



Surmodics Reports First Quarter of Fiscal Year 2023 Financial Results; Updates Fiscal Year 2023 Financial Guidance

February 6, 2023

EDEN PRAIRIE, Minn.--(BUSINESS WIRE)--Feb. 6, 2023-- Surmodics, Inc. (Nasdaq: SRDX), a leading provider of medical device and in vitro diagnostic technologies to the healthcare industry, today reported financial results for its first quarter ended December 31, 2022, and updated its financial outlook for its fiscal year ending September 30, 2023.

First Quarter Fiscal 2023 Financial Summary

- Total Revenue of \$24.9 million, an increase of 8% year-over-year
- GAAP Diluted EPS of \$(0.56), compared to \$(0.20) in the prior-year period
- Non-GAAP Diluted EPS of \$(0.50), compared to \$(0.13) in the prior-year period

First Quarter and Recent Business Highlights

- On October 13, 2022, Surmodics submitted a complete response to U.S. Food and Drug Administration ("FDA" or the "Agency") comments on its application for premarket approval ("PMA") of the SurVeil™ drug-coated balloon ("DCB").
- On October 17, 2022, Surmodics announced that it has entered into a new, five-year credit agreement with MidCap Financial ("MidCap"), consisting of up to \$100 million in term loans and a \$25 million revolving credit facility.
- On November 2, 2022, Surmodics announced that 24-month data from its TRANSCEND clinical trial of the SurVeil DCB was presented at the Vascular InterVentional Advances ("VIVA") conference, with the SurVeil DCB demonstrating sustained durability of the trial's safety and efficacy endpoints.
- On November 17, 2022 and January 19, 2023, Surmodics announced that 12-month data from its SWING first-in-human study of the Company's Sundance™ Sirolimus DCB was presented at the Symposium on Vascular and Endovascular Issues ("VEITHsymposium") and the International Symposium on Endovascular Therapy ("ISET"), respectively, with primary efficacy data indicating that the large luminal gain achieved immediately after the procedure was sustained post procedure.
- On January 19, 2023, Surmodics announced it received a letter from the FDA related to its PMA application for the SurVeil DCB. In the letter, the FDA indicated that the application is not currently approvable, while providing guidance as to a path forward.

"We were pleased to achieve total revenue growth that exceeded our expectations for the first quarter, driven by strong revenue performance within our Medical Device business which grew 12% year-over-year," said Gary Maharaj, President and CEO of Surmodics, Inc. "On January 19th, we announced the receipt of an FDA letter related to our PMA application for the SurVeil DCB. We remain focused on making progress with respect to our regulatory strategy for the SurVeil DCB and are preparing to engage with the FDA to evaluate the appropriate path forward. In light of this development, we have implemented a spending reduction plan to preserve capital and more closely align our capital allocation priorities with our strategic objectives, which includes a restructuring to reduce our workforce by approximately 13% and additional cost saving measures. This spending reduction plan is expected to reduce our planned use of cash by an estimated \$10 million to \$11 million over the remainder of fiscal 2023, prior to restructuring charges."

Mr. Maharaj continued, "We are updating our guidance today to reflect our financial performance in the first quarter, as well as our revised expectations for the remaining nine months of fiscal 2023. Looking ahead, we remain focused on pursuing our three key strategic objectives for 2023 as efficiently as possible, with the goal of achieving strong, sustainable, long-term growth. Specifically, we will continue to make progress with respect to our regulatory strategy for the SurVeil DCB, while advancing the initial commercialization of our Sublime™ radial and Pounce™ arterial thrombectomy platforms and driving revenue and cash flow growth from our Medical Device performance coating offerings and In Vitro Diagnostics business. With a recently enhanced balance sheet and access to approximately \$60 million in incremental debt financing, a disciplined approach to spending and capital allocation, strong and stable core businesses and a portfolio of innovative vascular intervention technologies, we believe we are well-positioned for the future as we progress through fiscal 2023."

