$2.6 million and \$0.19 per share tax-effected benefit, respectively, recorded in the fourth quarter of fiscal 2021 related to the reimbursement of certain expenses under the employee retention credit provisions of the Coronavirus Aid, Relief and Economic Security Act (the "CARES Act").

As of September 30, 2021, Surmodics reported cash and investments totaling \$40.9 million and \$10 million in outstanding borrowings on its \$25 million line of credit. Surmodics reported \$0.9 million of cash provided by operating activities and \$2.4 million in capital expenditures in the fourth quarter of fiscal 2021. Surmodics completed its acquisition of Vetex Medical Limited during the fourth quarter of fiscal 2021, with the upfront cash payment of \$39.9 million funded using cash on hand and \$10 million from the Company's \$25 million line of credit.

Fiscal 2022 Guidance

Surmodics has the potential to receive a \$30 million milestone payment during fiscal 2022 related to premarket approval of the *SurVeil* DCB pursuant to the Abbott Development and Distribution Agreement. The potential revenue associated with this milestone payment would be approximately \$25 million. As has been the Company's practice with past guidance, revenue from regulatory-related milestones is not included in guidance until they are achieved.

Surmodics expects fiscal year 2022 revenue to range from \$97 million to \$101 million. The Company expects fiscal 2022 diluted GAAP EPS to range from a loss per share of \$(2.05) to \$(1.55), which reflects increased investments to accelerate the Company's strategy. Non-GAAP diluted EPS for fiscal 2022 is expected to range from a loss per share of \$(1.75) to \$(1.25).

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 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 2633660. The audio replay will be available beginning at 10:30 a.m. CT on Wednesday, November 10, 2021, until 10:30 a.m. CT on Wednesday, November 17, 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 loss expectations for fiscal 2022; expectations regarding acceleration of the commercialization of the Company's radial access, thrombectomy and drug-coated balloon platforms; expectations regarding design verification, process validation, and manufacturing validation related to the Company's products; our fiscal 2022 objectives; 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 2022 full-year license revenue associated with the Development and Distribution Agreement with Abbott; expectations regarding FDA premarket review timing and process and the potential approval of our *SurVeil DCB*; the potential receipt of a premarket approval milestone payment from Abbott; the expected timing of completion and delivery of the SWING first-inhuman clinical trial results; the potential of the Company's products and fiscal 2022 activities to create long-term value; the Company's strategy; plans for clinical product evaluations; the anticipated reimbursement under CARES Act Employee Retention Credit; expectations regarding revenue from our Sublime and Pounce product portfolios and growth in the value of those portfolios; and expectations regarding fiscal 2022 revenue growth, operating expenses and tax expense, are forwardlooking 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), AvessTM DCB, SundanceTM DCB, and other proprietary products; (2) whether and when the FDA grants premarket approval to the SurVeil DCB; (3) 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; (4) possible adverse market conditions and possible adverse impacts on our cash flows; (5) 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; (6) our ability to integrate the acquisition of Vetex Medical Limited successfully and realize the anticipated benefits of the acquisition; and (7) 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 loss per share for fiscal 2022. 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 Operations (in thousands, except per share data) (Unaudited)

		Fiscal Year Ended						
		Septen	ıber (30,	 Septen	ıber	30,	
		2021		2020	 2021		2020	
Revenue:								
Product sales	\$	12,509	\$	10,586	\$ 46,478	\$	44,317	
Royalties and license fees		8,874		9,867	47,056		40,634	
Research, development and other		2,588		2,090	11,602		9,913	
Total revenue		23,971		22,543	 105,136		94,864	
Operating costs and expenses:								
Product costs		4,159		3,902	17,177		15,317	
Research and development		10,731		12,787	46,734		50,188	
Selling, general and administrative		7,865		7,300	30,680		28,392	
Acquired intangible asset amortization		1,117		547	2,793		2,218	
Acquisition transaction, integration and other costs		588			 1,049			
Total operating costs and expenses		24,460		24,536	 98,433		96,115	
Operating (loss) income		(489)		(1,993)	6,703		(1,251)	
Other expense, net		(73)		(85)	 (357)		(203)	
(Loss) income before income taxes		(562)		(2,078)	6,346		(1,454)	
Income tax benefit (provision)		273		(868)	 (2,109)		2,577	
Net (loss) income	\$	(289)	\$	(2,946)	\$ 4,237	\$	1,123	
Basic (loss) income per share:	\$	(0.02)	\$	(0.22)	\$ 0.31	\$	0.08	
Diluted (loss) income per share:	\$	(0.02)	\$	(0.22)	\$ 0.30	\$	0.08	
Weighted average number of shares outstanding:								
Basic		13,851		13,639	13,765		13,552	
Diluted		13,851		13,639	13,989		13,812	

