

SurModics Reports Fourth Quarter Fiscal 2015 Results

November 10, 2015

- GAAP Revenue Growth of 13% to \$17.4 Million and GAAP EPS of \$0.22
- Non-GAAP Revenue Up 8% and Non-GAAP EPS of \$0.30
- FDA IDE Approval for Early Feasibility Study of the SurVeil™ Drug-Coated Balloon
- Increase in Share Repurchase Authorization to \$30.0 Million
- Fiscal 2016 Guidance Outlined

EDEN PRAIRIE, Minn.--(BUSINESS WIRE)--Nov. 10, 2015-- 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 2015 fourth quarter, ended September 30, 2015.

"The SurModics team had an excellent fiscal 2015," said Gary Maharaj, president and chief executive officer. "We focused on delivering outstanding results from our core businesses while strengthening the transformation for SurModics to become a provider of whole-product solutions to our medical device customers. We continued this momentum into fiscal 2016 as we announced the FDA approval of an early feasibility first-in-human study for the SurModics SurVeilTM drug-coated balloon (DCB)."

Fourth Quarter Revenue and Earnings Summary

GAAP revenue for the fiscal 2015 fourth quarter totaled \$17.4 million, compared with \$15.3 million in the fiscal 2014 fourth quarter. Fiscal 2015 fourth quarter revenue included \$0.8 million of hydrophilic royalty revenue that was deferred because of customer-related contingencies that were resolved during the quarter. These royalties related to the first three quarters of fiscal 2015. Excluding this item, revenue rose 8% in the fiscal 2015 fourth quarter.

Diluted GAAP earnings per share from continuing operations in the fourth quarter of fiscal 2015 were \$0.22 compared with \$0.18 a year ago. The fourth quarter fiscal 2015 earnings include a \$0.04 per share benefit from the contingent royalty revenue items discussed above, offset by a \$0.12 per share reduction from a customer claim settlement. The prior-year quarter included a \$0.08 per share strategic asset impairment charge. On a non-GAAP comparative basis, earnings per share from continuing operations were \$0.30 in the fourth quarter of fiscal 2015 versus \$0.26 last year.

Medical Device Segment

The Medical Device business unit accounts for approximately three-quarters of the Company's revenue. This business, which includes hydrophilic coatings and device drug delivery technologies, posted revenue of \$13.1 million in the fourth quarter of fiscal 2015, an increase of 17% compared to the year-ago period as a result of the contingent royalty revenue items noted above, as well as increases in non-contingent hydrophilic royalties, reagent product sales, and research and development contract coating services. Fiscal fourth quarter 2015 hydrophilic coating royalty revenue was \$8.9 million, an increase of 13% compared to the year-earlier period, or 4% net of the contingent royalty revenue items. The Medical Device business unit generated \$4.7 million of operating income during the fourth quarter, a 24% decline from the year-ago period, with the higher revenue offset by the \$2.5 million pre-tax customer claim settlement in September 2015, as well as compensation costs.

Drug-Coated Balloon Update

"We are pleased with our recent milestone: obtaining investigational device exemption (IDE) approval from the FDA to move forward with our *SurVeil* DCB clinical trial," said Maharaj. "We are currently developing plans for up to three U.S. sites and expect to enroll our first patient in the second quarter of fiscal 2016."

In Vitro Diagnostics Segment

The In Vitro Diagnostics (IVD) business unit accounts for approximately one-quarter of the Company's revenue. Revenue for the fourth quarter of fiscal 2015 totaled \$4.2 million, an increase of 3% compared to the year-ago period. The IVD business unit generated \$1.3 million of operating income in the fourth quarter of fiscal 2015, which reflects a 7% improvement from a year ago. Operating income benefited from higher revenue and lower sales, general and administrative expenses.

Balance Sheet and Cash Flow

As of September 30, 2015, the Company had \$55.6 million of cash and investments and no outstanding debt. SurModics generated cash from operating activities of \$15.1 million in fiscal 2015. Capital expenditures and share repurchases totaled \$1.9 million and \$20.0 million, respectively, for fiscal 2015. The \$20.0 million of share repurchases resulted from the first quarter fiscal 2015 accelerated share repurchase program that was announced in SurModics' fourth quarter fiscal 2014 earnings release. The accelerated share repurchase program was finalized in July 2015 with the retirement of an additional 89,721 common shares. In aggregate, the Company repurchased 847,864 common shares under this program in fiscal 2015.