First Quarter Fiscal 2023 Financial Results

Three Months Ended December 31,		Increase (Decrease)	
2022	2021	\$	%

Revenue:

Medical Device	\$ 19,018	\$ 16,908	\$ 2,110	12	%
In Vitro Diagnostics	5,915	6,095	(180)	(3)	%
Total revenue	\$ 24,933	\$ 23,003	\$ 1,930	8	%

Total revenue increased \$1.9 million, or 8%, to \$24.9 million, compared to \$23.0 million in the first quarter of fiscal 2022.

Medical Device revenue increased \$2.1 million, or 12%, to \$19.0 million, compared to \$16.9 million in the first quarter of fiscal 2022, driven by growth in sales of performance coating reagent and device products, as well as higher performance coating royalties revenue. Medical Device revenue in the first quarter of fiscal 2023 included \$1.3 million from the Company's Development and Distribution Agreement with Abbott Vascular, Inc. ("Abbott") for the *SurVeil* DCB, compared to \$1.2 million in the prior-year period. In Vitro Diagnostics ("IVD") revenue decreased \$0.2 million, or 3%, to \$5.9 million, compared to \$6.1 million in the first quarter of fiscal 2022, as growth in product sales was offset by lower research and development and other revenue due to the completion of a customer development program.

Product gross profit (defined as product sales less product costs) increased \$1.1 million, or 14%, to \$9.0 million, compared to \$7.8 million in the first quarter of fiscal 2022. Product gross margin (defined as product gross profit as a percentage of product sales) was 63.0%, compared to 63.6% in the first quarter of fiscal 2022. Product gross margin in the first quarter of fiscal 2023 was adversely impacted relative to the prior year by certain manufacturing inefficiencies associated with ramp up of production of new products, which was partly offset by the favorable impact of product mix.

Operating costs and expenses, excluding product costs, increased \$5.0 million, or 23%, to \$26.9 million, compared to \$21.9 million in the first quarter of fiscal 2022. The increase was driven primarily by higher selling, general and administrative expenses associated with the expansion of the Company's direct medical device salesforce in fiscal 2022.

GAAP net loss was \$(7.8) million, or \$(0.56) per diluted share, compared to \$(2.8) million, or \$(0.20) per diluted share in the first quarter of fiscal 2022. Non-GAAP net loss was \$(7.0) million, or \$(0.50) per diluted share, compared to \$(1.8) million, or \$(0.13) per diluted share in the first quarter of fiscal 2022.

Adjusted EBITDA loss was \$(3.3) million, compared to Adjusted EBITDA of \$0.6 million in the first quarter of fiscal 2022.

Balance Sheet Summary

On October 17, 2022, Surmodics entered into a new, five-year credit agreement with MidCap, comprised of up to \$100.0 million in term loans and a \$25.0 million revolving credit facility. The Company drew \$25.0 million on the term loan and \$5.0 million on the revolving credit facility at close. These proceeds were partially used to retire the Company's existing \$25.0 million revolving credit facility with Bridgewater Bank, of which \$10.0 million was outstanding.

As of December 31, 2022, Surmodics reported \$26.4 million in cash, \$5.0 million in outstanding borrowings on its \$25.0 million revolving credit facility, and \$25.0 million in outstanding borrowings on its term loan facility. Additional draws on the term loan facility may be made in \$10.0 million minimum increments, up to a total of \$75.0 million through December 31, 2024. A second tranche of up to \$25.0 million on the term loan facility may be available through December 31, 2024 at MidCap's option. Surmodics reported \$10.8 million of cash used in operating activities and \$1.0 million in capital expenditures in the first quarter of fiscal 2023.

Fiscal Year 2023 Financial Guidance

Surmodics now expects fiscal year 2023 total revenue to range from \$102 million to \$106 million, representing an increase of 2% to 6% compared to the prior year. The Company's prior guidance called for fiscal year 2023 total revenue to range from \$103 million to \$107 million, representing an increase of 3% to 7% compared to the prior year.

The Company now expects fiscal 2023 GAAP diluted loss per share to range from \$(2.40) to \$(2.00). The Company's prior guidance called for fiscal 2023 GAAP diluted loss per share to range from \$(2.80) to \$(2.40).

