

**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**

July 27, 2022

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 July 27, 2022, Surmodics, Inc. (the “Company”) issued a press release (the “Press Release”) announcing the Company’s financial results for the quarter ended June 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.

Item 9.01 Financial Statements and Exhibits.

(d) *Exhibits.*

Exhibit**Number Description**

[99.1](#) [Press Release dated July 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: July 27, 2022

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

Surmodics Reports Third Quarter Fiscal 2022 Results

EDEN PRAIRIE, Minn.--(BUSINESS WIRE)--July 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 third quarter ended June 30, 2022 and updated its financial outlook for its fiscal 2022.

Summary of Third Quarter and Recent Highlights

- Revenue of \$24.9 million, an increase of 4% year-over-year
- GAAP EPS of \$(0.41), non-GAAP EPS of \$(0.34)
- Fourth consecutive quarter of double-digit product sales growth year-over-year

“We delivered solid financial results that were in line with our expectations, while continuing to make meaningful investments in our growth initiatives,” said Gary Maharaj, President and CEO of Surmodics, Inc. “Importantly, we are demonstrating early and promising commercial viability for our Pounce™ and Sublime™ products with our commercial footprint and customer base.”

Third Quarter Fiscal 2022 Financial Results

Total revenue for the third quarter of fiscal 2022 was \$24.9 million, compared to \$23.9 million in the prior-year period. Medical Device revenue was \$17.5 million for the third quarter of fiscal 2022, compared to \$16.8 million in the prior-year period, an increase of 5%. Medical Device revenue in both the third quarter of fiscal 2022 and 2021 includes \$1.0 million from our Development and Distribution Agreement with Abbott Vascular, Inc. (“Abbott”) for the SurVeil™ drug-coated balloon (“DCB”). In Vitro Diagnostics revenue was \$7.3 million for the third quarter of fiscal 2022, compared to \$7.1 million in the prior-year quarter, an increase of 3%.

Diluted GAAP loss per share in the third quarter of fiscal 2022 was \$(0.41), compared to \$(0.24) in the same prior-year period. On a non-GAAP basis, loss per share in the third quarter of fiscal 2022 was \$(0.34), compared to \$(0.17) in the same prior-year quarter.

As of June 30, 2022, Surmodics reported cash and investments totaling \$22.1 million and \$10 million in outstanding borrowings on its \$25 million line of credit. Surmodics reported \$3.5 million of cash used in operating activities and \$0.9 million in capital expenditures for the third quarter of fiscal 2022.

Updated Fiscal 2022 Guidance

Surmodics is revising its fiscal year 2022 revenue guidance to reflect expected softness in customer demand and raising its fiscal year 2022 EPS guidance to reflect solid year-to-date results. Surmodics expects full year fiscal 2022 revenue to range from \$97 million to \$99 million, from the previous range of \$98 million to \$101 million. Surmodics expects fiscal 2022 diluted GAAP EPS, which reflects continued investments to accelerate the Company’s strategy, to a range from a loss per share of \$(1.50) to \$(1.35), from the previous range of \$(1.70) to \$(1.35). Non-GAAP diluted EPS for fiscal 2022 is expected to range from a loss per share of \$(1.23) to \$(1.08).

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 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, or dial in at 888-220-8451 and enter conference call ID passcode 1989664. 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 1989664. The audio replay will be available beginning at 10:30 a.m. CT on Wednesday, July 27, 2022, until 10:30 a.m. CT on Wednesday, August 3, 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 and the amount of fiscal 2022 license fee revenue associated with the Abbott agreement; expectations regarding full-year fiscal 2022 income tax benefit; expectations regarding revenue components and the potential causes for changes in revenue in the fourth quarter of our fiscal 2022; expectations related to product gross margins in the fourth quarter of our fiscal 2022; expectations regarding when testing data may be available related to our premarket approval application (“PMA”) with the U.S. Food and Drug Administration’s (“FDA”) the for our *SurVeil* DCB; the potential timing of FDA approval of the PMA for our *SurVeil* DCB; the potential receipt of a premarket approval milestone payment from Abbott; expectations regarding continuing discussions Abbott about its commercialization plans and forecasts for, and the U.S. launch of, the *SurVeil* DCB; expectations regarding the potential presentation publication of data efficacy and safety results from the SWING first-in-human clinical trial for the Sundance™ DCB; the possibility for our *Sundance* DCB to improve the treatment of arterial blockage below-the-knee; the Company’s strategy; expectations regarding the number of *Sublime* and *Pounce* product customers we will have by the end of fiscal 2022; expectation regarding the timing of product evaluations for the *Pounce* Venous Thrombectomy platform; expectations regarding our Medical Device coating offerings and our IVD business to continue to generate meaningful cash flow, contributing to our growth initiatives; expectations that long-term growth will reward our shareholders; expectations regarding future disclosure related to potential financing options; expectations regarding fiscal 2022 operating expenses; expectation regarding the future size of our sales team; 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), *A vess*™ DCB, *Sundance* 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 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)