Share Repurchase Program

SurModics also announced today that its Board of Directors has authorized a \$20 million increase to its existing share repurchase program, bringing the total amount currently authorized and available under the program to an aggregate of \$30 million. Repurchases may be effected through open market purchases, privately negotiated transactions, block trades, accelerated share repurchase transactions, tender offers or by any combination of these methods. The number of shares to be repurchased and the timing of any repurchases will depend on factors such as our stock price, economic

and market conditions, the relative attractiveness of corporate development opportunities and other alternative uses of capital, and corporate and regulatory requirements. The share repurchase authorization does not have a fixed expiration.

Fiscal 2016 Outlook

"We enter fiscal 2016 with three clear priorities: complete an acquisition to accelerate our transformation to providing whole-products solutions to our medical device customers, move ahead with a drug-coated balloon first-in-human clinical trial, and continue to deliver differentiated innovation and service in our medical device and in vitro diagnostics businesses for current and prospective customers," said Maharaj.

SurModics estimates GAAP revenue for fiscal 2016 to be in the range of \$56.0 million to \$60.0 million. Fiscal 2016 revenue anticipates the previously disclosed expiration of the U. S. patent protecting the Company's third generation hydrophilic coatings. Management anticipates diluted GAAP earnings to be in the range of \$0.70 to \$0.80 per share. The fiscal 2016 earnings per share guidance includes an increase of approximately 15% to 20% in research and development investment over fiscal 2015 levels primarily related to drug coated balloon activities, including paclitaxel and sirolimus applications of the drug-coated balloon platform. The Company also expects slightly lower SG&A expenses as compared to fiscal 2015 levels and a 33.0% to 35.0% income tax rate. The earnings per share and income tax rate guidance exclude the impact of any investment gains or losses. Capital expenditures for fiscal 2016 are projected to range between \$3.0 and \$3.5 million. The guidance also excludes any shares SurModics may repurchase under the \$30.0 million authorization.

Live Webcast

SurModics will host a webcast at 7:30 a.m. CT (8:30 a.m. ET) today to discuss fourth quarter results. To access the webcast, go to the investor relations portion of the Company's website at <u>www.surmodics.com</u> and click on the webcast icon. A replay of the fourth quarter conference call will be available by dialing 888-203-1112 and entering conference call ID passcode 944630. The audio replay will be available beginning at 10:30 a.m. CT on Tuesday, November 10, 2015, until 10:30 a.m. CT on Tuesday, November 17, 2015.

About SurModics SurVeil[™] Drug-Coated Balloon

The *SurVeil* drug-coated balloon incorporates SurModics' decades of experience as a leading supplier of surface modification technologies to the medical device industry. It includes a SurModics-proprietary drug-excipient formulation for the balloon coating, and a new and proprietary manufacturing process for the coating applications. It also includes the SurModics Serene[™] low-friction, low-particulate hydrophilic coating on the catheter shaft. The *SurVeil* DCB is not available for sale in the US and is for investigational use only. We plan to initiate a first-in-human clinical trial using SurModics *SurVeil* drug-coated balloon by the end of the second quarter of fiscal 2016.

About SurModics, Inc.

SurModics partners with the world's leading and emerging medical device, diagnostic and life science companies to develop and commercialize innovative products designed to improve lives by enabling the detection and treatment of disease. Our mission is to be a trusted partner to our customers by providing the most advanced surface modification technologies and *in vitro* diagnostic chemical components that help enhance the well-being of patients. The Company's core offerings include surface modification coating technologies that impart lubricity, prohealing, and biocompatibility characteristics and components for *in vitro* diagnostic test kits and microarrays. SurModics' strategy is to build on the product and technical leadership within these fields, and expand the core offerings to generate opportunities for longer term sustained growth. SurModics is headquartered in Eden Prairie, Minnesota. For more information about the Company, 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 SEC.

