UNITED STATES SECURITIES AND EXCHANGE COMMISSION Washington, D. C. 20549

	Washington, D. C. 20549		
	FORM 10-Q		
(Mark One)			
☑ QUARTERLY REPORT PURSUANT TO SECTION	ON 13 OR 15(d) OF THE SECU	RITIES EXCHANGE ACT OF 1934	
For th	e quarterly period ended March	31, 2018	
	or		
☐ TRANSITION REPORT PURSUANT TO SECTI	ON 13 OR 15(d) OF THE SECU	RITIES EXCHANGE ACT OF 1934	
	Commission File Number: 0-238	37	
(Exact n	Surmodics, Inc. ame of registrant as specified in	its charter)	
MINNESOTA		41-1356149	
(State of incorporation)		(I.R.S. Employer Identification No.)	
(Addres	9924 West 74th Street Eden Prairie, Minnesota 55344 ss of principal executive offices) (1	
Registrant's tele	phone number, including area co	ode: (952) 500-7000	
Indicate by check mark whether the registrant: (1) has filed during the preceding 12 months (or for such shorter perior requirements for the past 90 days. Yes \boxtimes No \square			
Indicate by check mark whether the registrant has submitted be submitted and posted pursuant to Rule 405 of Regulation the registrant was required to submit and post such files).	n S-T (§ 232.405 of this chapter) d		
Indicate by check mark whether the registrant is a large acceeding growth company. See the definitions of "large accein Rule 12b-2 of the Exchange Act.			
Large accelerated filer □		Accelerated filer	\times
Non-accelerated filer \Box (Do not check if a smaller	reporting company)	Smaller reporting company Emerging Growth Company	
If an emerging growth company, indicate by check mark if the revised financial accounting standards provided pursuant to the standards pursuant to the standard pursua			y new or
Indicate by check mark whether the registrant is a shell comp	pany (as defined in Rule 12b-2 of t	he Exchange Act). Yes □ No ⊠	
The number of shares of the registrant's Common Stock, \$.0	5 par value per share, outstanding	as of May 2, 2018 was 13,257,956.	

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PART I. FINANCIAL INFORMATION

Item 1. Unaudited Condensed Financial Statements

Surmodics, Inc. and Subsidiaries

Condensed Consolidated Balance Sheets

ASSETS Current Assets: 27,712 \$ 16,534 Cesh and cash equivalents \$ 27,712 \$ 16,534 Restricted cash 38,30 31,300 Available-fors-sale securities 38,30 31,300 Accounts receivable, net of allowance for doubtful accounts of \$160 and \$230 7,216 7,211 Inventories, net 4,046 3,516 Income tax receivable 2,342 1,212 Total Current Assets 81,341 60,883 Available-for-sale securities 3,356 4,027 Preparids and other 19,725 20,542 Property and equipment, net 25,841 22,942 Intangible assets, net 19,725 20,542 Goodwill 27,933 27,282 Other assets 1,197 89 Total Assets \$ 13,25 2,342 Accounced babilities: \$ 2,302 2,332 Accounced babilities: \$ 2,302 2,332 Accured other 1,207 6 Compensation 3,259 1,750		March 31, 2018			September 30, 2017
Current Assets: S 27,712 \$ 16,534 Cash and cash equivalents 3,500 — Available-for-sale securities 3,500 — Accounts receivable, net of allowance for doubtful accounts of \$160 and \$230 7,211 Inventories, net 4,046 3,516 Income tax receivable 2,342 1,221 Prepaids and other 2,342 1,221 Total Current Assets 81,341 60,833 Available-for-sale securities 3,356 4,027 Prepaids and other 2,342 1,221 Total Current Assets 3,356 4,027 Prepaids and sasets 3,366 4,027 Property and equipment, net 25,844 22,942 Intangible assets, net 19,725 20,562 Goodwill 27,933 27,282 Other assets \$ 13,197 897 Total Assets \$ 2,012 2,356 Account parable \$ 2,012 3,326 Accured liabilities 4,022 1,773 Acc	(in thousands, except share and per share data)			ıdited)	
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Finance tax receivable			7,216		7,211
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Total Current Assets 81,341 60,883 Available-for-sale securities 3,953 — Deferred tax sestes 3,326 4,027 Property and equipment, net 25,844 22,942 Intangible assets, net 19,725 20,562 Goodwill 27,933 72,762 Codwill 1,197 897 Total Assets 1,197 897 Total Assets \$ 163,319 \$ 136,593 LIMBILITIES AND STOCKHOLDERS' EQUITY Current Liabilities Accounts payable \$ 2,012 \$ 2,396 Accounts payable	Income tax receivable		1,345		599
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Godwill 27,933 27,282 Other assets 1,197 897 Total Assets \$ 163,319 \$ 136,593 LIABILITIES AND STOCKHOLDERS' EQUITY Current Liabilities: Accounts payable \$ 2,012 \$ 2,396 Accrued Idabilities: \$ 2,012 \$ 2,396 Compensation 3,859 3,822 Accrued other 4,022 1,773 Deferred revenue 12,035 1,750 Contingent consideration 12,235 1,750 Total Current Liabilities 34,225 9,803 Contingent consideration, less current portion 1,110 13,114 Deferred revenue, less current portion 1,110 13,114 Other long-term liabilities 1,918 1,938 Total Liabilities 4,963 25,036 Commitments and Contingencies (Note 16) 5 2,036 Scockholders' Equity: 5 1,24 1,24 1,24 Series A Preferred stock- \$.05 par value, 45,000,000 shares authorized; no shares issued and outstanding and 13,04,398 shares issued and ou	Property and equipment, net		25,844		22,942
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LIABILITIES AND STOCKHOLDERS' EQUITY Current Liabilities: \$ 2,012 \$ 2,396 Accounts payable \$ 2,012 \$ 2,396 Accrued liabilities: \$ 2,002 1,773 Compensation 3,859 3,822 Accrued other 4,022 1,773 Deferred revenue 12,097 62 Contingent consideration 12,235 1,750 Total Current Liabilities 34,225 9,803 Contingent consideration, less current portion 1,110 13,114 Deferred revenue, less current portion 12,710 181 Other long-term liabilities 1,918 1,938 Total Liabilities 49,963 25,036 Commitments and Contingencies (Note 16) 5 1,938 Stockholders' Equity: 5 — — — Common stock-\$.05 par value, 45,000,000 shares authorized; no shares issued and outstanding — — — Common stock-\$.05 par value, 45,000,000 shares authorized; no shares issued and outstanding — — — Common stock-\$.05 par value, 45,00	Other assets		1,197		897
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Accounts payable \$ 2,012 \$ 2,396 Accrued liabilities: Compensation 3,859 3,822 Accrued other 4,022 1,773 Deferred revenue 12,097 62 Contingent consideration 12,235 1,550 Total Current Liabilities 3,4225 9,803 Contingent consideration, less current portion 1,110 13,114 Deferred revenue, less current portion 12,710 181 Other long-term liabilities 1,918 1,938 Total Liabilities 49,963 25,036 Commitments and Contingencies (Note 16) 5 5 Stockholders' Equity: 5 5 6 6 Common stock- \$.05 par value, 45,000,000 shares authorized; no shares issued and outstanding — — — Series A Preferred stock- \$.05 par value, 45,000,000 shares authorized; 13,247,068 and 5 6 6 6 5 September 30, 2017, respectively 662 655 6 6 6 6 5 431 3,417 6 6	LIABILITIES AND STOCKHOLDERS' EQUITY				
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Accrued other 4,022 1,773 Deferred revenue 12,097 62 Contingent consideration 12,235 1,750 Total Current Liabilities 34,225 9,803 Contingent consideration, less current portion 1,110 13,114 Deferred revenue, less current portion 12,710 181 Other long-term liabilities 1,918 1,938 Total Liabilities 49,963 25,036 Commitments and Contingencies (Note 16) 5 Stockholders' Equity: 5 - - Series A Preferred stock- \$.05 par value, 45,000,000 shares authorized; no shares issued and outstanding - - - Common stock- \$.05 par value, 45,000,000 shares authorized; 13,247,068 and 3 - - - 13,094,988 shares issued and outstanding as of March 31, 2018 and 5 662 655 Additional paid-in capital 662 655 Additional paid-in capital 5,431 5,413 Accumulated other comprehensive income 5,213 3,417 Retained earnings 102,050 102,072 Total Stockholders' Equity 113,356	Accrued liabilities:				
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Contingent consideration 12,235 1,750 Total Current Liabilities 34,225 9,803 Contingent consideration, less current portion 1,110 13,114 Deferred revenue, less current portion 12,710 181 Other long-term liabilities 1,918 1,938 Total Liabilities 49,963 25,036 Commitments and Contingencies (Note 16) *** *** Steries A Preferred stock- \$.05 par value, 450,000 shares authorized; no shares issued and outstanding — — Common stock- \$.05 par value, 45,000,000 shares authorized; 13,247,068 and *** — 13,094,988 shares issued and outstanding as of March 31, 2018 and *** — September 30, 2017, respectively 662 655 Additional paid-in capital 5,431 5,413 Accumulated other comprehensive income 5,213 3,417 Retained earnings 102,072 102,072 Total Stockholders' Equity 111,557					
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Deferred revenue, less current portion 12,710 181 Other long-term liabilities 1,918 1,938 Total Liabilities 49,963 25,036 Commitments and Contingencies (Note 16) Stockholders' Equity: Series A Preferred stock- \$.05 par value, 450,000 shares authorized; no shares issued and outstanding — — — Common stock- \$.05 par value, 45,000,000 shares authorized; 13,247,068 and 13,094,988 shares issued and outstanding as of March 31, 2018 and September 30, 2017, respectively 662 655 Additional paid-in capital 5,431 5,413 Accumulated other comprehensive income 5,213 3,417 Retained earnings 102,050 102,072 Total Stockholders' Equity 111,557	Total Current Liabilities		34,225		9,803
Other long-term liabilities1,9181,938Total Liabilities49,96325,036Commitments and Contingencies (Note 16)******Stockholders' Equity:******Series A Preferred stock- \$.05 par value, 45,000,000 shares authorized; 13,247,068 and 13,094,988 shares issued and outstanding as of March 31, 2018 and September 30, 2017, respectively662655Additional paid-in capital5,4315,413Accumulated other comprehensive income5,2133,417Retained earnings102,050102,072Total Stockholders' Equity113,356111,557	Contingent consideration, less current portion		1,110		13,114
Total Liabilities 49,963 25,036 Commitments and Contingencies (Note 16) Stockholders' Equity: Series A Preferred stock- \$.05 par value, 450,000 shares authorized; no shares issued and outstanding — — — Common stock- \$.05 par value, 45,000,000 shares authorized; 13,247,068 and 13,094,988 shares issued and outstanding as of March 31, 2018 and September 30, 2017, respectively 662 655 Additional paid-in capital 5,431 5,413 Accumulated other comprehensive income 5,213 3,417 Retained earnings 102,050 102,072 Total Stockholders' Equity 113,356 111,557	Deferred revenue, less current portion		12,710		181
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Stockholders' Equity: Series A Preferred stock- \$.05 par value, 450,000 shares authorized; no shares issued and outstanding Common stock- \$.05 par value, 45,000,000 shares authorized; 13,247,068 and 13,094,988 shares issued and outstanding as of March 31, 2018 and September 30, 2017, respectively Additional paid-in capital Accumulated other comprehensive income Retained earnings Total Stockholders' Equity Series A Preferred stock- \$.05 par value, 45,0000 shares authorized; 13,247,068 and 5,213 5,413 5,413 662 655 Additional paid-in capital 5,431 5,413 612,050 102,072 113,356 111,557	Total Liabilities		49,963		25,036
Series A Preferred stock- \$.05 par value, 450,000 shares authorized; no shares issued and outstanding Common stock- \$.05 par value, 45,000,000 shares authorized; 13,247,068 and 13,094,988 shares issued and outstanding as of March 31, 2018 and September 30, 2017, respectively Additional paid-in capital Accumulated other comprehensive income 5,213 Accumulated earnings 102,050 102,072 Total Stockholders' Equity Total Stockholders' Equity	Commitments and Contingencies (Note 16)				
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Additional paid-in capital 5,431 5,413 Accumulated other comprehensive income 5,213 3,417 Retained earnings 102,050 102,072 Total Stockholders' Equity 113,356 111,557			662		655
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Retained earnings 102,050 102,072 Total Stockholders' Equity 113,356 111,557					3,417
Total Stockholders' Equity 113,356 111,557	•				
	The state of the s				
	• •	\$		\$	

The accompanying notes are an integral part of these unaudited condensed consolidated financial statements.

Surmodics, Inc. and Subsidiaries

Condensed Consolidated Statements of Operations

		Three Months Ended March 31,				Six Months	Six Months Ended			
						March	31,			
		2018		2017		2018		2017		
(In thousands, except per share data)		(Unaı	ıdited)			(Unaudite	ed)			
Revenue:										
Product sales	\$	8,686	\$	7,936	\$		\$	15,637		
Royalties and license fees		8,428		7,319		15,504		15,320		
Research, development and other		1,944		2,248		3,793		4,307		
Total revenue		19,058		17,503		36,071		35,264		
Operating costs and expenses:										
Product costs		2,913		2,562		5,804		5,190		
Research and development		10,774		8,208		18,605		14,178		
Selling, general and administrative		6,440		5,076		11,628		9,938		
Acquired intangible asset amortization		636		591		1,254		1,187		
Contingent consideration gain		(2,230)		(611)		(1,112)		(174)		
Total operating costs and expenses		18,533		15,826		36,179		30,319		
Operating income (loss)		525		1,677		(108)		4,945		
Other (loss) income:										
Investment income, net		142		85		263		170		
Foreign exchange (loss) gain		(353)		(201)		(539)		473		
Gain on strategic investment		_		_		177		_		
Other (loss) income, net		(211)		(116)		(99)		643		
Income (loss) before income taxes		314		1,561		(207)		5,588		
Income tax benefit (provision)		1,220		(1,055)		185		(2,782)		
Net income (loss)	\$	1,534	\$	506	\$	(22)	\$	2,806		
Basic net income (loss) per share	\$	0.12	\$	0.04	\$	(0.00)	\$	0.21		
Diluted net income (loss) per share	\$	0.11	\$	0.04	\$	` ′	\$	0.21		
Weighted average number of shares outstanding:						` ,				
Basic		13,102		13,220		13,078		13,207		
Diluted		13,465		13,428		13,078		13,415		

The accompanying notes are an integral part of these unaudited condensed consolidated financial statements.

Surmodics, Inc. and Subsidiaries

Condensed Consolidated Statements of Comprehensive Income

	Three Months Ended March 31,					Six Months Ended March 31,			
		2018		2017		2018		2017	
(In thousands)		(Unaı	ıdited)	_		(Unau	ıdited)		
Net income (loss)	\$	1,534	\$	506	\$	(22)	\$	2,806	
Other comprehensive income (loss):									
Unrealized holding (losses) gains on available-for-sale securities, net of tax		(28)		4		(41)		50	
Foreign currency translation adjustments		1,207		660		1,837		(1,594)	
Other comprehensive income (loss)		1,179		664		1,796		(1,544)	
Comprehensive income	\$	2,713	\$	1,170	\$	1,774	\$	1,262	

The accompanying notes are an integral part of these unaudited condensed consolidated financial statements.

Surmodics, Inc. and Subsidiaries

Condensed Consolidated Statements of Cash Flows

		Six Months Ended March 31,				
		2018		2017		
(in thousands)		(Unau	dited)			
Operating Activities:	ф	(22)	ф	2.006		
Net (loss) income	\$	(22)	\$	2,806		
Adjustments to reconcile net (loss) income to net cash provided by operating activities:		2.100		2.610		
Depreciation and amortization		3,106		2,610		
Stock-based compensation		2,003		1,671		
Contingent consideration gain		(1,112)		(174)		
Unrealized foreign exchange loss (income)		518		(473)		
Deferred taxes		701		525		
Gain on strategic investment		(177)		_		
Provision for bad debts		25		_		
Other		92		(25)		
Change in operating assets and liabilities:						
Accounts receivable		(15)		(223)		
Inventories		(500)		132		
Prepaids and other		(1,366)		(1,006)		
Accounts payable and accrued liabilities		392		(1,959)		
Income taxes		(776)		358		
Deferred revenue		24,562		21		
Net cash provided by operating activities		27,431		4,263		
Investing Activities:						
Purchases of property and equipment		(4,020)		(2,866)		
Purchases of available-for-sale securities		(43,517)		(40,051)		
Maturities of available-for-sale securities		33,000		27,071		
Cash proceeds from sales of property and equipment		4		_		
Cash received from sale of strategic investment		177		_		
Net cash used in investing activities		(14,356)		(15,846)		
Financing Activities:			_			
Issuance of common stock		377		188		
Payments for taxes related to net share settlement of equity awards		(1,132)		(2,127)		
Payment of contingent consideration obligations		(925)		(_,,		
Payment of deferred financing costs		(020)		(97)		
Net cash used in financing activities		(1,680)		(2,036)		
Effect of exchange rate changes on cash and cash equivalents		133		(109)		
		11,528				
Net change in cash and cash equivalents Cash and Cash Equivalents:		11,528		(13,728)		
-		16 524		24.007		
Beginning of period	ф.	16,534	Φ.	24,987		
End of period	\$	28,062	\$	11,259		
Supplemental Information:						
Cash paid for income taxes	\$	782	\$	1,881		
Noncash transactions from investing and financing activities:						
Acquisition of property and equipment on account	\$	329	\$	303		

The accompanying notes are an integral part of these unaudited condensed consolidated financial statements.

Accrued taxes related to net share settlement of equity awards

1,222

Surmodics, Inc. and Subsidiaries Notes to Condensed Consolidated Financial Statements Period Ended March 31, 2018 (Unaudited)

1. Basis of Presentation

The accompanying unaudited interim condensed consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America ("U.S.") ("GAAP") and, in the opinion of management, reflect all adjustments, consisting of normal recurring adjustments, needed to fairly present the financial results of Surmodics, Inc. and subsidiaries ("Surmodics" or the "Company") for the periods presented. These financial statements include amounts that are based on management's best estimates and judgments. These estimates may be adjusted as more information becomes available, and any adjustment could be significant. The impact of any change in estimates is included in the determination of net income (loss) in the period in which the change in estimate is identified. The results of operations for the three and six months ended March 31, 2018 are not necessarily indicative of the results that may be expected for the entire 2018 fiscal year.

In accordance with the rules and regulations of the U.S. Securities and Exchange Commission ("SEC"), the Company has omitted footnote disclosures that would substantially duplicate the disclosures contained in the audited consolidated financial statements of the Company. These unaudited condensed consolidated financial statements should be read together with the audited consolidated financial statements for the fiscal year ended September 30, 2017, and footnotes thereto included in the Company's Form 10-K as filed with the SEC on December 1, 2017.

2. New Accounting Pronouncements

Accounting Standards to be Adopted

In May 2014, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Codification ("ASC") Update No. 2014-09, *Revenue from Contracts with Customers (ASC Topic 606)*. Principles of this guidance require entities to recognize revenue in a manner that depicts the transfer of goods or services to customers in amounts that reflect the consideration an entity expects to be entitled to in exchange for those goods or services. The guidance also requires expanded disclosures relating to the nature, amount, timing, and uncertainty of revenue and cash flows arising from contracts with customers. Additionally, qualitative and quantitative disclosures are required about customer contracts, significant judgments and changes in judgments, and assets recognized from the costs to obtain or fulfill a contract. This accounting standard will be effective for the Company beginning in the first quarter of fiscal year 2019 (October 1, 2018) using one of two prescribed retrospective methods. The Company is currently evaluating the impact that the adoption of this standard will have on the Company's business model and consolidated results of operations, cash flows and financial position. The Company currently plans to adopt the standard using the modified retrospective approach and expects the impact will be material to the consolidated financial statements due to an anticipated one-quarter acceleration of minimum license fees and royalty revenue earned under its hydrophilic license agreements, as well as several additional required financial statement footnote disclosures. Additionally, the Company is currently evaluating the effect of this standard on the recognition of revenue for the payments the Company may earn under its agreement related to the Company's SurVeil® drug-coated balloon with Abbott Vascular, Inc. ("Abbott") entered into in fiscal 2018, which is disclosed in Note 3 to the condensed consolidated financial statements. Under the modified retrospective approach, the Company will apply the new reven

In February 2016, the FASB issued Accounting Standards Update ASU 2016-02, *Leases (ASC Topic 842)*. The new guidance primarily affects lessee accounting, while accounting by lessors will not be significantly impacted by the update. The update maintains two classifications of leases: finance leases, which replace capital leases, and operating leases. Lessees will need to recognize a right-of-use asset and a lease liability on the statement of financial position for those leases previously classified as operating leases under the old guidance. The liability will be equal to the present value of remaining contractual lease payments. The asset will be based on the liability, subject to adjustment, such as for direct costs. The accounting standard will be effective for the Company beginning the first quarter of fiscal year 2020 (October 1, 2019) and will be applied using a modified retrospective approach. The Company is currently evaluating the impact that the adoption of this standard will have on the Company's results of operations, cash flows and financial position. The Company believes the impact will be material due to the right-of-use assets and lease liabilities that will be recorded on the Company's consolidated balance sheets upon adoption of the standard.

In June 2016, the FASB issued ASU No 2016-13, *Financial Instruments – Credit Losses (ASC Topic 326)*, *Measurement of Credit Losses on Financial Statements*. This ASU requires a financial asset (or a group of financial assets) measured at an amortized cost

basis to be presented at the net amount expected to be collected. The allowance for credit losses is a valuation account that is deducted from the amortized cost basis of the financial asset(s) to present the net carrying value at the amount expected to be collected on the financial asset. The accounting standard will be effective for the Company beginning in the first quarter of fiscal 2020 (October 1, 2019). Early adoption is permitted and the guidance will be applied using a modified retrospective approach. The Company is currently evaluating the impact that the adoption of this standard will have on the Company's results of operations, cash flows and financial position.

No other new accounting pronouncement issued or effective has had, or is expected to have, a material impact on the Company's condensed consolidated financial statements.

3. Collaborative Arrangement

On February 26, 2018, the Company entered into an agreement with Abbott whereby Abbott will have exclusive worldwide commercialization rights for Surmodics' SurVeil® drug-coated balloon to treat the superficial femoral artery, which is currently being evaluated in a U.S. pivotal clinical trial. Separately, Abbott also received options to negotiate agreements for Surmodics' below-the-knee and arteriovenous (AV) fistula drug-coated balloon products, which are currently in pre-clinical development. Surmodics is responsible for conducting all necessary clinical trials and other activities required to achieve U.S. and European Union regulatory clearances for *SurVeil*, including completion of the ongoing TRANSCEND clinical trial. Abbott and Surmodics will participate on a joint development committee charged with providing guidance on the Company's clinical and regulatory activities with regard to the *SurVeil* product.

The Company has received a \$25 million upfront fee and may receive up to \$67 million of additional payments upon achievement of various clinical and regulatory milestones. The upfront fee and potential milestone payments will be recognized as royalty and license fee revenue as the clinical and regulatory activities are performed on a proportional performance basis, relative to the expected total cost of each underlying unit of account. For the three and six-month periods ended March 31, 2018, the Company recognized revenue totaling \$0.5 million from the Abbott arrangement. The remainder of the \$25 million upfront payment received is included in deferred revenue as of March 31, 2018. Upon the regulatory approval of the SurVeil® drug-coated balloon, Surmodics will be responsible for the manufacture and supply of clinical and commercial quantities of the product and will realize revenue based on initial product sales to Abbott as well as a share of net profits resulting from third-party sales by Abbott.

4. Fair Value Measurements

The accounting guidance on fair value measurements defines fair value, establishes a framework for measuring fair value under GAAP, and expands disclosures about fair value measurements. The guidance is applicable for all financial assets and financial liabilities and for all nonfinancial assets and nonfinancial liabilities recognized or disclosed at fair value in the financial statements on a recurring basis (at least annually). Fair value is defined as the exchange price that would be received from selling an asset or paid to transfer a liability (an exit price) in an orderly transaction between market participants at the measurement date. When determining the fair value measurements for assets and liabilities required or permitted to be recorded at fair value, the Company considers the principal or most advantageous market in which it would transact and also considers assumptions that market participants would use when pricing the asset or liability, such as inherent risk, transfer restrictions and risk of nonperformance.

Fair Value Hierarchy

Accounting guidance on fair value measurements requires that assets and liabilities carried at fair value be classified and disclosed in one of the following three categories:

Level 1 — Quoted (unadjusted) prices in active markets for identical assets or liabilities.

The Company did not have any Level 1 assets as of March 31, 2018 and September 30, 2017.

Level 2 — Observable inputs other than quoted prices included in Level 1, such as quoted prices for similar assets or liabilities in active markets; quoted prices for identical or similar assets or liabilities in markets that are not active; or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the asset or liability.

The Company's Level 2 assets as of March 31, 2018 and September 30, 2017 consisted of money market funds, commercial paper instruments and corporate bonds.

Level 3 — Unobservable inputs to the valuation methodology that are supported by little or no market activity and that are significant to the measurement of the fair value of the assets or liabilities. Level 3 assets and liabilities include those whose fair value measurements are determined using pricing models, discounted cash flow methodologies or similar valuation techniques, as well as significant management judgment or estimation.

Level 3 liabilities as of March 31, 2018 and September 30, 2017 consist of contingent consideration obligations related to the fiscal 2016 acquisitions of Creagh Medical Ltd. ("Creagh Medical") and NorMedix, Inc. ("NorMedix"). Consideration owed to the sellers of Creagh Medical upon achievement of revenue and value-creating milestones through September 30, 2018, is due to be paid during the quarter ending December 31, 2018. Consideration owed to the sellers of NorMedix upon achievement of revenue and value-creating milestones through September 30, 2019, is due to be paid within sixty days following the quarter in which each milestone is achieved. Contingent consideration included in current liabilities of \$12.2 million and \$1.8 million as of March 31, 2018 and September 30, 2017, respectively, represents the Company's estimated fair value of amounts expected to be paid within one year of each respective balance sheet date. During the three months ended March 31, 2018, the Company paid contingent consideration obligations related to the NorMedix acquisition totaling \$0.9 million, which are included in cash flows used in financing activities on the condensed consolidated statement of cash flows.

In valuing assets and liabilities, the Company is required to maximize the use of quoted market prices and minimize the use of unobservable inputs.

Assets and Liabilities Measured at Fair Value on a Recurring Basis

In instances where the inputs used to measure fair value fall into different levels of the fair value hierarchy, the fair value measurement has been determined based on the lowest level input that is significant to the fair value measurement in its entirety. The Company's assessment of the significance of a particular item to the fair value measurement in its entirety requires judgment, including the consideration of inputs specific to the asset or liability.

The following table presents information about the Company's assets and liabilities measured at fair value on a recurring basis as of March 31, 2018:

(Dollars in thousands)	Quoted Prices in Active Markets for Identical Instruments (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)	Total Fair Value as of March 31, 2018
Assets				
Cash equivalents	\$ —	\$ 21,432	\$ —	\$ 21,432
Available-for-sale securities	_	42,283	_	42,283
Total assets	<u> </u>	\$ 63,715	<u>\$</u>	\$ 63,715
Liabilities				
Contingent consideration	\$ —	\$ —	\$ (13,345)	\$ (13,345)
Total liabilities	<u> </u>	\$ —	\$ (13,345)	\$ (13,345)

The following table presents information about the Company's assets and liabilities measured at fair value on a recurring basis as of September 30, 2017:

(Dollars in thousands)	Quoted Prices Active Marke for Identica Instruments (Level 1)	ets l	O Obse	ificant ther ervable puts vel 2)	Signifi Unobser Inpu (Leve	rvable its	•	Total Fair Value as of ptember 30, 2017
Assets							_	
Cash equivalents	\$	_	\$	6,639	\$	_	\$	6,639
Available-for-sale securities		—		31,802		_	\$	31,802
Total assets	\$	=	\$	38,441	\$		\$	38,441
Liabilities								
Contingent consideration	\$	_	\$	_	\$	(14,864)	\$	(14,864)
Total liabilities	\$	_	\$		\$	(14,864)	\$	(14,864)

The following table summarizes the changes in the contingent consideration liabilities measured at fair value using Level 3 inputs for the three and six months ended March 31, 2018 and 2017:

	Three Months Ended March 31,			Six Months E March 31				
(Dollars in thousands)		2018		2017		2018		2017
Beginning balance	\$	16,162	\$	14,291	\$	14,864	\$	14,517
Additions		_		_		_		_
Fair value adjustments		(2,317)		(1,159)		(1,298)		(1,159)
Settlements		(925)		_		(925)		_
Interest accretion		87		548		186		985
Foreign currency translation loss (gain)		338		190		518		(473)
Ending balance	\$	13,345	\$	13,870	\$	13,345	\$	13,870

There were no transfers of assets or liabilities between amounts measured using Level 1, Level 2, or Level 3 fair value measurements during fiscal 2018 to date or fiscal 2017.

Valuation Techniques

The valuation techniques used to measure the fair value of assets are as follows:

Cash equivalents — These assets are classified as Level 2 and are carried at historical cost which is a reasonable estimate of fair value because of the relatively short time between origination of the instrument and its expected realization.

Available-for-sale securities — Fair market values for these assets are based on quoted vendor prices and broker pricing in active markets underlying the securities where all significant inputs are observable. To ensure the accuracy of quoted vendor prices and broker pricing, the Company performs regular reviews of investment returns to industry benchmarks and sample tests of individual securities to validate quoted vendor prices with other available market data.

Contingent consideration — The contingent consideration liabilities were determined based on discounted cash flow analyses that included revenue estimates, probability of strategic milestone achievement and a discount rate, which are considered significant unobservable inputs. For the NorMedix revenue-based milestones, the Company discounted forecasted revenue by 23.0%, which represents the Company's weighted average cost of capital for this transaction, adjusted for the short-term nature of the cash flows. The present value of forecasted revenue was used as an input into an option pricing approach, which also considered the Company's risk of non-payment of the NorMedix revenue-based milestones. Expected payments of the Creagh Medical revenue milestones were discounted using the Company's estimated cost of debt at March 31, 2018. Non-revenue milestones for the Creagh Medical and NorMedix acquisitions that have not already been achieved were projected to have a 0-90% probability of achievement and expected payments were discounted using the Company's estimated cost of debt, or 2.3% to 4.5%. To the extent that actual

results differ from these estimates, the fair value of the contingent consideration liabilities could change significantly. Accretion expense is recorded as an increase to the contingent consideration liabilities due to the passage of time. Fair value adjustments represent changes in the value of the obligations related to adjustments to forecasted revenue and probability of strategic milestone completion. The contingent consideration liability related to the Creagh Medical acquisition is denominated in Euros and is not hedged. Foreign currency translation and losses are recorded as this obligation is marked to period-end exchange rates.

5. Investments

Investments consisted principally of commercial paper and corporate bond securities and are classified as available-for-sale as of March 31, 2018 and September 30, 2017. Available-for-sale securities are reported at fair value with unrealized gains and losses, net of tax, excluded from the condensed consolidated statements of operations and reported in the condensed consolidated statements of comprehensive income as well as a separate component of stockholders' equity in the condensed consolidated balance sheets, except for other-than-temporary impairments, which are reported as a charge to current earnings. A loss would be recognized when there is an other-than-temporary impairment in the fair value of any individual security classified as available-for-sale, with the associated net unrealized loss reclassified out of accumulated other comprehensive income with a corresponding adjustment to other (loss) income. This adjustment results in a new cost basis for the investment. Interest earned on debt securities, including amortization of premiums and accretion of discounts, is included in investment income, net within other (loss) income. Realized gains and losses from the sales of debt securities, which are included in other (loss) income, are determined using the specific identification method. Investment purchases are accounted for on the date the trade is executed, which may not be the same as the date the transaction is cash settled.