	Three Months Ended		Nine Months Ended	
	June 30,		June 30,	
	2022	2021	2022	2021
Revenue:				
Product sales	\$ 13,919	\$ 12,084	\$ 40,227	\$ 33,969
Royalties and license fees	8,795	8,796	26,738	38,182
Research, development and other	2,140	2,993	6,998	9,014
Total revenue	<u>24,854</u>	<u>23,873</u>	<u>73,963</u>	<u>81,165</u>
Operating costs and expenses:				
Product costs	5,141	5,105	14,745	13,018
Research and development	12,975	12,246	38,350	36,003
Selling, general and administrative	12,857	7,885	33,168	22,815
Acquired intangible asset amortization	1,024	560	3,184	1,676
Acquisition transaction, integration and other costs	—	461	—	461
Total operating costs and expenses	<u>31,997</u>	<u>26,257</u>	<u>89,447</u>	<u>73,973</u>
Operating (loss) income	<u>(7,143)</u>	<u>(2,384)</u>	<u>(15,484)</u>	<u>7,192</u>
Other expense	(38)	(127)	(217)	(284)
(Loss) income before income taxes	<u>(7,181)</u>	<u>(2,511)</u>	<u>(15,701)</u>	<u>6,908</u>
Income tax benefit (provision)	1,530	(776)	3,155	(2,382)
Net (loss) income	<u>\$ (5,651)</u>	<u>\$ (3,287)</u>	<u>\$ (12,546)</u>	<u>\$ 4,526</u>
Basic net (loss) income per share	\$ (0.41)	\$ (0.24)	\$ (0.90)	\$ 0.33
Diluted net (loss) income per share	\$ (0.41)	\$ (0.24)	\$ (0.90)	\$ 0.32
Weighted average number of shares outstanding:				
Basic	13,929	13,837	13,907	13,740
Diluted	13,929	13,837	13,907	13,959

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

	June 30,	September 30,
	2022	2021
	(Unaudited)	(See note)
Assets		
Current Assets:		
Cash and cash equivalents	\$ 20,074	\$ 31,153
Available-for-sale securities	2,012	7,717
Accounts receivable, net	9,382	9,169
Contract assets — royalties and license fees	7,584	7,091
Inventories, net	10,926	6,760
Prepays and other	10,057	8,365
Total Current Assets	<u>60,035</u>	<u>70,255</u>
Property and equipment, net	28,289	30,090
Available-for-sale securities	—	2,002
Deferred tax assets	8,479	5,867
Intangible assets, net	30,752	37,054
Goodwill	42,590	45,606
Other assets	5,507	3,718
Total Assets	<u>\$ 175,652</u>	<u>\$ 194,592</u>
Liabilities and Stockholders' Equity		
Current Liabilities:		
Short-term borrowings	10,000	10,000
Deferred revenue	4,007	4,647
Other current liabilities	15,380	15,168
Total Current Liabilities	<u>29,387</u>	<u>29,815</u>
Deferred revenue	7,402	10,301
Other long-term liabilities	13,751	14,391
Total Liabilities	<u>50,540</u>	<u>54,507</u>
Total Stockholders' Equity	<u>125,112</u>	<u>140,085</u>
Total Liabilities and Stockholders' Equity	<u>\$ 175,652</u>	<u>\$ 194,592</u>

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
	2022		2021		
	% of Total	% of Total	% of Total	% of Total	
Revenue:					
Medical Device	\$ 17,528	70.5%	\$ 16,755	70.2%	4.6%
In Vitro Diagnostics	7,326	29.5%	7,118	29.8%	2.9%
Total revenue	<u>\$ 24,854</u>		<u>\$ 23,873</u>		4.1%

	Nine Months Ended June 30,				% Change
	2022		2021		
	% of Total	% of Total	% of Total	% of Total	
Revenue:					
Medical Device	\$ 52,889	71.5%	\$ 60,858	75.0%	(13.1)%
In Vitro Diagnostics	21,074	28.5%	20,307	25.0%	3.8%
Total revenue	<u>\$ 73,963</u>		<u>\$ 81,165</u>		(8.9)%