Safe Harbor for Forward-Looking Statements

This press release contains forward-looking statements. Statements that are not historical or current facts, including statements about beliefs and expectations regarding the Company's performance in the near- and long-term, including our revenue, earnings and cash flow expectations for fiscal 2016, our fiscal 2016 priorities, and our *SurVeil* drug-coated balloon, 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 (1) our ability to successfully develop, obtain regulatory approval for, and commercialize our *SurVeil* drug-coated balloon product, including the timing associated with the initiation of our first-in-human clinical trial; (2) 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; (3) our ability to successfully identify and acquire target companies or achieve expected benefits from acquisitions that are consummated; (4) possible adverse market conditions and possible adverse impacts on our cash flows, and (5) 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, 2014, and updated in our subsequent reports filed with the SEC. These reports are available in the Investors section of our website at <u>www.surmodics.com</u> and at the SEC website at <u>www.sec.gov</u>. 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 generally accepted accounting principles, or GAAP, SurModics is reporting non-GAAP financial results including non-GAAP net income, non-GAAP diluted net income per share, and EBITDA. We believe that these non-GAAP measures 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 payout 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 Income

(in thousands, except per share data)

		Three Months Ended September 30,		ded er 30,
Revenue	2015 (Unaudited	2015 2014 (Unaudited)		2014 d)
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Royalties and license fees Product sales	\$ 9,197 6,844	\$ 8,098 6,166	\$ 31,763 24,925	\$ 30,277 22,798
Research and development	1,323	1,072	5,210	4,364
Total revenue	1,323	1,072	5,210 61,898	4,304 57,439
Operating costs and expenses	17,504	15,550	01,030	57,455
Product costs	2,588	2,279	8,619	8,016
Research and development	4,326	4,062	16,165	15,550
Selling, general and administrative	4,520 3,684	4,002 3,561	15,525	15,350
Claim settlement	2,500		2,500	
Total operating costs and expenses	13,098	9,902	42,809	38,863
Operating income from continuing operations	4,266	5,434	19,089	18,576
Other (loss) income:				
Investment income	7	44	156	238
Other income	—	8	496	842
Impairment loss on investments	—	(1,184)	—	(1,184)
Other (loss) income, net	7	(1,132)	652	(104)
Income from continuing operations before income taxes	4,273	4,302	19,741	18,472
Income tax provision	(1,415)	(1,858)	(6,294)	(6,265)
Income from continuing operations	2,858	2,444	13,447	12,207
Loss from discontinued operations, net of taxes		(100)		(176)
Net income	\$ 2,858	\$ 2,344	\$13,447	\$ 12,031
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Basic income (loss) per share:				
Continuing operations	\$0.22	\$0.18	\$1.03	\$0.90
Discontinued operations	(0.00)	()	(0.00)	(/
Net income	\$0.22	\$0.17	\$1.03	\$0.88
Diluted income (loss) per share:				
Continuing operations	\$ 0.22	\$ 0.18	\$1.01	\$0.88
Discontinued operations	•	(0.01)	(0.00)	•
Net income	\$ 0.22	\$ 0.17	\$1.01	\$0.87
Weighted average number of shares outstanding:				
Basic	12,934	13,593	13,029	13,632
Diluted	13,190	13,829	13,289	13,876

SurModics, Inc. and Subsidiaries Condensed Consolidated Balance Sheets

(in thousands)

	September 30, 2015	September 30, 2014
A	(Unaudited)	
Assets Cash and short-term investments	\$ 55,588	\$ 46,551

Accounts receivable	7,478	4,751
Inventories	2,979	2,817
Other current assets	1,744	1,145
Current assets of discontinued operations		16
Total current assets	67,789	55,280
Property and equipment, net	12,968	\$ 13,133
Long-term investments		16,823
Other assets	19,453	19,653
Total assets	\$ 100,210	104,889
Liabilities and Stockholders' Equity Current liabilities Current liabilities of discontinued operations Total current liabilities	\$ 4,700 4,700	\$ 4,022 45 4,067
Other liabilities	2,137	\$ 2,071
Total stockholders' equity	93,373	98,751
Total liabilities and stockholders' equity	\$ 100,210	104,889

SurModics, Inc. and Subsidiaries Condensed Consolidated Statements of Cash Flows

(in thousands)