The amortized cost, unrealized holding gains and losses, and fair value of available-for-sale securities were as follows:

	March 31, 2018								
(Dollars in thousands)	Amo	rtized Cost	Unre	alized Gains	Unrea	lized Losses	1	air Value	
Short-term commercial paper and corporate bonds	\$	38,371	\$	_	\$	(41)	\$	38,330	
Long-term corporate bonds		3,964		_		(11)		3,953	
Total	\$	42,335	\$		\$	(52)	\$	42,283	
				Septembe	er 30, 20	17			
(Dollars in thousands)	Amo	rtized Cost	Unre	alized Gains	Unrea	lized Losses	1	Fair Value	
Commercial paper and corporate bonds	\$	31,817	\$	_	\$	(15)	\$	31,802	
Total	\$	31,817	\$		\$	(15)	\$	31,802	

6. Inventories

Inventories are principally stated at the lower of cost or market using the specific identification method and include direct labor, materials and overhead, with cost of product sales determined on a first-in, first-out basis. Inventories consisted of the following components:

	Ma	rch 31,	September 30,		
(Dollars in thousands)	:	2018			
Raw materials	\$	2,002	\$	1,603	
Work-in process		843		659	
Finished products		1,201		1,254	
Total	\$	4,046	\$	3,516	

7. Other Assets

Other assets consist of the following:

	arch 31,	Sep	tember 30,		
(Dollars in thousands)	 2018		2017		
ViaCyte, Inc.	\$ 479	\$	479		
Other noncurrent assets	718		418		
Other assets, net	\$ 1,197	\$	897		

The Company has invested a total of \$5.3 million in ViaCyte, Inc. ("ViaCyte"), a privately-held California-based biotechnology firm that is developing a unique treatment for diabetes using coated islet cells, the cells that produce insulin in the human body. The balance of the investment of \$0.5 million, which is net of previously recorded other-than-temporary impairments of \$4.8 million, is accounted for under the cost method and represents less than a 1% ownership interest. The Company does not exert significant influence over ViaCyte's operating or financial activities.

The carrying value of each cost method investment is reviewed quarterly for changes in circumstances or the occurrence of events that suggest the Company's investment may not be recoverable. The fair value of cost method investments is not adjusted if there are no identified events or changes in circumstances that may have a material effect on the fair value of the investment.

8. Intangible Assets

Intangible assets consist principally of acquired patents and technology, customer lists and relationships, licenses and trademarks. The Company recorded amortization expense of \$0.7 million and \$0.6 million for the three months ended March 31, 2018 and 2017, respectively. The Company recorded amortization expense of \$1.4 million and \$1.3 million for the six months ended March 31, 2018 and 2017, respectively.

Intangible assets consisted of the following:

	March 31, 2018								
	Gross								
	Weighted Average	Carrying	Accumulated						
(Dollars in thousands)	Original Life (Years)	Amount	Amortization	Net					
Definite-lived intangible assets:									
Customer lists and relationships	8.9	\$ 18,832	\$ (8,777)	\$ 10,055					
Developed technology	11.5	9,829	(1,950)	7,879					
Non-compete	5.0	230	(127)	103					
Patents and other	16.5	2,321	(1,496)	825					
Subtotal		31,212	(12,350)	18,862					
Unamortized intangible assets:									
In-process research and development		283	_	283					
Trademarks and trade names		580		580					
Total		\$ 32,075	\$ (12,350)	\$ 19,725					

	September 30, 2017									
		Gross								
	Weighted Average	(Carrying	Ac	cumulated					
(Dollars in thousands)	Original Life (Years)		Amount Amo		nortization		Net			
Definite-lived intangible assets:										
Customer lists and relationships	8.9	\$	18,293	\$	(7,834)	\$	10,459			
Developed technology	11.7		9,297		(1,478)		7,819			
Non-compete	5.0		230		(103)		127			
Patents and other	16.5		2,321		(1,423)		898			
Subtotal			30,141		(10,838)		19,303			
Unamortized intangible assets:										
In-process research and development			679		_		679			
Trademarks and trade names			580		_		580			
Total		\$	31,400	\$	(10,838)	\$	20,562			

Based on the intangible assets in service as of March 31, 2018, excluding any possible future amortization associated with acquired in-process research and development ("IPR&D"), which has not met technological feasibility as of March 31, 2018, estimated amortization expense for the remainder of fiscal 2018 and each of the next five fiscal years is as follows (in thousands):

Remainder of 2018	\$ 1,398
2019	2,795
2020	2,620
2021	2,481
2022	2,441
2023	1,807

Future amortization amounts presented above are estimates. Actual future amortization expense may be different as a result of future acquisitions, impairments, completion or abandonment of IPR&D intangible assets, changes in amortization periods, or other factors.

The Company defines IPR&D as the value of technology acquired for which the related projects have substance and are incomplete. IPR&D acquired in a business acquisition is recognized at fair value and requires the IPR&D to be capitalized as an indefinite-lived intangible asset until completion of the IPR&D project or abandonment. Upon completion of the development project (generally when regulatory approval to market the product is obtained), an impairment assessment is performed prior to amortizing the asset over its estimated useful life. If the IPR&D projects are abandoned, the related IPR&D assets would be written off. During the second quarter of fiscal 2018, we reclassified \$0.4 million of acquired IPR&D to developed technology as the technology was commercialized.

9. Goodwill

Goodwill represents the excess of the cost of an acquired entity over the fair value assigned to the assets purchased and liabilities assumed in connection with a business acquisition. Goodwill is not amortized but is subject, at a minimum, to annual tests for impairment in accordance with accounting guidance for goodwill. The carrying amount of goodwill is evaluated annually, and between annual evaluations if events occur or circumstances change indicating that the carrying amount of goodwill may be impaired.

Goodwill as of March 31, 2018 and September 30, 2017 totaled \$27.9 million and \$27.3 million, respectively. Goodwill in the Medical Device reporting unit represents the gross value from the fiscal 2016 acquisitions of Creagh Medical and NorMedix. Goodwill in the In Vitro Diagnostics reporting unit represents the gross value from the acquisition of BioFX Laboratories, Inc. ("BioFX") in fiscal 2007.

Goodwill was not impaired in either reporting unit based on the outcome of the fiscal 2017 annual impairment test, and there have been no events or circumstances that have occurred in the first six months of fiscal 2018 to indicate that goodwill has been impaired.

The change in the carrying amount of goodwill by segment for the six months ended March 31, 2018 was as follows:

	In Vitro		Me	dical			
(Dollars in thousands)	Diagnostics		Diagnostic		De	vice	Total
Balance as of September 30, 2017	\$ 8,0	010	\$ 1	19,272	\$ 27,282		
Currency translation adjustment		_		651	651		
Balance as of March 31, 2018	\$ 8,0	010	\$ 1	19,923	\$ 27,933		

10. Accrued Liabilities

Accrued liabilities consisted of the following:

	March 31, 2018			September 30, 2017
Accrued professional fees	\$	362	\$	501
Accrued clinical study expense		1,424		411
Accrued inventory purchases		692		596
Construction in progress		198		_
Customer claim		1,000		_
Other		346		265
Total	\$	4,022	\$	1,773

11. Stock-based Compensation

The Company has stock-based compensation plans under which it grants stock options, restricted stock awards, performance share awards, restricted stock units and deferred stock units. Accounting guidance requires all share-based payments to be recognized as an operating expense, based on their fair values, over the requisite service period.

The Company's stock-based compensation expenses were allocated to the following expense categories:

	Three Months Ended March 31,					Six Mont Marc		
(Dollars in thousands)	2018		2017		2018		2017	
Product costs	\$	23	\$	37	\$	17	\$	50
Research and development		179		123		337		248
Selling, general and administrative		899		722		1,649		1,373
Total	\$ 1,101		\$	882	\$	2,003	\$	1,671

As of March 31, 2018, approximately \$7.6 million of total unrecognized compensation costs related to non-vested awards is expected to be recognized over a weighted average period of approximately 2.4 years. The unrecognized compensation costs above include \$1.0 million, remaining to be expensed over the life of the awards, based on payout levels associated with performance share awards that are currently anticipated to be fully expensed because the performance conditions are expected to exceed minimum threshold levels.

Stock Option Awards

The Company uses the Black-Scholes option pricing model to determine the weighted average grant date fair value of stock options granted. The weighted average per share fair values of stock options granted during the three months ended March 31, 2018 and 2017 were \$9.00 and \$7.59, respectively, and \$10.32 and \$7.59 during the six months ended March 31, 2018 and 2017, respectively.

	Three Month March 3		Six Months I March 3	
	2018 2017		2018	2017
Risk-free interest rates	2.6%	1.9%	2.1%	1.7%
Expected life (years)	4.8	4.7	4.8	4.6
Expected volatility	33.0%	34.1%	33.0%	34.4%
Dividend yield	0.0%	0.0%	0.0%	0.0%

The risk-free interest rate assumption was based on the U.S. Treasury's rates for U.S. Treasury zero-coupon bonds with maturities similar to those of the expected term of the awards. The expected life of options granted was determined based on the Company's experience. Expected volatility was based on the Company's stock price movement over a period approximating the expected term. Based on management's judgment, dividend yields were expected to be 0.0% for the expected life of the options. The Company also estimated forfeitures of options granted, which were based on historical experience.

Non-qualified stock options are granted at fair market value on the date of grant. Non-qualified stock options expire in seven to ten years or upon termination of employment or service as a Board member. With respect to members of our Board, non-qualified stock options generally become exercisable on a pro-rata basis within the one-year period following the date of grant. With respect to our employees, non-qualified stock options generally become exercisable with respect to 25% of the shares on each of the first four anniversaries following the grant date. The stock-based compensation table above includes stock option expenses recognized related to these awards, which totaled \$0.4 million and \$0.3 million for the three months ended March 31, 2018 and 2017, respectively, and \$0.8 million and \$0.6 million for the six months ended March 31, 2018 and 2017, respectively.

The total pre-tax intrinsic value of options exercised during the three months ended March 31, 2018 and 2017 was \$3.1 million and less than \$0.1 million, respectively. The total pre-tax intrinsic value of options exercised during the six months ended March 31, 2018 and 2017 was \$3.3 million and less than \$0.1 million, respectively. The intrinsic value represents the difference between the Company's common stock fair market value on the date of exercise and the option's exercise price.

Restricted Stock Awards

The Company has entered into restricted stock agreements with certain key employees, covering the issuance of common stock ("Restricted Stock"). Under accounting guidance, these shares are considered to be non-vested shares. The Restricted Stock is released to the key employees if they are employed by the Company at the end of the vesting period. Restricted Stock vesting periods range from one to three years. During the six months ended March 31, 2018 and 2017, the Company awarded 53,455 and 41,433 Restricted Stock shares, respectively, to certain key employees and officers. Forfeiture of 3,482, and 1,406 Restricted Stock shares occurred during the six months ended March 31, 2018 and 2017, respectively. As of March 31, 2018 and September 30, 2017, 94,197 and 67,917 Restricted Stock shares were outstanding, respectively. Compensation expense has been recognized for the estimated fair value of the common shares, net of estimated forfeitures, and is being charged to operating expenses over the vesting term. The stock-based compensation expense table includes Restricted Stock expenses recognized related to these awards, which totaled \$0.3 million and \$0.1 million for the three months ended March 31, 2018 and 2017, respectively. The stock-based compensation expense table includes Restricted Stock expenses recognized related to these awards, which totaled \$0.5 million and \$0.3 million for the six months ended March 31, 2018 and 2017, respectively.

Performance Share Awards

The Company has entered into performance share agreements with certain key employees and executives, covering the issuance of common stock ("Performance Shares"). Performance Shares vest upon the achievement of all or a portion of certain performance objectives (which may include financial or project objectives), which must be achieved during the performance period. The Organization and Compensation Committee of the Board of Directors (the "Committee") approves the performance objectives used for our executive compensation programs, which objectives were cumulative revenue and cumulative earnings before interest, income taxes, depreciation and amortization ("EBITDA") for the three-year performance periods for awards granted in fiscal 2015

(2015 – 2017), fiscal 2016 (2016 – 2018) and fiscal 2017 (2017 – 2019). The fiscal 2017 awards also include performance objectives related to achievement of the Company's strategic initiatives. Assuming that the minimum performance level is attained, the number of shares that may actually vest will vary based on performance from 20% (minimum) to 200% (maximum) of the target number of shares. Shares will be issued to participants as soon as practicable following the end of each performance period, subject to Committee approval and verification of results. Awards granted in fiscal 2015 were finalized in the six months ended March 31, 2018 and resulted in the issuance of 51,478 shares (maximum was 84,398 shares) based on the performance objectives relative to actual results achieved during the performance period. The per share compensation cost for each award is fixed on the grant date. Compensation expense is recognized in each period based on management's estimate of the achievement level of actual and forecasted results, as appropriate, compared with the specified performance objectives and the related impact on the number of Performance Shares expected to vest. The stock-based compensation expense table includes Performance Shares expenses recognized related to these awards, which totaled \$0.2 million and \$0.4 million, respectively, for the three months ended March 31, 2018 and 2017, respectively. The stock-based compensation expense table includes the Performance Shares expenses recognized related to these awards, which totaled \$0.4 million and \$0.6 million for the six months ended March 31, 2018 and 2017, respectively.

The fair values of the Performance Shares, at target, were \$1.2 million, and \$1.3 million for awards granted in fiscal 2017 and 2016, respectively.

The aggregate number of shares that could be awarded to our executives if the minimum, target and maximum performance goals are met, based on the fair value at the date of grant is as follows:

	Minimum		
Performance Period	Shares	Target Shares	Maximum Shares
Fiscal 2016 – 2018	13,268	66,338	132,676
Fiscal 2017 – 2019	10,437	52,185	104,370

Employee Stock Purchase Plan

Under the Employee Stock Purchase Plan ("Stock Purchase Plan"), the Company is authorized to issue up to 600,000 shares of common stock. All full-time and part-time U.S. employees can choose to have up to 10% of their annual compensation withheld, with a limit of \$25,000, to purchase the Company's common stock at purchase prices defined within the provisions of the Stock Purchase Plan. As of March 31, 2018 and September 30, 2017, there was less than \$0.1 million of employee contributions included in accrued liabilities in the condensed consolidated balance sheets. Stock compensation expense recognized related to the Stock Purchase Plan for the three and six months ended March 31, 2018 and 2017 totaled less than \$0.1 million in each respective period. The stock-based compensation table includes the Stock Purchase Plan expenses.

Restricted Stock and Deferred Stock Units

During the six months ended March 31, 2018 and 2017, the Company awarded 21,265 and 14,728 restricted stock units ("RSUs"), respectively, to non-employee directors and certain key employees in foreign jurisdictions. As of March 31, 2018 and September 30, 2017, 60,440 and 44,391 RSUs were outstanding. RSU awards are not considered issued or outstanding common stock of the Company until they vest. The estimated fair value of the RSUs was calculated based on the closing market price of Surmodics' common stock on the grant date. Compensation expense has been recognized for the estimated fair value of the common shares and is being charged to operating expenses over the vesting term. The stock-based compensation table includes RSU expenses recognized related to these awards, which totaled \$0.1 million for both the three-month periods ended March 31, 2018 and 2017. The stock-based compensation table includes RSU expenses recognized related to these awards, which totaled \$0.2 million and \$0.1 million for the six months ended March 31, 2018 and 2017, respectively.

Directors can also elect to receive their annual fees for services to the Board in deferred stock units ("DSUs"). Certain directors elected this option beginning on January 1, 2013 with deferral elections made annually. During the six months ended March 31, 2018 and 2017, 1,432 and 2,501 units, respectively, were issued with a total fair value of less than \$0.1 million in each period. As of March 31, 2018 and September 30, 2017, outstanding DSUs totaled 25,873 and 24,441, respectively. These DSUs are fully vested. Stock-based compensation expense related to DSU awards totaled less than \$0.1 million for both the three-month periods ended March 31, 2018 and 2017. Stock-based compensation expense related to DSU awards totaled \$0.1 million for both the six-month periods ended March 31, 2018 and 2017.

12. Revolving Credit Facility

The Company had a revolving credit facility with available principal totaling \$30.0 million, which was scheduled to terminate on November 2019. The Company terminated this agreement on March 30, 2018, at which time there was no outstanding balance.

13. Net Income (Loss) Per Share Data

Basic net income (loss) per common share is calculated by dividing net income (loss) by the weighted average number of common shares outstanding during the period. Diluted net income per common share is computed by dividing net income by the weighted average number of common and dilutive common equivalent shares outstanding during the period. The Company's potentially dilutive common shares are those that result from dilutive common stock options, non-vested stock relating to restricted stock awards, restricted stock units, deferred stock units and performance shares. Options to purchase common stock as well as unvested restricted stock and performance stock units are considered to be potentially dilutive common shares, but have been excluded from the calculation of diluted net loss per share as their effect is anti-dilutive for the six months ended March 31, 2018 as a result of the net loss incurred for that period. Therefore, diluted net loss per share was the same as basic net loss per share for the six months ended March 31, 2018. The calculation of weighted average diluted shares outstanding excludes outstanding stock options associated with the right to purchase less than 0.1 million shares of common stock for the three months ended March 31, 2018, as their inclusion would have had an antidilutive effect on diluted net income per share.

The calculation of weighted average diluted shares outstanding excludes outstanding stock options associated with the right to purchase 0.5 million and 0.3 million shares of common stock for the three and six months ended March 31, 2017, respectively, as their inclusion would have had an antidilutive effect on diluted net income per share.

The following table sets forth the denominator for the computation of basic and diluted net income (loss) per share (in thousands):

	Three Months Ended March 31,				Six Month Marcl			
		2018	2017		2017 2			2017
Net income (loss) available to common shareholders	\$	1,534	\$	506	\$	(22)	\$	2,806
Basic weighted average shares outstanding		13,102		13,220		13,078		13,207
Dilutive effect of outstanding stock options, non-vested restricted stock, restricted stock units, deferred stock units and								
performance shares		363		208		<u> </u>		208
Diluted weighted average shares outstanding		13,465		13,428		13,078		13,415

The Company's Board of Directors has authorized the repurchase of up to \$25.3 million of the Company's outstanding common stock. This authorization does not have an expiration date.

14. Income Taxes

For interim income tax reporting, the Company estimates its annual effective tax rate and applies it to year-to-date pretax income (loss), excluding unusual or infrequently occurring discrete items. Tax jurisdictions with losses for which tax benefits cannot be realized are excluded. The Company recorded income tax (benefit) provision of (\$1.2) million and \$1.1 million for the three months ended March 31, 2018 and 2017, respectively. The Company recorded income tax (benefit) provision of (\$0.2) million and \$2.8 million for the six months ended March 31, 2018 and 2017, respectively. In December 2017, the Tax Cuts and Jobs Act tax legislation was signed into law, which reduced the U.S. Federal statutory tax rate from 35% to 21%, among other changes. As a result of the enactment of this legislation, the tax provision for the first six months of fiscal 2018 includes discrete tax expense of \$1.2 million from the Company's net deferred tax assets revaluation based on the enacted tax rate of 21%, as compared with the previous rate of 35%. U.S. tax law requires that taxpayers with a fiscal year beginning before and ending after the effective date of a rate change calculate a blended tax rate for the year based on the pro rata number of days in the year before and after such effective date. As a result, for the fiscal year ending September 30, 2018, our U.S. federal statutory income tax rate is expected to be 24.5%. The effective income tax rate for the three and six months ended March 31, 2018 and 2017 differs from the U.S. federal statutory tax rate of 24.5% and 35%, respectively, primarily due to operating losses incurred in Ireland, where tax benefits are offset by a valuation allowance, and non-deductible acquired intangible asset amortization, contingent consideration gain, including fair

value adjustments, as well as unrealized foreign currency translation gains and losses on Euro-denominated contingent consideration liabilities. These increases to the effective income tax rate were partially offset by the U.S. federal research and development income tax credit and, in fiscal 2017, the domestic production manufacturing deduction. The effective income tax rate for the three months ended March 31, 2018 was impacted by discrete tax benefit of \$0.2 million related to share awards vested, expired, cancelled and exercised during the periods. The effective income tax rate for the six months ended March 31, 2018 and 2017 was impacted by discrete tax benefit (expense) of \$0.4 million and (\$0.3) million, respectively, related to share awards vested, expired, cancelled and exercised during the periods.

The total amount of unrecognized tax benefits, excluding interest and penalties that, if recognized, would affect the effective tax rate is \$1.5 million and \$1.2 million as of March 31, 2018 and September 30, 2017, respectively. Interest and penalties related to unrecognized tax benefits are recorded in the income tax provision.

The Company files income tax returns, including returns for its subsidiaries, in the U.S. federal jurisdiction and in various state jurisdictions as well as several non-U.S. jurisdictions. Uncertain tax positions are related to tax years that remain subject to examination. U.S. income tax returns for years prior to fiscal 2013 are no longer subject to examination by federal tax authorities. For tax returns for state and local jurisdictions, the Company is no longer subject to examination for tax years generally before fiscal 2007. For tax returns for non-U.S. jurisdictions, the Company is no longer subject to income tax examination for years prior to 2012. Additionally, the Company has been indemnified of liability for any taxes relating to Creagh Medical and NorMedix for periods prior to their respective acquisition dates, pursuant to the terms of the related share purchase agreements. As of March 31, 2018 and September 30, 2017, there were no undistributed earnings in foreign subsidiaries. The Internal Revenue Service ("IRS") commenced an examination of our fiscal 2016 U.S. federal income tax return in the fourth quarter of fiscal 2017. The examination has not been completed.

15. Segment and Geographical Information

The Company's management evaluates performance and allocates resources based on reported results for two reportable segments, as follows: (1) the Medical Device unit, which is comprised of manufacturing balloons and catheters used for a variety of interventional cardiology, peripheral and other applications, surface modification coating technologies to improve access, deliverability, and predictable deployment of medical devices, as well as drug delivery coating technologies to provide site-specific drug delivery from the surface of a medical device, with end markets that include coronary, peripheral, and neurovascular, and urology, among others, and (2) the In Vitro Diagnostics unit, which consists of component products and technologies for diagnostic immunoassay as well as molecular tests and biomedical research applications, with products that include protein stabilization reagents, substrates, antigens and surface coatings.

The tables below present segment revenue, operating income (loss) and depreciation and amortization, as follows:

	Three Months Ended March 31,				Six Months March 3				
(Dollars in thousands)	2018		2017		2018			2017	
Revenue:									
Medical Device	\$	14,052	\$	12,726	\$	26,826	\$	26,482	
In Vitro Diagnostics		5,006		4,777		9,245		8,782	
Total revenue	\$	19,058	\$	17,503	\$	36,071	\$	35,264	
Operating income (loss):									
Medical Device	\$	232	\$	1,504	\$	(157)	\$	5,223	
In Vitro Diagnostics		2,423		2,236		4,093		3,692	
Total segment operating income		2,655		3,740		3,936		8,915	
Corporate		(2,130)		(2,063)		(4,044)		(3,970)	
Total operating income (loss)	\$	525	\$	1,677	\$	(108)	\$	4,945	
Depreciation and amortization:									
•	ф	4.004	ф	4.050	Ф	2 506	ф	2.050	
Medical Device	\$	1,324	\$	1,053	\$	2,596	\$	2,058	
In Vitro Diagnostics		100		103		190		206	
Corporate		162		172		320		346	
Total depreciation and amortization	\$	1,586	\$	1,328	\$	3,106	\$	2,610	

The Corporate category includes expenses that are not fully allocated to Medical Device and In Vitro Diagnostics segments. These Corporate costs are related to functions, such as executive management, corporate accounting, legal, human resources and Board of Directors. Corporate may also include expenses, such as litigation, which are not specific to a segment and thus not allocated to the operating segments.

Asset information by operating segment is not presented because the Company does not provide its chief operating decision maker assets by operating segment, as the data is not readily available or significant to the decision-making process.

16. Commitments and Contingencies

Litigation. From time to time, the Company may become involved in various legal actions involving its operations, products and technologies, including intellectual property and employment disputes. The outcomes of these legal actions are not within the Company's complete control and may not be known for prolonged periods of time. In some actions, the claimants seek damages as well as other relief, including injunctions barring the sale of products that are the subject of the lawsuit, which if granted, could require significant expenditures or result in lost revenue. The Company records a liability in the condensed consolidated financial statements for these actions when a loss is known or considered probable and the amount can be reasonably estimated. If the reasonable estimate of a known or probable loss is a range, and no amount within the range is a better estimate, the minimum amount of the range is accrued. If a loss is possible but not known or probable, and can be reasonably estimated, the estimated loss or range of loss is disclosed. In most cases, significant judgment is required to estimate the amount and timing of a loss to be recorded.

On January 17, 2018, we entered into a settlement agreement fully resolving the previously disclosed litigation involving Merit Medical Systems, Inc. ("Merit") and NorMedix.In April 2018, a customer notified the Company that it believes it overpaid hydrophilic coating royalties to the Company from January 2009 through December 2017. The Company recorded a \$1.0 million accrual for this claim in other accrued liabilities and selling, general and administrative expenses, as of and for the three-month period ended March 31, 2018.

InnoCore Technologies BV. In March 2006, the Company entered into a license agreement whereby Surmodics obtained an exclusive license to a drug delivery coating for licensed products within the vascular field which included peripheral, coronary and neurovascular biodurable stent products. The license requires an annual minimum payment of 200,000 euros (equivalent to \$246,000 using a euro to US dollar exchange rate of \$1.2319 to the Euro as of March 31, 2018) until the last patent expires which is currently estimated to be September 2027. The total minimum future payments associated with this license are approximately \$2.5 million. The license is currently utilized by one of the Company's drug delivery customers.

Operating Leases. The Company leases certain facilities under noncancelable operating lease agreements. Rent expense for the three months ended March 31, 2018 and 2017 was \$0.1 million for each period. Rent expense for the six months ended March 31, 2018 and 2017 was \$0.2 million for each period. In November 2017, the Company executed a lease for a 36,000 square feet facility in Eden Prairie, Minnesota. This facility will consolidate substantially all of our whole products solutions research and development operations into one location. Contractual obligations under the lease agreement total \$4.0 million over the ten-year lease term, which is expected to commence in May 2018. In connection with this lease, the Company deposited \$0.4 million into a restricted cash account, to be held until the leased facility is occupied, at which point the cash will be returned to the Company. In connection with the buildout of this leased facility, the Company has capitalized \$2.0 million of leasehold improvements in progress as of March 31, 2018, which is included in property and equipment on the consolidated balance sheet. Annual commitments pursuant to operating lease agreements in place as of March 31, 2018 for the remainder of fiscal 2018 and each of the next five fiscal years are as follows (in thousands):

Remainder of 2018	\$ 247
2019	441
2020	450
2021	396
2022	391
2023	399
Thereafter	1,933
Total minimum lease payments	\$ 4,257

Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations

The following discussion and analysis provides information management believes is useful in understanding the operating results, cash flows and financial condition of Surmodics, Inc. and subsidiaries (referred to as "Surmodics," the "Company," "we," "us," "our" and other like terms). The discussion should be read in conjunction with both the unaudited condensed consolidated financial statements and related notes included in this Form 10-Q and our audited consolidated financial statements and related notes and Management's Discussion and Analysis of Financial Condition and Results of Operations each included in our Annual Report on Form 10-K for the fiscal year ended September 30, 2017. This discussion contains various "Forward-Looking Statements" within the meaning of the Private Securities Litigation Reform Act of 1995. We refer readers to the statement entitled "Forward-Looking Statements" located at the end of this Item 2.

Overview

Surmodics is a leading provider of medical device and *in vitro* diagnostic technologies to the healthcare industry. In fiscal 2018, our revenue performance continues to be driven by our core Medical Device and In Vitro Diagnostics ("IVD") businesses. Revenue in the Medical Device business is composed of product sales, hydrophilic coatings royalties, and contract research and development services. Medical Device segment revenue increased 1% for the first six months of fiscal 2018 as compared with the same prior-year period. Medical Device revenue was favorably impacted by increased reagent and medical device product sales and royalty and license fee revenue from our Abbott Vascular, Inc. ("Abbott") agreement described below. These favorable impacts were partly offset by declines in research, development and other revenue. Our IVD business derives its revenue from diagnostic technology product sales. Revenue from the IVD segment increased 5% in the first six months of fiscal 2018 as compared with the same prior-year period.

We continue to derive our revenue from three primary sources: (1) product sales revenue from the sale of reagent chemicals to licensees, the sale of stabilization products, antigens, substrates and surface coatings to the diagnostic and biomedical research markets as well as the sale of medical devices and related products (such as balloons and catheters) to original equipment manufacturer (OEM) suppliers and distributors; (2) royalties and license fees from licensing our proprietary surface modification and device drug delivery technologies to customers; the vast majority (typically in excess of 90%) of revenue in the "royalties and license fees" category is in the form of royalties; and (3) research and commercial development fees generated on customer projects. Revenue fluctuates from quarter to quarter depending on, among other factors: our customers' success in selling products incorporating our technologies; the timing of introductions of licensed products by our customers; the timing of introductions of products that compete with our customers' products; the number and activity level associated with customer development projects; the number and terms of new license agreements that are finalized each quarter; and the value of reagent chemicals and other products sold to customers.

Since fiscal 2013, with our investment in our drug-coated balloon ("DCB") platform, we have been focused on a strategy to develop and manufacture proprietary medical device products that combine our surface modification coatings with medical devices or delivery systems ("whole-product solutions"). Our aim is to provide customers earlier access to highly differentiated whole-product solutions that address unmet clinical needs. On February 26, 2018, we entered into an agreement with Abbott whereby Abbott will have exclusive worldwide commercialization rights for Surmodics' SurVeil® drug-coated balloon to treat the superficial femoral artery ("SurVeil"), which is currently being evaluated in a U.S. pivotal clinical trial. Separately, Abbott also received options to negotiate agreements for Surmodics' below-the-knee and arteriovenous (AV) fistula drug-coated balloon products, which are currently in preclinical development. We will collaborate with Abbott on product development, clinical trials and regulatory activities to obtain marketing clearances in the U.S. and the European Union. Expenses related to these activities will primarily be paid by Surmodics. We received an upfront payment of \$25 million and may earn up to an additional \$67 million upon achievement of certain milestones related to regulatory approval and clinical trial activities. Upon the regulatory approval of SurVeil, Surmodics will be responsible for the manufacture and supply of clinical and commercial quantities of the product and will realize revenue from product sales to Abbott, as well as a share of profits resulting from third-party sales. The agreement with Abbott represents a significant step forward in our whole-product solutions strategy. In the second quarter of fiscal 2018, we recognized revenue of \$0.5 million related to the Abbott agreement which is included in royalties and license fees in our medical device segment. Revenue from the upfront fee will be recognized as regulatory and clinical activities are performed. Revenue from the contingent milestones will be recognized when the contingencies are resolved. We are currently evaluating the effects of Accounting Standards Update ("ASU") No. 2014-09, Revenue from Contracts with Customers (ASC Topic 606), which was issued by the Financial Accounting Standards Board ("FASB") in May 2014, on the upfront and potential milestone payments from Abbott, and those effects may be material upon adoption of the standard in fiscal 2019.

