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

	April 27, 2022	
	Date of report (Date of earliest event reported)	
	Surmodics, Inc.	
	(Exact Name of Registrant as Specified in its Charter)	
Minnesota	0-23837	41-1356149
(State of Incorporation)	(Commission File Number)	(I.R.S. Employer Identification No.)
9924 West 74th Street		
Eden Prairie, Minnesot	a	55344
(Address of Principal Executive	Offices)	(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:

Title of Each Class	Trading Symbol(s)	Name of Each Exchange on Which Registered
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 \Box

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 \Box 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 April 27, 2022, 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 March 31, 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 April 27, 2022.
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: April 27, 2022

/s/ Timothy J. Arens

Timothy J. Arens Senior Vice President of Finance and Chief Financial Officer

Surmodics Reports Second Quarter Fiscal 2022 Results

EDEN PRAIRIE, Minn.--(BUSINESS WIRE)--April 27, 2022--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 2022 second quarter ended March 31, 2022 and updated its financial outlook for its fiscal 2022.

Summary of Second Quarter and Recent Highlights

- Revenue of \$26.1 million, a sequential increase of 13%
- Record In Vitro Diagnostics revenue of \$7.7 million
- GAAP EPS of \$(0.29), non-GAAP EPS of \$(0.22)
- Double-digit product sales growth year-over-year from both Medical Device and In Vitro Diagnostics businesses

"In our second quarter, we continued to grow our customer pipeline and secure new customer accounts for our Sublime[™] radial and Pounce[™] arterial thrombectomy platforms, further validating our commercialization strategy," said Gary Maharaj, President and CEO of Surmodics, Inc. "In addition, we made progress on our SurVeil[™] DCB PMA application by submitting responses to key information requested by the FDA."

Second Quarter Fiscal 2022 Financial Results

Total revenue for the second quarter of fiscal 2022 was \$26.1 million, a sequential increase of 13% from total revenue of \$23.0 million in the first quarter of fiscal 2022. Total revenue was \$35.0 million in the prior-year second quarter, which included \$10.8 million in revenue recognized on a \$15 million clinical report milestone payment. Medical Device revenue was \$18.5 million for the second quarter of fiscal 2022, compared to \$27.9 million in the prior-year period. Medical Device revenue in the second quarter of fiscal 2022 includes \$1.4 million from our Development and Distribution Agreement with Abbott Vascular, Inc. ("Abbott") for the SurVeilTM drug-coated balloon, compared to \$12.5 million in the prior-year quarter, which included the revenue recognized on the clinical report milestone payment. In Vitro Diagnostics revenue was \$7.7 million for the second quarter of fiscal 2022, compared to \$7.1 million in the prior-year quarter, an increase of 8% and a new record for the In Vitro Diagnostics business.

Diluted GAAP earnings per share in the second quarter of fiscal 2022 was a loss per share of (0.29), compared to earnings per share of 0.58 in the same prior-year period. On a non-GAAP basis, loss per share in the second quarter of fiscal 2022 was (0.22), compared to earnings per share of 0.62 in the same prior-year quarter.

As of March 31, 2022, Surmodics reported cash and investments totaling \$26.7 million and \$10 million in outstanding borrowings on its \$25 million line of credit. Surmodics reported \$4.2 million of cash used in operating activities and \$1.2 million in capital expenditures for the second quarter of fiscal 2022.

Updated Fiscal 2022 Guidance

As a result of our operating performance for the first six months of fiscal 2022, we are raising our full-year revenue and EPS guidance for fiscal 2022. We are increasing our fiscal 2022 revenue expectations to a range of \$98 million to \$101 million, from our previous range of \$97 million to \$101 million. We are raising our fiscal 2022 diluted GAAP EPS expectations to a range from a loss per share of \$(1.70) to \$(1.35), which reflects continued investments to accelerate the Company's strategy. Non-GAAP diluted EPS for fiscal 2022 is expected to range from a loss per share of \$(1.07).