Surmodics, Inc. and Subsidiaries Condensed Consolidated Balance Sheets

(in thousands)

	Septem	ıber 30,
	2021	2020
Assets		
Current Assets:		
Cash and cash equivalents	\$ 31,153	\$ 30,785
Available-for-sale securities	7,717	30,313
Accounts receivable, net	9,169	7,675
Contract assets — royalties and license fees	7,091	6,108
Inventories, net	6,760	5,966
Prepaids and other	8,365	5,761
Total Current Assets	70,255	86,608
Property and equipment, net	30,090	30,103
Available-for-sale securities	2,002	_
Deferred income taxes	5,867	7,315
Intangible assets, net	37,054	13,283
Goodwill	45,606	27,185
Other assets	3,718	4,269
Total Assets	\$194,592	\$168,763
Liabilities and Stockholders' Equity		·
Current Liabilities:		
Short-term borrowings	10,000	_
Deferred revenue	4,647	5,200
Other current liabilities	15,168	13,692
Total Current Liabilities	29,815	18,892
Deferred revenue	10,301	10,796
Other long-term liabilities	14,391	8,020
Total Liabilities	54,507	37,708
Total Stockholders' Equity	140,085	131,055
Total Liabilities and Stockholders' Equity	\$194,592	\$168,763

Surmodics, Inc. and Subsidiaries Supplemental Segment Information

(in thousands) (Unaudited)

2021

Three Months Ended Septemb	oer 30.
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2020

	% (of Total			%	of Total	% Change
\$ 17,395	7	2.6%	\$	17,179		76.2%	1.3%
 6,576	2	7.4%		5,364		23.8%	22.6%
\$ 23,971			\$	22,543			6.3%
	Fiscal	Year Ended	d Sept	tember 30,			
 20	21			20	20		
	% (of Total			%	of Total	% Change
\$ 78,253	7	4.4%	\$	71,401		75.3%	9.6%
 26,883	2	5.6%		23,463		24.7%	14.6%
\$ 105,136			\$	94,864			10.8%
Three Mon	ths En	ded		Fiscal Yea	ar En	ded	
Septem	ber 30,			Septem	0,		
 2021	2	2020		2021		2020	
\$ (797)	\$	(1,902)	\$	4,683	\$	(3,246)	
3,363		2,456		13,770		11,771	
 2,566		554		18,453		8,525	
 (3,055)		(2,547)		(11,750)		(9,776)	
\$ (489)	\$	(1.993)	\$	6.703	\$	(1.251)	
\$ \$	6,576 \$ 23,971 20 \$ 78,253	\$ 17,395	Color	\$ 17,395 72.6% \$ 6,576 27.4% \$ 23,971 \$ \$ \$ \$ 23,971 \$ \$ \$ \$ \$ \$ 2021 \$ \$ \$ \$ 26,883 25.6% \$ \$ 105,136 \$ \$ \$ \$ \$ \$ 2020 \$ \$ \$ (797) \$ \$ (1,902) \$ \$ 3,363 2,456 2,566 554 (3,055) \$ (2,547) \$ \$ \$ \$ \$ 25.6% \$ \$ \$ \$ \$ \$ \$ \$ \$ \$ \$ \$ \$ \$ \$ \$ \$ \$ \$	\$ 17,395	\$ 17,395	$ \begin{array}{c ccccccccccccccccccccccccccccccccccc$

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 Mon Septem		Fiscal Yea				
	 2021	DCI 50	2020	 2021	iber :	2020	
Net (loss) income	\$ (289)	\$	(2,946)	\$ 4,237	\$	1,123	
Income tax (benefit) provision	(273)		868	2,109		(2,577)	
Depreciation and amortization	2,407		1,873	8,017		7,263	
Investment income, net	(28)		(72)	(123)		(656)	
Interest expense	132		34	310		133	
EBITDA	1,949		(243)	 14,550		5,286	
Adjustments:							
Acquisition transaction, integration and other costs (1)	588			1,049		_	
CARES Act Employee Retention Credit (2)	(3,577)			(3,577)		_	
Loss on strategic investment (3)	_		_	_		479	
Adjusted EBITDA	\$ (1,040)	\$	(243)	\$ 12,022	\$	5,765	
Net Cash Provided by Operating Activities	\$ 889	\$	1,314	\$ 15,389	\$	14,010	

Guidance Reconciliation: Estimated Non-GAAP Diluted Earnings Per Share For the Fiscal Year Ending September 30, 2022

(Unaudited)

]	Fiscal 2022 Full	-Year	Estimate
		Low		High
GAAP diluted EPS	\$	(2.05)	\$	(1.55)
Amortization of acquired intangibles per diluted share (4)		0.30		0.30

Surmodics, Inc., and Subsidiaries Net Loss and Diluted EPS GAAP to Non-GAAP Reconciliation