We have several U.S. and international issued patents and pending international patent applications protecting various aspects of proprietary surface modification technologies, including compositions, methods of manufacture and methods of coating

devices. The expiration dates for these patents and the anticipated expiration dates of patent applications that cover our hydrophilic coating technologies range from fiscal 2020 to fiscal 2035. Our third-generation *PhotoLink* technology was protected by a family of patents that expired in November 2015 (in the U.S.) and October 2016 (in certain other countries). The royalty revenue associated with our third-generation technology was approximately 12% of our fiscal 2017 revenue. Approximately 21% of our total revenue in fiscal 2017 was generated from our fourth-generation *PhotoLink* technology, which is protected by a family of patents that begin to expire in fiscal 2020. Of the license agreements using our early-generation technologies, most continue to generate royalty revenue at a reduced royalty rate beyond patent expiration. Our remaining hydrophilic royalty revenue is primarily derived from other Surmodics coating technologies that are protected by a number of patents extending to fiscal 2035. While we are actively seeking to convert our customers to one of our advanced generations of our hydrophilic coating technology, there can be no assurance that we will be successful in doing so, or that those customers that have converted, or will convert, will sell products utilizing our technology which will generate earned royalty revenue for us.

Overview of Research and Development Activities

Throughout fiscal 2018, we will continue to invest in our whole-product solutions strategy through research and development ("R&D") activities in our proprietary products pipeline, including clinical and regulatory activities necessary to bring these products to market. Tangible results of these investments in fiscal 2018 include initializing the TRANSCEND *Surveil* pivotal clinical trial and the related partnership with Abbott to develop and commercialize the *SurVeil* product, as well as U.S. Food and Drug Administration ("FDA") clearances for our Telemark™ coronary/peripheral support microcatheter and our .018" low-profile percutaneous transluminal angioplasty balloon dilation catheter (".018" PTA balloon catheter"). Additionally, in late fiscal 2017, we received FDA and Conformité Européenne clearances for our .014" low-profile PTA balloon catheter, designed for peripheral angioplasty procedures.

The development of these products is a major step forward in our strategy to offer whole-product solutions for the medical device industry. The *SurVeil* DCB early feasibility clinical study, conducted in the U.S., met its primary endpoint by demonstrating peak paclitaxel plasma concentrations post-index procedure. Consistent with pre-clinical data, systemic levels were low and cleared rapidly.

In July 2017, we received an investigational device exemption ("IDE") from the FDA to initiate a pivotal clinical trial of the *SurVeil* DCB. The randomized clinical trial, TRANSCEND, is evaluating the *SurVeil* DCB for treatment for PAD in the upper leg compared with the Medtronic IN.PACT® Admiral® DCB. The objective of the TRANSCEND clinical trial is to evaluate the safety and effectiveness of the *SurVeil* DCB device for treatment of subjects with symptomatic PAD due to stenosis of the femoral and/or popliteal arteries. If successful, the TRANSCEND clinical trial will be used to support regulatory approvals and reimbursement in the U.S. and Europe. The trial will enroll up to 446 subjects at up to 60 sites in the U.S. and 18 outside the U.S. Study participants will be randomized to receive either treatment with *SurVeil* DCB or *IN.PACT Admiral* DCB. The trial's primary efficacy endpoint is primary patency, defined as a composite of freedom from restenosis and clinically-driven target lesion revascularization through 12 months post-index procedure. All randomized subjects will be followed through 60 months post-index procedure. We initiated enrollment in the TRANSCEND clinical trial in October 2017 and have engaged a clinical research organization to assist us with the administration of the clinical trial. There is no assurance that the TRANSCEND clinical trial will support regulatory approval, or that any anticipated time frame will be met. We estimate that the total cost of the TRANSCEND clinical trial will range between \$32 million to \$40 million over the next several years, of which approximately \$6.4 million has been incurred through March 31, 2018. To the extent that we achieve certain agreed-upon milestones in connection with the TRANSCEND clinical trial, we may receive up to \$67 million of additional milestone payments pursuant to the Abbott agreement discussed above.

We are executing on our plan to develop and commercialize 12-15 medical device products over the next 5 years. Additional planned activities include initiation of surface modification experiments that improve medical device performance, as well as incorporation of our catheter technology platform into various other devices intended for the emerging peripheral vascular treatment market. Additionally, we are developing other products that utilize our DCB platform, including DCB's for treatment of PAD below-the-knee and arteriovenous fistulae, commonly associated with hemodialysis. We may also acquire technologies, when appropriate, to complement or integrate with our existing proprietary products.

We prioritize our internal R&D programs based on a number of factors, including a program's strategic fit, commercial impact, potential competitive advantage, technical feasibility, and the amount of investment required. The measures and metrics used to monitor a program's progress vary, but typically include key deliverables, milestones, timelines, and an overall program budget. We typically make decisions to continue or terminate a program based on research results (relative to the above measures and metrics) and other factors, including our own strategic and/or business priorities, and the amount of additional investment required.

With respect to cost components, R&D expenses consist of labor, materials and overhead costs (for example, utilities, depreciation, and indirect labor) for both customer R&D and internal R&D programs. We manage our R&D organization in a flexible manner, balancing workloads/resources between customer R&D and internal R&D programs, based on the level of customer program activity and resource needs for our internally developed product programs. Therefore, costs incurred for customer R&D and internal R&D can shift as customer activity increases or decreases.

Critical Accounting Policies

Critical accounting policies are those policies that require the application of management's most challenging, subjective or complex judgment, often as a result of the need to make estimates about the effect of matters that are inherently uncertain and may change in subsequent periods. Critical accounting policies involve judgments and uncertainties that are sufficiently likely to result in materially different results under different assumptions and conditions. For the quarter ended March 31, 2018, there were no significant changes in our critical accounting policies.

For a detailed description of our critical accounting policies, see Management's Discussion and Analysis of Financial Condition and Results of Operations under Item 7 in our Annual Report on Form 10-K for the fiscal year ended September 30, 2017.

Results of Operations – Three and Six Months Ended March 31

Revenue. Revenue for the second quarter of fiscal 2018 was \$19.1 million, an increase of \$1.6 million, or 8.9%, as compared with the second quarter of fiscal 2017. Revenue for the first six months of fiscal 2018 was \$36.1 million, an increase of \$0.8 million, or 2.3%, compared with the first six months of fiscal 2017. The following is a summary of revenue by segment.

	Three Montl March		%	%		
(<u>Dollars in thousands)</u>	2018	2017	Change	2018	2017	Change
Revenue						
Medical Device	\$ 14,052 \$	12,726	10.4%	26,826	\$ 26,482	1.3%
In Vitro Diagnostics	5,006	4,777	4.8%	9,245	8,782	5.3%
Total Revenue	\$ 19,058	17,503	8.9%	36,071	\$ 35,264	2.3%

Medical Device. Medical Device revenue was \$14.1 million in the second quarter of fiscal 2018, an increase of 10.4% as compared with \$12.7 million for the second quarter of fiscal 2017. Medical Device revenue was \$26.8 million in the first six months of fiscal 2018, an increase of 1.3% as compared with \$26.5 million for first six months of fiscal 2017. Royalties and license fee revenue increased \$1.1 million in the current quarter as compared with the prior-year quarter as a result of strength in our hydrophilic royalties business, as well as \$0.5 million of license fee revenue from our SurVeil® drug-coated balloon arrangement with Abbott. Additionally, product sales increased 16%, or \$0.5 million, in the current quarter as compared with the prior-year quarter, due primarily to an increase in balloon catheter shipments. These increases were partly offset by a reduction in research, development and other revenue of \$0.3 million in the second quarter of fiscal 2018 as compared with the second quarter of fiscal 2017. Product sales and royalty and license fee revenue increased \$0.6 million and \$0.2 million, respectively, for the first six months of fiscal 2018, while research, development and other revenue decreased by \$0.5 million. Product sales increases for this period were primarily driven by increased reagent sales. License fee revenue of \$0.5 million from our collaborative arrangement with Abbott in the first six months of fiscal 2018 was partly offset by reductions in royalty revenue attributable to previously disclosed patent expirations. We continue to experience delays in customer research and development programs, which has had a negative impact on revenue as compared with the prior three and six-month periods.

As previously reported, the family of patents covering our third-generation *PhotoLink* technology expired in November 2015 (in the U.S.) and October 2016 (in certain other countries). There is a royalty rate step down for licensed customers at the time these patents expire. For fiscal 2018, we expect royalty and license fee revenue for our third-generation *Photolink* technology will to decline between \$2.5 million to \$3.0 million compared with fiscal 2017 as the result of these patent expirations.

In Vitro Diagnostics. In Vitro Diagnostics revenue increased 4.8% to \$5.0 million in the second quarter of fiscal 2018 as compared with \$4.8 million for the second quarter of fiscal 2017, primarily due to an increase in microarray slide and BioFX product sales. In Vitro Diagnostics revenue was \$9.2 million in the first six months of fiscal 2018, an increase of 5.3%, as compared with \$8.8 million for the first six months of fiscal 2017, primarily due to an increase in microarray slide and BioFX product sales.

Costs and Operating Expenses

The following is a summary of major costs and expenses as a percent of total revenue:

	Three Months Ended March 31,			Six	31,			
	20	18	2017			18	20	17
		% Total	'	% Total		% Total		% Total
(<u>Dollars in thousands)</u>	Amount	Revenue	Amount	Revenue	Amount	Revenue	Amount	Revenue
Product costs	\$ 2,913	15%	\$ 2,562	15%	\$ 5,804	16%	\$ 5,190	15%
Research and development	10,774	57	8,208	47	18,605	52	14,178	40
Selling, general and								
administrative	6,440	34	5,076	29	11,628	32	9,938	28
Acquired intangible asset								
amortization	636	3	591	3	1,254	3	1,187	3
Contingent consideration								
(gain) expense	(2,230)	(12)	(611)	(3)	(1,112)	(3)	(174)	(0)

Product costs. Product gross margins (defined as product sales less related product costs) were 66.5% and 67.7%, of product sales for the second quarter of fiscal 2018 and 2017, respectively. Product gross margins were 65.4% and 66.8%, respectively, of product sales for the first six months of fiscal 2018 and 2017, respectively. The decline in product gross margins in the three months ended March 31, 2018, as compared with the prior-year period, was due to product mix between our IVD and medical device businesses. Product gross margins on IVD and reagent sales increased from the prior-year quarter, however an increase in lower-margin medical device product sales resulted in a 1.9% reduction in product gross margins as compared with the same prior-year period. In the six months ended March 31, 2018, the scale-up of our Irish manufacturing facility and non-proprietary medical device product mix negatively impacted gross margins by 3.8%. This factor was partially offset by increases in reagent and IVD product sales, which positively affected product gross margins by 2.4%.

Research and development (R&D) expenses. R&D expenses increased \$2.6 million and \$4.4 million in the three and six months ended March 31, 2018, respectively, from the same prior-year periods, which was primarily the result of higher planned spending for our DCB and proprietary product development and clinical activities. We plan to increase R&D spending in fiscal 2018 to support our whole-product solutions strategy, including a significant increase in clinical and regulatory expenses. We anticipate fiscal 2018 R&D expense will range between 55% and 60% of revenue.

Selling, general and administrative (SG&A) expenses. SG&A expenses increased \$1.4 million and \$1.7 million in the three and six months ended March 31, 2018, respectively, from the same prior-year periods. These increases reflect a \$1.0 million estimated customer claim accrual as well as \$0.5 million of costs associated with the Abbott agreement incurred in the second quarter of fiscal 2018. We expect fiscal 2018 SG&A expenses will range between 28% and 30%, as a percent of revenue.

Intangible asset amortization. As part of our fiscal 2016 acquisitions in our Medical Device business, we acquired certain intangible assets which are being amortized over periods ranging from 4 to 14 years. In addition, we own certain intangible assets related to the BioFx acquisition in fiscal 2007. We recognized \$0.6 million and \$1.3 million in amortization expense related to these acquisitions in the three and six months ended March 31, 2018, respectively. We recognized \$0.6 million and \$1.2 million in amortization expense related to these acquisitions in the three and six months ended March 31, 2017, respectively. Acquired intangible asset amortization is estimated to total \$2.5 million in fiscal 2018.

Contingent consideration accretion expense. For the three and six months ended March 31, 2018, we recorded a net gain of \$2.2 million and \$1.1 million, respectively, related to our contingent consideration liabilities from prior-year acquisitions. For the three and six months ended March 31, 2017, we recorded a net gain of \$0.6 million and \$0.2 million, respectively, related to these contingent consideration liabilities. The increase in the gain in the second quarter from the prior-year quarter is due to a reduction in the estimated probability of achievement of certain revenue and strategic milestones. The decrease in the gain in the first six months of fiscal 2018 from the same prior-year period is due to a reduction in the estimated probability of achievement of certain revenue and strategic milestones, offset by the achievement of revenue and product development milestones in the first quarter of fiscal 2018. We expect to recognize a net gain of \$0.9 million for fiscal 2018 related to our contingent consideration liabilities. If there are any changes in the amount, probability or timing of contingent consideration milestone achievement, there may be adjustments, which could be material, in the statements of operations to reflect changes in the fair value of contingent consideration liabilities.

Other (loss) income, net. Major classifications of other (loss) income, net are as follows:

		Three Months Ended March 31,			Six Months Ended March 31,			
(<u>Dollars in thousands)</u>	2018		2017		2018		2017	
Investment income, net	\$	142	\$	85	\$	263	\$	170
Foreign exchange (loss) gain		(353)		(201)		(539)		473
Gains on strategic investment and other						177		_
Other (loss) income, net	\$	(211)		\$ (116)		(99)	\$	643

The increase in investment income in the second quarter and first six months of fiscal 2018, as compared with the prior-year periods, is the result of higher interest rates on debt investments as well as an increase in investment principal from the \$25 million Abbott payment. The foreign exchange (loss) gain in the three and six months ended March 31, 2018 and 2017 is related to the change in exchange rates associated with the Euro-denominated contingent consideration liability from the Creagh Medical acquisition, which is scheduled to be paid in the first quarter of fiscal 2019. In the three and six months ended March 31, 2018, and during the three months ended March 31, 2017, the Euro strengthened against the U.S. Dollar, resulting in losses for each of the periods. The Euro weakened against the U.S. Dollar in the six months ended March 31, 2017, resulting in a gain for the period. We recognized a gain on a previously sold strategic investment in the first six months of fiscal 2018 as additional consideration was released from escrow.

Income tax provision. The income tax (benefit) provision was (\$1.2) million and \$1.1 million for the three months ended March 31, 2018 and 2017, respectively. The income tax (benefit) provision was (\$0.2) million and \$2.8 million for the six months ended March 31, 2018 and 2017, respectively. In December 2017, the Tax Cuts and Jobs Act tax legislation was signed into law, which reduced the U.S. Federal statutory tax rate from 35% to 21%, among other changes. As a result of the enactment of this legislation, the Company's net loss for the six months ended March 31, 2018 includes discrete tax expense of \$1.2 million from our net deferred tax assets revaluation based on the change in the statutory tax rate. U.S. tax law requires that taxpayers with a fiscal year beginning before and ending after the effective date of a rate change calculate a blended tax rate for the year based on the pro rata number of days in the year before and after such effective date. Accordingly, for fiscal 2018, our statutory income tax rate is expected to be 24.5%. The Company's effective tax reflects the impact of state income taxes, permanent tax items and discrete tax benefits. The difference between the U.S. federal statutory tax rates of 24.5% and 35.0% for the three and six months ended March 31, 2018 and 2017, respectively, and our effective tax rates for the same periods is primarily due to operating losses in Ireland, where tax benefits are offset by a valuation allowance, non-deductible amortization and contingent consideration accretion, including fair value adjustments, associated with prior-year acquisitions, as well as foreign currency translation gains and losses on Euro-denominated contingent consideration liabilities. Offsetting these items are benefits from an increased federal R&D tax credit and, in the 2017 periods, the domestic production manufacturing deduction.

Discrete items, other than the revaluation of deferred tax assets discussed above, largely consist of the effects of expirations and cancellations of stock option awards. Discrete tax (benefit) expense from (excess tax benefits) tax deficiencies realized from share awards vested, expired, cancelled and exercised of \$(0.2) and \$(0.4) million for the respective three and six-month periods ended March 31, 2018 and \$0.1 million and \$0.3 million for the respective three and six-month periods ended March 31, 2017.

We expect income tax benefit, including the impact of tax reform, for fiscal 2018 to be in the range of \$0.5 million to \$1.0 million. Currently, income and losses generated in Ireland from our Creagh Medical acquisition do not reflect an Irish income tax expense (benefit) as they are offset by a valuation allowance. Therefore, taxable income or losses in Ireland will result in no reported tax benefit or expense in fiscal 2018. Certain provisions of the Tax Cuts and Jobs Act significantly change the treatment of accumulated and future earnings of foreign subsidiaries. While we do not have accumulated earnings subject to a repatriation tax under the law, we may be subject to additional U.S. tax on our foreign subsidiary's income in future years. Additionally, in the future we may be subject to limitations on deductibility of officer and executive compensation under the new legislation.

Segment Operating Results

Operating income (loss) for each of our reportable segments is as follows:

	Three Months Ended March 31,			Six N	ded	
(Dollars in thousands)	2018	2017	% Change	2018	2017	% Change
Operating income (loss):				·		
Medical Device	\$ 232	\$ 1,504	(85)%	\$ (157)	\$ 5,223	(103)%
In Vitro Diagnostics	2,423	2,236	8%	4,093	3,692	11%
Total segment operating income	2,655	3,740		3,936	8,915	
Corporate	(2,130)	(2,063)	3%	(4,044)	(3,970)	2%
Total operating income (loss)	\$ 525	\$ 1,677	(69)%	\$ (108)	\$ 4,945	(102)%

Medical Device. Operating income declined by \$1.3 million and \$5.4 million in the three and six months ended March 31, 2018, respectively, as compared with the same prior-year periods. Operating income (loss) as a percentage of revenue was 1.6% and 11.8% in the second quarter of fiscal 2018 and 2017, respectively, and (0.6)% and 19.7% in the first six months of fiscal 2018 and 2017, respectively. Operating income decreased in the current-year quarter from the comparable prior-year quarter as a result of a \$2.6 million increase in R&D expenses related to our planned investment in our DCB and proprietary medical device product development and clinical programs and a \$1.4 million increase in SG&A expenses as a result of an accrued customer claim and costs attributable to the Abbott agreement. These increased product sales and royalty and license fee revenue. Operating (loss) income in the six months ended March 31, 2018 as compared with the same fiscal 2017 period was impacted by an additional \$4.4 million of R&D expenses related to our planned investment in our DCB and proprietary medical device product development and clinical programs and a \$1.5 million increase in SG&A expenses as a result of an accrued customer claim and costs attributable to the Abbott agreement. These expense increases were partly offset by a \$0.9 million increase in contingent consideration gains and a \$0.3 million increase in revenue attributable to increase in revenue attributable to increase in revenue.

In Vitro Diagnostics. Operating income increased by \$0.2 million and \$0.4 million in the three and six months ended March 31, 2018, respectively, as compared with the same prior-year periods. Operating income as a percentage of revenue was 48.4% and 44.3% in the three and six months ended March 31, 2018, respectively. Operating income as a percentage of revenue was 46.8% and 42.0% in the three and six months ended March 31, 2017, respectively. Product gross margins increased to 71.9% and 68.4% in the three and six months ended March 31, 2018, respectively, from 70.0% and 65.9%, in the respective prior-year periods. Product gross margins and operating income in the three and six months ended March 31, 2018 benefited from increased revenue, favorable product mix and reduced scrap rates. The three-month period ended March 31, 2017 benefited from a \$0.1 million insurance reimbursement stemming from a casualty loss incurred in the first quarter of fiscal 2017 related to a damaged shipment of product.

Corporate. The Corporate category includes expenses for administrative corporate functions, such as executive, corporate accounting, legal, human resources and Board of Directors related fees and expenses, which have not been fully allocated to the Medical Device and In Vitro Diagnostics segments. Corporate also includes expenses, such as litigation, which are not specific to a segment and thus not allocated to our operating segments.

Liquidity and Capital Resources

As of March 31, 2018, we had working capital of \$47.1 million, a decrease of \$4.0 million from September 30, 2017. Working capital is defined by us as current assets minus current liabilities. The decrease from the prior year-end is a result of contingent consideration obligations totaling \$11.4 million related to the Creagh Medical acquisition that are classified as current liabilities as of March 31, 2018 as well as \$4.0 million of cash invested in long-term available-for-sale debt securities in the second quarter of fiscal 2018. These working capital reductions were partly offset by the receipt of the \$25.0 million upfront payment from Abbott, of which \$12.0 million is included in the current portion of deferred revenue as of March 31, 2018. As of September 30, 2017, the Creagh Medical contingent consideration obligations, which are recorded at their estimated fair market value using Level 3 inputs, were included in long-term liabilities. Contingent consideration earned for this acquisition is scheduled to be paid in December 2018. Our cash and cash equivalents and available-for-sale investments totaled \$70.3 million at March 31, 2018, an increase of \$22.0 million from \$48.3 million at September 30, 2017. This change was primarily driven by the \$25.0 million upfront payment received from Abbott, partially offset by \$4.0 million of investments in plant and capital equipment, \$1.1 million of cash payments for taxes related

to net share settlement of equity awards during the first six months of fiscal 2018 and payment of \$0.9 million of contingent consideration obligations related to the prior-year acquisition of NorMedix, Inc.

The Company's investment policy excludes ownership of collateralized mortgage obligations, mortgage-backed derivatives and other derivative securities without prior written approval of the Board of Directors. Our investments primarily consist of money market, corporate bond and commercial paper securities. Our investment policy requires that no more than 5% of investments be held in any one credit or issue, excluding U.S. government and government agency obligations. The primary investment objective of the portfolio is to provide for the safety of principal and appropriate liquidity while generating an above-benchmark ("Barclays Short Treasury 1-3 Month Index") total rate of return on a pre-tax basis. Management plans to continue to direct its investment advisors to manage the Company's securities investments primarily for the safety of principal for the foreseeable future as it continues to assess other investment opportunities and uses of its cash and securities investments, including those described below.

On March 30, 2018, we terminated our Amended and Restated Credit Agreement (the "Credit Agreement") with Wells Fargo Bank, National Association. In connection with the termination of the Credit Agreement, we wrote off less than \$0.1 million of deferred financing costs to interest expense in the second quarter of fiscal 2018.

Operating Activities. We generated cash flows from operating activities of approximately \$27.4 million and \$4.3 million in the six months ended March 31, 2018 and 2017, respectively. The following table depicts our cash flows provided by operating activities:

	Six Months Ended March 31,			
(<u>Dollars in thousands)</u>	2018 2017			2017
Net (loss) income	\$	(22)	\$	2,806
Depreciation and amortization		3,106		2,610
Stock-based compensation 2,003				1,671
Contingent consideration gain	(1,112)			(174)
Unrealized foreign exchange loss (income)	518 ((473)
Deferred taxes		701		
Gain on strategic investment		(177)		
Net other operating activities 117			(25)	
Net change in other operating assets and liabilities 22,297			(2,677)	
Net cash provided by operating activities \$ 27,431 \$			\$	4,263

During the first six months of fiscal 2018 and 2017, operating cash flow was primarily generated by net (loss) income, as adjusted for non-cash expenses for depreciation and amortization, stock-based compensation, contingent consideration gains, unrealized foreign exchange loss (income), and deferred taxes, partially offset by a gain on a strategic investment. Deferred tax asset reductions during the fiscal 2018 period were primarily related to changes in statutory tax rates from the enactment of the Tax Cuts and Jobs Act, resulting in a reduction of deferred tax assets totaling \$1.2 million. Net changes in operating assets and liabilities had a positive impact on cash flows of \$22.3 million in the six months ended March 31, 2018 as compared with a negative impact of \$2.7 million in the six months ended March 31, 2017. Significant changes in operating assets and liabilities during these periods included:

- Cash provided by deferred revenue was \$24.6 million in the fiscal 2018 period, as compared with less than \$0.1 million in the fiscal 2017 period, due to the \$25.0 million upfront fee received from Abbott.
- Cash used for inventory was \$0.5 million in the fiscal 2018 period as compared with cash provided by inventory of \$0.1 million in the fiscal 2017 period. In the fiscal 2018 period, we purchased more inventory to support increased reagent and medical device product sales.
- Cash used for prepaids and other current assets totaled \$1.4 million in the fiscal 2018 period as compared with \$1.0 million in the prior-year period. This change is primarily due to a \$0.3 million increase in refundable Irish research and development tax credit assets and other reimbursable R&D expenses in the fiscal 2018 period.
- Cash provided by accrued liabilities was \$2.2 million for the first six months of fiscal 2018, as accrued clinical study expense increased by \$1.0 million and a customer claim related to an overpayment of coating royalties totaling \$1.0 million was accrued in the second quarter of fiscal 2018. Cash used for accrued liabilities of \$0.5 million, driven by reduction of an amount owed to a customer, contributed to the \$1.9 million of cash used for accounts payable and accrued liabilities in the first six months of fiscal 2017.

- Changes in accrued compensation resulted in cash used of \$1.3 million and \$1.7 million, in the first six months of fiscal 2018 and 2017, respectively, which is the result of incentive compensation paid in the first quarter of each fiscal year, partly offset by incentive compensation accrued during the first six months of each fiscal year.
- Changes in income taxes payable and receivable resulted in cash used of \$0.8 million for the first six months of fiscal 2018, as compared with cash provided of \$0.4 million in the comparable fiscal 2017 period. This change is a result of a receivable generated in fiscal 2018, whereas in the fiscal 2017 period a prior-year tax receivable was applied to taxes due in that period.

Investing Activities. We used cash in investing activities of \$14.4 million in the first six months of fiscal 2018 as compared with cash used in investing activities of \$15.8 million in the first six months of fiscal 2017. We invested \$4.0 million and \$2.9 million in property and equipment in the first six months of fiscal 2018 and fiscal 2017, respectively. In the first six months of fiscal 2018 and 2017, we invested \$10.5 million and \$13.0 million, respectively, in available-for-sale debt securities, net of maturities of other investments.

Financing Activities. We used cash in financing activities of \$1.7 million and \$2.0 million in the first six months of fiscal 2018 and 2017, respectively. In the first six months of fiscal 2018 and 2017, we paid \$1.1 million and \$2.1 million, respectively, to purchase common stock to pay employee taxes resulting from the exercise of stock options. In the first six months of fiscal 2018, we paid contingent consideration of \$0.9 million related to the NorMedix, Inc. acquisition. Cash paid for financing activities was partially offset by cash received from the issuance of shares related to exercises of employee stock options totaling \$0.4 million and \$0.2 million for the respective six-month periods ended March 31, 2018 and 2017.

We believe that our existing cash, and cash equivalents and investments, which totaled \$70.3 million as of March 31, 2018, together with cash flow from operations will provide liquidity sufficient to meet our cash needs and fund our operations and planned capital expenditures for the next twelve months. There can be no assurance, however, that Surmodics' business will continue to generate cash flows at current levels, and disruptions in financial markets may negatively impact our ability to access capital in a timely manner and on attractive terms.

Customer Concentrations. Our licensed technologies provide royalty revenue, which represents the largest revenue stream to the Company. We have licenses with a diverse base of customers and certain customers have multiple products using our technology. Medtronic plc ("Medtronic") is our largest customer comprising 18% of our consolidated revenue for fiscal 2017 and 17% of our consolidated revenue for the first six months of fiscal 2018. Medtronic has several separately licensed products that generate royalty revenue for Surmodics, none of which represented more than 4% of our total revenue. No other individual customer using licensed technology constitutes more than 7% of Surmodics' total fiscal 2018 to date or fiscal 2017 revenue.

Share Purchase Activity

Our Board of Directors has authorized the repurchase of up to an additional \$25.3 million of the Company's outstanding stock in open-market purchases, privately negotiated transactions, block trades, accelerated share repurchase transactions, tender offers or by any combination of such methods. The authorization has no fixed expiration date.

Off-Balance Sheet Arrangements

As of March 31, 2018 and September 30, 2017, we did not have any off-balance sheet arrangements that have, or are reasonably likely to have, a current or future effect on our financial condition, changes in financial condition, revenue or expenses, results of operations, liquidity, capital expenditures or capital resources that is material to investors.

Forward-Looking Statements

This Quarterly Report on Form 10-Q, including "Management's Discussion and Analysis of Financial Condition and Results of Operations" in Item 2, contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. These statements include expectations concerning our growth strategy, including our ability to sign new license agreements, bring new products to market and broaden our hydrophilic coatings royalty revenue, the impact of patent expirations on our hydrophilic coatings royalty revenue, product development programs, various milestone achievements, research and development expenses, including the estimated cost associated with the TRANSCEND clinical trial, future cash flow and sources of funding, short-term requirements, future property and equipment investment levels, the impact of potential lawsuits or claims, the impact of Medtronic, as well as other significant customers, including new diagnostic kit customers, our ability to recognize the expected benefits of our acquisitions and the Company's strategy to transform to a provider of whole-product solutions, the timing, impact and success of the clinical evaluation of the *SurVeil* DCB, and our expectations related to our income tax expense for fiscal 2018.

Without limiting the foregoing, words or phrases such as "anticipate," "believe," "could," "estimate," "expect," "forecast," "intend," "may," "plan," "possible," "project," "will" and similar terminology, generally identify forward-looking statements. Forward-looking statements may also represent challenging goals for us. These statements, which represent the Company's expectations or beliefs concerning various future events, are based on current expectations that involve a number of risks and uncertainties that could cause actual results to differ materially from those of such forward-looking statements. We caution that undue reliance should not be placed on such forward-looking statements, which speak only as of the date made. Some of the factors which could cause results to differ from those expressed in any forward-looking statement are set forth under "Risk Factors" in Part I, Item 1A of our Annual Report on Form 10-K for the fiscal year ended September 30, 2017. We disclaim any intent or obligation to update publicly these forward-looking statements, whether because of new information, future events or otherwise.

