Surmodics Reports First Quarter Fiscal 2021 Results

February 9, 2021

EDEN PRAIRIE, Minn.--(BUSINESS WIRE)--Feb. 9, 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 first quarter ended December 31, 2020.

Summary of First Quarter and Recent Highlights

- Revenue of $22.3 million, a decrease of 1% year-over-year
- GAAP EPS of ($0.02), non-GAAP EPS of $0.02
- SurVeil™ drug-coated balloon (DCB) pivotal clinical trial meets both primary endpoints to demonstrate non-inferior safety and efficacy vs. IN.PACT® Admiral® DCB
- Achieved $15 million TRANSCEND clinical report milestone under the *SurVeil* Development and Distribution Agreement with Abbott Vascular
- Completed enrollment in SWING first-in-human clinical trial for Sundance™ sirolimus-coated, below-the-knee DCB

TRANSCEND Clinical Study

“The entire Surmodics team is wholeheartedly pleased with the results of our TRANSCEND clinical trial, which demonstrates comparable safety and effectiveness of our SurVeil drug-coated balloon using a substantially lower drug dose than the comparative product,” said Gary Maharaj, President and CEO of Surmodics, Inc. “Our proprietary coating technology is the key to SurVeil, which was designed to optimize drug delivery, transfer, retention and durability. We are one step closer to our goal of providing physicians with an attractive therapeutic alternative to improve the treatment of peripheral arterial disease.”

Subsequent to the end of its first quarter of fiscal 2021, Surmodics delivered to Abbott Vascular, Inc. (“Abbott”) the final written clinical report and related materials that demonstrated the primary safety endpoint and primary efficacy endpoint for the TRANSCEND clinical study had been met. Receipt by Abbott of the materials fulfilled the requirements for a $15 million milestone payment under Surmodics’ Development and Distribution Agreement with Abbott (the “Abbott Agreement”). Abbott is analyzing the materials in accordance with the terms of the Abbott Agreement. Surmodics expects to receive the milestone payment in the second quarter of fiscal 2021. The revenue associated with this $15 million milestone payment is expected to range between $11.3 and $11.6 million in fiscal 2021, of which approximately $10.5 million will be recognized in the second quarter of fiscal 2021. Furthermore, the Company estimates full year fiscal 2021 license fee revenue associated with the Abbott Agreement, including the $15 million milestone, to range between $16.0 and $17.0 million.

First Quarter Fiscal 2021 Financial Results

Total revenue for the first quarter of fiscal 2021 was $22.3 million, compared to $22.6 million in the prior-year period. Medical Device revenue was $16.2 million in the first quarter of fiscal 2021, compared to $17.4 million in the year-ago period, a decrease of 7%. Revenue in both the first quarter of fiscal 2021 and 2020 includes $1.3 million from the Abbott Agreement for the *SurVeil* DCB. In Vitro Diagnostics revenue was $6.1 million for the first quarter of fiscal 2021, compared to $5.2 million in the same prior-year quarter, an increase of 17%.

GAAP loss per share in the first quarter of fiscal 2021 was ($0.02), compared to earnings per share of $0.01 in the year-ago period. On a non-GAAP basis, earnings per share in the first quarter of fiscal 2021 was $0.02, compared to earnings per share of $0.05 in the same prior-year quarter.

As of December 31, 2020, Surmodics reported cash and short-term investments totaling $53.9 million and no debt. Surmodics reported $4.3 million of cash used in operating activities in the first quarter of fiscal 2021. Capital expenditures totaled $1.3 million for the first quarter of fiscal 2021.

Fiscal 2021 Guidance

Due to the continued uncertainty surrounding the duration and magnitude of the COVID-19 pandemic, the Company will not provide financial guidance at this time.

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 8857837. The audio replay will be available beginning at 10:30 a.m. CT on Tuesday, February 9, 2021, until 10:30 a.m. CT on Tuesday, February 16, 2021.