	2015 (Unaudit	ed)	2014	
Operating Activities:	,	,		
Net income	\$13,447		\$12,031	
Loss from discontinued operations	_		176	
Depreciation and amortization	2,805		2,715	
Stock-based compensation	2,381		3,337	
Gains on sale of available-for-sale securities and strategic investments	(492)	(842)
Impairment loss on strategic investment	_		1,184	
Net other operating activities	(603)	(586)
Change in operating assets and liabilities:				
Accounts receivable	(2,727)	581	
Accounts payable and accrued liabilities	373		(738)
Income taxes	(84)	116	
Net change in other operating assets and liabilities	(34)	563	
Net cash provided by operating activities from continuing operations	15,066		18,537	,
Investing Activities: Net purchases of property and equipment Cash transferred to discontinued operations Net other investing activities Net cash provided by investing activities from continuing operations	(1,877 (45 18,616 16,694)	(2,278 (354 25,019 22,387)
Financing Activities:				
Purchase of common stock to fund employee taxes Repurchase of common stock Net other financing activities Net cash used in financing activities from continuing operations	(825 (20,000 1,142 (19,683	3)	(1,111 (12,54) 748 (12,90)	5) 8)
Net cash provided by continuing operations Discontinued operations: Net cash used in operating activities	12,077 (45)	28,016 (354)

Years Ended September 30,

Net cash provided by financing activities	45	354
Net cash provided by discontinued operations	—	—
Net change in cash and cash equivalents	12,077	28,016
Cash and Cash Equivalents:		
Beginning of year	43,511	15,495
End of year	\$55,588	\$43,511

SurModics, Inc. and Subsidiaries Supplemental Segment Information

(in thousands)

(Unaudited)

	Three Months Ended September 30,							
	2015			2014			% Cha	ange
Revenue		% of T	otal		% of T	otal		
Medical Device	\$13,118	75.5	%	\$11,216	73.1	%	16.9	%
In Vitro Diagnostics	4,246	24.5		4,120	26.9		3.1	
Total revenue	\$ 17,364	100.0	%	\$ 15,336	100.0	%	13.2	%

Years Ended September 30,

	2015			2014			% Cha	ange
Revenue		% of T	otal		% of T	otal		
Medical Device	\$45,944	74.2	%	\$43,068	75.0	%	6.7	%
In Vitro Diagnostics	15,954	25.8		14,371	25.0		11.0	
Total revenue	\$61,898	100.0	%	\$57,439	100.0	%	7.8	%

	Three Mon Septembe	iths Ended r 30,	Years Ended September 30,		
	2015	2014	2015	2014	
Operating Income					
Medical Device	\$ 4,687	\$ 6,170	\$21,192	\$22,636	
In Vitro Diagnostics	1,264	1,182	4,484	3,459	
Corporate	(1,685)	(1,918)	(6,587)	(7,519)	
Total operating income	\$ 4,266	\$ 5,434	\$ 19,089	\$18,576	

SurModics, Inc. and Subsidiaries Supplemental Non-GAAP Information For the Three Months Ended September 30, 2015

(in thousands, except per share data)

(Unaudited)

	As Reported GAAP(1)	Adjustments	Adjusted Non-GAAP(2)
Revenue			
Royalties and license fees	\$ 9,197	\$ (763)	\$ 8,434
Product sales	6,844		6,844

Research and development Total revenue	1,323 \$ 17,364	\$ (763)	1,323 \$ 16,601
Operating income	\$ 4,266	\$ 1,737	(3)	\$ 6,003
Net Income	\$ 2,858	\$ 1,124	(4)	\$ 3,982
Diluted earnings per share (5)	\$ 0.22			\$ 0.30

(1) Reflects operating results in accordance with U.S. generally accepted accounting principles (GAAP).

Adjusted Non-GAAP amount considers a \$763 reduction in revenue related to pre-fourth quarter fiscal 2015 royalties recognized during the (2) quarter as two customer-related contingencies were resolved; and a \$2,500 adjustment reducing expense, and increase operating income for a customer claim settlement. These adjustments resulted in a net tax expense of \$613.

(3) Adjusted to reflect the pre-tax adjustments discussed in note (2) above.

(4) Adjusted to reflect the after-tax impact of the adjustments discussed in note (2) above.

(5) Diluted earnings per share from continuing operations is calculated using the diluted weighted average shares outstanding for the period presented.

SurModics, Inc. and Subsidiaries Supplemental Non-GAAP Information For the Three Months Ended September 30, 2014

(in thousands, except per share data)

(Unaudited)

	As Reported GAAP(1)	Adjustments	Adjusted Non-GAAP(2)
Revenue	A 0.000		• • • • • •
Royalties and license fees Product sales	\$ 8,098 6,166		\$ 8,098 6,166
Research and development Total revenue	1,072 \$ 15,336		1,072 \$ 15,336
Operating income from continuing operations	\$ 5,434		\$ 5,434
Income from continuing operations	\$ 2,444	\$ 1,184 (3)\$3,628
Diluted earnings per share from continuing operations(4)	\$ 0.18		\$ 0.26

(1) Reflects operating results in accordance with U.S. generally accepted accounting principles (GAAP).