Although it is not possible to create a comprehensive list of all factors that may cause actual results to differ from our forward-looking statements, such factors include, among others:

- our reliance on a small number of significant customers, including our largest customer, Medtronic, which causes our financial results and stock
 price to be subject to factors affecting those significant customers and their products, the timing of market introduction of their or competing
 products, product safety or efficacy concerns and intellectual property litigation could adversely affect our growth strategy and the royalty
 revenue we derive;
- general economic conditions which are beyond our control, such as the impact of recession, customer mergers and acquisitions, business investment and changes in consumer confidence;
- a decrease in our available cash or failure to generate cash flows from operations could impact short-term liquidity requirements and expected capital and other expenditures;
- the difficulties and uncertainties associated with the lengthy and costly new product development and foreign and domestic regulatory approval processes, such as delays, difficulties or failures in achieving acceptable clinical results or obtaining foreign or U.S. Food and Drug Administration marketing clearances or approvals, which may result in lost market opportunities, failure to bring new products to market or postpone or preclude product commercialization by licensees or ourselves;
- the development of new products or technologies by competitors, technological obsolescence and other changes in competitive factors;
- our ability to successfully develop, obtain regulatory approval for, and commercialize our *SurVeil* DCB product, including our reliance on a clinical research organization to manage the TRANSCEND clinical trial, other DCB products and other catheter and balloon-based products, which will impact our ability to receive additional milestone payments under our agreement with Abbott;
- our ability to perform successfully certain product development activities, the related R&D expense impact and governmental and regulatory compliance activities which we have not previously undertaken in any significant manner;
- our ability to successfully convert our customers from the third generation of our PhotoLink® hydrophilic technology protected by a family of patents which expired in November 2015 (in the U.S.) and October 2016 (in certain other countries) to one of our advanced generation technologies and to offset any decline in revenue from customers that we are unlikely to convert;
- our ability to identify and execute new acquisition opportunities as well as the process of integrating acquired businesses poses numerous risks, including an inability to integrate acquired operations, personnel, technology, information systems, and internal control systems and products; a lack of understanding of tax, legal and cultural differences; diversion of management's attention; difficulties and uncertainties in transitioning the customers or other business relationships from the acquired entity to us; the loss of key employees of acquired companies;
- there may be certain aspects of the recently enacted Tax Cuts and Jobs Act tax legislation that may adversely impact our expectations about our income tax expense for fiscal 2018; and
- other factors described in "Risk Factors" and other sections of Surmodics' Annual Report on Form 10-K for the fiscal year ended September 30, 2017, which you are encouraged to read carefully.

Many of these factors are outside the control and knowledge of us, and could result in increased volatility in period-to-period results. Investors are advised not to place undue reliance upon our forward-looking statements and to consult any further disclosures by us on this subject in our filings with the SEC.

Item 3. Quantitative and Qualitative Disclosures About Market Risk

Our investment policy requires investments with high credit quality issuers and limits the amount of credit exposure to any one issuer. Our investments consist principally of interest-bearing corporate debt securities with varying maturity dates, which are less than one year. Because of the credit criteria of our investment policies, the primary market risk associated with these investments is interest rate risk. We do not use derivative financial instruments to manage interest rate risk or to speculate on future changes in interest rates. As of March 31, 2018, we held \$42.3 million in available-for-sale debt securities, all with maturity dates of less than one year, therefore interest rate fluctuations would have an insignificant impact on our results of operations or cash flows. Our policy also allows the Company to hold a substantial portion of funds in cash and cash equivalents, which are defined as financial instruments with original maturities of three months or less and may include money market instruments, certificates of deposit, repurchase agreements, corporate bonds and commercial paper instruments.

Management believes that a reasonable change in raw material prices would not have a material impact on future earnings or cash flows because the Company's inventory exposure is not material.

We are exposed to increasing Euro currency risk with respect to our manufacturing operations in Ireland. In a period where the U.S. dollar is strengthening or weakening as compared with the Euro, our revenue and expenses denominated in Euro currency are translated into U.S. dollars at a lower or higher value than they would be in an otherwise constant currency exchange rate environment. All sales transactions are denominated in U.S. dollars or Euros. We generate royalty revenue from the sale of customer products in foreign jurisdictions. Royalties generated in foreign jurisdictions by customers are converted and paid in U.S. dollars per contractual terms. Substantially all of our purchasing transactions are denominated in U.S. Dollars or Euros. Further, we are subject to foreign currency risk associated with the payment of up to €12.0 million of Creagh Medical contingent consideration in approximately December 2018. For the first six months of fiscal 2018, we have recorded a foreign currency exchange loss of \$0.5 million related to this future payment. A 10% increase or decrease in the U.S. Dollar to Euro exchange rate could have a \$1.2 million impact on this payment based on the exchange rate as of March 31, 2018. To date, we have not entered into any foreign currency forward exchange contracts or other derivative financial instruments to hedge the effects of adverse fluctuations in foreign currency exchange.

Item 4. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

The Company maintains disclosure controls and procedures as defined in Rules 13a-15(e) and 15d-15(e) of the Securities Exchange Act of 1934, as amended (the "Exchange Act"). The Company's management, under the supervision and with the participation of the Company's Chief Executive Officer and Chief Financial Officer, referred to collectively herein as the Certifying Officers, carried out an evaluation of the effectiveness of the design and operation of the Company's disclosure controls and procedures as of March 31, 2018. Based on that evaluation, the Company's Certifying Officers concluded that, as of the end of the period covered by this report, the Company's disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) of the Exchange Act) were effective to ensure that information required to be disclosed by the Company in reports that it files under the Exchange Act is recorded, processed, summarized and reported within the time period specified in the Securities and Exchange Commission rules and forms, and to ensure that information required to be disclosed by the Company in the reports the Company files or submits under the Exchange Act is accumulated and communicated to the Company's management, including its Certifying Officers, as appropriate, to allow timely decisions regarding required disclosures.

Changes in Internal Controls over Financial Reporting

There were no changes in our internal control over financial reporting (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act) during the three months ended March 31, 2018 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II — OTHER INFORMATION

Item 1. Legal Proceedings

From time to time, the Company has been involved in various legal actions involving its operations, products and technologies, including intellectual property and employment disputes. See footnote 16 to the condensed, consolidated financial statements, which describes a matter with Merit which arose during fiscal 2017. We entered into a settlement agreement fully resolving the matter in January 2018.

Item 1A. Risk Factors

In our report on Form 10-K for the fiscal year ended September 30, 2017, filed with the SEC on December 1, 2017, we identify under "Part 1, Item 1A. Risk Factors." important factors which could affect our financial performance and could cause our actual results for future periods to differ materially from our anticipated results or other expectations, including those expressed in any forward-looking statements made in this Form 10-Q.

There have been no material changes in our risk factors subsequent to the filing of our Form 10-K for the fiscal year ended September 30, 2017.

Item 2. Unregistered Sales of Equity Securities and Use of Proceeds

(c) Issuer Purchases of Equity Securities

The following table presents information with respect to purchases of common stock of the Company made during the three months ended March 31, 2018, by the Company or on behalf of the Company or any "affiliated purchaser" of the Company, as defined in Rule 10b-18(a)(3) under the Exchange Act.

Period	Total Number of Shares Purchased	Average Price Paid per Share	Total Number of Shares Purchased as Part of Publicly Announced Plans or Programs	Aŗ	oproximate Dollar Value of Shares That May Yet Be Purchased Under the Plans or Programs (1)
01/1/18 — 01/31/18	_	N/A		\$	25,298,238
02/1/18 — 02/28/18	_	N/A	_	\$	25,298,238
03/1/18 — 03/31/18	_	N/A	_	\$	25,298,238
Total		N/A		\$	25,298,238

(1) As of March 31, 2018, the Company has an aggregate of \$25.3 million available for future common stock repurchase under an authorization approved by the Board of Directors for up to \$20.0 million on November 6, 2015, all of which is remaining, and an authorization approved by the Board of Directors on November 5, 2014 for which \$5.3 million is remaining. These authorizations for share repurchases do not have a fixed expiration date.

Item 3. Defaults Upon Senior Securities

None.

Item 4. Mine Safety Disclosures

Not Applicable.

Item 5. Other Information

None.

Item 6. Exhibits

Exhibit	Description
2.1	Share Purchase Agreement by and among Surmodics, Inc. and the shareholders of Creagh Medical Ltd. dated as of November 20, 2015 — incorporated by reference to Exhibit 2.1 to the Company's 8-K dated November 27, 2015, SEC File No. 0-23837.
<u>2.2</u>	Put and Call Option Agreement by and among Surmodics, Inc. and the shareholders of Creagh Medical Ltd. dated as of November 20, 2015 — incorporated by reference to Exhibit 2.2 to the Company's 8-K filed on, SEC File No. 0-23837.
2.3	Stock Purchase Agreement, dated January 8, 2016, among Surmodics, Inc. and the shareholders of NorMedix, Inc. and Gregg Sutton as Seller's Agent — incorporated by reference to Exhibit 2.1 to the Company's Form 8-K filed on January 13, 2016, SEC File No. 0-23837.
3.1	Restated Articles of Incorporation, as amended — incorporated by reference to Exhibit 3.1 of the Company's Quarterly Report on Form 10-Q filed on July 29, 2016, SEC File No. 0-23837.
3.2	Restated Bylaws of Surmodics, Inc., as amended December 18, 2015 — incorporated by reference to Exhibit 3.2 of the Company's Current Report on Form 8-K filed on December 23, 2015.
<u>10.1</u>	Change of Control Agreement by and between Surmodics, Inc. and Thomas A. Greaney, dated as of February 22, 2018 – incorporated by reference to Exhibit 10.1 to the Company's Form 8-K filed on February 23, 2018, SEC File No. 0-23837.
10.2*	Development and Distribution Agreement between Surmodics, Inc. and Abbott Vascular, Inc., dated as of February 26, 2018.**
31.1*	Certification of Chief Executive Officer Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
<u>31.2*</u>	Certification of Chief Financial Officer Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
<u>32.1*</u>	Certification of Chief Executive Officer Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2*	Certification of Chief Financial Officer Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101*	Financial statements from the Quarterly Report on Form 10-Q for Surmodics, Inc. for the quarterly period ended March 31, 2018, filed on May 4, 2018, formatted in Extensible Business Reporting Language (XBRL): (i) Condensed Consolidated Balance Sheets, (ii) Condensed Consolidated Statements of Operations, (iii) Condensed Consolidated Statements of Cash Flows, and (v) Notes to Condensed Consolidated Financial Statements.

^{*} Filed herewith

^{**} Portions of this document, which have been separately filed with the Securities and Exchange Commission, have been omitted pursuant to a request for confidential treatment.

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 thereunto duly authorized.

May 4, 2018 Surmodics, Inc.

By: /s/ Andrew D.C. LaFrence

Andrew D.C. LaFrence

Vice President of Finance, Information Systems and

Chief Financial Officer

(duly authorized signatory, principal financial officer, and principal

accounting officer)

DEVELOPMENT AND DISTRIBUTION AGREEMENT

between

SURMODICS, INC.

and

ABBOTT VASCULAR, INC.

Dated as of February 26, 2018

*CONFIDENTIAL INFORMATION HAS BEEN OMITTED AND FILED SEPARATELY WITH THE SECURITIES AND EXCHANGE COMMISSION. BRACKETED ASTERISKS ([**]) MARK THE PRECISE PLACES IN THE DOCUMENT WHERE CONFIDENTIAL TREATMENT IS REQUESTED WITH RESPECT TO OMITTED INFORMATION.

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CERTAIN INFORMATION IN THIS EXHIBIT HAS BEEN OMITTED AND FILED SEPARATELY WITH THE COMMISSION. CONFIDENTIAL TREATMENT HAS BEEN REQUESTED WITH RESPECT TO THE OMITTED PORTIONS.

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-ii - Certain information in this exhibit has been omitted and filed separately with the commission. Confidential treatment has been requested with respect to the omitted portions.

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DEVELOPMENT AND DISTRIBUTION AGREEMENT

This Development and Distribution Agreement (the "**Agreement**") is made and entered into effective as of February 26, 2018 (the "**Effective Date**") by and between Surmodics, Inc., a Minnesota corporation ("**Surmodics**"), and Abbott Vascular, Inc., a subsidiary of Abbott Laboratories, a Delaware corporation ("**Abbott**"). Surmodics and Abbott are sometimes referred to herein individually as a "**Party**" and collectively as the "**Parties**."

RECITALS

WHEREAS, Surmodics has Developed and is continuing to Develop the Product; and

WHEREAS, Surmodics desires to appoint Abbott as its exclusive worldwide distributor of the Product and Abbott desires to accept such appointment and also to conduct certain additional Development relating to the Product in the Territory, in each case in accordance with the terms and conditions set forth below.

NOW, THEREFORE, in consideration of the premises and the mutual promises and conditions hereinafter set forth, and other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the Parties, intending to be legally bound, do hereby agree as follows:

ARTICLE 1 DEFINITIONS

Unless otherwise specifically provided herein, the following terms shall have the following meanings, and grammatical variations thereof shall have corresponding meanings:

- **1.1** "**Accounting Standards**" means, with respect to a Party or its Affiliates, standard internal accounting policies and procedures, in accordance with GAAP, applied on a consistent basis.
- **1.2** "Acquisition" means, with respect to a Party, a merger, acquisition (whether of all of the stock or all or substantially all of the assets of a Person or any operating or business division of a Person) or similar transaction by or with the Party or its Affiliates, other than a Change in Control of the Party.
 - **1.3 "Action"** has the meaning set forth in Section 9.3.2.
 - **1.4** "Adjusted Order Lot" has the meaning set forth in <u>Schedule 4.1.2</u>.
 - **1.5** "**Adverse Ruling**" has the meaning set forth in Section 13.2.1.
- **1.6** "**Affiliate**" means, with respect to a Party, any Person that, directly or indirectly, through one or more intermediaries, controls, is controlled by or is under common control with such Party. For purposes of this definition, "control" and, with correlative meanings, the terms "controlled by" and "under common control with" means (i) the possession,

directly or indirectly, of the power to direct the management or policies of a business entity, whether through the ownership of voting securities, by contract relating to voting rights or corporate governance, or otherwise; or (ii) the ownership, directly or indirectly, of more than fifty percent (50%) of the voting securities or other ownership interest of a business entity (or, with respect to a limited partnership or other similar entity, its general partner or controlling entity).

- **1.7** "**Agreement Inventions**" has the meaning set forth in Section 9.1.1.
- **1.8** "**Applicable Law**" means federal, state, local, national and supra-national laws, statutes, rules, and regulations, including any rules, regulations, guidelines, or other requirements of any Regulatory Authorities, major national securities exchanges or major securities listing organizations, that may be in effect from time to time during the Term and applicable to a particular activity or country or other jurisdiction hereunder.
 - **1.9 "Approved Subcontractors"** has the meaning set forth in Section 2.1.1(ii).
 - **1.10** "Auditor" has the meaning set forth in Section 7.9.2.
 - **1.11** "AVF Option Product" means [**].
 - **1.12** "AVF Option Product Exercise Agreement" has the meaning set forth in Section 8.3.3(i).
 - **1.13** "AVF Option Product Option Period" means [**].
 - **1.14 "Breaching Party"** has the meaning set forth in Section 13.2.1.
 - **1.15** "BTK Option Product" means [**].
 - **1.16 "BTK Option Product Exercise Agreement"** has the meaning set forth in Section 8.3.2(i).
 - **1.17** "BTK Option Product Option Period" means [**].
- **1.18** "Business Day" means a day other than a Saturday or Sunday on which banking institutions in New York, New York are open for business.
- **1.19** "Calendar Quarter" means each successive period of three (3) calendar months commencing on January 1, April 1, July 1 and October 1, except that the first Calendar Quarter of the Term shall commence on the Effective Date and end on the day immediately prior to the first to occur of January 1, April 1, July 1 or October 1 after the Effective Date, and the last Calendar Quarter of the Term shall end on the last day of the Term.
- **1.20** "Challenge" means, with respect to any Patent, directly or indirectly, (i) to assert in any court, patent office or other competent governmental authority that such Patent is, in whole or in part, invalid or unenforceable, (ii) to oppose the issuance of, or to challenge or

seek to narrow the issued or applied for claims, scope or duration of, any claim of such Patent, (iii) to seek a declaratory judgment or similar relief, other than as a counterclaim to, or other defensive countermeasure in respect of, a patent infringement claim threatened to be brought or brought by or on behalf of Surmodics, that any product or service of Abbott or one of its Affiliates does not infringe any such Patent or is licensed or otherwise authorized under this Agreement or otherwise, (iv) to seek, request or otherwise take any action that results in the declaration, initiation or continuation of an interference or derivative proceeding, opposition, reexamination, post-grant review or *inter partes* review (or their equivalents) of such Patent, or (v) to assist or cooperate with any other Person to do any of the foregoing.

- **1.21** "Change in Control," with respect to a Party, shall be deemed to have occurred if any of the following occurs after the Effective Date with respect to such Party or a parent company of such Party (such Party or such parent, considered separately, the "Change in Control Party"):
- 1.21.1 any "person" or "group" (as such terms are defined below) (i) is or becomes the "beneficial owner" (as defined below), directly or indirectly, of shares of capital stock or other interests (including partnership interests) of such Change in Control Party then outstanding and normally entitled (without regard to the occurrence of any contingency) to vote in the election of the directors, managers or similar supervisory positions ("Voting Stock") of such Change in Control Party representing more than fifty percent (50%) of the total voting power of all outstanding classes of Voting Stock of such Change in Control Party or (ii) has the power, directly or indirectly, to elect a majority of the members of the Change in Control Party's board of directors, or similar governing body ("Board of Directors"); or
- 1.21.2 such Change in Control Party enters into a merger, consolidation or similar transaction with another Person (whether or not such Change in Control Party is the surviving entity) and as a result of such merger, consolidation or similar transaction (i) the members of the Board of Directors of such Change in Control Party immediately prior to such transaction constitute less than a majority of the members of the Board of Directors of such Change in Control Party or such surviving Person immediately following such transaction or (ii) the Persons that beneficially owned, directly or indirectly, the shares of Voting Stock of such Change in Control Party immediately prior to such transaction cease to beneficially own, directly or indirectly, shares of Voting Stock of such Change in Control Party representing at least a majority of the total voting power of all outstanding classes of Voting Stock of the surviving Person in substantially the same proportions as their ownership of Voting Stock of such Change in Control Party immediately prior to such transaction; or
- **1.21.3** such Change in Control Party sells or transfers to any Third Party, in one or more related transactions, properties or assets representing all or substantially all of such Change in Control Party's consolidated total assets to which this Agreement relates; or
- **1.21.4** the holders of capital stock of such Change in Control Party approve a plan or proposal for the liquidation or dissolution of such Change in Control Party.

For the purpose of this definition of Change in Control, (i) "person" and "group" have the meanings given such terms under Section 13(d) and 14(d) of the United States Securities

Exchange Act of 1934 and the term "group" includes any group acting for the purpose of acquiring, holding or disposing of securities within the meaning of Rule 13d-5(b)(1) under the said Act; (ii) a "beneficial owner" shall be determined in accordance with Rule 13d-3 under the aforesaid Act; and (iii) the terms "beneficially owned" and "beneficially own" shall have meanings correlative to that of "beneficial owner."

- **1.22 "Change in Control Party"** has the meaning set forth in the definition of "**Change in Control**".
- **1.23** "Clinical Data" means all Information that is made, collected, or otherwise generated under or in connection with Clinical Studies for the Product, including any data, reports, and results with respect thereto.
- **1.24** "Clinical Development" means the performance of clinical Development, including statistical analysis, Clinical Studies or related clinical activities, in each case for purposes of complying with, obtaining or maintaining Regulatory Approvals with respect to the Product.
- 1.25 "Clinical Studies" means the tests and studies in human subjects conducted to Develop the Product, including feasibility or pilot studies and studies required by Applicable Law, or otherwise recommended by applicable Regulatory Authorities, to obtain or maintain Regulatory Approvals for the Product for one (1) or more indications, including tests or studies that are intended to expand the Product Labeling with respect to an indication.
- **1.26** "**Combination Product**" means a Product that is sold in combination with one (1) or more other products or services sold together as separate units in a single package or sold in separate packages for a single price.
 - **1.27 "Commercial Forecast Commencement Date"** has the meaning set forth in Section 4.1.3.
- 1.28 "Commercialization" means any and all activities directed to the preparation for sale of, offering for sale of, or sale of the Product, including activities related to marketing, promoting, distributing, importing, and exporting the Product, and interacting with Regulatory Authorities regarding any of the foregoing, including pre-launch activities, and including obtaining and maintaining any Pricing Approvals, but excluding Development or Manufacture of the Product. When used as a verb, "to Commercialize" and "Commercializing" means to engage in Commercialization, and "Commercialized" has a corresponding meaning.
- **1.29** "Commercially Reasonable Efforts" means [**]. "Commercially Reasonable Efforts" shall be determined for any country taking into account the potential impact of such country on the overall worldwide Product opportunity.
 - **1.30** "Competing Product" has the meaning set forth in Section 8.4.1.
 - **1.31** "[**]" shall mean [**].

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- **1.32** "Competitor" means [**].
- **1.33** "**Complaint**" means any written, electronic, or oral communication that alleges deficiencies related to the identity, quality, durability, reliability, safety, effectiveness, or performance of a device after it is released for distribution.
 - **1.34 "Confidential Information"** has the meaning set forth in Section 10.1.
- 1.35 "Control" means, with respect to any item of Information, Regulatory Documentation, material, Patent or other intellectual property right, possession of the right, whether directly or indirectly and whether by ownership, license or otherwise (other than by operation of any license or other right granted by a Party to the other Party hereunder), to grant a license, sublicense or other right (including the right to reference Regulatory Documentation) to or under such Information, Regulatory Documentation, material, Patent or other intellectual property right as provided for herein without violating the terms of any agreement with any Third Party.
- **1.36 "Controlling Party"** means, with respect to a Prosecution, or an Action with respect to (i) any alleged or threatened infringement of the Surmodics Product Patents, the Surmodics Other Patents, the Joint Patents, or the Product Trademarks, or the Existing Serene Trademark, (ii) a Third Party Patent Infringement Claim, (iii) an Invalidity Claim, or (iv) a Third Party Trademark Infringement Claim, the Party controlling such Prosecution, or Action.
 - **1.37** "Core European Countries" [**].
 - **1.38** "**Default Notice**" has the meaning set forth in Section 13.2.1.
- 1.39 "Development" means, in respect of the Product, all activities related to research, bench, preclinical and other non-clinical testing, test method development, process development, manufacturing scale-up, qualification and validation, quality assurance/quality control, Clinical Studies, including Manufacturing in support thereof, statistical analysis and report writing, the preparation and submission of Device Approval Applications, regulatory affairs with respect to the foregoing and all other activities necessary or reasonably useful or otherwise requested or required by a Regulatory Authority as a condition or in support of obtaining or maintaining a Regulatory Approval. When used as a verb, "Develop" means to engage in Development.
- **1.40** "Device Approval Application" means an application for Premarket Approval as defined in the FFDCA ("PMA"), or any corresponding foreign application in the Territory, including, with respect to the European Union, a submission to a Notified Body for the performance of a conformity assessment to demonstrate conformity with the requirements of the Medical Devices Directive and permit the application of the CE Mark to a device.
 - **1.41 "Dispute"** has the meaning set forth in Section 14.7.
- **1.42** "**Distributor**" means, with respect to a country, any Person (i) that is in Abbott's customary distribution chain for distributing products in such country or (ii) that Abbott has, in its reasonable discretion, selected as appropriate to distribute, market and sell the Product

in such country consistent with Abbott's common practices for selection of distributors in such country generally.

- **1.43** "**Dollars**" or "\$" means United States Dollars.
- **1.44** "EAV" has the meaning set forth in Schedule 4.1.2.
- **1.45** "**EEA**" means the European Economic Area as its membership may be constituted from time to time, and any successor thereto, and which, as of the Effective Date, is comprised of the members of the European Union together with Iceland, Liechtenstein and Norway.
 - **1.46** "**Effective Date**" has the meaning set forth in the preamble hereto.
 - **1.47 "EU Launch Quantity"** has the meaning set forth in Section 4.1.3.
 - **1.48** "European Union" means [**].
 - **1.49 "Existing Product Patents"** has the meaning set forth in Section 11.2.2.
- **1.50** "Existing Serene Trademark" means Serene, and its existing registrations as set forth in Schedule 1.50.
- **1.51** "Existing SurVeil Trademark" means SurVeil, and its existing registrations as set forth in Schedule 1.51, or such replacement Trademark as may be accepted by Surmodics pursuant to Section 3.6.2.
- **1.52** "Existing Third Party Patent" means any Patent in the United States or under the European Patent Convention issued or published as of the Effective Date and owned by a Third Party.
- **1.53** "Exploit" or "Exploitation" means to make, have made, import, use, sell, or offer for sale, including to research, Develop, Commercialize, register, modify, enhance, improve, Manufacture, have Manufactured, hold, or keep (whether for disposal or otherwise), formulate, optimize, export, transport, distribute, promote, market, or have sold or otherwise dispose of.
 - **1.54 "Extended Term"** has the meaning set forth in Section 13.1.
- **1.55** "**FDA**" means the United States Food and Drug Administration and any successor agency(ies) or authority having substantially the same function.
- **1.56** "**FFDCA**" means the United States Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 301 *et seq.*, as amended from time to time, together with any rules, regulations and requirements promulgated thereunder (including all additions, supplements, extensions, and modifications thereto).

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- 1.57 "First Commercial Sale" means, with respect to a country, the first sale for monetary value to an end user following Regulatory Approval for the Product in such country, excluding any transfers of the Product for use in prelaunch physician preference testing, pre-launch clinical trials or registries, and excluding any transfer between or among a Party and its Affiliates. Sales prior to receipt of Regulatory Approval for the Product, including "named patient sales" and "compassionate use sales," shall not be construed as a First Commercial Sale of the Product.
 - **1.58 "Forecast"** has the meaning set forth in Section 4.1.3.
 - **1.59 "GAAP"** means generally accepted accounting principles in the United States, consistently applied.
 - **1.60 "Good Faith Efforts Orders"** has the meaning set forth in Section 4.1.4.
- **1.61** "IDE" means an application, including an application filed with a Regulatory Authority, for authorization to commence human clinical studies, including (i) an Investigational Device Exemption as defined in the FFDCA or any successor application or procedure filed with the FDA, (ii) an abbreviated IDE as specified in FDA regulations, (iii) any equivalent of a United States IDE in other countries or regulatory jurisdictions, and (iv) all amendments, variations, extensions and renewals thereof that may be filed with respect to the foregoing.
 - **1.62 "In-License Agreement"** has the meaning set forth in Section 11.2.3.
 - **1.63** [**].
 - **1.64 "Indemnification Claim Notice"** has the meaning set forth in Section 12.3.1.
 - **1.65** "**Indemnified Party**" has the meaning set forth in Section 12.3.1.
- **1.66** "**Information**" means all technical, scientific, and other know-how and information, trade secrets, knowledge, technology, means, methods, processes, practices, formulae, instructions, skills, techniques, procedures, experiences, ideas, technical assistance, designs, drawings, assembly procedures, computer programs, apparatuses, specifications, data, results and other material, including: biological, chemical, pharmacological, toxicological, pharmaceutical, physical and analytical, preclinical, clinical, safety, manufacturing and quality control data and information, including study designs and protocols; assays; and biological methodology; in each case (whether or not confidential, proprietary, patented or patentable) in written, electronic or any other form now known or hereafter developed.
 - **1.67** "Initial Indication" means [**].
 - **1.68** "**Initial Term**" has the meaning set forth in Section 13.1.

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- **1.69** "**Invalidity Claim**" means any claim, suit or proceeding by a Third Party alleging or asserting the invalidity or unenforceability of a Surmodics Product Patent, Surmodics Other Patent, or Joint Patent.
 - **1.70** "**JDC**" has the meaning set forth in Section 6.1.1.
 - **1.71 "Joint Know-How"** has the meaning set forth in Section 9.1.2.
 - **1.72** "**Joint Patents**" has the meaning set forth in Section 9.1.2.
 - **1.73** "**Losses**" has the meaning set forth in Section 12.1.
- 1.74 "Manufacture" and "Manufacturing" means, with respect to the Product, all activities related to the production, manufacture, processing, finishing, packaging, labeling, shipping, and holding of the Product or any intermediate thereof, including process development, process qualification and validation, scale-up, pre-clinical, clinical and commercial manufacture and analytic development, quality assurance, and quality control; provided, however, when used in the context of Abbott's right or license to Manufacture or a Technology Transfer hereunder, "Manufacture" and "Manufacturing" means the use or practice of the Manufacturing Process.
 - **1.75 "Manufacturing Process"** has the meaning set forth in Section 4.3.2(i).
 - **1.76 "Manufacturing Transfer Event"** has the meaning set forth in Section 4.3.1.
 - **1.77 "Market Mix Table"** has the meaning set forth in <u>Schedule 4.1.2</u>.
 - **1.78** "**MDR**" has the meaning set forth in Section 5.4.
- **1.79** "**Medical Devices Directive**" means Council Directive 93/42/EEC concerning medical devices, as amended from time to time, or any subsequent or superseding law, statute or regulation, including Regulation (EU) 2017/745 on medical devices.
 - **1.80 "Milestone"** has the meaning set forth in Section 7.2.
 - **1.81 "Milestone Payment"** has the meaning set forth in Section 7.2.
 - **1.82 "Net Profit Payment"** has the meaning set forth in <u>Schedule 7</u>.
 - **1.83** "**Net Profits**" has the meaning set forth in <u>Schedule 7</u>.
 - **1.84** "**Net Sales**" has the meaning set forth in <u>Schedule 7</u>.
 - **1.85** "**Non-Conforming Product**" has the meaning set forth in Section 4.1.10(i).
- **1.86** "Non-Controlling Party" means, with respect to a Prosecution, or an Action with respect to (i) any alleged or threatened infringement of the Surmodics Product

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Patents, the Surmodics Other Patents, the Joint Patents, or the Product Trademarks, or the Existing Serene Trademark, (ii) a Third Party Patent Infringement Claim, (iii) an Invalidity Claim, or (iv) a Third Party Trademark Infringement Claim, the Party not controlling such Prosecution, or Action.

- **1.87 "Non-Sales Revenue"** has the meaning set forth in <u>Schedule 7</u>.
- **1.88** "**Notified Body**" means an entity licensed, authorized or approved by the applicable government agency, department or other authority to assess and certify the conformity of a medical device with the requirements of the Medical Devices Directive.
 - **1.89** "**Notifying Party**" has the meaning set forth in Section 13.2.1.
- **1.90 "Option Exercise Agreement"** means, in respect of the AVF Option Product, the AVF Option Product Exercise Agreement, and in respect of the BTK Option Product, the BTK Option Product Exercise Agreement.
 - **1.91 "Option Product"** means the AVF Option Product or the BTK Option Product, as applicable.
- **1.92** "Other Abbott Trademark" means any Trademark Controlled by Abbott or its Affiliates that is used in the Commercialization of the Product other than any Product Trademark.
 - **1.93 "Other SFA Product"** has the meaning set forth in Section 8.3.4.
 - **"Other SFA Product Notice"** has the meaning set forth in Section 8.3.4.
 - **1.95 "Party"** and **"Parties"** have the meaning set forth in the preamble hereto.
- **1.96 "Party Development Activities"** means, with respect to a Party, the Development activities conducted by such Party pursuant to this Agreement.
- 1.97 "Patents" means (i) all national, regional and international patents and patent applications, including provisional patent applications; (ii) all patent applications filed either from such patents, patent applications or provisional applications or from an application claiming priority from either of these, including divisionals, continuations, continuations-in-part, provisionals, converted provisionals and continued prosecution applications; (iii) any and all patents that have issued or in the future issue from the foregoing patent applications ((i) and (ii)), including utility models, petty patents and design patents and certificates of invention; and (iv) any and all extensions or restorations by existing or future extension or restoration mechanisms, including revalidations, reissues, re-examinations and extensions (including any supplementary protection certificates and the like) of the foregoing patents or patent applications ((i), (ii), and (iii)).
 - **1.98 "Payment"** has the meaning set forth in Section 7.7.1.