	Three Months Ended June 30,		Nine Months Ended June 30,	
	2022	2021	2022	2021
	Operating (loss) income:			
Medical Device	\$ (7,308)	\$ (2,491)	\$ (16,712)	\$ 5,480
In Vitro Diagnostics	3,387	3,378	10,262	10,407
Total segment operating (loss) income	(3,921)	887	(6,450)	15,887
Corporate	(3,222)	(3,271)	(9,034)	(8,695)
Total operating (loss) income	<u>\$ (7,143)</u>	<u>\$ (2,384)</u>	<u>\$ (15,484)</u>	<u>\$ 7,192</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,	
	2022	2021	2022	2021
EBITDA and Adjusted EBITDA				
Net (loss) income	\$ (5,651)	\$ (3,287)	\$ (12,546)	\$ 4,526
Income tax (benefit) provision	(1,530)	776	(3,155)	2,382
Depreciation and amortization	2,206	1,844	6,902	5,610
Investment income, net	(22)	(26)	(73)	(95)
Interest expense	145	59	410	178
EBITDA	(4,852)	(634)	(8,462)	12,601
Adjustments:				
Acquisition transaction, integration and other costs (1)	—	461	—	461
Adjusted EBITDA	\$ (4,852)	\$ (173)	\$ (8,462)	\$ 13,062
Cash Flows from Operations				
Net cash (used in) provided by operating activities	\$ (3,497)	\$ 2,755	\$ (14,723)	\$ 14,500

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	\$ (1.50)	\$ (1.35)
Amortization of acquired intangibles per diluted share (2)	0.27	0.27
Non-GAAP diluted EPS	\$ (1.23)	\$ (1.08)

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, 2022

	Total Revenue	Operating Loss	Operating Loss Percentage	Loss Before Income Taxes	Net Loss (3)	Diluted EPS (4)	Effective Tax Rate
GAAP	\$ 24,854	\$ (7,143)	(28.7)%	\$ (7,181)	\$ (5,651)	\$ (0.41)	21.3%
Adjustments:							
Amortization of acquired intangible assets (2)	—	1,024	4.1%	1,024	930	0.07	
Non-GAAP	<u>\$ 24,854</u>	<u>\$ (6,119)</u>	<u>(24.6)%</u>	<u>\$ (6,157)</u>	<u>\$ (4,721)</u>	<u>\$ (0.34)</u>	<u>23.3%</u>

For the Three Months Ended June 30, 2021

	Total Revenue	Operating Loss	Operating Loss Percentage	Loss Before Income Taxes	Net Loss (3)	Diluted EPS (4)	Effective Tax Rate
GAAP	\$ 23,873	\$ (2,384)	(10.0)%	\$ (2,511)	\$ (3,287)	\$ (0.24)	(30.9)%
Adjustments:							
Amortization of acquired intangible assets (2)	—	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>

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

For the Nine Months Ended June 30, 2022							
	Total Revenue	Operating Loss	Operating Loss Percentage	Loss Before Income Taxes	Net Loss (3)	Diluted EPS (4)	Effective Tax Rate
GAAP	\$ 73,963	\$ (15,484)	(20.9)%	\$ (15,701)	\$ (12,546)	\$ (0.90)	20.1%
Adjustments:							
Amortization of acquired intangible assets (2)	—	3,184	4.3%	3,184	2,893	0.21	
Non-GAAP	<u>\$ 73,963</u>	<u>\$ (12,300)</u>	<u>(16.6)%</u>	<u>\$ (12,517)</u>	<u>\$ (9,653)</u>	<u>\$ (0.69)</u>	<u>22.9%</u>

For the Nine Months Ended June 30, 2021							
	Total Revenue	Operating Income	Operating Income Percentage	Income Before Income Taxes	Net Income (3)	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 (2)	—	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>

- (1) Represents expenses specifically associated with the business acquisition of Vetex Medical Limited; these expenses are not tax deductible.
- (2) Amortization of business acquisition-related intangible assets and associated tax impact. A significant portion of the business acquisition-related amortization is not tax deductible.
- (3) 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).
- (4) 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 EPS as their effect was antidilutive for the three months ended June 30, 2022 and 2021 and for the nine months ended June 30, 2022 as a result of the net loss for these periods.

Contacts

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