Non-GAAP diluted loss per share in fiscal 2023 is expected to range from \$(2.09) to \$(1.69). The Company's prior guidance called for fiscal 2023 Non-GAAP diluted loss per share in fiscal 2023 to range from \$(2.54) to \$(2.14).

As has been the Company's practice with past guidance, revenue from regulatory-related milestones, such as upon receipt of PMA for the *SurVeil* DCB, is not included in guidance until after they are achieved.

Conference Call Today at 4:00 p.m. CT (5:00 p.m. ET)

Surmodics is hosting a live webcast at 4:00 p.m. CT (5:00 p.m. ET) today to discuss the first quarter fiscal 2023 financial results and accomplishments and host a question-and-answer session. To access the webcast, please go to "Events & Presentations" under the "Investors" section of the Company's website at <https://surmodics.qcs-web.com/events-and-presentations>, and click on the webcast icon under "Upcoming Events." To listen to the live teleconference, dial 877-407-8293 (international callers may dial 201-689-8349) and provide access ID: 13735326.

An audio replay of the conference call will be available beginning at 8:00 p.m. CT on Monday, February 6, until 8:00 p.m. CT on Monday, February 20, and can be accessed by dialing 877-660-6853 (international callers may dial 201-612-7415) and entering access ID: 13735326. In addition, the webcast and transcript will be archived on the Company's website following the call.

About Surmodics, Inc.

Surmodics, Inc. is a leading provider of performance coating technologies for intravascular medical devices and chemical and biological components

for in vitro diagnostic immunoassay tests and microarrays. Surmodics also develops and commercializes highly differentiated vascular intervention 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 modification and drug-delivery coating technologies, along with its device design, development and manufacturing capabilities. The Company's mission is to improve the detection and treatment of disease. Surmodics is headquartered in Eden Prairie, Minnesota.

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: engaging with the FDA in order to evaluate the appropriate path forward for the PMA application for our *SurVeil* DCB, including requesting feedback through the FDA's Q-submission process; anticipated timing of FDA feedback; obtaining additional clarity from the FDA on what is required for an amended PMA application to receive an approval decision; determining an appropriate path forward and making progress with respect to our regulatory strategy for the *SurVeil* DCB; providing additional details on our strategy as we obtain additional information from the FDA and determine our path forward for the *SurVeil* DCB; our future prospects; achieving strong, sustainable long-term growth; advancing the initial commercialization of our *Sublime* radial and *Pounce* arterial thrombectomy platforms; driving revenue and cash flow growth from our Medical Device performance coating offerings and In Vitro Diagnostics business; our fiscal 2023 financial guidance and related assumptions, including assumptions in our revenue guidance provided for modeling purposes, expected product gross margins for the remainder of fiscal 2023 and factors that we expect to impact product gross margins, expected operating expenses, expected severance costs, expected interest expense, expected tax benefit, expected cash use for fiscal 2023 and the assumptions behind our expected cash use; our expected cash balance at the end of fiscal 2023; our expectation regarding borrowings on our revolving credit facility and term loans; being well-positioned for the future and strong future growth; our intent to streamline and refocus the teams in several areas of our business, including manufacturing and operations, R&D and clinical, sales operations, and our direct salesforce, so that we can execute our growth strategy more efficiently in fiscal 2023; the expected reduction in planned cash use for the remainder of fiscal 2023 from our spending reduction plan, and the sources of the expected spending reduction; whether the spending reduction plan will impact our ability to serve our customers and our ability to respond to the FDA; reductions in our planned capital expenditures and changes in our hiring plan for fiscal 2023; the future focus of our product development efforts; our fiscal 2023 strategic objectives and their ability to achieve strong, sustainable growth and creating long-term shareholder value; the potential and timing of receipt of a PMA milestone payment from Abbott; continued engagement with the FDA and Abbott regarding the *SurVeil* DCB; the promise of our *Sundance* DCB; our plan to use the experience we gain from the *SurVeil* product PMA application process to develop our commercial and regulatory strategies for our other DCB products; our availability of debt capital, 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* DCB, and other proprietary products; (2) whether and when the FDA grants PMA 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) our ability to successfully and profitably commercialize our vascular intervention products; (6) current and future supply chain constraints; (7) whether 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, 2022 and subsequent SEC filings. These reports are available in the Investors section of our website at <https://surmodics.qcs-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, non-GAAP operating loss percentage, non-GAAP loss before income taxes, non-GAAP net loss, and non-GAAP loss per diluted share. 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 loss per diluted share for fiscal 2023. 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,