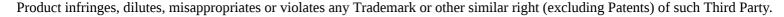
- **1.99** "**Person**" means an individual, sole proprietorship, partnership, limited partnership, limited liability partnership, corporation, limited liability company, business trust, joint stock company, trust, unincorporated association, joint venture or other similar entity or organization, including a government or political subdivision, department or agency of a government.
 - **1.100 "PO"** has the meaning set forth in Section 4.1.2.
- **1.101** "Post-Approval Study" means, with respect to an indication, any Clinical Study that constitutes a post-marketing requirement of a Regulatory Authority to, or a commitment to a Regulatory Authority that is required to, maintain any Regulatory Approval given by such Regulatory Authority for the Product for such indication.
- **1.102 "Pricing Approvals"** means pricing and reimbursement approvals from a Regulatory Authority that are necessary or desirable in order to sell the Product in a country or jurisdiction in the Territory.
 - **1.103 "Primary Efficacy Endpoint"** has the meaning set forth in <u>Schedule 7</u>.
 - **1.104 "Primary Safety Endpoint"** has the meaning set forth in <u>Schedule 7</u>.
- **1.105 "Product"** means the paclitaxel-coated balloon dilatation catheter in Development as of the Effective Date by Surmodics and its Affiliates as described in IDE G150121 and any improvements, derivatives, and iterations thereof, [**].
 - **1.106 "Product Concerns"** has the meaning set forth in Section 5.7.
- **1.107 "Product Labeling"** means, with respect to a country or other jurisdiction in the Territory, (i) the Regulatory Authority-approved labeling and instructions for use for the Product for such country or other jurisdiction, and (ii) all labels and other written, printed, or graphic matter upon a container, wrapper, or any package insert utilized with or for the Product in such country or other jurisdiction.
 - **1.108 "Product Regulatory Filings"** has the meaning set forth in Section 2.2.6.
- **1.109** "**Product Trademarks**" means any Trademark(s) to be used by Abbott or its Affiliates or its or their respective (sub)distributors, or subcontractors only for the Commercialization of the Product in the Territory, including the Existing SurVeil Trademark and the Existing Serene Trademark, and any registrations thereof or any pending applications relating thereto in the Territory (excluding, in any event, any trademarks, service marks, names or logos that include any corporate name or logo of either Party or its respective Affiliates).
 - **1.110 "Proposed In-License Agreement"** has the meaning set forth in Section 8.7.2.
- **1.111** "**Prosecute**" means, with respect to a Patent, to prepare, file, prosecute, and maintain the Patent; with respect to a Trademark, to register, prosecute and maintain the Trademark; and "**Prosecution**" and "**Prosecuting**" shall have corresponding meanings.

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- 1.112 "QSR" means: (i) the requirements applicable to manufacturers of finished medical devices (including current Good Manufacturing Practices) pertaining to the methods used in, and the facilities and controls used for, the design, manufacture, packaging, labeling, storage, installation, and servicing of all finished devices intended for human use, as specified in the U.S. Code of Federal Regulations and FDA's guidance documents, and all successor applicable regulations and guidance documents thereto, (ii) applicable standards under or arising out of the Medical Devices Directive, and (iii) requirements for quality systems contained in applicable international standards for medical devices, including those of the International Organization for Standardization (ISO).
 - **1.113** "Quality Agreement" has the meaning set forth in Section 4.1.9.
- **1.114** "Regulatory Approval" means, with respect to a country or other jurisdiction in the Territory, any and all approvals or premarket notifications (including Device Approval Applications), licenses, registrations, certificates, or authorizations of any Regulatory Authority or Notified Body necessary to commercially distribute, sell, or market the Product in such country or other jurisdiction, including, where applicable, pre- and post-approval marketing authorizations, but excluding Pricing Approvals and any approvals of any promotional materials.
- 1.115 "Regulatory Authority" means any applicable supra-national, federal, national, regional, state, provincial, or local governmental or regulatory authority, agency, department, bureau, commission, council, or other entities (e.g., FDA) regulating or otherwise exercising authority with respect to activities contemplated in this Agreement, including the Exploitation of the Product in the Territory.
- 1.116 "Regulatory Documentation" means all (i) applications (including all IDEs and Device Approval Applications, and amendments or supplements thereto, and other regulatory filings and documents), registrations, licenses, authorizations, notifications, certificates, and approvals (including Regulatory Approvals); (ii) correspondence and reports submitted to or received from Regulatory Authorities and Notified Bodies, (iii) minutes and contact reports relating to any communications with any Regulatory Authority or Notified Body, (iv) device history files, (v) advertising and promotion documents, (vi) MDR files and associated complaint files; and (vii) Clinical Data and data contained or relied upon in any of the foregoing, in each case ((i) through (vii)) relating to the Product.
- **1.117 "Secondary Party"** means, where a Party is identified as having the first right to take or control an action, the other Party.
- **1.118** "Senior Officer" means, with respect to Surmodics, its President, and with respect to Abbott, its President of Abbott Vascular.
 - **1.119** "SG&A Adjustment" has the meaning set forth in <u>Schedule 7</u>.
 - **1.120** "**Specifications**" has the meaning set forth in Section 4.1.7(i).
 - **1.121** "Supplied Materials" has the meaning set forth in Section 4.3.2(i).
 - **1.122 "Supply Disruption"** has the meaning set forth in <u>Schedule 1.122</u>.

	1.123	"Surmodics Know-How" means [**].
	1.124	"Surmodics Other Patents" means, other than any Joint Patents, [**].
	1.125	"Surmodics Product Patents" means [**].
	1.126	"Suspension Period" has the meaning set forth in Section 13.3.1(i).
	1.127	"Suspension Period Commencement Date" has the meaning set forth in Section 13.3.1(i).
	1.128	"Target Order Lot" has the meaning set forth in Schedule 4.1.2.
	1.129	"Technology Transfer" means [**].
	1.130	"Technology Transfer Event" has the meaning set forth in Section 4.3.2(i).
	1.131	"Term" has the meaning set forth in Section 13.1.
	1.132	"Territory" means the entire world.
Affiliates.	1.133	"Third Party" means any Person other than the Parties, their successors, and their respective
	1.134	"Third Party Claim" has the meaning set forth in Section 12.1.

- **1.135** "Third Party Infringement Claim" means any claim, suit or proceeding by a Third Party alleging infringement by the Exploitation of the Product by the Parties, their Affiliates or their respective (sub)licensees, (sub)distributors, subcontractors, or customers of any intellectual property right owned by a Third Party, including any defense or counterclaim in connection with an Action initiated pursuant to Section 9.3.
 - **1.136 "Third Party Infringement Claim Losses"** has the meaning set forth in Section 9.9.
- **1.137** "**Third Party Patent Infringement Claim**" means any claim, suit or proceeding by a Third Party alleging infringement by the Exploitation of the Product by the Parties, their Affiliates or their respective (sub)licensees, (sub)distributors, subcontractors or customers of a Patent.
- **1.138** "Third Party Right" means an intellectual property right of a Third Party (including a Patent or trade secret) that is infringed or misappropriated, or is reasonably expected to be infringed or misappropriated, by the Exploitation of the Product by Abbott or any of its Affiliates or any of its or their (sub)licensees, (sub)distributors, subcontractors, or customers.
- **1.139 "Third Party Trademark Infringement Claim"** means any claim, suit or proceeding by a Third Party alleging that the use of a Product Trademark in connection with the



- **1.140** "**Trademark Infringement**" means any alleged or threatened infringement, dilution, misappropriation or other violation of, or unfair trade practices or any other like offense by a Third Party relating to the Product Trademarks, except the Existing Serene Trademark.
- **1.141** "**Trademarks**" means any word, name, symbol, color, shape, designation or any combination thereof, including any trademark, service mark, trade name, brand name, sub-brand name, trade dress, product configuration rights, program name, delivery form name, certification mark, collective mark, logo, tagline, slogan, design or business symbol, that functions as an identifier of source, origin or quality, whether or not registered, and all statutory and common law rights therein and all registrations and applications therefor, together with all goodwill associated with, or symbolized by, any of the foregoing.
- **1.142** "**TRANSCEND Clinical Study**" means that certain Clinical Study of the Product allowed under IDE G150121 under protocol SUR17-001, as such Clinical Study may be modified from time to time.
 - **1.143 "Transfer Price"** has the meaning set forth in <u>Schedule 7</u>.
- **1.144** "**United States**" or "**U.S.**" means the United States of America and its territories and possessions (including the District of Columbia and Puerto Rico).
 - **1.145** "U.S. Launch Quantity" has the meaning set forth in Section 4.1.3.
 - **1.146** "VAT" has the meaning set forth in Section 7.7.2.
 - **1.147 "Working Group"** has the meaning set forth in Section 6.2.6.

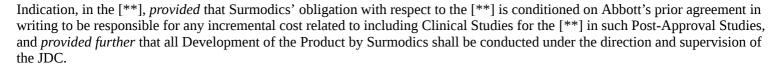
ARTICLE 2 DEVELOPMENT AND REGULATORY ACTIVITIES

2.1 Development.

2.1.1 Surmodics Development Activities.

(i) As between the Parties, excluding only the Clinical Development that Abbott has the right to conduct pursuant to Section 2.1.2, Surmodics shall be solely responsible for undertaking, and shall use Commercially Reasonable Efforts to complete, all Development in respect of the Product, including (a) the TRANSCEND Clinical Study and corresponding Post-Approval Studies and (b) all other Development, including using Commercially Reasonable Efforts to undertake and complete sufficient Development, to support obtaining and maintaining Regulatory Approvals for the United States and the European Union for use of the Product in the Initial Indication and, in the event that Regulatory Approvals for the United States or the European Union, as applicable, for use of the Product in the [**] can be reasonably obtained through required Post-Approval Studies for the Product in the Initial

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- (ii) <u>Schedule 2.1.1(ii)</u> sets forth the list of Surmodics' current (sub)contractors. Such (sub)contractors are deemed "**Approved Subcontractors**." Prior to the use of any (sub)contractor other than an Approved Subcontractor, or the expansion of the use of any Approved Subcontractors to new activities hereunder, Surmodics shall propose such (sub)contractor or expansion to the JDC and Surmodics shall take into good faith consideration any comments that Abbott may have regarding such proposal and shall ensure that any corresponding required regulatory filings are made.
- (iii) Other than as expressly set out in this Agreement, Surmodics shall be solely responsible for its own costs and expenses in carrying out its Party Development Activities.
- (iv) Abbott shall, giving due regard to Abbott's anticipated expenses and the expected benefits to the Parties, reasonably cooperate with any reasonable requests for assistance from Surmodics with respect to any Development conducted by or on behalf of Surmodics hereunder.

2.1.2 Abbott Development Activities.

- (i) Subject to the terms and conditions of this Agreement, Abbott shall have the sole right to conduct (a) all Clinical Development as required to obtain or maintain Regulatory Approvals for the Product outside of the United States and the European Union, (b) all Post-Approval Studies related to the Product, other than those certain Post-Approval Studies for which Surmodics is responsible pursuant to Section 2.1.1(i), and (c) all Clinical Development as required to obtain or maintain Regulatory Approvals in the Territory for use of the Product in all indications other than the Initial Indication. For any Clinical Studies conducted by Abbott under this Agreement, Surmodics shall serve as the "sponsor" of the applicable Clinical Study unless otherwise agreed by Abbott in writing.
- (ii) Other than as expressly set out in this Agreement, Abbott shall be solely responsible for its own costs and expenses in carrying out its Party Development Activities.
- (iii) Surmodics shall, giving due regard to Surmodics' anticipated expenses and the expected benefits to the Parties, reasonably cooperate with any reasonable requests for assistance from Abbott with respect to any Development conducted by or on behalf of Abbott hereunder.

2.2 Regulatory Activities.

2.2.1 All IDEs and Regulatory Approvals shall be held in the name of Surmodics, except in cases in which (i) Surmodics is not permitted by Applicable Law to hold an

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IDE or a Regulatory Approval in a given country, (ii) Surmodics does not meet the requirements of Applicable Law in a given country to hold an IDE or a Regulatory Approval, or (iii) Abbott has the right to obtain and maintain a Regulatory Approval pursuant to Section 2.2.4, in which case ((i), (ii), or (iii)) Abbott may elect for Abbott or its Affiliate or a Third Party mutually agreed by the Parties in writing (with each Party's agreement not to be unreasonably withheld, conditioned, or delayed) to own or hold such IDEs or Regulatory Approvals, as applicable.

- 2.2.2 Regardless of whether or not Surmodics holds an IDE or Regulatory Approval in a given country or jurisdiction, Surmodics shall be responsible for preparing and submitting all IDEs and Device Approval Applications, supplements thereto, and any other submissions necessary to obtain and maintain any IDE or Regulatory Approval, including preparing any supplements or other filings to support new indications and for conducting all communications with Regulatory Authorities with regard to the Product, including responses to additional information letters or deficiency letters, except (i) those communications relating to Pricing Approvals or relating to the approval of promotional materials for use with the Product and (ii) communications relating to Commercialization or Manufacturing activities of Abbott or its Affiliates or their respective (sub)licensees or (sub)distributors. Without limiting Surmodics' obligations under this Section 2.2.2, if Abbott has the right to obtain and maintain a Regulatory Approval pursuant to Section 2.2.4, Abbott shall have the right, but not the obligation, to prepare and submit all IDEs and Device Approval Applications, supplements thereto, and any other submissions necessary to obtain and maintain such Regulatory Approval, including preparing any supplements or other filings to support new indications and for conducting all communications with Regulatory Authorities with regard to the Product with respect to such Regulatory Approval, including responses to additional information letters or deficiency letters.
- **2.2.3** The Parties will confer and cooperate with one another through the JDC with respect to all dealings with Regulatory Authorities and with all aspects of Regulatory Approval for the Product.
- 2.2.4 Surmodics shall obtain and maintain Regulatory Approvals for the Product in the United States and the European Union and shall, upon Abbott's request in respect of a country in the Territory outside of the United States and the European Union, and subject to Abbott's satisfaction of its obligations, if any, under Section 2.1.2 with respect to such country, use Commercially Reasonable Efforts to obtain and maintain Regulatory Approvals for the Product in such country. Abbott shall support Surmodics, on Surmodics' request and as may be reasonably necessary, in obtaining and maintaining Regulatory Approvals for the Product. The Parties shall mutually agree on a commercially reasonable timeframe to obtain any Regulatory Approval for the Product in any country in the Territory for which Abbott has requested Surmodics obtain and maintain Regulatory Approvals pursuant to this Section 2.2.4. If Surmodics fails to obtain any such Regulatory Approval for the Product within the mutually agreed timeframe, or fails to maintain any such Regulatory Approval for the Product, Abbott shall have the right, but not the obligation, to obtain and maintain such Regulatory Approvals for the Product in the applicable country, and Surmodics shall provide such support and assistance as Abbott may reasonably request (including by

providing information or granting rights of reference to Abbott or its Affiliates) in connection with obtaining and maintaining such Regulatory Approvals.

- **2.2.5** If a Party is the sponsor of a Clinical Study conducted as part of its Party Development Activities, such Party (or its designee) shall have the right and responsibility to fulfil the obligations of a sponsor as specified in 21 C.F.R. Part 812, Subpart C, and the equivalent obligations in other countries or regulatory jurisdictions, including any reports, filings, or communications with Regulatory Authorities that may be required to fulfil such obligations, and the other Party shall support the sponsoring Party, as may be reasonably necessary, in respect of such obligations.
- **2.2.6** Surmodics shall provide Abbott with an opportunity to review and comment on all Regulatory Authority meeting requests and on all submissions, filings, and proposed communications to Regulatory Authorities, in each case relating to the Product in the Territory (collectively, "**Product Regulatory Filings**"). Surmodics shall provide access to interim drafts of such Product Regulatory Filings to Abbott via the access methods (such as secure databases) established by the JDC, and Abbott shall provide its comments on such Product Regulatory Filings or on proposed material actions within [**], or such other longer period of time mutually agreed to by the Parties. In the event that a Regulatory Authority establishes a response deadline for any such Product Regulatory Filing or material action shorter than such period, the Parties shall work cooperatively to ensure the other Party has a reasonable opportunity for review and comment within such deadlines. Surmodics shall reasonably consider Abbott's comments, requests and suggestions.
- 2.2.7 Subject to Section 2.2.8, Surmodics shall provide Abbott with (i) access to or copies of all written or electronic correspondence (other than Product Regulatory Filings) relating to the Development or Commercialization of the Product received after the Effective Date by Surmodics or its designee from, or forwarded by Surmodics or its designee to, the Regulatory Authorities in the Territory, and (ii) copies of all meeting minutes and summaries of all meetings, conferences, teleconferences, and discussions held by Surmodics or its designee after the Effective Date with the Regulatory Authorities in the Territory, including copies of all contact reports produced by Surmodics or its designee, in each case ((i) and (ii)) within [**] of its receipt, forwarding or production of the foregoing, as applicable.
- **2.2.8** Each Party shall provide the other Party with prior written notice, to the extent such Party has advance knowledge, of any scheduled meeting, conference, or discussion (including any advisory committee meeting) with a Regulatory Authority in the Territory relating to the Product, within [**] after such Party or its designee first receives notice of the scheduling of such meeting, conference, or discussion (or within such shorter period as may be necessary in order to give the other Party a reasonable opportunity to attend as an observer (but not participate in) such meeting, conference, or discussion). The other Party shall have the right to have two (2) of its representatives attend as an observer (but not participate in) all such meetings, conferences, and discussions.
- **2.3 Regulatory Data.** From time to time within a reasonable time following a request from the other Party, each Party shall promptly provide to such other Party copies of or access to all non-clinical data and Clinical Data generated hereunder, and in the case of

Surmodics, any other Information, results, and analyses that is Surmodics Know-How, with respect to the Product and that such Party requires to perform its obligations hereunder. Without limiting the foregoing, Surmodics shall, within [**] after the Effective Date, provide to Abbott, in such form and format as Abbott may reasonably request, copies of all Regulatory Documentation existing as of the Effective Date that relates to the Product.

ARTICLE 3 DISTRIBUTION RIGHTS AND OTHER COMMERCIALIZATION MATTERS

- **3.1 Appointment of Abbott as Exclusive Distributor.** Subject to the terms and conditions of this Agreement, Surmodics hereby appoints Abbott as Surmodics' exclusive distributor of the Product in the Territory during the Term, and Abbott hereby accepts such appointment. Subject to the terms and conditions of this Agreement, Abbott (itself or through its Affiliates or Distributors) shall have the sole right to Commercialize the Product in the Territory, and Surmodics shall have no right to Commercialize, directly or indirectly, the Product anywhere in the Territory.
- **3.2 (Sub)distributorships.** Abbott shall have the right, in its sole discretion, to appoint its Affiliates, and Abbott and its Affiliates shall have the right, in their sole discretion, to appoint any other Distributors, in the Territory or in any country or other jurisdiction of the Territory, to distribute, market, and sell the Product.
 - 3.3 Commercialization Diligence.
 - **3.3.1 United States.** Abbott shall [**].
 - **3.3.2 European Union.** Abbott shall [**].
- **3.3.3 Commercial Launch Plans.** At least [**] prior to the anticipated date of Regulatory Approval of the Product in each of the United States and the European Union, the Parties shall meet to review and discuss Abbott's commercial launch plan for such region.
- **3.3.4 Annual Marketing Plans.** For any calendar year in which Abbott plans to Commercialize the Product, Abbott shall draft and provide to Surmodics an annual marketing plan for the promotion, marketing, and sale of the Product for such calendar year through its customary planning process, and the Parties shall meet to review and discuss such annual marketing plan.
- **3.4 Booking of Sales; Distribution.** Subject to the terms and conditions of this Agreement, Abbott shall have the sole right to invoice and book sales, establish all terms of sale (including pricing and discounts) and warehousing, distribute the Product in the Territory, and perform or cause to be performed all related services. Without limiting the foregoing, Abbott shall handle all returns, recalls, corrections, removals, order processing, invoicing, collection, distribution, and inventory management with respect to the Product in the Territory.
- **3.5 Pricing Approvals and Approvals of Promotional Materials.** As between the Parties, in the United States and the Core European Countries, Abbott shall use Commercially Reasonable Efforts to make submissions for Pricing Approvals and for any

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approvals sought from a Regulatory Authority with regard to promotional materials in respect of the Product as reasonably necessary to Commercialize the Product. Surmodics shall, and shall cause its Affiliates to, cooperate with and provide support to Abbott and its Affiliates as reasonably requested by Abbott in respect of the preparation and submission of any Regulatory Documentation that is reasonably required in connection with such submissions for Pricing Approvals, including by drafting such dossiers as Abbott may request.

3.6 Product Trademarks.

3.6.1 Preparation of Marketing Materials and Determination of Product

Trademarks. Subject to the terms and conditions of the remainder of this Section 3.6, as between the Parties, Abbott shall be solely responsible for preparing all advertising, promotional sales, social media and other related literature and materials ("**Marketing Materials**") to promote or market the Product. Abbott shall ensure that all Marketing Materials comply with all Applicable Law in the applicable countries in the Territory. Abbott shall have the sole right to determine the Product Trademarks and Other Abbott Trademarks to be used with respect to the Exploitation of the Product on a worldwide basis; *provided, however*, that

- (i) Abbott shall use the Existing SurVeil Trademark and the Existing Serene Trademark on all Product Labeling in the United States and the European Union, with such usage of the Existing SurVeil Trademark occurring in the tradename of the Product,
- (ii) for any country outside the United States and the European Union, (1) if the Existing SurVeil Trademark or the Existing Serene Trademark is registered by Surmodics in such country, Abbott shall use the Existing SurVeil Trademark or the Existing Serene Trademark, as applicable, on all Product Labeling in such country, with any such usage of the Existing SurVeil Trademark occurring in the tradename of the Product, or (2) if the Existing SurVeil Trademark or the Existing Serene Trademark is not registered by Surmodics in such country, Abbott shall decide in its reasonable discretion (with such decision for China or Japan subject to Surmodics' consent (not to be unreasonably withheld, conditioned, or delayed)) whether to use the Existing SurVeil Trademark or the Existing Serene Trademark, as applicable, on Product Labeling in such country, with any such usage on the Product Labeling of the Existing SurVeil Trademark occurring in the tradename of the Product,
- (iii) Abbott shall identify Surmodics as the manufacturer on all Product Labeling (to the extent Surmodics is the manufacturer thereof),
- (iv) Abbott may use the Existing SurVeil Trademark and the Existing Serene Trademark on Marketing Materials for the Product and may identify Surmodics as the manufacturer thereon (to the extent Surmodics is the manufacturer thereof), and
- (v) Abbott may use Abbott trade dress and logos and Other Abbott Trademarks on the Marketing Materials for the Product as deemed appropriate in Abbott's sole discretion.
- **3.6.2 Replacement Trademark.** Notwithstanding anything to the contrary in Section 3.6.1, in the event that the Existing SurVeil Trademark is not reasonably likely to be registered in the United States and each country in the European Union on or before

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the first receipt of Regulatory Approval in the United States or the European Union, Abbott may select a replacement Trademark, provided that such replacement Trademark is reasonably acceptable to Surmodics. Such replacement Trademark shall be owned by Surmodics, and, from and after acceptance by Surmodics, shall be deemed to be the Existing SurVeil Trademark for all purposes under this Agreement.

- 3.6.3 Surmodics Covenants. Surmodics shall not, and shall not permit its Affiliates to, (i) use any Product Trademark or Other Abbott Trademark, other than the Existing Serene Trademark, for the purpose of commercializing any product (other than the Product sold to Abbott or its Affiliates), (ii) use in their respective businesses, any Trademark that is confusingly similar to, misleading or deceptive with respect to or that dilutes any (or any part) of the Product Trademarks or Other Abbott Trademarks, other than the Existing Serene Trademark, (iii) commit any act which endangers, destroys, or similarly affects, in any material respect, the value of the goodwill pertaining to the Product Trademarks or Other Abbott Trademarks, other than the Existing Serene Trademark, dispute, or contest the validity of or ownership of any Product Trademark or Other Abbott Trademark, other than the Existing Serene Trademark, anywhere in the Territory.
- **3.6.4 Abbott Covenants.** Abbott shall not, and shall not permit its Affiliates to, (i) use the Existing SurVeil Trademark or the Existing Serene Trademark for the purpose of commercializing any product (other than the Product sold to Abbott or its Affiliates or pursuant to a separate agreement with Surmodics or one of its Affiliates), (ii) use in their respective businesses, any Trademark that is confusingly similar to, misleading or deceptive with respect to or that dilutes any (or any part) of the Existing SurVeil Trademark or the Existing Serene Trademark, (iii) commit any act which endangers, destroys, or similarly affects, in any material respect, the value of the goodwill pertaining to the Existing SurVeil Trademark or the Existing Serene Trademark, or (iv) attack, dispute, or contest the validity of or ownership of the Existing SurVeil Trademark or the Existing Serene Trademark, anywhere in the Territory.

ARTICLE 4 MANUFACTURING AND SUPPLY

4.1 Supply.

- **4.1.1 Obligation to Supply.** During the Term and subject to the terms and conditions of this Agreement, Surmodics shall Manufacture and supply the Product to Abbott or its Affiliates at the Transfer Price in effect at the time the applicable PO is placed as set forth herein.
- **4.1.2 POs and Delivery.** Abbott may, from time to time, order a quantity of the Product from Surmodics by submitting a purchase order ("**PO**") to Surmodics, subject to the requirements set forth in <u>Schedule 4.1.2</u>. For any PO accepted by Surmodics pursuant to Section 4.1.4, Surmodics shall deliver the Product to Abbott on the delivery date(s) specified in such PO. Surmodics shall have the right to vary the quantity of Product shipped pursuant to a PO to the extent reasonably necessary to avoid dividing production lots, *provided*, *however*, that any such variance shall not exceed [**] of the quantities specified in the PO. The Product shall be delivered [**] (Incoterms 2010) origin, *provided* that Surmodics shall, in

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accordance with Abbott's instructions and as agent for Abbott, (a) at Abbott's expense, use Commercially Reasonable Efforts to obtain any export license or other official authorization necessary to export the Products, and (b) act as the exporter of record or principal party in interest for customs and export reporting and compliance purposes, but with Abbott to reimburse Surmodics for the amount of any customs duties or other similar payments that may be made by Surmodics pursuant to Applicable Law in connection with the export of the Product. Surmodics shall also cooperate and provide assistance to Abbott or Abbott's designee for purposes of obtaining any license or approval required for the import of Product into a country in the Territory, including upon Abbott's request and at Abbott's expense obtaining any necessary certificates of free sale for medical devices from the applicable Regulatory Authority. Surmodics shall, with all shipments of the Product, provide to Abbott or its designee an invoice with respect thereto along with a certificate of conformance (the form of which shall be mutually agreed upon by the Parties) verifying compliance with the Specifications and the QSRs. Subject to Section 4.1.10, Abbott shall pay all undisputed amounts on each invoice within [**] of receipt thereof. In the event of a conflict between the terms and conditions of any PO and this Agreement, the terms and conditions of this Agreement shall prevail.

4.1.3 **Forecasts.** Within [**], Abbott shall provide Surmodics with a good faith estimate of [**] order volume to support the commercial launch of the Product in the European Union, and thereafter shall update such good faith estimate from time to time until Abbott provides the first Forecast. Within [**], Abbott shall provide Surmodics with a good faith estimate of [**] order volume to support the commercial launch of the Product in the United States, and thereafter shall update such good faith estimate from time to time until Abbott provides the first Forecast that contains any of the U.S. Launch Quantity (defined below). Commencing [**] in advance of the first day of the calendar month in which the commercial launch of the Product in any country in the Territory is expected to occur (such date that is [**] in advance, the "Commercial Forecast **Commencement Date**"), and prior to the first day of each calendar month thereafter during the Term, Abbott shall provide Surmodics a rolling [**] forecast of anticipated purchases of the Product (the "Forecast"). [**]. The initial Forecast shall be accompanied by a PO for the first [**] thereof. Each subsequent Forecast shall be accompanied by a PO for the [**] of each such Forecast. Any specification of the mix of SKUs that may be reflected in the [**] of any Forecast shall be non-binding and shall not restrict the mix of SKUs in any month of any subsequent Forecast. Once a PO is placed, there shall be no further changes in the mix of SKUs for such PO without the prior express written consent of Surmodics. [**] Abbott shall reasonably identify in its Forecast the specific quantities in the specific months in such Forecast that are intended for the commercial launch of the Product in the European Union or the United States, as applicable (such identified commercial launch quantities, the "EU Launch Quantity" or the "U.S. Launch Quantity", as applicable).

4.1.4 Order Acceptance. Subject to the terms and conditions of this Agreement, Surmodics shall be required to accept within [**] any PO consistent with the terms and conditions of this Agreement placed by Abbott so long as, if an applicable Forecast exists, the quantity of Product ordered on such PO for delivery in any month, together with the quantity of all other Product ordered by Abbott for delivery in such month, does not exceed [**] of the quantity of the Product indicated in any binding portion of any Forecast in respect of such month. Abbott may place a PO for additional quantities of Product above such [**] threshold, *provided* that Abbott shall identify such additional quantities as "Good Faith Efforts Orders"

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(such identified additional quantities, the "**Good Faith Efforts Orders**") and Surmodics shall use good faith efforts to fill such Good Faith Efforts Orders. If Surmodics fails to provide acceptance of a PO to Abbott within such [**] period, Surmodics will be deemed to have accepted such PO.

- **4.1.5 Shortages.** In the event of any shortage experienced by Surmodics or its Affiliates with respect to any inputs or capacity that may reasonably be expected to affect Surmodics' ability to satisfy its Manufacturing and supply obligations hereunder, Surmodics shall allocate its available inputs and capacity to the Manufacture of the Product to ensure that Abbott actually receives at least as high of a percentage of the Product ordered by Abbott pursuant to Section 4.1.2 and accepted by Surmodics in accordance with Section 4.1.4 as [**]. Surmodics shall notify Abbott as soon as it becomes aware of circumstances that could reasonably be expected to result in any such shortage. The obligations of this Section 4.1.5 shall not apply after Surmodics' receipt of any notice of termination for convenience from Abbott pursuant to Section 13.3.2.
- **4.1.6 Approved Supplier.** The Parties acknowledge that Surmodics is already, as of the Effective Date, an Abbott approved supplier. Surmodics shall use reasonable efforts to maintain its status as an Abbott approved supplier and to maintain the approved status of Surmodics' applicable manufacturing facility(ies), *provided* that Abbott's requirements for Surmodics to maintain its approved supplier status are generally consistent with Abbott's corresponding requirements for suppliers of other products to Abbott. Surmodics acknowledges that execution of a mutually agreed upon Quality Agreement in respect of this Agreement is a requirement to maintain its status as an Abbott approved supplier.

4.1.7 Changes to Specifications and Manufacturing.

- (i) **Changes to Specifications.** The initial specifications for the Product are set forth on <u>Schedule 4.1.7(i)</u> hereto (the "**Specifications**"). Specifications may only be amended by written agreement of the Parties on a timetable mutually agreed by the Parties; *provided*, *however*, that Surmodics shall not withhold its consent to making any change required or requested by a Regulatory Authority or reasonably required by Applicable Law.
- (ii) **Changes to Manufacturing.** Surmodics shall notify Abbott in writing at least [**] prior to (A) making any proposed change or relocation of the manufacturing site for the Product or (B) engaging or substituting any Third Party to perform any of Surmodics' obligations hereunder. Relocation of the manufacturing site or engagement or substitution of a Third Party to perform any of Surmodics' obligations hereunder shall require the prior written consent of Abbott. Upon receipt by Abbott of any such request for consent, Abbott shall respond in writing within [**] following its receipt of notice from Surmodics. Any new facility or Third Party to be utilized by Surmodics shall be subject to a new and separate audit by Abbott quality assurance personnel in accordance with Section 4.1.8, and Surmodics shall use Commercially Reasonable Efforts to have the new manufacturing site or Third Party become acceptable to Abbott quality policies within [**] of relocating Product Manufacture or engaging such Third Party. Except as otherwise provided herein, no relocation or engagement or substitution of a Third Party to perform any of Surmodics' obligations hereunder shall relieve

Surmodics of its obligations to timely deliver the Product in accordance with the Specifications hereunder.