Surmodics has the potential to receive a \$30 million milestone payment during fiscal 2022 or fiscal 2023 related to premarket approval of the *SurVeil* DCB pursuant to the Abbott Development and Distribution Agreement. The potential revenue associated with the \$30 million milestone payment would be approximately \$25 million. The milestone payment is reduced to \$27 million if premarket approval is received after December 31, 2022. As has been the Company's practice with past guidance, revenue from regulatory-related milestones is not included in guidance until they are achieved.

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 second 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, or dial in at 888-394-8218 and enter conference call ID passcode 9978316. The webcast will be archived on the Company's website for 90 days. A replay of the second quarter conference call will be available by dialing 888-203-1112 and entering conference call ID passcode 9978316. The audio replay will be available beginning at 10:30 a.m. CT on Wednesday, April 27, 2022, until 10:30 a.m. CT on Wednesday, May 4, 2022.

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 our fiscal 2022 strategic objectives and our ability to deliver on our fiscal 2022 financial and strategic objectives; our revenue and loss expectations for fiscal 2022 and beyond, including our fiscal 2022 financial guidance; expectations regarding full-year fiscal 2022 income tax benefit; expectations regarding revenue growth; expectations regarding actions related to the U.S. Food and Drug Administration's ("FDA") review of the premarket approval application for, and the potential FDA approval of, our SurVeil DCB; the potential receipt of a premarket approval milestone payment from Abbott; expectations regarding the potential presentation of data from the SWING first-in-human clinical trial; the Company's strategy; expectations regarding the U.S. launch of the SurVeil DCB; plans for clinical product evaluations; expectations regarding revenue from our Sublime and Pounce product portfolios; expectations regarding fiscal 2022 operating expenses; and our anticipated fiscal 2022 year-end cash balance, 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), 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; (7) current and future supply chain constraints; (8) whether anticipated increases in our operating expenses are effective in generating profitable revenues; and (9) 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, 2021 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)

	Т	Three Months Ended March 31,					ths Ended ch 31,		
	_	2022		2021		2022		2021	
Revenue:									
Product sales	\$	13,964	\$	11,783	\$	26,308	\$	21,885	
Royalties and license fees		9,844		20,052		17,943		29,386	
Research, development and other		2,298		3,160		4,858		6,021	
Total revenue		26,106		34,995		49,109		57,292	
Operating costs and expenses:									
Product costs		5,107		4,170		9,604		7,913	
Research and development		13,712		12,875		25,375		23,757	
Selling, general and administrative		11,116		7,907		20,311		14,930	
Acquired intangible asset amortization		1,071		560		2,160		1,116	
Total operating costs and expenses		31,006		25,512	_	57,450		47,716	
Operating (loss) income		(4,900)		9,483		(8,341)		9,576	
Other (expense) income		(102)		42		(179)		(157)	
(Loss) income before income taxes		(5,002)		9,525		(8,520)		9,419	
Income tax benefit (provision)		919		(1,438)		1,625		(1,606)	
Net (loss) income	\$	(4,083)	\$	8,087	\$	(6,895)	\$	7,813	
Basic net (loss) income per share	\$	(0.29)	\$	0.59	\$	(0.50)	\$	0.57	
Diluted net (loss) income per share	\$	(0.29)	\$	0.58	\$	(0.50)	\$	0.56	
Weighted average number of shares outstanding:									
Basic		13,917		13,746		13,896		13,699	
Diluted		13,917		13,981		13,896		13,915	

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

September March 31, 30, 2021 2022 (Unaudited) (See note) Assets Current Assets: \$ Cash and cash equivalents 24,712 \$ 31,153 Available-for-sale securities 2,007 7,717 11,037 9,169 Accounts receivable, net Contract assets - royalties and license fees 7,242 7,091 Inventories, net 9,471 6,760 Prepaids and other 10,212 8,365 Total Current Assets 64,681 70,255 Property and equipment, net 29,079 30,090 Available-for-sale securities 2,002 7,181 Deferred tax assets 5,867 Intangible assets, net 33,511 37,054 Goodwill 44,248 45,606 Other assets 5,487 3,718 184,187 \$ 194,592 \$ Total Assets Liabilities and Stockholders' Equity Current Liabilities: Short-term borrowings 10,000 10,000 Deferred revenue 4,019 4,647 14,350 15,168 Other current liabilities 29,815 Total Current Liabilities 28,369 Deferred revenue 10,301 8,423 Other long-term liabilities 14,132 14,391 Total Liabilities 50,924 54,507 133,263 Total Stockholders' Equity 140,085 184,187 194,592 \$ \$ Total Liabilities and Stockholders' Equity