	2022		2021	
Revenue:				
Product sales	\$ 14,234		\$ 12,344	
Royalties and license fees	8,765		8,099	
Research, development and other	1,934		2,560	
Total revenue	24,933		23,003	
Operating costs and expenses:				
Product costs	5,267		4,497	
Research and development	12,743		11,663	
Selling, general and administrative	13,239		9,195	
Acquired intangible asset amortization	913		1,089	
Total operating costs and expenses	32,162		26,444	
Operating loss	(7,229)	(3,441)
Other expense, net	(779)	(77)
Loss before income taxes	(8,008)	(3,518)
Income tax benefit	165		706	
Net loss	\$ (7,843)	\$ (2,812)
Basic net loss per share	\$ (0.56)	\$ (0.20)
Diluted net loss per share	\$ (0.56)	\$ (0.20)

Weighted average number of shares outstanding:

Basic	13,983	13,878
Diluted	13,983	13,878

Surmodics, Inc. and Subsidiaries

Condensed Consolidated Balance Sheets

(in thousands)

	December 31,	September 30,
	2022	2022
Assets	(Unaudited)	(See Note)
Current Assets:		
Cash and cash equivalents	\$ 26,430	\$ 18,998
Accounts receivable, net	10,068	10,452
Contract assets — royalties and license fees	7,047	7,116
Inventories, net	12,724	11,819
Prepays and other	8,193	9,202
Total Current Assets	64,462	57,587
Property and equipment, net	27,717	27,148
Intangible assets, net	29,262	28,145
Goodwill	43,308	40,710
Other assets	5,006	4,769
Total Assets	\$ 169,755	\$ 158,359
Liabilities and Stockholders' Equity		
Current Liabilities:		
Short-term borrowings	\$ —	\$ 10,000
Deferred revenue	3,771	4,160
Other current liabilities	13,493	17,919
Total Current Liabilities	17,264	32,079
Long-term debt, net	29,495	—
Deferred revenue	4,115	5,088
Other long-term liabilities	11,620	12,800
Total Liabilities	62,494	49,967

Total Stockholders' Equity	107,261	108,392
Total Liabilities and Stockholders' Equity	\$ 169,755	\$ 158,359

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

Surmodics, Inc. and Subsidiaries

Condensed Consolidated Statements of Cash Flows

(in thousands)

(Unaudited)

	Three Months Ended December 31,	
	2022	2021
Operating Activities:		
Net loss	\$ (7,843)	\$ (2,812)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	2,122	2,376
Stock-based compensation	1,965	1,680
Deferred taxes	(107)	(640)
Other	374	172
Change in operating assets and liabilities:		
Accounts receivable and contract assets	546	1,547
Inventories	(905)	(1,570)
Prepays and other	(1,857)	(1,432)
Accounts payable	(1,254)	200
Accrued liabilities	(4,700)	(5,227)
Income taxes	2,218	(95)
Deferred revenue	(1,361)	(1,225)

Net cash used in operating activities	(10,802)	(7,026)
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Investing Activities:

Purchases of property and equipment	(977)	(782)
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Maturities of available-for-sale securities	—	4,000
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Net cash (used in) provided by investing activities	(977)	3,218
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Financing Activities:

Payments of short-term borrowings	(10,000)	—
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Proceeds from issuance of long-term debt	29,664	—
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Payments of debt issuance costs	(353)	—
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Issuance of common stock	347	230
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Payments for taxes related to net share settlement of equity awards	(858)	(853)
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Net cash provided by (used in) financing activities	18,800	(623)
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Effect of exchange rate changes on cash	411	(72)
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Net change in cash and cash equivalents	7,432	(4,503)
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Cash and Cash Equivalents:

Beginning of year	18,998	31,153
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End of year	\$ 26,430	\$ 26,650
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Surmodics, Inc. and Subsidiaries

Supplemental Segment Information

(in thousands)

(Unaudited)

Three Months Ended December 31,

2022

2021

Medical Device Revenue

Product sales	\$ 8,380	\$ 6,788
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Royalties	7,409	6,886
License fees	1,356	1,213
Research, development and other	1,873	2,021
Medical Device revenue	19,018	16,908

In Vitro Diagnostics Revenue

Product sales	5,854	5,556
Research, development and other	61	539
In Vitro Diagnostics revenue	5,915	6,095
Total Revenue	\$ 24,933	\$ 23,003

Three Months Ended December 31,

2022 2021

Operating (loss) income:

Medical Device	\$ (7,235)	\$ (3,792)
In Vitro Diagnostics	2,948	3,155
Total segment operating (loss) income	(4,287)	(637)
Corporate	(2,942)	(2,804)
Total operating (loss) income	\$ (7,229)	\$ (3,441)

Surmodics, Inc. and Subsidiaries

Reconciliation of GAAP Measures to Non-GAAP Amounts

Schedule of EBITDA and Adjusted EBITDA

(in thousands)

(Unaudited)

Three Months Ended December 31,

2022 2021

Net loss	\$ (7,843)	\$ (2,812)
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Income tax benefit	(165)	(706)
Depreciation and amortization	2,122	2,376
Interest expense, net	826	136
Investment income, net	(172)	(26)
EBITDA	(5,232)	(1,032)

Adjustments:

Stock-based compensation expense	1,965	1,680
Adjusted EBITDA	\$ (3,267)	\$ 648

Surmodics, Inc. and Subsidiaries

Guidance Reconciliation: Estimated Non-GAAP Diluted EPS

For the Fiscal Year Ending September 30, 2023

(Unaudited)

	Fiscal 2023 Full-Year Estimate	
	Low	High
GAAP Diluted EPS	\$ (2.40)	\$ (2.00)
Amortization of acquired intangibles per diluted share (1)	0.23	0.23
Restructuring expense (2)	0.08	0.08
Non-GAAP Diluted EPS	\$ (2.09)	\$ (1.69)
Diluted weighted average shares outstanding	14,030	

Surmodics, Inc. and Subsidiaries

Net Loss and Diluted EPS GAAP to Non-GAAP Reconciliation

(in thousands, except per share data)

(Unaudited)

Three Months Ended December 31, 2022

	Revenue	Operating Loss		Loss Before Income Taxes	Net Loss (3)	Diluted EPS
GAAP	\$ 24,933	\$ (7,229)	(29.0)%	\$ (8,008)	\$ (7,843)	\$ (0.56)
Adjustments:						
Amortization of acquired intangible assets (1)	—	913	3.7 %	913	851	0.06
Non-GAAP	\$ 24,933	\$ (6,316)	(25.3)%	\$ (7,095)	\$ (6,992)	\$ (0.50)
Diluted weighted average shares outstanding (4)						13,983

Three Months Ended December 31, 2021

	Revenue	Operating Loss		Loss Before Income Taxes	Net Loss (3)	Diluted EPS
GAAP	\$ 23,003	\$ (3,441)	(15.0)%	\$ (3,518)	\$ (2,812)	\$ (0.20)
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)
Diluted weighted average shares outstanding (4)						13,878

(1) Represents 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) Restructuring expense consists of costs specifically associated with the workforce reduction in the second quarter of fiscal 2023. Income tax impacts were estimated using the applicable statutory rate (21% in the U.S. and 12.5% in Ireland).

(3) Net loss includes the effect of the above adjustments on income tax benefit, 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) Diluted weighted average shares outstanding used in the calculation of EPS was the same for GAAP EPS and Non-GAAP EPS. 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 December 31, 2022 and 2021 as a result of the net loss for these periods.

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