4.1.8 Quality Assurance Inspections. Surmodics shall, from time to time during the Term and upon reasonable advance written notice from Abbott, no more than [**] (plus such additional inspections as are reasonably advisable, in Abbott's reasonable discretion, due to a Complaint of a serious nature whereby information received by Abbott reasonably suggests that the Product may not meet its specifications for safety or quality), allow representatives of Abbott to tour and inspect during regular business hours the non-confidential and non-proprietary portions of all facilities utilized by Surmodics in Development, Manufacturing, testing, quality control, packaging and shipping of the Product sold to Abbott under this Agreement for the purposes of verifying Surmodics' compliance with all Applicable Laws; provided that such representatives enter into Surmodics' standard nondisclosure agreement prior to entering such facilities. Abbott shall provide reasonable notice of such inspection or audit and shall not unreasonably interfere with Surmodics' operations under the circumstances. During such visits, Surmodics shall provide reasonable access to its manufacturing quality control documentation and shall reasonably cooperate with such representatives. Abbott shall cause all such representatives to comply with Surmodics' policies regarding visitors to such facilities, and Abbott shall be responsible for any noncompliance therewith. Surmodics shall use reasonable efforts to cure any deficiencies in Surmodics' compliance with Applicable Law identified by Abbott as a result of such inspections and audits.

4.1.9 Quality Agreement. The Parties shall each use reasonable efforts to complete and mutually agree upon a quality agreement that describes the relationship of the Parties hereunder and the responsibilities of each Party regarding quality systems practices and activities concerning the Product (the "**Quality Agreement**"), within [**] of the execution of this Agreement by both Parties. The Quality Agreement will be reviewed, revised and approved by senior quality assurance representatives from both Parties on a periodic basis, as required. Without limiting the foregoing, the Quality Agreement shall be amended (or a separate agreement entered into) in connection with each Option Exercise Agreement. In the event of a conflict between the terms and conditions of this Agreement and the Quality Agreement, the terms and conditions of this Agreement shall control.

4.1.10 Non-Conforming Product.

(i) **In General.** Within [**] of Surmodics' delivery of a quantity of the Product, Abbott may inspect and reject any such quantities of the Product supplied hereunder which do not conform to the applicable Specifications or Surmodics' warranty for the Product set forth in Section 11.2.13 at the time of delivery (a "**Non-Conforming Product**"); *provided* that such Non-Conforming Product has not become non-conforming due to any action or omission by Abbott.

(ii) **Return and Replacement.** Abbott shall return any Non-Conforming Product quantities to Surmodics at Surmodics' expense, and Surmodics shall, at Abbott's option, promptly either (A) reimburse Abbott for the Transfer Price paid by Abbott with respect to such Non-Conforming Product or (B) supply Abbott with a conforming quantity of the Product at Surmodics' expense. In the event of a dispute with respect to whether the

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Product is in fact non-conforming, and should the Parties fail to otherwise resolve the dispute, the Parties shall submit the Product to a mutually acceptable independent Third Party for evaluation. The determination of the Product's conformance or non-conformance to the Specifications by such independent Third Party shall be binding upon the Parties. Should the independent Third Party determine that the Product is conforming, Abbott shall pay all independent Third Party and shipping costs incurred by Surmodics, and should such independent Third Party confirm that the Product is Non-Conforming Product, Surmodics shall pay all independent Third Party costs. Any such Third Parties shall be required to enter into a confidentiality agreement with Surmodics and Abbott with terms no less restrictive than those provided herein for Confidential Information.

4.2 Supply Assurance. As soon as reasonably practical after Regulatory Approval of the Product, Surmodics shall secure and maintain a secondary source of supply of the Product with sufficient capacity within a reasonable timeframe to meet Abbott's reasonably projected commercial demand for the Product, at Surmodics' sole expense, which may be at another Surmodics facility.

4.3 Right to Manufacture; Manufacturing Technology Transfer.

4.3.1 Right to Manufacture. Notwithstanding anything to the contrary in this Agreement, from and after the occurrence of any [**] (each, a "**Manufacturing Transfer Event**"), Abbott shall have the right to Manufacture (or have Manufactured by its designee (which designee may only be an Affiliate or, solely with respect to the services listed on Schedule 2.1.1(ii), a Third Party service provider)) the Product to be used for Development or Commercialization pursuant to this Agreement (and may use and sell any saleable validation or qualification lots or batches Manufactured as part of any Technology Transfer); *provided* that Abbott shall not directly or indirectly Manufacture (or have Manufactured) unless and until the occurrence of a Manufacturing Transfer Event.

4.3.2 Manufacturing Technology Transfer.

(i) Notwithstanding anything to the contrary in this Agreement, from and after the earlier of [**] the occurrence of a Manufacturing Transfer Event (each, a "**Technology Transfer Event**"), Abbott shall be entitled to request and receive from Surmodics a Technology Transfer, Surmodics shall use Commercially Reasonable Efforts to effect, and to work with Abbott and its Affiliates to effect, such Technology Transfer, and Surmodics shall use Commercially Reasonable Efforts [**] under Applicable Law and in accordance with the timeline set forth in the implementation plan agreed by the Parties pursuant to Section 4.3.2(iv). Surmodics shall also provide any inputs or components that are needed to conduct the Technology Transfer. In furtherance thereof, within [**] following Abbott's request for a Technology Transfer, the Parties shall enter into a commercially reasonable supply agreement for the supply [**], and such raw materials, coating reagents, and components as are reasonably requested by Abbott and are reasonably necessary in order for Abbott to Manufacture the Product (the "**Supplied Materials**"), [**]. As part of the Technology Transfer, Surmodics shall transfer to Abbott or its Affiliate the applicable Surmodics Know-How regarding [**], and the assembly of the raw materials, components and coatings comprising the Product into the Product, all as described in the Technology Transfer and any other Surmodics Know-How that is

reasonably necessary to Manufacture the Product (except for any Surmodics Know-How for the manufacture of Supplied Materials, to the extent such Supplied Materials are actually supplied by Surmodics to Abbott pursuant to a supply agreement entered into pursuant to this Section 4.3.2(i)) (the "**Manufacturing Process**"), and shall provide such support as reasonably necessary to Abbott or its Affiliate, as applicable, to use and practice the Manufacturing Process for the Product, including by [**]. Abbott shall have the right to continue to order Product from Surmodics hereunder after any such Technology Transfer.

- (ii) Without limiting the foregoing, following any transaction described in Section 4.3.1(ii) or Section 4.3.1(iii), Abbott shall have the right to submit binding POs including quantities of Product that exceed the quantities that Surmodics is required to accept pursuant to Section 4.1.4, and Surmodics shall use Commercially Reasonable Efforts to fulfill such POs, *provided* that Surmodics' failure to fulfill any quantities of Product ordered pursuant to such POs that exceed the quantities that Surmodics is required to accept pursuant to Section 4.1.4 shall be disregarded for purposes of determining whether there has been a Supply Disruption hereunder, and *provided further* that Surmodics shall not, in respect of its obligation to use Commercially Reasonable Efforts to fulfill such POs, be required to use any efforts that Surmodics reasonably expects would increase its overall average Manufacturing cost per unit of Product in order to fulfill any quantities of Product ordered pursuant to such POs that exceed the quantities that Surmodics is required to accept pursuant to Section 4.1.4.
- (iii) Without limiting the foregoing, following a Technology Transfer Event, Abbott shall have the right to, at any time, by giving written notice to Surmodics, request that Surmodics procure, and Surmodics shall use Commercially Reasonable Efforts to procure, at Abbott's cost and expense (including [**], at which time, following request by Abbott, Surmodics shall promptly [**]. Upon expiration or termination of this Agreement, Surmodics shall [**].
- (iv) Within [**] following the Effective Date, Surmodics shall develop and provide to Abbott a high level plan describing the steps to be carried out in connection with a Technology Transfer. The Parties shall then cooperate to complete, within [**] of the Effective Date, the preparation of a reasonable implementation plan for a Technology Transfer, with such plan to include (a) specific timelines and milestones that are consistent with completion of the Technology Transfer within [**] (exclusive of any [**]) of Abbott's request, if any, for a Technology Transfer pursuant to this Section 4.3.2, and (b) a list of [**], including a description of [**]. The Parties shall memorialize such implementation plan in a writing that is acknowledged by each Party.

ARTICLE 5 COMPLIANCE AND RELATED MATTERS

- **5.1 Compliance.** Each Party shall perform, or cause to be performed, any and all of the activities to be performed by such Party hereunder in good scientific manner and in compliance with all Applicable Law.
- **5.2 Records.** Surmodics shall, and shall require that its Affiliates and its or their applicable subcontractors, maintain records in sufficient detail and in good scientific

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manner appropriate for patent and regulatory purposes, and in compliance with Applicable Law (including 21 C.F.R. Part 820), which shall be complete and accurate and shall properly reflect all work done and results achieved in the performance of Surmodics' Development and Manufacturing activities hereunder. Without limiting the foregoing, such records shall include batch records, validation data, and quality control data in respect of the Manufacture of the Product. Such records shall be retained by Surmodics for at least [**] after the expiration or termination of this Agreement, or for such longer period as may be required by Applicable Law. Upon request, Surmodics shall provide copies of such records to Abbott. Abbott shall also have the right, during normal business hours and upon reasonable notice, to inspect and copy such records. Abbott shall maintain such records and the information disclosed therein in confidence in accordance with Article 10.

- **5.3 Authorized Representative.** As and to the extent necessary in order to comply with Applicable Law in connection with Surmodics' Development and Manufacturing activities hereunder, Surmodics shall appoint an authorized representative in the EEA, *provided* that, unless otherwise agreed in writing by the Parties through a separate agreement, Surmodics shall not, and shall require that its Affiliates shall not, appoint Abbott or any of its Affiliates as Surmodics' or its Affiliates' authorized representative in the EEA in connection with any of Surmodics' Development or Manufacturing activities hereunder.
- **5.4 Safety Data.** Each Party shall provide the other Party with all information that is Controlled by such Party and that is necessary to allow the other Party to comply with its safety-related reporting rights and responsibilities in the Territory, including, as applicable, any device-related problems or adverse events from pre-clinical or clinical laboratory, animal toxicology and pharmacology studies, Clinical Studies (including evaluations of unanticipated adverse device effects, as defined in 21 C.F.R. § 812.150), and commercial experiences with the Product (including medical device report ("**MDR**") reportable events, as defined in 21 C.F.R. § 803.3), in each case in the form reasonably requested by such other Party.
- 5.5 Complaints. If Abbott receives a Complaint regarding the Product, Abbott shall forward the Complaint information to Surmodics promptly, but in any event no more than [**] from receipt of such Complaint by Abbott. In the event a Complaint is reported directly to Surmodics, Surmodics shall forward the Complaint via email to the Abbott contact at [**] within [**] solely for Abbott's internal quality control tracking purposes. Abbott shall cooperate with Surmodics as reasonably necessary to collect customer information regarding Complaints regarding the Product in order to satisfy Regulatory Authority inquiries. Surmodics shall have the right to make the final determination of whether any Complaint represents an event that must be reported to FDA as an MDR, and shall have the sole right and responsibility to make any such MDR report to FDA and to make any equivalent reports to other Regulatory Authorities. Without limiting the foregoing, Abbott shall be responsible for carrying out in its reasonable discretion all customer support and resolution of Complaints; *provided* that Surmodics shall provide reasonable assistance in connection therewith upon Abbott's reasonable request.
- 5.6 Notification Regarding Regulatory Inquiries and Potential Adverse Events. Each Party shall promptly inform the other Party of any formal or informal inquiry by any Regulatory Authority relating to the Product sold hereunder. If either Party becomes aware

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of any problem or adverse condition in the Product purchased hereunder (including any failure of the Product, change in the statistically demonstrated reliability of the Product, other material information relevant to the reliability of the Product or any liability claims related to the Product or any other event that would reasonably be expected to have a material adverse effect on the manufacture, marketing or sale of the Product), such Party will (subject to compliance with Applicable Laws) promptly notify the other Party of such problem or adverse condition. Without limitation to the foregoing, Surmodics shall immediately notify Abbott if, at any time, it discovers that any quantities of the Product delivered hereunder do not conform to the Product warranty set forth in Section 11.2.13.

5.7 **Recalls.** Each Party shall promptly report in writing to the other Party any failure of the Product, change in the statistically demonstrated reliability of the Product, concerns regarding safety of the Product, other material information relevant to the reliability of the Product or any liability claims related to the Product or any other event that might reasonably be expected to have a material adverse effect on the Manufacture, marketing or sale of the Product of which either Party becomes aware (collectively, "Product Concerns"). The Party that Manufactured the applicable quantity of the Product shall be responsible for evaluating all Product Concerns, and shall use Commercially Reasonable Efforts to take such actions or make such changes in the Product or the Manufacturing thereof as may be necessary or desirable in light of such Product Concerns. The other Party shall reasonably cooperate with the manufacturing Party in any such evaluation and actions or changes. If either Party reasonably believes that a recall of the Product, in whole or in part, or the issuance of an advisory letter regarding reliability of or defects in the Product is advisable or necessary, it will, prior to making a final determination concerning any such recall or issuance of an advisory letter, promptly notify the other Party and the Parties will promptly and in good faith discuss such proposed recall or advisory letter; provided, however, that either Party may, in good faith, initiate a recall or issue an advisory letter. In making a determination to initiate a recall or issue an advisory letter, the applicable Party shall follow the same processes and procedures that it customarily follows with respect to determinations concerning recalls or advisory letters involving product that is manufactured and sold by such Party. In the event the Parties do not agree regarding the advisability or necessity of any such recall or advisory letter and Abbott's Quality Assurance policies or procedures would, in Abbott's reasonable judgment, prohibit Abbott from placing further orders with Surmodics for the Product or from shipping the Product to customers, Abbott shall notify Surmodics, and the Parties shall then proceed as provided in Section 13.3.1(i). In the event of a recall or advisory letter, the Party whose act or omission gave rise to such recall or advisory letter: (A) shall, at its own expense, use its reasonable efforts to promptly correct the problems that caused the recall or advisory letter; and (B) shall be responsible for and shall reimburse the other Party for all the reasonable out-of-pocket costs and expenses of the recall or advisory letter, including costs of goods, payments to customers, notification, and shipping and handling. In all other cases, each Party shall bear its own costs for the recall or advisory letter. Notwithstanding the foregoing, nothing in this Section 5.7 shall be construed to limit or prevent a Party from complying with the requirements of any law, regulation, or order of a Regulatory Authority.

ARTICLE 6 JOINT DEVELOPMENT COMMITTEE

6.1 Joint Development Committee.

6.1.1 Formation. As soon as practical after the Effective Date, the Parties shall establish a joint development committee (the "**JDC**"). The JDC shall consist of three (3) representatives from each of the Parties, each with the requisite experience and seniority to enable such person to make decisions on behalf of the Parties with respect to the issues falling within the jurisdiction of the JDC. From time to time, each Party may substitute one or more of its representatives to the JDC on written notice to the other Party. Abbott shall select from its representatives the chairperson for the JDC. From time to time, Abbott may change the representative who will serve as chairperson on written notice to Surmodics.

6.1.2 Specific Responsibilities. The JDC shall, consistent with the rights and obligations of the Parties set forth in this Agreement, develop the strategies for and oversee the Development, but not the Manufacturing or Commercialization, of the Product in the Territory, and shall serve as a forum for the coordination of Development, but not Manufacturing or Commercialization, activities for the Product for the Territory. In particular, the JDC shall:

- (i) review and provide input regarding the Development of and Regulatory Approvals for the Product for the Initial Indication and the [**] in the United States and the European Union;
- (ii) oversee all Clinical Studies and Post-Approval Studies for the Product for the Initial Indication and the [**] in the United States and the European Union;
- (iii) review, provide input and direction regarding, and oversee strategies for obtaining Regulatory Approvals, including Regulatory Approvals for Product Labeling for indications in addition to the Initial Indication, for the Product in the United States and the European Union;
- (iv) review, provide input and direction regarding, and oversee strategies for obtaining Regulatory Approvals, including Regulatory Approvals for Product Labeling, for the Product in the Territory outside of the United States and the European Union for any indication;
 - (v) review the progress reports made by each Party pursuant to Section 6.1.3;
- (vi) establish a common secure information exchange platform for the purpose of electronically sharing information accessible to each Party for the receipt, review, investigation, recording, communication, and exchange (as between the Parties) of Clinical Data and other Information arising from Clinical Studies and regulatory activities; and
- (vii) perform such other functions as are set forth herein or as the Parties may mutually agree in writing, except where in conflict with any provision of this Agreement.

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6.1.3 Development Reports; Updates. Each Party shall provide the JDC with (i) on at least a Calendar Quarter basis, unless otherwise agreed by the Parties, reports in reasonable detail regarding the status of Clinical Studies being conducted by it and any of its other Party Development Activities, and (ii) additional notifications regarding key events relating to the Development of the Product as may be requested by the JDC from time to time.

6.2 General Provisions Applicable to JDC.

6.2.1 Meetings and Minutes. The JDC shall meet quarterly, or as otherwise agreed to by the Parties, with the location of such meetings alternating between locations designated by Surmodics and locations designated by Abbott. The chairperson of the JDC shall be responsible for calling meetings on no less than [**] notice. Each Party shall make all proposals for agenda items and shall provide all appropriate information with respect to such proposed items at least [**] in advance of the applicable meeting; *provided* that under exigent circumstances requiring input by the JDC, a Party may provide its agenda items to the other Party within a shorter period of time in advance of the meeting, or may propose that there not be a specific agenda for a particular meeting, so long as the other Party consents to such later addition of such agenda items or the absence of a specific agenda for such meeting. The chairperson of the JDC shall prepare and circulate for review and approval of the Parties minutes of each meeting within [**] after the meeting. The Parties shall agree on the minutes of each meeting promptly, but in no event later than the next meeting of the JDC.

6.2.2 **Procedural Rules.** The JDC shall have the right to adopt such standing rules as are necessary for its work, to the extent that such rules are not inconsistent with this Agreement. A quorum of the JDC shall exist whenever there is present at a meeting at least one (1) representative appointed by each Party. JDC members may attend a meeting either in person or by telephone, video conference or similar means in which each participant can hear what is said by, and be heard by, the other participants. Representation by proxy shall be allowed. The JDC shall take action by consensus of the representatives present at a meeting at which a quorum exists, with each Party having a single vote irrespective of the number of representatives of such Party in attendance, or by a written resolution signed by at least one (1) representative appointed by each Party. Employees or consultants of either Party that are not representatives of the Parties on the JDC may attend meetings of the JDC; provided, however, that such attendees (i) shall not participate in matters reviewed by the JDC, and (ii) are bound by obligations of confidentiality and non-disclosure equivalent to those set forth in Article 10.

6.2.3 Limitations on Authority. Each Party shall retain the rights, powers, and discretion granted to it under this Agreement and no such rights, powers, or discretion shall be delegated to or vested in the JDC unless such delegation or vesting of rights is expressly provided for in this Agreement or the Parties expressly so agree in writing. The JDC shall not have the power to amend, modify, or waive compliance with this Agreement, which may only be amended or modified as provided in Section 14.10 or compliance with which may only be waived as provided in Section 14.13.

6.2.4 Disbanding. Subject to Section 14.3.2, the JDC shall continue to exist until the Parties mutually agree to disband the JDC. If the JDC is disbanded, the JDC shall be terminated and shall have no further rights or obligations under this Agreement, and thereafter

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any requirement of either Party to provide Information or other materials to the JDC shall be deemed a requirement to provide such Information or other materials to the other Party upon such other Party's reasonable request in order to facilitate the carrying out of such other Party's obligations under this Agreement.

- **6.2.5 Internal Decisions**. The Parties recognize that each Party possesses an internal structure (including various committees, teams and review boards) that will be involved in administering such Party's activities under this Agreement. Nothing contained in this Article 6 shall prevent a Party from making, in a manner consistent with the terms and conditions of this Agreement, routine day-to-day decisions relating to the conduct of those activities for which it has a performance obligation or other obligations hereunder.
- **6.2.6 Working Groups**. From time to time, the JDC may establish and delegate duties to subcommittees or directed teams (each, a "**Working Group**") on an "as-needed" basis to oversee particular projects or activities. Each such Working Group shall be constituted and shall operate as the JDC determines; *provided* that each Working Group shall have equal representation from each Party, unless otherwise mutually agreed. Working Groups may be established on an ad hoc basis for purposes of a specific project or on such other basis as the JDC may determine. Each Working Group and its activities shall be subject to the oversight, review and approval of, and shall report to, the JDC. In no event shall the authority of the Working Group exceed that specified for the JDC. All decisions of a Working Group shall be by consensus.
- **6.2.7 Expenses**. Each Party shall be responsible for all travel and related costs and expenses for its members and other representatives to attend meetings of, and otherwise participate on, the JDC or any Working Group.

ARTICLE 7 PAYMENTS AND RECORDS

- **7.1 Initial Payment.** No later than [**] following the Effective Date, Abbott shall pay Surmodics an amount equal to twenty-five million Dollars (\$25,000,000).
- **7.2 Milestones.** In partial consideration of the rights granted by Surmodics to Abbott hereunder and subject to the terms and conditions set forth in this Agreement, within [**] of the occurrence of each milestone specified in Section 1 of Schedule 7 (each, a "**Milestone**"), Abbott shall pay to Surmodics the corresponding amount specified for such Milestone, provided that such amount may be reduced by the operation of Section 3 of Schedule 7 (such amount, as it may be reduced, a "**Milestone Payment**"). Each Milestone Payment shall be payable pursuant to this Section 7.2 only upon the first achievement of the applicable Milestone and no amounts shall be due for subsequent or repeated achievements of such Milestone. Surmodics shall use Commercially Reasonable Efforts to achieve each Milestone. The maximum aggregate amount payable by Abbott pursuant to this Section 7.2 for the Product is the amount set forth in Section 2 of Schedule 7, provided that such amount may be reduced by the operation of Section 3 of Schedule 7. The milestone payments for each Option Product will be agreed by the Parties and set forth in the applicable Option Exercise Agreement.

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- **7.3 Net Profits Payment.** Subject to any applicable terms of this Agreement, for each Calendar Quarter, Abbott shall pay to Surmodics the amount of Net Profits Payment calculated in accordance with Section 4 of <u>Schedule 7</u> for such Calendar Quarter, if any.
- 7.4 Net Profit Share Payments and Reports. Abbott shall calculate all amounts payable to Surmodics pursuant to Section 7.3 (if any) at the end of each Calendar Quarter commencing with the Calendar Quarter in which the First Commercial Sale of the Product has occurred, which amounts shall be converted to Dollars, in accordance with Section 7.5, for purposes of Net Profits/Net Losses calculations hereunder. Any such payment shall be made within [**] after the end of each such Calendar Quarter. Each profit-sharing payment due to Surmodics shall be accompanied by a report setting forth the amount of the applicable Net Profits (or Net Losses for such Calendar Quarter, or for prior Calendar Quarters to the extent not yet offset against Net Profit Payments as described in Section 4 of Schedule 7) for each Product in each country in the Territory during the applicable Calendar Quarter (including such amounts expressed in local currency and as converted to Dollars) and a calculation in reasonably specific detail of the amount due to Surmodics hereunder based on the Net Profit Payment for such Calendar Quarter (including Net Losses for such Calendar Quarter, or for prior Calendar Quarters to the extent not yet offset against Net Profits as described in Section 4 of Schedule 7).
- 7.5 **Mode of Payment.** All payments to either Party under this Agreement shall be made by deposit of Dollars (or in the case of the Transfer Price, Euros) in the requisite amount to such bank account as the receiving Party may from time to time designate by notice to the paying Party. For any currency conversions required hereunder, the paying Party shall make the conversion using its or its Affiliate's standard conversion methodology consistent with Accounting Standards.
- 7.6 Offsets. Each Party shall have the right to offset any amount owed by the other Party to such Party under or in connection with this Agreement against any payments owed by such Party to such other Party under this Agreement. Such offsets shall be in addition to any other rights or remedies available under this Agreement or Applicable Law.

7.7 Taxes.

7.7.1 General. The initial payment hereunder, Milestone Payments, Transfer Price payments hereunder, and profit-sharing payments hereunder, and other amounts payable by Abbott to Surmodics hereunder (each, a "Payment"), shall be paid free and clear of any and all taxes, except for any withholding taxes required by Applicable Law. Except as provided in this Section 7.7, Surmodics shall be solely responsible for paying any and all taxes (other than withholding taxes required by Applicable Law to be deducted from Payments and remitted by Abbott) levied on account of, or measured in whole or in part by reference to, any Payments it receives. Abbott shall deduct or withhold from the Payments any taxes that it is required by Applicable Law to deduct or withhold. Notwithstanding the foregoing, if Surmodics is entitled under any applicable tax treaty to a reduction of rate of, or the elimination of, applicable withholding tax, it may deliver to Abbott or the appropriate governmental authority (with the assistance of Abbott to the extent that this is reasonably required and is expressly requested in writing) the prescribed forms necessary to reduce the applicable rate of withholding

or to relieve Abbott of its obligation to withhold such tax and Abbott shall apply the reduced rate of withholding or dispense with withholding, as the case may be; *provided* that Abbott has received evidence, in a form satisfactory to Abbott, of Surmodics' delivery of all applicable forms (and, if necessary, its receipt of appropriate governmental authorization) at least [**] prior to the time that the Payments are due. If, in accordance with the foregoing, Abbott withholds any amount, it shall pay to Surmodics the balance when due, make timely payment to the proper taxing authority of the withheld amount and send to Surmodics proof of such payment within [**] following such payment.

- **7.7.2 Value Added Tax.** Notwithstanding anything contained in Section 7.7.1, this Section 7.7.2 shall apply with respect to value added tax ("VAT"). All Payments are exclusive of VAT. If any VAT is chargeable in respect of any Payments, Abbott shall pay VAT at the applicable rate in respect of any such Payments following the receipt of a VAT invoice in the appropriate form issued by Surmodics in respect of those Payments, such VAT to be payable on the later of the due date of the Payments to which such VAT relates and [**] after the receipt by Abbott of the applicable invoice relating to such VAT.
- **7.8 Financial Records.** Abbott shall, and shall cause its Affiliates to, keep complete and accurate books and records pertaining to Net Profit Payments in sufficient detail to calculate all amounts payable hereunder and to verify compliance with its obligations under this Agreement. Such books and records shall be retained by Abbott and its Affiliates until the later of (i) [**] after the end of the period to which such books and records pertain, and (ii) the expiration of the applicable tax statute of limitations (or any extensions thereof), or for such longer period as may be required by Applicable Law.

7.9 Audits.

7.9.1 Procedures. At the request of Surmodics, Abbott shall, and shall cause its Affiliates to, permit an independent auditor designated by Surmodics and reasonably acceptable to Abbott, at reasonable times and upon reasonable notice, to audit the books and records maintained pursuant to Section 7.8 to ensure the accuracy of all reports and payments made hereunder. Such examinations may not (i) be conducted for any Calendar Quarter more than [**] after the end of such Calendar Quarter, (ii) be conducted more than [**] period (unless a previous audit during such [**] period revealed an underpayment (or with respect to any reimbursement, an overpayment) with respect to such period) or (iii) be repeated for any Calendar Quarter. Except as provided below, the cost of this audit shall be borne by Surmodics, unless the audit reveals a variance of more than [**] ([**]%) from the reported amounts, in which case Abbott shall bear the cost of the audit. Unless disputed pursuant to Section 7.9.2, if such audit concludes that (x) additional amounts were owed by Abbott, Abbott shall pay the additional amounts or (y) excess payments were made by Abbott, Surmodics shall reimburse such excess payments, in either case ((x) or (y)), within [**] after the date on which such audit is completed by Surmodics.

7.9.2 Audit Dispute. In the event of a dispute with respect to any audit under Section 7.9.1, the Parties shall work in good faith to resolve the dispute. If the Parties are unable to reach a mutually acceptable resolution of any such dispute within [**], the dispute shall be submitted for resolution to a certified public accounting firm jointly selected by each

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Party or to such other Person as the Parties shall mutually agree (the "**Auditor**"). The decision of the Auditor shall be final and the costs of such arbitration as well as the initial audit shall be borne between the Parties in such manner as the Auditor shall determine. Not later than [**] after such decision and in accordance with such decision, the audited Party shall pay the additional amounts or the auditing Party shall reimburse the excess payments, as applicable.

- **7.9.3 Confidentiality.** The receiving Party shall treat all information subject to review under this Section 7.9 in accordance with the confidentiality provisions of Article 10 and the Parties shall cause the Auditor to enter into a reasonably acceptable confidentiality agreement with the audited Party obligating such firm to retain all such financial information in confidence pursuant to such confidentiality agreement.
- **7.10 No Other Compensation.** Each Party hereby agrees that the terms of this Agreement fully define all consideration, compensation and benefits, monetary or otherwise, to be paid, granted or delivered by one Party to the other Party in connection with the transactions contemplated herein. Neither Party previously has paid or entered into any other commitment to pay, whether orally or in writing, any of the other Party's employees, directly or indirectly, any consideration, compensation or benefits, monetary or otherwise, in connection with the transaction contemplated herein.

ARTICLE 8 LICENSES AND OPTIONS

- **8.1 Licenses Granted to Abbott.** Subject to the terms and conditions of this Agreement (including Section 8.2), and subject to any applicable limitations on the (sub)licenses granted to Surmodics under the In-License Agreements, Surmodics (on behalf of itself and its Affiliates) hereby grants to Abbott:
- **8.1.1** an exclusive (except with respect to rights of Surmodics and its Affiliates as provided in Section 8.5.1) license (or sublicense), with the right to grant sublicenses in accordance with Section 8.2, under the Surmodics Product Patents, the Surmodics Know-How, and Surmodics' interests in the Joint Patents and the Joint Know-How, to Manufacture the Product in the Territory;
- **8.1.2** an exclusive (except with respect to rights of Surmodics and its Affiliates as provided in Section 8.5.1) license (or sublicense), with the right to grant sublicenses in accordance with Section 8.2, under the Surmodics Product Patents, the Surmodics Other Patents, the Surmodics Know-How, and Surmodics' interests in the Joint Patents and the Joint Know-How, to Develop the Product in the Territory;
- **8.1.3** an exclusive (except with respect to rights of Surmodics and its Affiliates as provided in Section 8.5.1) license (or sublicense), with the right to grant sublicenses in accordance with Section 8.2, under the Surmodics Product Patents, the Surmodics Other Patents, the Surmodics Know-How, and Surmodics' interests in the Joint Patents and the Joint Know-How, to Commercialize the Product in the Territory;
- **8.1.4** an exclusive (except with respect to rights of Surmodics and its Affiliates as provided in Section 8.5.1) license, with the right to grant sublicenses in accordance

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with Section 8.2, to use the Existing SurVeil Trademark and the Existing Serene Trademark to Develop the Product, to Manufacture the Product, and to Commercialize the Product, in each case, in the Territory (the goodwill for which shall inure to the sole benefit of Surmodics); and

- **8.1.5** an exclusive (except with respect to rights of Surmodics and its Affiliates as provided in Section 8.5.1) license and right of reference, with the right to grant sublicenses and further rights of reference in accordance with Section 8.2, under the Regulatory Approvals and any other Regulatory Documentation that Surmodics or its Affiliates may Control with respect to the Product to Develop the Product, to Manufacture the Product, and to Commercialize the Product, in each case, in the Territory.
- **8.2 Sublicenses.** Abbott shall have the right to grant sublicenses (or further rights of reference), through multiple tiers of sublicensees, under the licenses and rights of reference granted to Abbott in Section 8.1 to its Affiliates and, solely with respect to the services listed on <u>Schedule 2.1.1(ii)</u>, Third Party service providers (in the case of Manufacturing (sub)licenses or rights of reference) or to its Affiliates, contract research organizations, and applicable Distributors (in the case of Development or Commercialization (sub)licenses or rights of reference); *provided* that any such sublicenses or rights of reference shall be consistent with the terms and conditions of this Agreement.