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

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

(Unaudited)

Thre	e Months 1	Ended March	ı 31 ,	
20	22	20	21	_
	% of		% of	%
	Total		Total	Change
\$ 18,453	70.7%	\$ 27,907	79.7%	(33.9)%
7,653	29.3%	7,088	20.3%	8.0%
\$ 26,106		\$ 34,995		(25.4)%
	20 \$ 18,453 7,653	2022 % of Total \$ 18,453 70.7% 7,653 29.3%	2022 20 % of Total 70.7% \$ 27,907 7,653 29.3% 7,088	% of Total % of Total \$ 18,453 70.7% \$ 27,907 79.7% 7,653 29.3% 7,088 20.3%

	Six	Months E	nded March 3	81,	
	202	22	202	21	-
		% of		% of	%
Revenue:		Total	_	Total	Change
Medical Device	\$ 35,361	72.0%	\$ 44,103	77.0%	(19.8)%
In Vitro Diagnostics	13,748	28.0%	13,189	23.0%	4.2%
Total revenue	\$ 49,109		\$ 57,292		(14.3)%

	Т	Three Months Ended March 31,		Six Months E March 31				
		2022		2021		2022		2021
Operating (loss) income:								
Medical Device	\$	(5,612)	\$	8,564	\$	(9,404)	\$	7,971
In Vitro Diagnostics		3,720		3,809		6,875		7,029
Total segment operating (loss) income		(1,892)		12,373	_	(2,529)		15,000
Corporate		(3,008)		(2,890)		(5,812)		(5,424)
Total operating (loss) income	\$	(4,900)	\$	9,483	\$	(8,341)	\$	9,576

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)

March 31,		Six		nths Ended arch 31,			
	2022		2021	20	22		2021
\$	(4,083)	\$	8,087	\$ (6	,895)	\$	7,813
	(919)		1,438	(1	,625)		1,606
	2,320		1,906	4	,696		3,766
	(25)		(28)		(51)		(69)
	129		59		265		119
	(2,578)		11,462	(3	,610)		13,235
	_		_		_		
\$	(2,578)	\$	11,462	\$ (3	,610)	\$	13,235
		2022 \$ (4,083) (919) 2,320 (25) 129 (2,578)	2022 \$ (4,083) \$ (919) 2,320 (25) 129 (2,578)	2022 2021 \$ (4,083) \$ 8,087 (919) 1,438 2,320 1,906 (25) (28) 129 59 (2,578) 11,462	$\begin{array}{ c c c c c c c c c c c c c c c c c c c$	2022 2021 2022 \$ (4,083) \$ 8,087 \$ (6,895) (919) 1,438 (1,625) 2,320 1,906 4,696 (25) (28) (51) 129 59 265 (2,578) 11,462 (3,610)	$\begin{array}{ c c c c c c c c c c c c c c c c c c c$

Cash Flows from Operations

Net cash (used in) provided by operating activities

\$ (4,200) \$ 16,015 \$ (11,226) \$ 11,745

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

(Unaudited)

	Fi	scal 2022 Estim	Full-Year ate
		Low	High
GAAP diluted EPS	\$	(1.70)	\$ (1.35)
Amortization of acquired intangibles per diluted share (1)		0.28	0.28
Non-GAAP diluted EPS	\$	(1.42)	\$ (1.07)

