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

February 3, 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, Minnesota	**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 ☐

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 February 3, 2022, Surmodics, Inc. (the "Company") issued a press release (the "Press Release") announcing the Company's financial results for the quarter ended December 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
99.1	Press Release dated February 3, 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: February 3, 2022

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

Exhibit 99.1

Surmodics Reports First Quarter Fiscal 2022 Results

EDEN PRAIRIE, Minn.--(BUSINESS WIRE)--February 3, 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 first quarter ended December 31, 2021.

Summary of First Quarter and Recent Highlights

- Revenue of $23.0 million, an increase of 3% year-over-year
- GAAP EPS of $(0.20), non-GAAP EPS of $(0.13)
- First commercial sale of Pounce™ Arterial Thrombo-embolectomy System

“I am pleased with our first quarter performance. We delivered revenue growth and made critical progress on our SurVeil™ drug-coated balloon PMA submission and early commercialization of our Sublime™ radial and Pounce™ arterial thrombectomy platforms,” said Gary Maharaj, President and CEO of Surmodics, Inc. “I’m optimistic about our ability to deliver on our key strategic objectives this fiscal year.”

First Quarter Fiscal 2022 Financial Results
Total revenue for the first quarter of fiscal 2022 was $23.0 million, compared to $22.3 million in the prior-year period. Medical Device revenue was $16.9 million for the first quarter of fiscal 2022, compared to $16.2 million for the prior-year period, an increase of 4%. Medical Device revenue in the first quarter of fiscal 2022 includes $1.2 million from our Development and Distribution Agreement with Abbott Vascular, Inc. (“Abbott”) for the *SurVeil* drug-coated balloon, compared to $1.3 million in the prior-year quarter. In Vitro Diagnostics revenue was $6.1 million for both the first quarter of fiscal 2022 and 2021.

Diluted GAAP earnings per share in the first quarter of fiscal 2022 was a loss per share of $(0.20), compared to a loss per share of $(0.02) in the same prior-year period. On a non-GAAP basis, loss per share in the first quarter of fiscal 2022 was $(0.13), compared to earnings per share of $0.02 in the same prior-year quarter.

As of December 31, 2021, Surmodics reported cash and investments totaling $32.3 million and $10 million in outstanding borrowings on its $25 million line of credit. Surmodics reported $7.0 million of cash used in operating activities and $0.8 million in capital expenditures in the first quarter of fiscal 2022.

Company Reiterates Fiscal 2022 Guidance
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).

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 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.

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 first 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 first quarter conference call will be available by dialing 888-203-1112 and entering conference call ID passcode 5657051. The audio replay will be available beginning at 10:30 a.m. CT on Thursday, February 3, 2022, until 10:30 a.m. CT on Thursday, February 10, 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 the duration of factors impacting our royalty revenues and the return to growth of royalty revenues; expectations regarding medical device product revenue growth; expectations regarding design verification, process validation, and manufacturing validation related to the Company's products; the potential for the commercial success or our products; 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; the expected timing of completion and delivery of the SWING first-in-human clinical trial results; the Company's strategy; plans for clinical product evaluations; expectations regarding revenue from our *Sublime* and *Pounce* product portfolios; expectations regarding the return to growth of our In Vitro Diagnostics business and its level of growth for fiscal 2022; 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), Avess™ 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-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) whether anticipated increases in our operating expenses are effective in generating profitable revenues; and (8) 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 December 31,	
	2021	**2020**
Revenue:		
Product sales	$ 12,344	$ 10,102
Royalties and license fees	8,099	9,334
Research, development and other	2,560	2,861
Total revenue	23,003	22,297
Operating costs and expenses:		
Product costs	4,497	3,743
Research and development	11,663	10,882
Selling, general and administrative	9,195	7,023
Acquired intangible asset amortization	1,089	556
Total operating costs and expenses	26,444	22,204
Operating (loss) income	(3,441)	93
Other expense	(77)	(199)
Loss before income taxes	(3,518)	(106)
Income tax benefit (provision)	706	(168)
Net loss	$ (2,812)	$ (274)
Basic net loss per share	$ (0.20)	$ (0.02)
Diluted net loss per share	$ (0.20)	$ (0.02)
Weighted average number of shares outstanding:		
Basic	13,878	13,668
Diluted	13,878	13,668