8.3 Options Granted to Abbott.

- **8.3.1 Specification of Endpoints and Study Criteria for Option Products.** For each Option Product, Surmodics shall, at a reasonably appropriate time during the development of such Option Product, provide a draft of the safety and efficacy endpoints, and the criteria, for the first-in-human clinical study for such Option Product to Abbott. The Parties shall meet and discuss such endpoints and criteria as reasonably requested by either Party. Surmodics shall reasonably consider Abbott's comments, if any, and shall provide final safety and efficacy endpoints, and criteria, for the first-in-human clinical study for such Option Product to Abbott promptly following finalization thereof.
- **8.3.2 BTK Option Product.** Subject to the terms and conditions of this Agreement, Surmodics hereby grants to Abbott an exclusive option to obtain exclusive distribution rights for the BTK Option Product during the BTK Option Product Option Period as set forth in this Section 8.3.2, *provided*, *however*, that after the end of the first BTK Option Product Option Period there shall not be any subsequent BTK Option Products or BTK Option Product Option Periods.
- (i) On or after [**] prior to the expected expiration date of the BTK Option Product Option Period, Abbott may notify Surmodics that it desires Surmodics to enter into good faith negotiations regarding exclusive distribution rights for the BTK Option Product, in which case such negotiations shall commence and continue until the expiration date of the BTK Option Product Option Period or such earlier date on which Abbott provides written notice that it no longer desires to continue such negotiations (which Abbott may do in its sole and absolute discretion at any time). In the event that the Parties reach agreement regarding such exclusive distribution rights, the terms of such exclusive distribution rights shall be set forth in a separate written agreement (the "BTK Option Product Exercise Agreement"). Such terms

shall include (A) the payments to be made to Surmodics upon successful achievement of specified milestones in respect of the BTK Option Product, (B) a work plan for the continued development and clinical evaluation of the BTK Option Product, and (C) the transfer price for the BTK Option Product. In connection with the commencement of such negotiations, Surmodics would provide Abbott with a data package containing the results of any pre-clinical or clinical studies performed, in whole or in part, to date and such other information as is requested by Abbott, to the extent not previously disclosed to Abbott; *provided*, *however*, that the foregoing shall not require Surmodics to prepare, obtain or otherwise provide any information, data or materials other than those that are then in the Control of Surmodics or its Affiliates. During the BTK Option Product Option Period, Surmodics shall not (and shall cause its Affiliates, representatives and advisors not to) solicit, negotiate, engage in preliminary discussions or enter into any agreement with, any Third Party with respect to any distribution, commercial sublicense or other commercial transaction relating to the BTK Option Product, and shall not disclose to any Third Party for such purpose any non-public information regarding the BTK Option Product.

(ii) After the expiration of the BTK Option Product Option Period, if the Parties have not entered into an BTK Option Product Exercise Agreement, then Surmodics shall be free to enter into an agreement with a Third Party in respect of the BTK Option Product, *provided* that such agreement with such Third Party does not in any way conflict with any of Abbott's rights or Surmodics' obligations under this Agreement.

8.3.3 AVF Option Product. Subject to the terms and conditions of this Agreement, Surmodics hereby grants to Abbott an exclusive option to obtain exclusive distribution rights for the AVF Option Product during the AVF Option Product Option Period as set forth in this Section 8.3.3, *provided, however*, that after the end of the first AVF Option Product Option Period there shall not be any subsequent AVF Option Products or AVF Option Product Option Periods.

Option Period, Abbott may notify Surmodics that it desires Surmodics to enter into good faith negotiations regarding exclusive distribution rights for the AVF Option Product, in which case such negotiations shall commence and continue until the expiration date of the AVF Option Product Option Period or such earlier date on which Abbott provides written notice that it no longer desires to continue such negotiations (which Abbott may do in its sole and absolute discretion at any time). In the event that the Parties reach agreement regarding such exclusive distribution rights, the terms of such exclusive distribution rights shall be set forth in a separate written agreement (the "AVF Option Product Exercise Agreement"). Such terms shall include (A) the payments to be made to Surmodics upon successful achievement of specified milestones in respect of the AVF Option Product, (B) a work plan for the continued development and clinical evaluation of the AVF Option Product, and (C) the transfer price for the AVF Option Product. In connection with the commencement of such negotiations, Surmodics would provide Abbott with a data package containing the results of any pre-clinical or clinical studies performed, in whole or in part, to date and such other information as is requested by Abbott, to the extent not previously disclosed to Abbott *provided*, *however*, that the foregoing shall not require Surmodics to prepare, obtain or otherwise provide any information, data or materials other than those that are then in the Control of Surmodics or its Affiliates. During the

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AVF Option Product Option Period, Surmodics shall not (and shall cause its Affiliates, representatives and advisors not to) solicit, negotiate, engage in preliminary discussions or enter into any agreement with, any Third Party with respect to any distribution, commercial sublicense or other commercial transaction relating to the AVF Option Product, and shall not disclose to any Third Party for such purpose any non-public information regarding the AVF Option Product.

(ii) After the expiration of the AVF Option Product Option Period, if the Parties have not entered into an AVF Option Product Exercise Agreement, then Surmodics shall be free to enter into an agreement with a Third Party in respect of the AVF Option Product, *provided* that such agreement with such Third Party does not in any way conflict with any of Abbott's rights or Surmodics' obligations under this Agreement.

Other SFA Products. Subject to the terms and conditions of this Agreement, and without limiting Section 8.4, Surmodics hereby grants to Abbott an exclusive option to obtain exclusive distribution rights for [**] (an "Other SFA Product"), if any; provided, however, that "Other SFA Product" shall exclude [**]. If Surmodics files an application for Regulatory Approval for an Other SFA Product, Surmodics shall notify Abbott in writing (such notice, the "Other **SFA Product Notice**") reasonably promptly following such filing (or sooner, in Surmodics' reasonable discretion). Abbott shall have the right after receipt of the Other SFA Product Notice to notify Surmodics in writing that it desires Surmodics to enter into good faith negotiations regarding exclusive distribution rights for such Other SFA Product, in which case such negotiations shall then commence and continue for a period of [**], provided that Abbott may, in its sole and absolute discretion, end such negotiations by written notice at any time during such [**] period. In the event that the Parties reach agreement regarding such exclusive distribution rights, the terms of such exclusive distribution rights shall be set forth in a separate written agreement and shall include (A) the payments to be made to Surmodics upon successful achievement of specified milestones in respect of such Other SFA Product, (B) a work plan for the continued development and clinical evaluation of such Other SFA Product, and (C) the transfer price for such Other SFA Product. In connection with the commencement of such negotiations, Surmodics would provide Abbott with a data package containing the results of any pre-clinical or clinical studies performed, in whole or in part, to date and such other information as is requested by Abbott, to the extent not previously disclosed to Abbott, provided, however, that the foregoing shall not require Surmodics to prepare, obtain or otherwise provide any information, data or materials other than those that are then in the Control of Surmodics or its Affiliates. During the Term, Surmodics shall not (and shall cause its Affiliates, representatives and advisors not to) solicit, negotiate, engage in preliminary discussions or enter into any agreement with, any Third Party with respect to any distribution, commercial sublicense or other commercial transaction relating to any Other SFA Product, and shall not disclose to any Third Party for such purpose any non-public information regarding any Other SFA Product.

8.4 Exclusivity.

8.4.1 Other than as expressly set forth in this Agreement, or set forth on <u>Schedule 8.4.1</u>, each Party shall not, and shall cause its Affiliates not to, [**] (a "**Competing Product**"). Nothing in this Section 8.4.1 shall limit either Party's right to develop, manufacture or otherwise commercialize any of its technologies, components or products for uses other than in a Competing Product.

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8.4.2 If, during the Term, (i) there is a Change in Control of Abbott and immediately prior to the effectiveness of such Change in Control, the Third Party described in the definition of "Change in Control" or its Affiliate is then engaged, directly or indirectly, in any activities that, if carried out by Abbott, would be a breach of the exclusivity obligations set forth in Section 8.4.1, or (ii) as the result of an Acquisition of or by Abbott, Abbott directly or indirectly acquires rights to a Competing Product, then (a) (1) Abbott may, at its election, provide written notice to Surmodics within [**] after the effective date of such Change in Control or Acquisition of Abbott's intent to divest or discontinue commercialization of such Competing Product, and (2) if such notice was timely provided, Abbott shall then, within [**] after the effective date of such Change in Control or Acquisition, divest, or cause its Affiliates to divest, as applicable, all rights in the Competing Product, or discontinue commercialization of, and cause its Affiliates to discontinue commercialization of, such Competing Product; or (b) if such notice was not timely provided or such divestiture or discontinuance was not timely executed, then all appointments and licenses granted herein shall convert to non-exclusive appointments and licenses, and, without limiting the foregoing, the exclusivities and restrictions on Surmodics set forth in Article 3 and Sections 8.1 and 8.4.1 shall terminate.

8.4.3 If, during the Term, there is a Change in Control of Surmodics and immediately prior to the effectiveness of such Change in Control, the Third Party described in the definition of "Change in Control" or its Affiliate is then engaged, directly or indirectly, in any activities that, if carried out by Surmodics, would be a breach of the exclusivity obligations set forth in Section 8.4.1, then (a) (1) Surmodics may, at its election, provide written notice to Abbott within [**] after the effective date of such Change in Control of Surmodics' intent to divest or discontinue commercialization of such Competing Product; and (2) if such notice was timely provided, Surmodics shall then, within [**] after the effective date of such Change in Control, divest, or cause its Affiliates to divest, as applicable, all rights in the Competing Product, or discontinue commercialization of, and cause its Affiliates to discontinue commercialization of, such Competing Product; or (b) if such notice was not timely provided or such divestiture or discontinuance was not timely executed, then (1) Abbott shall have the rights set forth in Section 4.3 with respect to a [**], and (2) without limiting the foregoing, the exclusivities and restrictions set forth in Section 8.4.1 shall solely apply to Surmodics and its Affiliates, and all of its and their rights and assets, in each case as determined immediately prior to giving effect to such Change in Control.

8.4.4 Each Party acknowledges and agrees that (i) this Section 8.4 has been negotiated by the Parties, (ii) the geographical and time limitations on activities set forth in this Section 8.4 are reasonable, valid and necessary in light of the Parties' circumstances and necessary for the adequate protection of the business of the Product and (iii) neither Party would have entered into this Agreement without the protection afforded it by this Section 8.4. If, notwithstanding the foregoing, a court of competent jurisdiction determines that the restrictions set forth in this Section 8.4 are too broad or otherwise unreasonable under Applicable Law, including with respect to duration, geographic scope or space, the court is hereby requested and authorized by the Parties to revise this Section 8.4 to include the maximum restrictions allowable under Applicable Law.

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8.5 Retention of Rights.

- 8.5.1 Notwithstanding the exclusive licenses granted to Abbott pursuant to Section 8.1, Surmodics retains the right to practice under the Surmodics Product Patents, the Surmodics Other Patents, the Surmodics Know-How, Surmodics' interests in the Joint Patents and the Joint Know-How, and Regulatory Approvals and any other Regulatory Documentation that Surmodics or its Affiliates may Control to perform (and to sublicense Third Parties to perform) its obligations under this Agreement (including Development and the Manufacture and supply of the Product to Abbott, as applicable) and, subject to Section 8.4, in connection with its other products and businesses. Abbott shall not (and shall cause its Affiliates not to) use or exploit the Surmodics Product Patents, the Surmodics Other Patents, the Surmodics Know-How, or the Regulatory Documentation Controlled by Surmodics or its Affiliates for any purpose other than in accordance with the rights and licenses expressly granted hereunder. Except as expressly provided herein, Surmodics grants no other right or license, including any rights or licenses to the Surmodics Product Patents, the Surmodics Other Patents, the Surmodics Know-How, the Regulatory Documentation, or any other Patent or intellectual property rights.
- **8.5.2** Except as expressly provided herein, Abbott grants no right or license to any Patent, Regulatory Documentation or any other intellectual property rights.
- 8.6 Confirmatory Patent License. Surmodics shall, if requested to do so by Abbott, promptly enter into confirmatory license agreements in the form or substantially the form reasonably requested by Abbott for purposes of recording the licenses granted under this Agreement with such patent offices in the Territory as Abbott reasonably considers appropriate. Until the execution of any such confirmatory licenses, so far as may be legally possible, Surmodics and Abbott shall have the same rights in respect of the Surmodics Product Patents and the Surmodics Other Patents and be under the same obligations to each other in all respects as if the said confirmatory licenses had been executed.

8.7 In-License Agreements.

- **8.7.1 In General.** The Parties acknowledge that the licenses granted by Surmodics in Section 8.1 include sublicenses under the applicable In-License Agreements (unless and until Abbott provides notice that it does not desire such a sublicense). For each such sublicense, Abbott agrees to adhere to the terms and conditions of the applicable In-License Agreements as and to the extent such terms and conditions are applicable to Abbott. Surmodics shall be solely responsible for any payment obligations that may be triggered under any In-License Agreement as a result of the execution of this Agreement or the grant of any rights hereunder or as a result of activities in connection with this Agreement by or on behalf of either Party or its Affiliates, including any activities of its or their (sub)licensees, (sub)distributors, or subcontractors.
- **8.7.2 Proposed In-License Agreements.** If Surmodics or any of its Affiliates becomes a party to an agreement under which it or they obtain (sub)licenses or other rights with respect to any Information, Regulatory Documentation, material, Patents, or other intellectual property rights directed primarily to or reasonably related to the Product, (any such agreement described in this Section 8.7.2, a "**Proposed In-License Agreement**"), then

Surmodics shall notify Abbott and shall provide Abbott with a copy of such agreement, *provided*, *however*, that Surmodics shall have the right to redact any confidential terms that do not impose obligations on Abbott or restrict or affect Abbott's rights with respect to the Product from the copy provided to Abbott. Surmodics shall use commercially reasonable efforts to obtain the rights under any Proposed In-License Agreement for Abbott during the Term, to the extent related to Exploitation of the Product. In the event that Surmodics would be required by the provisions of a Proposed In-License Agreement to impose any obligations on Abbott or its Affiliates beyond those set forth in this Agreement, then Surmodics shall be required to obtain Abbott's prior written consent to such provisions as applied to the Product prior to executing such Proposed In-License Agreement. Without limiting the foregoing, Abbott may, in its sole discretion in respect of any Proposed In-License Agreement, notify Surmodics regarding whether such Proposed In-License Agreement will be deemed to be an In-License Agreement; if Abbott so notifies Surmodics, then such Proposed In-License Agreement shall be deemed to be an In-License Agreement for all purposes hereunder, and the Parties shall amend Schedule 11.2.3 to include such Proposed In-License Agreement on such Schedule.

8.8 No Impairment. Surmodics shall not, and shall cause its Affiliates not to, grant to any Third Party any (sub)licenses or other rights that conflict with any of the (sub)licenses or other rights granted to Abbott under this Article 8.

ARTICLE 9 INTELLECTUAL PROPERTY

9.1 Ownership of Intellectual Property.

9.1.1 Ownership of Technology. Subject to Section 9.1.2, [**] (such Information and inventions, "Agreement Inventions"), and (ii) other Information, inventions, Patents, and other intellectual property rights that are owned or otherwise Controlled (other than pursuant to the license grants set forth in Section 8.1) by such Party or its Affiliates prior to the Effective Date of this Agreement, or on or after the Effective Date and which do not arise pursuant to this Agreement as a result of Party Development Activities. In the event that Abbott determines that it or one of its Affiliates has made an Agreement Invention, Abbott shall promptly notify Surmodics. In the event that Surmodics believes that Abbott or one of Abbott's Affiliates has made an Agreement Invention, and Abbott has not yet given notice thereof to Surmodics, Surmodics shall promptly notify Abbott, and the Parties shall meet to discuss. [**]. Except as set forth herein, Surmodics shall have no right, title, or interest whatsoever in or to any Information, inventions, Patents, or other intellectual property rights that are owned or Controlled (other than pursuant to the license grants set forth in Section 8.1) by Abbott or its Affiliates.

9.1.2 Ownership of Joint Patents and Joint Know-How. As between the Parties, the Parties shall each own an equal, undivided interest in any and all (i) [**] (the "**Joint Know-How**"), and (ii) [**] (the "**Joint Patents**") and other intellectual property rights with respect to the Information and inventions described in clause (i) or clause (ii). Joint Patents and Joint Know-How shall be subject to the licenses and other rights granted under Section 8.1, [**].

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9.1.3 United States Law. The determination of whether Information and inventions are conceived, discovered, developed, or otherwise made jointly by the Parties for the purpose of allocating proprietary rights (including Patent, copyright or other intellectual property rights) therein, shall, for purposes of this Agreement, be made in accordance with Applicable Law in the United States as such law exists as of the Effective Date irrespective of where such conception, discovery, development or making occurs.

9.1.4 Assignment Obligation. Each Party shall cause all Persons who perform Development or Manufacturing activities on its behalf under this Agreement to be under an obligation to assign (or, if such Party is unable to cause such Person to agree to such assignment obligation despite using reasonable efforts to negotiate such assignment obligation, provide a license, with a right to sublicense through multiple tiers, to Exploit the Product under) their rights in any Information and inventions resulting therefrom to such Party, and shall use commercially reasonable efforts to cause such Persons to assign such rights, in each case except where Applicable Law requires otherwise and except in the case of governmental, not-for-profit and public institutions which have standard policies against such an assignment (in which case, such Party shall obtain a suitable license under such Information and inventions with a right to sublicense through multiple tiers for each applicable Product).

9.2 Maintenance and Prosecution.

9.2.1 Primary Control. [**] shall (i) have the first right, but not the obligation, to Prosecute the Surmodics Product Patents and the Surmodics Other Patents worldwide using internal or external counsel reasonably acceptable to [**] (with [**] acceptance not to be unreasonably withheld, conditioned, or delayed), (ii) have the first right, but not the obligation, to Prosecute worldwide the Existing SurVeil Trademark using internal or external counsel reasonably acceptable to [**] (with [**] acceptance not to be unreasonably withheld, conditioned, or delayed), and (iii) have the sole right, but not the obligation, to Prosecute the Existing Serene Trademark using counsel selected by it in its sole discretion, in each case for clauses (i) - (iii) at [**] sole cost and expense. [**] shall (A) have the first right, but not the obligation, to Prosecute the Joint Patents worldwide using outside counsel reasonably acceptable to [**] (with [**] acceptance not to be unreasonably withheld, conditioned, or delayed), and (B) have the sole right, but not the obligation, to Prosecute all Product Trademarks worldwide other than the Existing SurVeil Trademark and the Existing Serene Trademark using counsel selected by it in its sole discretion, in each case for clauses (A) - (B) at [**] sole cost and expense.

9.2.2 Abandonment. In the event that (i) [**] decides to abandon a Surmodics Product Patent, Surmodics Other Patent, or the Existing SurVeil Trademark in a country or other jurisdiction in the Territory, or (ii) [**] decides to abandon a Joint Patent in a country or other jurisdiction in the Territory, the abandoning Party shall provide reasonable prior written notice to the other Party of such intention. Such other Party shall have the right to request assignment of the applicable Patent or Trademark by providing notice to the abandoning Party within [**] after receipt of the notice to abandon. Upon receipt of the notice requesting assignment, the abandoning Party shall take all reasonable steps to assign the applicable Patent or Trademark to the other Party before abandonment of the applicable Patent or Trademark, and shall provide applicable correspondence with the relevant patent office or trademark office and other documents reasonably related to the Prosecution of such Patent or Trademark, and

reasonable access to the employees of the abandoning Party, to assist in transition of prosecution and maintenance of the applicable Patent or Trademark. If a Party assumes control of the Prosecution of a Surmodics Product Patent, Surmodics Other Patent, or Existing SurVeil Trademark following abandonment of the applicable Patent or Trademark by the abandoning Party, then the Party assuming control, on behalf of itself and its Affiliates, shall grant to the abandoning Party and its Affiliates a non-exclusive, perpetual, royalty-free, irrevocable license under such Patent or Trademark in the country or other jurisdiction that was the subject of the applicable abandonment, *provided*, that rights to the Existing SurVeil Trademark shall continue to be subject to the limitations described in Section 3.6.3.

9.2.3 Information Regarding Patent Prosecution. The Parties shall meet not less than [**] during the Term to discuss strategies for Prosecuting the Surmodics Product Patents, the Surmodics Other Patents, and the Joint Patents.

shall, and shall cause its Affiliates to, assist and cooperate with the Controlling Party, as the Controlling Party may reasonably request from time to time, in the Prosecution of the Joint Patents under this Agreement, including that the Non-Controlling Party shall, and shall cause its Affiliates to, (i) offer its comments, if any, at least [**] in advance of the deadline, if any, for the applicable action to be taken by the Controlling Party to which such comments relate, (ii) provide access to relevant documents and other evidence and make its employees available at reasonable business hours (provided that the Controlling Party shall reimburse the Non-Controlling Party for its reasonable and verifiable out-of-pocket costs and expenses incurred in connection therewith) and (iii) as applicable, provide the Controlling Party, upon its request, with copies of any patentability reports generated by the Non-Controlling Party's counsel with respect to the Joint Patents, including relevant Third Party patents and patent applications (provided that neither Party shall be required to provide legally privileged information with respect to such intellectual property unless and until procedures reasonably acceptable to such Party are in place to protect such privilege).

shall have the first right, but not the obligation, to make decisions regarding, and to apply for, patent term extensions specific to the Product in the Territory, including the United States with respect to extensions pursuant to 35 U.S.C. §156 et. seq. and in other jurisdictions pursuant to supplementary protection certificates, and in all jurisdictions with respect to any other extensions that are now or become available in the future, wherever applicable, for the Surmodics Product Patents, the Surmodics Other Patents, and any Joint Patents, in each case including whether or not to do so. [**] may use counsel selected by [**] in its sole discretion for such actions, and they shall be at [**] sole expense. If [**] fails to apply for and prosecute applications for patent term extensions specific to the Product in any country or other jurisdiction in the Territory, or otherwise fails to respond to inquiries from [**] as to whether [**] has applied for and prosecuted any such application, in each case no later than [**] prior to the next deadline for any action that may be taken with respect thereto, then [**] shall thereupon have the option, in its sole discretion and exercisable upon written notice thereof to [**], to assume the control thereof (including whether or not to do so) using counsel selected by [**] in its sole discretion and at [**] sole cost and expense.

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9.3 Enforcement.

9.3.1 Notification. Each Party shall promptly notify the other Party in writing of any alleged or threatened infringement of (i) the Surmodics Product Patents by a Third Party's Exploitation in the Territory of a drug-coated balloon product in the Initial Indication or the [**], (ii) the Surmodics Other Patents by a Third Party's Exploitation in the Territory of a drug-coated balloon product in the Initial Indication or the [**], except with respect to any such alleged or threatened infringement arising solely from (a) a lubricious coating on the catheter shaft of such product or (b) a lubricious coating on any such product for which such lubricious coating is the only coating, (iii) the Joint Patents, or (iv) the Product Trademarks by a Third Party, in each case of which such Party becomes aware (including alleged or threatened infringement based on the development, commercialization, or an application to market a product in the Territory).

9.3.2 **Primary Control**. [**] shall have the first right, but not the obligation to prosecute and control any claim, suit, proceeding, or action against a Third Party (an "**Action**") with respect to alleged or threatened infringement of (i) the Surmodics Product Patents by a Third Party's Exploitation in the Territory of a drug-coated balloon product in the Initial Indication or the [**], (ii) the Surmodics Other Patents by a Third Party's Exploitation in the Territory of a drug-coated balloon product in the Initial Indication or the [**], except with respect to any such alleged or threatened infringement arising solely from (a) a lubricious coating on the catheter shaft or (b) a lubricious coating on any such product for which such lubricious coating is the only coating, or (iii) the Joint Patents, in each case for clauses (i) – (iii) using counsel selected by [**] in its sole discretion and at [**] sole expense. [**] shall have the sole right, but not the obligation, to prosecute and control any Action with respect to alleged or threatened infringement by a Third Party of any Product Trademarks other than the Existing Serene Trademark, using counsel selected by [**] in its sole discretion and at [**] sole expense. [**] shall have the sole right, but not the obligation, to control any Action in connection with alleged or threatened infringement by a Third Party of the Existing Serene Trademark, using counsel selected by [**] in its sole discretion and at [**] sole expense.

9.3.3 Secondary Control. With respect to the Actions described in Section 9.3.2, if the Party that has the first right to prosecute and control any such Action does not take commercially reasonable steps toward such Action (including by engaging counsel or communicating with the applicable Third Party) by the earlier of (i) [**] following the notice provided pursuant to Section 9.3.1 of such alleged or threatened infringement, or (ii) [**] before the time limit, if any, set forth in Applicable Laws for filing of such actions *provided* such [**] period date occurs after the notice provided pursuant to Section 9.3.1 of such alleged or threatened infringement, then the Secondary Party may prosecute and control such Action. In the event a Secondary Party assumes control of an Action under this Section 9.3.3, such Party shall do so at its sole cost and expense (but subject to Sections 9.7, 9.8, and 9.9), using counsel selected by it at its sole discretion. This Section 9.3.3 shall not apply as to any Action as to which a Party has sole rights under Section 9.3.2.

9.4 Defense and Third Party Rights.

9.4.1 Notification. Each Party shall promptly notify the other Party in writing (i) of any Invalidity Claim, or (ii) if the Exploitation of the Product in the Territory pursuant to this Agreement results in, or is reasonably expected to result in, any Third Party Infringement Claim of which it becomes aware.

9.4.2 Primary Control. [**] shall have the first right, but not the obligation, to defend and control the defense of (i) Invalidity Claims, (ii) Third Party Patent Infringement Claims, and (iii) Third Party Trademark Infringement Claims (except those for the Existing SurVeil Trademark or the Existing Serene Trademark), in each case using counsel selected by [**] in its sole discretion and at [**] sole expense. [**] shall have the sole right, but not the obligation, to defend and control the defense of Third Party Trademark Infringement Claims for the Existing SurVeil Trademark, using counsel selected by [**] in its sole discretion and at [**] sole expense. [**] shall have the sole right, but not the obligation, to defend and control the defense of any Third Party Trademark Infringement Claim for the Existing Serene Trademark, using counsel selected by [**] in its sole discretion and at [**] sole expense. A Party's rights under this Section 9.4.2 shall include having the right to negotiate and obtain a license or other rights from a Third Party to such Third Party Rights as necessary or desirable for [**] or its [**] (sub)licensees, (sub)distributors, subcontractors, or customers to Exploit the Product.

9.4.3 Secondary Control. With respect to Actions and license rights described in Section 9.4.2, if [**] or its designee gives written notice to [**], within a reasonable amount of time after notice of such Action, that [**] elects not to defend, or otherwise fails to initiate and maintain the defense of such Action within such time periods so that [**] is not prejudiced by any delays, [**] may conduct and control the defense of such Action including having the right to negotiate and obtain a license or other rights from a Third Party to such Third Party Rights as necessary or desirable for [**] or its [**] (sub)licensees, (sub)distributors, subcontractors, or customers to Exploit the Product, such defense to be at the sole cost and expense of [**] (but subject to Sections 9.7, 9.8, and 9.9), using counsel selected by it at its sole discretion. A Party's rights under this Section 9.4.3 shall include having the right to negotiate and obtain a license or other rights from a Third Party to such Third Party Rights as necessary or desirable for [**] or its [**] (sub)licensees, (sub)distributors, subcontractors, or customers to Exploit the Product *provided*, that nothing in this Section 9.4.3 shall apply as to any Action or license rights as to which a Party has sole rights under Section 9.4.2.

9.5 Information. The Controlling Party for an Action described in Section 9.2.5, Section 9.3 or Section 9.4 shall keep the Non-Controlling Party reasonably informed with regard to such Action, including by providing the Non-Controlling Party with a copy of material communications to and from any adverse party, court or tribunal with respect to such Action, and by providing the Non-Controlling Party drafts of any material filings or responses sufficiently in advance of submitting such filings or responses so as to allow for a reasonable opportunity for review and comment thereon. The Controlling Party shall consider in good faith the comments, requests and suggestions of the Non-Controlling Party with respect to such drafts and with respect to strategies for prosecuting any such Action.

- 9.6 **Cooperation and Participation.** With regard to Actions of the type described in Section 9.2.5, Section 9.3 and Section 9.4, the Non-Controlling Party shall, and shall cause its Affiliates to, assist and cooperate with the Controlling Party, as the Controlling Party may reasonably request from time to time, in the prosecution of such Action, including that the Non-Controlling Party shall, and shall cause its Affiliates to, (i) offer its comments, if any, at least [**] in advance of the deadline, if any, for the applicable action to be taken by the Controlling Party to which such comments relate, (ii) provide access to relevant documents and other evidence and make its employees available at reasonable business hours (provided that the Controlling Party shall reimburse the Non-Controlling Party for its reasonable and verifiable out-of-pocket costs and expenses incurred in connection therewith) and (iii) furnish a power of attorney solely for the purpose of joining in, or be named as a necessary party to an Action; provided that neither Party shall be required to provide legally privileged information with respect to such Action unless and until procedures reasonably acceptable to such Party are in place to protect such privilege; and *provided*, *further*, that, except with respect to the Joint Patents, the Controlling Party shall reimburse the Non-Controlling Party for its reasonable costs and expenses incurred and accrued in connection therewith). The Non-Controlling Party in any Action described in Section 9.3 or Section 9.4 shall have the right to join as a party to such Action and participate with its own counsel at its own expense; *provided* that the Controlling Party shall retain control of such Action. With respect to any negotiation to obtain a license or other right to a Third Party Right, the Controlling Party in such negotiations shall consult with the Non-Controlling Party and the Non-Controlling Party shall reasonably cooperate with the Controlling Party.
- **9.7 Settlement.** With respect to (i) Actions of the type described in Section 9.3 and Section 9.4, and (ii) any negotiation of a license or other right to a Third Party Right, the Controlling Party shall have the right to settle such claim or finalize and execute such agreement for a license or other right; *provided* that neither Party shall have the right to settle any such Action if such settlement (A) [**], (B) [**], (D) [**], (E) [**], or (F) [**], in each case ((A)-(F)), without the prior express written consent of the Non-Controlling Party (which consent shall not be unreasonably withheld, conditioned or delayed).
- **9.8 Recovery.** Except as otherwise agreed by the Parties in connection with a cost sharing arrangement, any recovery realized as a result of an Action of the type described in Section 9.3 or Section 9.4, whether by way of settlement or otherwise shall be first allocated to reimburse the Parties for their reasonable costs and expenses incurred and accrued in making such recovery (which amounts shall be allocated pro rata based on the reasonable costs and expenses incurred and accrued by each Party if insufficient to cover the totality of such expenses). Any remainder after such reimbursement is made shall be divided by the Parties as follows: [**].
- **9.9 Liabilities.** All losses, damages (including, royalties, up-front payments, milestones and other consideration paid or otherwise assessed), liabilities, costs and expenses (including reasonable attorneys' fees and expenses) of the Controlling and Non-Controlling Parties (and their respective Affiliates, and the respective directors, officers, employees and agents) resulting from an Action of the type described in Section 9.3 or Section 9.4 shall constitute the "**Third Party Infringement Claim Losses**". All payments (including, royalties, up-front payments, milestones and other consideration paid or otherwise assessed), costs and

expenses (including reasonable attorneys' fees and expenses) of the Party or Affiliate of a Party which executes an agreement for a license or other right to a Third Party Right shall constitute the "**Third Party Right Payments**". [**] The Parties shall reimburse each other, on a monthly basis or such other timeframe as may be mutually agreed, as necessary to effect the foregoing allocation. Without limiting the generality of Section 7.6, Abbott may offset Third Party Infringement Claim Losses and the Third Party Right Payments paid or incurred by Abbott for which Surmodics is responsible.