(in thousands, except per share data) (Unaudited)

For the Three Months Ended September 30, 2021

	Total evenue	OĮ	perating Loss	Operating Loss Percentage	E In	Loss Before ncome Taxes	Net Loss (6)	 iluted EPS (7)	Effective tax rate
GAAP	\$ 23,971	\$	(489)	(2.0)%	\$	(562)	\$ (289)	\$ (0.02)	48.6%
Adjustments:									
Amortization of acquired intangible assets (4)	_		1,117	4.7%		1,117	1,014	0.07	
Acquisition transaction, integration and other costs									
(1)	_		588	2.4%		588	554	0.04	
CARES Act Employee Retention Credit (2)	_		(3,577)	(14.9)%		(3,577)	(2,617)	(0.19)	
Non-GAAP	\$ 23,971	\$	(2,361)	(9.8)%	\$	(2,434)	\$ (1,338)	\$ (0.10)	45.0%

For the Three Months Ended September 30, 2020

			Loss Operating Before Net Diluted											
		Total	Oı	perating	Operating Loss		Before ncome		Net Loss		nutea EPS	Effective		
	R	evenue		Loss	Percentage	Taxes		(6)		(7)		tax rate		
GAAP	\$	22,543	\$	(1,993)	(8.8)%	\$	(2,078)	\$	(2,946)	\$	(0.22)	(41.8)%		
Adjustments:														
Amortization of acquired intangible assets (4)		_		547	2.4%		547		517		0.04			
Non-GAAP	\$	22,543	\$	(1,446)	(6.4)%	\$	(1,531)	\$	(2,429)	\$	(0.18)	(58.7)%		

Surmodics, Inc., and Subsidiaries Net Income and Diluted EPS GAAP to Non-GAAP Reconciliation

(in thousands, except per share data)
(Unaudited)

Fiscal Year Ended September 30, 2021

	Total Revenue	erating ncome	Operating Income Percentage	B Ir	ncome Before ncome Taxes	Net icome (6)	iluted EPS	Effective tax rate
GAAP	\$ 105,136	\$ 6,703	6.4%	\$	6,346	\$ 4,237	\$ 0.30	33.2%
Adjustments:								
Amortization of acquired intangible assets (4)	_	2,793	2.7%		2,793	2,600	0.19	
Acquisition transaction, integration and other costs								
(1)		1,049	1.0%		1,049	1,015	0.07	
CARES Act Employee Retention Credit (2)		(3,577)	(3.5)%		(3,577)	(2,617)	(0.19)	
Non-GAAP	\$ 105,136	\$ 6,968	6.6%	\$	6,611	\$ 5,235	\$ 0.37	20.8%

Fiscal Year Ended September 30, 2020

	Total evenue	(perating Loss) ncome	Operating (Loss) Income Percentage	In E In	Loss) ncome Before ncome Taxes	Net ncome (6)	luted EPS	Effective tax rate
GAAP	\$ 94,864	\$	(1,251)	(1.3)%	\$	(1,454)	\$ 1,123	\$ 0.08	177.2%
Adjustments:									
Amortization of acquired intangible assets (4)	_		2,218	2.3%		2,218	2,076	0.15	
Loss on strategic investment (3)	_		_	_		479	378	0.03	
Discrete tax impact of CARES Act (5)	_		_	_		_	(1,768)	(0.13)	
Non-GAAP	\$ 94,864	\$	967	1.0%	\$	1,243	\$ 1,809	\$ 0.13	(45.5)%

- (1) Represents expenses specifically associated with the business acquisition of Vetex Medical Limited and associated tax impact. A significant proportion of the acquisition expenses are not tax deductible.
- (2) Represents the benefit recorded as a result of the employee retention credit that the Company filed for under the provisions of the Coronavirus Aid, Relief and Economic Security Act (the "CARES Act") enacted in March 2020. The estimated tax impact reflects the combined impact of the statutory tax rate of 21% and a reduction in research and development tax credits.
- (3) In fiscal 2020, represents the loss recognized on the impairment of a strategic investment and associated tax impact.
- (4) Amortization of business acquisition-related intangible assets and associated tax impact. A significant portion of the business acquisition-related amortization is not tax deductible.
- (5) Represents the discrete income tax benefit recognized in fiscal 2020 from the carryback of net operating losses under the provisions of the CARES Act.
- (6) Net (loss) income includes the effect of the above adjustments on the income tax benefit (provision), taking into account deferred taxes and non-deductible items. Income tax impacts were estimated using the applicable statutory rate (21% in the U.S. and 12.5% in Ireland).
- (7) 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 September 30, 2021 and 2020 as a result of the GAAP net loss for these periods.

Contacts

Surmodics, Inc. Tim Arens, 952-500-7000 ir@surmodics.com