About the TRANSCEND Clinical Trial

The TRANSCEND trial is a global, multi-center, randomized, controlled clinical trial (“RCT”) with 1:1 randomization to the *SurVeil* DCB (Surmodics, Inc.) or IN.PACT® Admiral® DCB (Medtronic), in patients with symptomatic femoropopliteal artery disease. The primary efficacy endpoint was primary patency at 12 months, defined as a composite of freedom from clinically driven target lesion revascularization (“CD-TLR”) and binary restenosis. The primary safety endpoint was a composite of freedom from device or procedure related death through 30 days and freedom from above-ankle amputation and clinically driven target vessel revascularization (“CD-TVR”) within 12 months.

About the *SurVeil* DCB and the Abbott Agreement

The *SurVeil* DCB, a next-generation device that utilizes best-in-class technology in the treatment of peripheral artery disease, includes a proprietary drug-excipient formulation for a durable balloon coating and is manufactured using an innovative process to improve coating uniformity. The design of the SurVeil drug-coated balloon reflects Surmodics' industry leadership in the development of surface technology for vascular medical devices. The *SurVeil* DCB received CE Mark Certification in the European Union in June 2020. The *SurVeil* DCB is not available for sale, and is for investigational use only, in the United States.

In February 2018, Surmodics entered into an agreement with Abbott (NYSE: ABT) that provided Abbott with exclusive worldwide commercialization rights for the *SurVeil* DCB. Pursuant to the terms of the Abbott Agreement, Surmodics has received a $45.8 million in upfront and milestone payments. As of December 31, 2020, the Company may receive up to $45 million of additional contingent milestone payments under the Abbott Agreement, consisting of: (i) $15 million upon successful completion of the clinical study report of the TRANSCEND pivotal trial demonstrating safety and clinical non-inferiority with the control device, and (ii) $30 million upon premarket approval of the *SurVeil* DCB by the U.S. Food and Drug Administration. Under the Abbott Agreement, Surmodics will be responsible for the manufacture and supply of clinical and commercial quantities of the *SurVeil* DCB product and will recognize revenue based on product sales to Abbott as well as a share of profits resulting from third-party sales.

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 expectations of the receipt of milestone payments from Abbott; the revenue associated with the payment and the anticipated fiscal 2021 full year license revenue associated with the Abbott agreement; the Company's strategic objectives for fiscal 2021; the Company's strategy; expectations regarding the conduct and timing of clinical studies; target dates for the receipt of regulatory clearances; potential products in the Company's development pipeline; target dates for regulatory filing, plans for regulatory strategies, product releases, clinical evaluations and clinical use; potential future revenue amounts under our Distribution and Development Agreement with Abbott Vascular; expectation regarding the Company's positioning for long-term sustained growth and shareholder value creation; and the adequacy of cash and investments to provide capacity to support the Company's strategic growth initiatives, 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) Abbott's analysis of the final written clinical report and related materials from the TRANSCEND clinical trial; (2) 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; (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; and (6) 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. 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 income, non-GAAP operating income percentage, non-GAAP income before income taxes, non-GAAP net income, non-GAAP diluted 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 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,	
	2020	2019
Revenue:		
Product sales	$ 10,102	$ 9,974
Royalties and license fees	9,334	10,148
Research, development and other	2,861	2,494
Total revenue	22,297	22,616
Operating costs and expenses:		
Product costs	3,743	3,203
Research and development	10,882	12,142
Selling, general and administrative	7,023	6,943
Acquired intangible asset amortization	556	594
Total operating costs and expenses	22,204	22,882
Operating income (loss)	93	(266)
Other (expense) income	(199)	164
Loss before income taxes	(106)	(102)
Income tax (provision) benefit	(168)	250
Net (loss) income	$ (274)	$ 148
Basic net (loss) income per share	$ (0.02)	$ 0.01
Diluted net (loss) income per share	$ (0.02)	$ 0.01
Weighted average number of shares outstanding:		

Basic	13,668	13,469
Diluted	13,668	13,769

Surmodics, Inc. and Subsidiaries

Condensed Consolidated Balance Sheets

(in thousands)