Adjusted Non-GAAP amounts consider adjustments to increase net investment income by \$1,184 associated with an investment impairment

(2) charge associated with the strategic investment in ThermopeutiX. The adjustment to increase net investment income did not generate an income tax expense as there was an offsetting release of a capital loss valuation reserve allowance.

(3) Adjusted to reflect the adjustment discussed in note (2) above.

(4) Diluted earnings per share from continuing operations is calculated using the diluted weighted average shares outstanding for the period presented.

SurModics, Inc. and Subsidiaries Supplemental Non-GAAP Information For the Year Ended September 30, 2015

(in thousands, except per share data)

(Unaudited)

	As Reported GAAP(1)	Adjustments	Adjusted Non-GAAP(2)
Revenue			
Royalties and license fees	\$ 31,763	\$ (560)	\$ 31,203
Product sales	24,925		24,925
Research and development	5,210		5,210
Total revenue	\$ 61,898	\$ (560)	\$ 61,338
Operating income	\$ 19,089	\$ 1,940 (3)	\$ 21,029
Net Income	\$ 13,447	\$ 531 (4)	\$ 13,978
Diluted net income per share (5)	\$ 1.01		\$ 1.05

(1) Reflects operating results in accordance with U.S. generally accepted accounting principles (GAAP). Adjusted to reflect a reduction in revenue by \$560 for the portion of a one-time customer royalty payment related to periods prior to fiscal 2015, a \$523 reduction in net investment income associated with the sale of Intersect ENT shares and a \$2,500 increase to operating income related to a customer claim settlement. The adjustments to reduce royalty revenues and increase operating income related to a claim settlement reflects a net

(2) tax expense of \$685. The reduction for net investment income did not generate a tax benefit as there was an offsetting establishment of a capital loss valuation reserve. Finally, the income tax provision is increased to reflect a discrete income tax benefits of \$201 associated with the December 2014 signing of the Tax Increase Prevention Act of 2014 which retroactively reinstated federal R&D income tax credits for calendar 2014.

(3) Adjusted to reflect the pre-tax impact of the royalty revenue and customer claim settlement adjustments discussed in note (2) above.

(4) Adjusted to reflect the after-tax impact of the adjustments discussed in note (2) above.

(5) Diluted net income per share is calculated using the diluted weighted average shares outstanding for the period presented.

SurModics, Inc. and Subsidiaries Supplemental Non-GAAP Information For the Year Ended September 30, 2014

(in thousands, except per share data)

(Unaudited)

	As Reported GAAP(1)	Adjustments	Adjusted Non-GAAP(2)
Revenue Royalties and license fees Product sales Research and development Total revenue	\$ 30,277 22,798 4,364 \$ 57,439		\$ 30,277 22,798 4,364 \$ 57,439
Operating income	\$ 18,576	\$ 914	(3) \$ 19,490
Income from continuing operations	\$ 12,207	\$ 1,055	(4) \$ 13,262
Diluted earnings per share from continuing operations(5)	\$ 0.88		\$ 0.96

(1) Reflects operating results in accordance with U.S. generally accepted accounting principles (GAAP).

Adjusted Non-GAAP amounts consider adjustments to reduce operating expenses by \$914 associated with acceleration of Board of Director stock-based compensation awards, a \$709 reduction in net investment income associated with contingent milestone payments related to the sale

- (2) of Vessix Vascular shares which were sold in fiscal 2014 and a \$1,184 increase in net investment income associated with an investment impairment charge associated with the strategic investment in ThermopeutiX. The income tax provision includes a \$334 expense associated with the Board of Director stock-based compensation expense reduction. The adjustments to increase net investment income did not generate an income tax expense as there was an offsetting release of a capital loss valuation reserve allowance.
- (3) Adjusted to reflect the pre-tax impact of the operating expense adjustment discussed in note (2) above.
- (4) Adjusted to reflect the after-tax impact of the adjustments discussed in note in (2) above.
- (5) Diluted earnings per share from continuing operations is calculated using the diluted weighted average shares outstanding for the period presented.

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Source: SurModics, Inc.

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