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

	December 31, 2021	September 30, 2021
Assets	**(Unaudited)**	**(See note)**
Current Assets:		
Cash and cash equivalents	$ 26,650	$ 31,153
Available-for-sale securities	5,693	7,717
Accounts receivable, net	8,010	9,169
Contract assets — royalties and license fees	6,668	7,091
Inventories, net	8,290	6,760
Prepaids and other	9,605	8,365
Total Current Assets	64,916	70,255
Property and equipment, net	29,319	30,090
Available-for-sale securities	—	2,002
Deferred tax assets	6,372	5,867
Intangible assets, net	35,238	37,054
Goodwill	44,900	45,606
Other assets	4,121	3,718
Total Assets	$ 184,866	$ 194,592
Liabilities and Stockholders' Equity		
Current Liabilities:		
Short-term borrowings	10,000	10,000
Deferred revenue	4,430	4,647
Other current liabilities	11,213	15,168
Total Current Liabilities	25,643	29,815
Deferred revenue	9,292	10,301
Other long-term liabilities	13,260	14,391
Total Liabilities	48,195	54,507
Total Stockholders' Equity	136,671	140,085
Total Liabilities and Stockholders' Equity	$ 184,866	$ 194,592

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

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

	Three Months Ended December 31,				
	2021		2020		
Revenue:		% of Total		% of Total	% Change
Medical Device	$ 16,908	73.5%	$ 16,196	72.6%	4.4%
In Vitro Diagnostics	6,095	26.5%	6,101	27.4%	(0.1)%
Total revenue	$ 23,003		$ 22,297		3.2%

	Three Months Ended December 31,	
	2021	2020
Operating (loss) income:		
Medical Device	$ (3,792)	$ (593)
In Vitro Diagnostics	3,155	3,220
Total segment operating (loss) income	(637)	2,627
Corporate	(2,804)	(2,534)
Total operating (loss) income	$ (3,441)	$ 93

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 December 31,	
	2021	**2020**
EBITDA and Adjusted EBITDA		
Net loss	$ (2,812)	$ (274)
Income tax (benefit) provision	(706)	168
Depreciation and amortization	2,376	1,860
Investment income, net	(26)	(41)
Interest expense	136	60
EBITDA	**(1,032)**	**1,773**
Adjustments:		
None	—	—
Adjusted EBITDA	**$ (1,032)**	**$ 1,773**
Cash Flows from Operations		
Net cash used in operating activities	**$ (7,026)**	**$ (4,270)**

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 (1)	0.30	0.30
Non-GAAP diluted EPS	$ (1.75)	$ (1.25)

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 December 31, 2021						
	Total Revenue	**Operating Loss**	**Operating Loss Percentage**	**Loss Before Income Taxes**	**Net Loss (2)**	**Diluted EPS (3)**	**Effective tax rate**
GAAP	$ 23,003	$ (3,441)	(15.0)%	$ (3,518)	$ (2,812)	$ (0.20)	20.1%
Adjustments:							
Amortization of acquired intangible assets (1)	—	1,089	4.8%	1,089	990	0.07	
Non-GAAP	$ 23,003	$ (2,352)	(10.2)%	$ (2,429)	$ (1,822)	$ (0.13)	25.0%

	For the Three Months Ended December 31, 2020						
	Total Revenue	**Operating Income**	**Operating Income Percentage**	**(Loss) Income Before Income Taxes**	**Net (Loss) Income (2)**	**Diluted EPS (3)**	**Effective tax rate**
GAAP	$ 22,297	$ 93	0.4%	$ (106)	$ (274)	$ (0.02)	(158.5)%
Adjustments:							
Amortization of acquired intangible assets (1)	—	556	2.5%	556	526	0.04	
Non-GAAP	$ 22,297	$ 649	2.9%	$ 450	$ 252	$ 0.02	44.0%

(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 months ended December 31, 2021 and 2020 as a result of the GAAP net loss for these periods.

Contacts

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