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 Mo	nths Ended	March 31,	2022	
	Total Revenue	Operating Loss	Operating Loss Percentage	Loss Before Income Taxes	Net Loss (2)	Diluted EPS (3)	Effective Tax Rate
GAAP	\$ 26,106	5 \$ (4,900)	(18.8)%	\$ (5,002)	\$ (4,083)	\$ (0.29)	18.4%
Adjustments: Amortization of acquired intangible assets (1)		- 1,071	4.1%	1,071	973 \$ (3,110)	$\frac{0.07}{(0.22)}$	20.0%
Non-GAAP	\$ 26,106	\$ (3,829)	(14.7)%	\$ (3,931)	\$ (3,110)	\$ (0.22)	20.9%
		For	the Three Mo	onths Ended	March 31,	2021	
	Total Revenue	Operating Income	Operating Income Percentage	Income Before Income Taxes	Net Income (2)	Diluted EPS	Effective Tax Rate
GAAP Adjustments: Amortization of acquired	\$ 34,995	\$ 9,483	27.1%	\$ 9,525	\$ 8,087	\$ 0.58	15.1%
intangible assets (1)	_	560	1.6%	560	530	0.04	
Non-GAAP	\$ 34,995	\$ 10,043	28.7%	\$ 10,085	\$ 8,617	\$ 0.62	14.6%
			r the Six Mont Operating	Loss Before	Net	Diluted	Effective
	Total Revenue	Operating Loss		Income Taxes	Loss (2)	EPS (3)	Tax
GAAP		1055	гегсентяре				Rate
Adjustments: Amortization of acquired	\$ 49,109	\$ (8,341)	Percentage (17.0)%				Rate 19.1%
Adjustments: Amortization of acquired intangible assets (1)	\$ 49,109	\$ (8,341) 2,160	0				
Amortization of acquired	\$ 49,109 		(17.0)%	\$ (8,520)	\$ (6,895)	\$ (0.50) 0.15	19.1%
Amortization of acquired intangible assets (1)		2,160	(17.0)%	\$ (8,520) 2,160 \$ (6,360)	\$ (6,895) <u>1,963</u> <u>\$ (4,932)</u>	\$ (0.50) 0.15 \$ (0.35)	19.1%
Amortization of acquired intangible assets (1)		2,160	(17.0)% 4.4% (12.6)% r the Six Mon	\$ (8,520) 2,160 \$ (6,360) ths Ended M Income	$\frac{1,963}{\$ (4,932)}$	\$ (0.50) 0.15 \$ (0.35)	22.5%
Amortization of acquired intangible assets (1)	\$ 49,109 Total	2,160 (6,181) Fo Operating	(17.0)% 4.4% (12.6)% r the Six Mon Operating Income	\$ (8,520) 2,160 \$ (6,360) ths Ended M Income Before Income	\$ (6,895) <u>1,963</u> <u>\$ (4,932)</u> Warch 31, 2 Net Income	\$ (0.50) 0.15 \$ (0.35) 021 Diluted	19.1% 22.5% Effective Tax
Amortization of acquired intangible assets (1) Non-GAAP GAAP Adjustments:	\$ 49,109	2,160 \$ (6,181) Fo	(17.0)% 4.4% (12.6)% r the Six Mon Operating	\$ (8,520) 2,160 \$ (6,360) ths Ended M Income Before Income Taxes	\$ (6,895) <u>1,963</u> <u>\$ (4,932)</u> March 31, 2 Net	\$ (0.50) 0.15 \$ (0.35) 021	19.1% 22.5% Effective Tax Rate
Amortization of acquired intangible assets (1) Non-GAAP GAAP	\$ 49,109 Total Revenue	2,160 \$ (6,181) Fo Operating Income	(17.0)% 4.4% (12.6)% r the Six Mon Operating Income Percentage	\$ (8,520) 2,160 \$ (6,360) ths Ended M Income Before Income Taxes \$ 9,419 1,116	\$ (6,895) <u>1,963</u> <u>\$ (4,932)</u> March 31, 2 Net Income (2)	\$ (0.50) 0.15 \$ (0.35) 021 Diluted EPS	19.1% 22.5% Effective Tax

- (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) 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).
- (3) 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 and six months ended March 31, 2022 as a result of the GAAP net loss for these periods.

Contacts

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