(Unaudited)

	December 31, 2020	**September 30, 2020**
Assets	**(Unaudited)**	**(See note)**
Current Assets:		
Cash and cash equivalents	$ 35,754	$ 30,785
Available-for-sale securities	18,120	30,313
Accounts receivable, net	8,065	7,675
Contract assets - royalties and license fees	6,566	6,108
Inventories, net	6,261	5,966
Prepaids and other	6,097	5,761
Total Current Assets	80,863	86,608
Property and equipment, net	30,346	30,103
Deferred tax assets	7,004	7,315
Intangible assets, net	12,945	13,283
Goodwill	27,864	27,185
Other assets	4,534	4,269
Total Assets	$ 163,556	$ 168,763
Liabilities and Stockholders' Equity		
Current Liabilities:		
Deferred revenue	4,553	5,200
Other current liabilities	7,893	13,692

Total Current Liabilities	12,446	18,892
Deferred revenue	10,073	10,796
Other long-term liabilities	7,630	8,020
Total Liabilities	30,149	37,708
Total Stockholders' Equity	133,407	131,055
Total Liabilities and Stockholders' Equity	$ 163,556	$ 168,763

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,				
	2020		**2019**		
Revenue:		**% of Total**		**% of Total**	**% Change**
Medical Device	$ 16,196	72.6%	$ 17,404	77.0%	(6.9)%
In Vitro Diagnostics	6,101	27.4%	5,212	23.0%	17.1%
Total revenue	$ 22,297		$ 22,616		(1.4)%

	Three Months Ended December 31,	
	2020	**2019**
Operating income (loss):		
Medical Device	$ (593)	$ (423)
In Vitro Diagnostics	3,220	2,599
Total segment operating income	2,627	2,176
Corporate	(2,534)	(2,442)

Total operating income (loss)	$ 93	$ (266)

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,	
	2020	**2019**
EBITDA and Adjusted EBITDA		
Net (loss) income	$ (274)	$ 148
Income tax provision (benefit)	168	(250)
Depreciation and amortization	1,860	1,804
Investment income, net	(41)	(250)
Interest expense	60	40
EBITDA	1,773	1,492
Adjustments:		
None	—	—
Adjusted EBITDA	$ 1,773	$ 1,492
Cash Flows from Operations		
Net cash used in operating activities	$ (4,270)	$ (909)

Surmodics, Inc., and Subsidiaries

Net Income and Diluted EPS GAAP to Non-GAAP Reconciliation

(in thousands, except per share data)

(Unaudited)

	For the Three Months Ended December 31, 2020						
	Total Revenue	Operating Income	Operating Income Percentage	(Loss) Income Before Income Taxes	Net (Loss) Income (3)	Diluted EPS (2)	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 %

	For the Three Months Ended December 31, 2019						
	Total Revenue	Operating (Loss) Income	Operating (Loss) Income Percentage	(Loss) Income Before Income Taxes	Net Income (3)	Diluted EPS	Effective tax rate
GAAP	$ 22,616	$ (266)	(1.2)%	$ (102)	$ 148	$ 0.01	245.1 %
Adjustments:							
Amortization of acquired intangible assets (1)	—	594	2.7 %	594	549	0.04	
Non-GAAP	$ 22,616	$ 328	1.5 %	$ 492	$ 697	$ 0.05	(41.7)%

(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) 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, 2020 as a result of the GAAP net loss for the period. However, as the Non-GAAP adjustments result in Non-GAAP net income, the dilutive effect of these outstanding stock awards has been included in the calculation of Non-GAAP earnings per share, which resulted in no change to calculation of Non-GAAP EPS for the three months ended December 31, 2020.

(3) Net (loss) income includes the effect of the above adjustments on the income tax provision (benefit), taking into account deferred taxes and non-deductible items. In both fiscal 2021 and fiscal 201, an effective rate of 21% was used to estimate the income tax impact of the adjustments, except that expenses occurring in Ireland have not been tax-effected as all tax benefits are offset by a full valuation allowance.

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