- **9.10 Inventor's Remuneration.** As between the Parties, each Party shall be solely responsible for any remuneration that may be due under any applicable inventor remuneration laws to any inventors who are employees of such Party or its Affiliates or are otherwise conducting activities on behalf of such Party or its Affiliates. The Parties agree that activities by or on behalf of Surmodics under this Agreement shall not constitute activities on behalf of Abbott or its Affiliates.
- 9.11 Patent Marking. For Product Manufactured by Surmodics hereunder, Surmodics shall, for each Surmodics Product Patent that covers the Product, place (or cause to be placed) all appropriate patent notices or markings on the Product itself or on such other media as are considered reasonable in Surmodics' reasonable discretion. In the event that Abbott Manufactures any Product hereunder, Abbott shall, for each Surmodics Product Patent that covers the Product and that is notified to Abbott as covering the Product by Surmodics, place (or cause to be placed) all appropriate patent notices or markings on the Product itself or on such other media as are considered reasonable in Abbott's reasonable discretion. Each Party shall ensure that all patent notices or markings placed (or caused to be placed) by it pursuant to this Section 9.11 are in conformance with such Party's customary procedures and policies for similar products and with Applicable Law (including patent law) of the country of manufacture, use or sale of the applicable Product.

ARTICLE 10 CONFIDENTIALITY

termination or expiration of this Agreement, each Party shall and shall cause its Affiliates and its and their respective officers, directors, employees, (sub)contractors, (sub)distributors and agents to, keep confidential and not publish or otherwise disclose to a Third Party and not use, directly or indirectly, for any purpose, any Confidential Information furnished or otherwise made known to it, directly or indirectly, by the other Party, except to the extent such disclosure or use is expressly permitted by the terms of this Agreement. "Confidential Information" means any technical, business or other information provided by or on behalf of one Party to the other Party in connection with this Agreement, whether prior to, on or after the Effective Date, including Information relating to the Product (including the Regulatory Documentation), any Development or Commercialization of the Product, any know-how with respect thereto, or the scientific, regulatory or business affairs or other activities of either Party. Notwithstanding the foregoing, during the Term, any Information relating to the Product or the Exploitation thereof that is owned or Controlled by Surmodics or any of its Affiliates and that is exclusively licensed to Abbott pursuant to Section 8.1 shall be deemed to be the Confidential Information of both Parties (and both Parties shall be deemed to be the receiving Party and the

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disclosing Party with respect thereto); *provided*, that (i) Surmodics shall have the right, to the extent consistent with Section 8.4.1, to use and disclose (subject to customary confidentiality obligations) such Confidential Information relating to its non-exclusive reagents and other products and technologies consistent with its customary practices, and (ii) Abbott shall have the right to use and disclose the such Confidential Information in connection with Abbott's reasonable exercise and performance, consistent with Abbott's practices for its own products, of its rights and obligations hereunder. The confidentiality and non-use obligations under this Section 10.1 with respect to any Confidential Information shall not apply to any information that:

- **10.1.1** is or hereafter becomes part of the public domain by public use, publication, general knowledge or the like through no breach of this Agreement by the receiving Party;
- **10.1.2** can be demonstrated by documentation or other competent proof to have been in the receiving Party's possession prior to disclosure by the disclosing Party without any obligation of confidentiality with respect to such information;
- **10.1.3** is subsequently received by the receiving Party from a Third Party who is not bound by any obligation of confidentiality with respect to such information;
- **10.1.4** has been published by a Third Party or otherwise enters the public domain through no fault of the receiving Party in breach of this Agreement; or
- **10.1.5** can be demonstrated by documentation or other competent evidence to have been independently developed by or for the receiving Party or its Affiliates outside of the receiving Party's or its Affiliates' activities relating to the Product hereunder without reference to the disclosing Party's Confidential Information.

Specific aspects or details of Confidential Information shall not be deemed to be within the public domain or in the possession of the receiving Party merely because the Confidential Information is embraced by more general information in the public domain or in the possession of the receiving Party. Further, any combination of Confidential Information shall not be considered in the public domain or in the possession of the receiving Party merely because individual elements of such Confidential Information are in the public domain or in the possession of the receiving Party unless the combination and its principles are in the public domain or in the possession of the receiving Party.

- **10.2 Permitted Disclosures.** Each Party may disclose Confidential Information of the other Party solely to the extent that such disclosure is:
- **10.2.1** made in response to a valid order of a court of competent jurisdiction or other supranational, federal, national, regional, state, provincial and local governmental or regulatory body of competent jurisdiction or, if in the reasonable opinion of the receiving Party's legal counsel, such disclosure is otherwise required by law, including by reason of filing with securities regulators; *provided*, *however*, that the receiving Party shall first have given notice to the disclosing Party and given the disclosing Party a reasonable opportunity to quash such order or to obtain a protective order or to seek, or request that the receiving Party seek, confidential treatment requiring that the Confidential Information and documents that are

the subject of such order or required to be disclosed be held in confidence by such court or governmental or regulatory body or, if disclosed, be used only for the purposes for which the order was issued or such disclosure was required by law (including in the case of submission of the terms of this Agreement to the SEC or other securities regulators, at least [**] in order to request redactions of the terms of this Agreement); and *provided*, *further*, that the Confidential Information disclosed in response to such court or governmental order or as required by law shall be limited to the information that is legally required to be disclosed in response to such court or governmental order or by such law;

- **10.2.2** made by or on behalf of the receiving Party to a patent authority as may be reasonably necessary or useful for purposes of obtaining or enforcing a Patent; *provided*, *however*, that reasonable measures shall be taken to assure confidential treatment of such information, to the extent such protection is available;
- **10.2.3** made by or on behalf of the receiving Party to a Regulatory Authority as may be reasonably necessary or useful for purposes of obtaining or maintaining a Regulatory Approval; *provided*, *however*, that reasonable measures shall be taken to assure confidential treatment of such information, to the extent such protection is available; or
- **10.2.4** made by or on behalf of the receiving Party to potential or actual investors or acquirers as may be necessary in connection with their evaluation of such potential or actual investment or acquisition; *provided*, *however*, that such persons shall be subject to obligations of confidentiality and non-use with respect to such Confidential Information substantially similar to the obligations of confidentiality and non-use of the receiving Party pursuant to this Article 10 (with a duration of confidentiality and non-use obligations as appropriate that is no less than [**] from the date of disclosure).
- 10.3 Use of Name. Except as expressly provided herein, neither Party shall mention or otherwise use the name, logo or Trademark of the other Party or any of its Affiliates or any of its or their (sub)licensees (or any abbreviation or adaptation thereof) in any publication, press release, marketing and promotional material or other form of publicity without the prior written approval of such other Party in each instance. The restrictions imposed by this Section 10.3 shall not prohibit (i) Abbott from making any disclosure identifying Surmodics to the extent required in connection with its exercise of its rights or obligations under this Agreement, (ii) either Party from making any disclosure identifying the other Party consistent with prior permitted public disclosures or such other Party's prior written approval, or (iii) either Party from making any disclosure identifying the other Party that is required by Applicable Law or the rules of a stock exchange on which the securities of the disclosing Party are listed (or to which an application for listing has been submitted).
- **10.4 Public Announcements.** The Parties have agreed upon the content of one (1) or more press releases which shall be issued substantially in the form(s) attached hereto as <u>Schedule 10.4</u>, the release of which the Parties shall coordinate in order to accomplish such release promptly upon execution of this Agreement. Neither Party shall issue any other public announcement, press release or other public disclosure regarding this Agreement, its terms, or its subject matter without the other Party's prior written consent, except for any such disclosure that is, in the opinion of the disclosing Party's counsel, required by Applicable Law or the rules of a

stock exchange on which the securities of the disclosing Party are listed (or to which an application for listing has been submitted). In the event a Party is, in the opinion of its counsel, required by Applicable Law or the rules of a stock exchange on which its securities are listed (or to which an application for listing has been submitted) to make such a public disclosure, such Party shall submit the proposed disclosure in writing to the other Party as far in advance as reasonably practicable (and in no event less than [**] prior to the anticipated date of disclosure) so as to provide a reasonable opportunity to comment thereon. Neither Party shall be required to seek the permission of the other Party to repeat any information regarding the terms of this Agreement or any amendment hereto that has already been publicly disclosed by such Party or by the other Party, in accordance with this Section 10.4, provided that such information remains accurate as of such time and provided the frequency and form of such disclosure are reasonable.

- 10.5 Publications. The Parties recognize the desirability of publishing and publicly disclosing the results of and information regarding, activities under this Agreement. Accordingly, Abbott shall be free to publicly disclose the results of and information regarding, activities under this Agreement, subject to prior review and consent by Surmodics of any disclosure of Surmodics' Confidential Information. Accordingly, prior to publishing or disclosing any Surmodics Confidential Information, Abbott shall provide Surmodics with drafts of proposed abstracts, manuscripts or summaries of presentations that cover such Confidential Information. Surmodics shall respond promptly through its designated representative and in any event no later than [**] after receipt of such proposed publication or presentation. Surmodics shall not, and shall cause each of its Affiliates and its and their licensees not to, make any publications or public disclosures of any Confidential Information of Abbott without Abbott's prior written consent.
- Agreement for any reason, upon the written request of a Party, the non-requesting Party shall either, at the requesting Party's election: (i) promptly destroy all copies of such Confidential Information in the possession or control of the non-requesting Party and confirm such destruction in writing to the requesting Party; or (ii) promptly deliver to the requesting Party, at the non-requesting Party's sole cost and expense, all copies of such Confidential Information in the possession or control of the non-requesting Party. Notwithstanding the foregoing, the non-requesting Party shall be permitted to retain such Confidential Information (x) to the extent necessary or useful for purposes of performing any continuing obligations or exercising any ongoing rights hereunder and, in any event, a single copy of such Confidential Information for archival purposes and (y) any computer records or files containing such Confidential Information that have been created solely by such non-requesting Party's automatic archiving and back-up procedures, to the extent created and retained in a manner consistent with such non-requesting Party's standard archiving and back-up procedures, but not for any other uses or purposes. All Confidential Information shall continue to be subject to the terms of this Agreement for the period set forth in Section 10.1.
- **10.7 Privileged Communications.** In furtherance of this Agreement, it is expected that the Parties will, from time to time, disclose to one another privileged communications with counsel, including opinions, memoranda, letters and other written, electronic and verbal communications. Such disclosures are made with the understanding that they shall remain confidential in accordance with this Article 10, that they will not be deemed to

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waive any applicable attorney-client or attorney work product or other privilege and that they are made in connection with the shared community of legal interests existing between Abbott and Surmodics, including the community of legal interests in avoiding infringement of any valid, enforceable patents of Third Parties and maintaining the validity of the Surmodics Product Patents, Surmodics Other Patents, and Joint Patents. In the event of any litigation (or potential litigation) with a Third Party related to this Agreement or the subject matter hereof, the Parties shall, upon either Party's request, enter into a reasonable and customary joint defense agreement. In any event, each Party shall consult in a timely manner with the other Party before engaging in any conduct (e.g., producing information or documents) in connection with litigation or other proceedings that could conceivably implicate privileges maintained by the other Party. Notwithstanding anything contained in this Section 10.7, nothing in this Agreement shall prejudice a Party's ability to take discovery of the other Party in disputes between them relating to this Agreement and no information otherwise admissible or discoverable by a Party shall become inadmissible or immune from discovery solely due to this Section 10.7.

ARTICLE 11 REPRESENTATIONS AND WARRANTIES

- **11.1 Mutual Representations, Warranties, and Covenants.** Surmodics and Abbott each represents and warrants to the other, as of the Effective Date, and covenants, that:
- **11.1.1** It is a corporation duly organized, validly existing and in good standing under the laws of the jurisdiction of its organization and has all requisite power and authority, corporate or otherwise, to execute, deliver and perform this Agreement;
- 11.1.2 The execution and delivery of this Agreement and the performance by it of the transactions contemplated hereby have been duly authorized by all necessary corporate action and do not violate: (i) such Party's charter documents, bylaws or other organizational documents; (ii) in any material respect, any agreement, instrument or contractual obligation to which such Party is bound; (iii) any requirement of any Applicable Law; or (iv) any order, writ, judgment, injunction, decree, determination or award of any court or governmental agency presently in effect applicable to such Party;
- **11.1.3** This Agreement is a legal, valid and binding obligation of such Party enforceable against it in accordance with its terms and conditions, subject to the effects of bankruptcy, insolvency or other laws of general application affecting the enforcement of creditor rights, judicial principles affecting the availability of specific performance and general principles of equity (whether enforceability is considered a proceeding at law or equity);
- **11.1.4** It is not under any obligation, contractual or otherwise, to any Person that conflicts with or is inconsistent in any material respect with the terms of this Agreement or that would impede the diligent and complete fulfillment of its obligations hereunder; and
- **11.1.5** Neither it nor any of its Affiliates has been debarred or is subject to debarment and neither it nor any of its Affiliates will use in any capacity, in connection with the services to be performed under this Agreement, any Person who has been debarred pursuant to

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Section 306 of the FFDCA or who is the subject of a conviction described in such section. It agrees to inform the other Party in writing promptly if it or any such Person who is performing services hereunder is debarred or is the subject of a conviction described in Section 306 or if any action, suit, claim, investigation or legal or administrative proceeding is pending or, to the best of its or its Affiliates' knowledge, is threatened, relating to the debarment or conviction of it or any such Person performing services hereunder.

- **11.2 Additional Representations, Warranties, and Covenants of Surmodics.** Surmodics further represents and warrants to Abbott, as of the Effective Date, and covenants, as follows:
- **11.2.1** Surmodics is entitled to grant the licenses and other rights specified herein and during the Term;
- **11.2.2** All Surmodics Product Patents existing as of the Effective Date (the "**Existing Product Patents**") are listed on <u>Schedule 11.2.2</u>, and all Existing Product Patents, and the Existing SurVeil Trademark and Existing Serene Trademark, are solely and exclusively owned or exclusively licensed by Surmodics, free of any encumbrance, lien or claim of ownership by any Third Party (other than licenses to Third Parties that do not conflict with or diminish the licenses granted hereunder). [**];
- 11.2.3 True, complete and correct (as of the Effective Date) copies of (i) the file wrappers and other documents and materials relating to the prosecution, defense, maintenance, validity and enforceability of the Existing Product Patents, other than those that are publicly available as of the Effective Date, and (ii) all license or similar agreements pursuant to which Surmodics obtains rights regarding any intellectual property rights licensed to Abbott hereunder, including the Existing Product Patents, as amended to the date hereof (the "In-License Agreements"), in each case ((i) and (ii)) have been provided to Abbott at least [**] prior to the Effective Date. All of the In-License Agreements are listed on Schedule 11.2.3 and are in good standing. Surmodics will not (x) commit any acts or permit the occurrence of any omissions that would cause material breach or termination of any In-License Agreement or (y) amend or otherwise modify or permit to be amended or modified, any In-License Agreement;
- 11.2.4 The Exploitation of the Product as contemplated herein does not, and would not if any such Exploitation (including Commercialization) were to occur as of the Effective Date, infringe any Existing Third Party Patent or, to Surmodics' knowledge, misappropriate any proprietary Information of any Third Party. As of the Effective Date, neither the Existing SurVeil Trademark nor the Existing Serene Trademark infringes any Trademark owned by a Third Party in the country in which the applicable Existing SurVeil Trademark or Existing Serene Trademark is registered. As of the Effective Date, no claim or litigation has been brought or asserted in writing [**] by any Person alleging that (i) the [**] are invalid or unenforceable (which claim is first made after the issuance of such Patent or the issuance of the registration of such Trademark) or (ii) the conception, development, reduction to practice, disclosing, copying, making, assigning or licensing of the Existing Regulatory Documentation, the Existing Product Patents, the Existing SurVeil Trademark, or the Surmodics Know-How existing as of the Effective Date or the Exploitation of the Product as contemplated herein, violates, infringes, constitutes misappropriation or otherwise conflicts or interferes with or would

violate, infringe or otherwise conflict or interfere with, any intellectual property or proprietary right of any Person;

- 11.2.5 To Surmodics' knowledge and as of the Effective Date, no Person is infringing or misappropriating the Existing Product Patents, the Existing SurVeil Trademark, the Existing Serene Trademark, the Surmodics Know-How or the Regulatory Documentation to an extent material to the Commercialization of the Product;
- of its Affiliates who are inventors or authors of or have otherwise contributed in a material manner to the invention, creation or development or authorship of any Existing Product Patent or Surmodics Know-How or who otherwise have access to any Confidential Information of Abbott have executed and delivered to Surmodics or such Affiliate an assignment or other agreement regarding the (i) protection of proprietary information and (ii) assignment to Surmodics or such Affiliate to the extent, in the case of any Information, such Information did not constitute a "work made for hire" (as defined in the Copyright Act of 1976, as amended) for Surmodics or such Affiliate of any Surmodics Product Patents, Surmodics Know-How and any and all other Information that relates to the Product, the current form(s) of which have been made available for review by Abbott. To Surmodics' knowledge and as of the Effective Date, no current officer, employee, agent or consultant of Surmodics or any of its Affiliates is in violation of any term of any assignment or other agreement regarding the protection of Patents or other intellectual property or proprietary information of Surmodics or such Affiliate or of any employment contract or any other contractual obligation relating to the relationship of any such Person with Surmodics;
- 11.2.7 Surmodics has obtained the right (including under any Patents and other intellectual property rights) to use all Information and all other materials (including any formulations and manufacturing processes and procedures) developed or delivered by any Third Party under any agreements between Surmodics and any such Third Party with respect to the Product as it exists as of the Effective Date, and Surmodics has the rights under each such agreement to transfer such rights, Information or other materials to Abbott and its designees and to grant Abbott the right to use such rights, Information or other materials in the Exploitation of the Product as contemplated hereunder;
- 11.2.8 The inventions claimed or covered by the Existing Product Patents (i) were not conceived, discovered, developed or otherwise made in connection with any research activities funded, in whole or in part, by the federal government of the United States or any agency thereof and (ii) are not a "subject invention" as that term is described in 35 U.S.C. Section 201(e) and (iii) are not otherwise subject to the provisions of the Patent and Trademark Law Amendments Act of 1980, as amended, codified at 35 U.S.C. §§ 200-212, as amended, as well as any regulations promulgated pursuant thereto, including in 37 C.F.R. Part 401;
- 11.2.9 Surmodics and its Affiliates have generated, prepared, maintained and retained all Regulatory Documentation that is required to be maintained or retained pursuant to and in accordance with Applicable Law;

- 11.2.10 Neither Surmodics nor any of its Affiliates, nor any of its or their respective officers, employees or agents has (i) committed (or after the Effective Date, will commit) an act, (ii) made (or after the Effective Date, will make) a statement, or (iii) failed (or after the Effective Date, will fail) to act or make a statement that, in any case ((i), (ii), or (iii)), (x) would be or create an untrue statement of material fact or fraudulent statement to the FDA or any other Regulatory Authority with respect to the Exploitation of the Product or (y) could reasonably be expected to provide a basis for the FDA to invoke its policy respecting "Fraud, Untrue Statements of Material Facts, Bribery and Illegal Gratuities", set forth in 56 Fed. Reg. 46191 (September 10, 1991) and any amendments thereto or any analogous laws or policies in the Territory, with respect the Exploitation of the Product;
- 11.2.11 Surmodics, its Affiliates, and its and their respective contractors and consultants have conducted, and with respect to Development occurring after the Effective Date, will conduct, all Development of the Product in accordance with good laboratory and clinical practice as applicable and Applicable Law, including compliance with 21 C.F.R. Parts 50, 54, 56, 58, 812 and similar regulatory or legal obligations outside the United States. Surmodics and its Affiliates have employed (and, with respect to Development that Surmodics will conduct, will employ) Persons with appropriate education, knowledge and experience to conduct and to oversee the Development to be conducted by Surmodics hereunder;
- 11.2.12 True, complete and correct (as of the Effective Date) copies of all material adverse information with respect to the safety and efficacy of the Product known to Surmodics have been provided to Abbott prior to the Effective Date; and
- Development and Manufacture of the Product in all material respects in compliance with Applicable Law. With respect to the Product Manufactured and supplied by or on behalf of Surmodics, (i) the Product shall be in conformity with the Specifications for the Product, (ii) the Product shall, at the time of delivery, have a remaining shelf life not less than [**] of the then-approved shelf life remaining, (iii) the Product shall have been Manufactured in conformance in all material respects with QSR, all other Applicable Law, this Agreement and any Quality Agreement, if applicable, (iv) the Product shall have been Manufactured in facilities that are in compliance with Applicable Law at the time of such Manufacture (including applicable inspection requirements of FDA and other Regulatory Authorities), (v) the Product shall not be adulterated or misbranded under the FFDCA or similar provisions of any other Applicable Law, and (vi) the Product may be introduced into interstate commerce pursuant to the FFDCA.
- 11.3 DISCLAIMER OF WARRANTIES. EXCEPT FOR THE EXPRESS WARRANTIES SET FORTH HEREIN, NEITHER PARTY MAKES ANY REPRESENTATIONS OR GRANTS ANY WARRANTIES, EXPRESS OR IMPLIED, EITHER IN FACT OR BY OPERATION OF LAW, BY STATUTE OR OTHERWISE AND EACH PARTY SPECIFICALLY DISCLAIMS ANY OTHER WARRANTIES, WHETHER WRITTEN OR ORAL OR EXPRESS OR IMPLIED, INCLUDING ANY WARRANTY OF QUALITY, MERCHANTABILITY OR FITNESS FOR A PARTICULAR USE OR PURPOSE OR ANY WARRANTY AS TO THE VALIDITY OF ANY PATENTS OR THE NON-INFRINGEMENT OF ANY INTELLECTUAL PROPERTY RIGHTS OF THIRD PARTIES.

ARTICLE 12 INDEMNITY

12.1 Indemnification of Surmodics. Abbott shall indemnify Surmodics, its Affiliates and its and their respective directors, officers, employees and agents and defend and save each of them harmless, from and against any and all losses, damages, liabilities, costs and expenses (including reasonable attorneys' fees and expenses) (collectively, "**Losses**") in connection with any and all suits, investigations, claims or demands of Third Parties (collectively, "**Third Party Claims**") arising from or occurring as a result of: (i) the breach by Abbott of this Agreement; (ii) the gross negligence or willful misconduct on the part of Abbott or its Affiliates or its or their respective directors, officers, employees or agents in performing its or their obligations under this Agreement; or (iii) except for the use of any Marketing Materials to the extent that any claim in such Marketing Materials is (a) provided by or on behalf of Surmodics to Abbott or its Affiliates for use in such Marketing Materials or (b) otherwise expressly verified in writing by Surmodics, the Exploitation of the Product by or on behalf of Abbott or its Affiliates, except, in each case ((i), (ii), and (iii)), for those Losses for which Surmodics has an obligation to indemnify Abbott pursuant to Section 12.2, as to which Losses each Party shall indemnify the other to the extent of their respective liability. Notwithstanding anything to the contrary in this Section 12.1, the foregoing indemnification obligations shall not apply to Third Party Claims for the infringement of any Patent, Trademark, or other intellectual property rights of any Third Party in connection with the Exploitation of the Product or other activities hereunder, which shall be governed by Article 9.

12.2 Indemnification of Abbott. Surmodics shall indemnify Abbott, its Affiliates and its and their respective directors, officers, employees and agents and defend and save each of them harmless, from and against any and all Losses in connection with any and all Third Party Claims arising from or occurring as a result of: (i) the breach by Surmodics of this Agreement; (ii) the gross negligence or willful misconduct on the part of Surmodics or its Affiliates or its or their respective directors, officers, employees or agents in performing its or their obligations under this Agreement; (iii) the Exploitation of the Product by or on behalf of Surmodics or its Affiliates anywhere in the world during the Term, prior to the Effective Date, or after the Term; or (iv) the misappropriation by Surmodics or its Affiliates or its or their respective directors, officers, employees or agents of any proprietary Information of any Third Party in connection with the Exploitation of the Product or other activities hereunder, except, in each case ((i), (ii), (iii), and (iv)), for those Losses for which Abbott has an obligation to indemnify Surmodics pursuant to Section 12.1, as to which Losses each Party shall indemnify the other to the extent of their respective liability. Notwithstanding anything to the contrary in this Section 12.2, the foregoing indemnification obligations (other than the obligation in clause (iv) of this Section 12.2) shall not apply to Third Party Claims for the infringement of any Patent, Trademark, or other intellectual property rights of any Third Party in the Exploitation of the Product or other activities hereunder, which shall be governed by Article 9.

12.3 Indemnification Procedures.

12.3.1 Notice of Claim. All indemnification claims in respect of a Party, its Affiliates, or its or their respective directors, officers, employees or agents shall be made solely by such Party to this Agreement (the "**Indemnified Party**"). The Indemnified Party shall

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give the indemnifying Party prompt written notice (an "**Indemnification Claim Notice**") of any Losses or discovery of fact upon which such Indemnified Party intends to base a request for indemnification under this Article 12, but in no event shall the indemnifying Party be liable for any Losses that result from any delay in providing such notice. Each Indemnification Claim Notice must contain a description of the claim and the nature and amount of such Loss (to the extent that the nature and amount of such Loss is known at such time). The Indemnified Party shall furnish promptly to the indemnifying Party copies of all papers and official documents received in respect of any Losses and Third Party Claims.

Control of Defense. At its option, the indemnifying Party may assume the defense of 12.3.2 any Third Party Claim by giving written notice to the Indemnified Party within [**] after the indemnifying Party's receipt of an Indemnification Claim Notice. The assumption of the defense of a Third Party Claim by the indemnifying Party shall not be construed as an acknowledgment that the indemnifying Party is liable to indemnify the Indemnified Party in respect of the Third Party Claim, nor shall it constitute a waiver by the indemnifying Party of any defenses it may assert against the Indemnified Party's claim for indemnification. Upon assuming the defense of a Third Party Claim, the indemnifying Party may appoint as lead counsel in the defense of the Third Party Claim any legal counsel selected by the indemnifying Party. In the event the indemnifying Party assumes the defense of a Third Party Claim, the Indemnified Party shall immediately deliver to the indemnifying Party all original notices and documents (including court papers) received by the Indemnified Party in connection with the Third Party Claim. Should the indemnifying Party assume the defense of a Third Party Claim, except as provided in Section 12.3.3, the indemnifying Party shall not be liable to the Indemnified Party for any legal expenses subsequently incurred by such Indemnified Party in connection with the analysis, defense or settlement of the Third Party Claim unless specifically requested in writing by the indemnifying Party. In the event that it is ultimately determined that the indemnifying Party is not obligated to indemnify, defend or hold harmless the Indemnified Party from and against the Third Party Claim, the Indemnified Party shall reimburse the indemnifying Party for any and all reasonable costs and expenses (including reasonable attorneys' fees and costs of suit) and any Losses incurred by the indemnifying Party in its defense of the Third Party Claim.

12.3.3 Right to Participate in Defense. Any Indemnified Party shall be entitled to participate in, but not control, the defense of such Third Party Claim and to employ counsel of its choice for such purpose; *provided*, *however*, that such employment shall be at the Indemnified Party's sole cost and expense unless (i) the employment thereof has been specifically authorized in writing by the indemnifying Party, (ii) the indemnifying Party has failed to assume the defense and employ counsel in accordance with Section 12.3.2 (in which case the Indemnified Party shall control the defense) or (iii) the interests of the applicable indemnitee and the indemnifying Party with respect to such Third Party Claim are sufficiently adverse to prohibit the representation by the same counsel of both parties under Applicable Law, ethical rules or equitable principles.

12.3.4 Settlement. With respect to any Losses relating solely to the payment of money damages in connection with a Third Party Claim and that shall not result in the applicable indemnitee becoming subject to injunctive or other relief or otherwise adversely affect the business of the Indemnified Party in any manner and as to which the indemnifying

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Party shall have acknowledged in writing the obligation to indemnify the applicable indemnitee hereunder, the indemnifying Party shall have the sole right to consent to the entry of any judgment, enter into any settlement or otherwise dispose of such Loss, on such terms as the indemnifying Party, in its sole discretion, shall deem appropriate. With respect to all other Losses in connection with Third Party Claims, where the indemnifying Party has assumed the defense of the Third Party Claim in accordance with Section 12.3.2, the indemnifying Party shall have authority to consent to the entry of any judgment, enter into any settlement or otherwise dispose of such Loss; *provided* it obtains the prior written consent of the Indemnified Party (which consent shall not be unreasonably withheld, conditioned or delayed). If the indemnifying Party does not assume and conduct the defense of a Third Party Claim as provided above, the Indemnified Party may defend against such Third Party Claim; *provided* that the Indemnified Party shall not settle any Third Party Claim without the prior written consent of the indemnifying Party (which consent shall not be unreasonably withheld, conditioned or delayed).

12.3.5 Cooperation. Regardless of whether the indemnifying Party chooses to defend or prosecute any Third Party Claim, the Indemnified Party shall and shall cause each applicable indemnitee to, cooperate in the defense or prosecution thereof and shall furnish such records, information and testimony, provide such witnesses and attend such conferences, discovery proceedings, hearings, trials and appeals as may be reasonably requested in connection therewith. Such cooperation shall include access during normal business hours afforded to the indemnifying Party to, and reasonable retention by the Indemnified Party of, records and information that are reasonably relevant to such Third Party Claim and making applicable indemnitees and other employees and agents available on a mutually convenient basis to provide additional information and explanation of any material provided hereunder and the indemnifying Party shall reimburse the Indemnified Party for all its reasonable and verifiable out-of-pocket expenses in connection therewith.

12.3.6 Expenses. Except as provided above, the reasonable and verifiable costs and expenses, including fees and disbursements of counsel, incurred by the Indemnified Party in connection with any Third Party Claim shall be reimbursed on a Calendar Quarter basis in arrears by the indemnifying Party, without prejudice to the indemnifying Party's right to contest the Indemnified Party's right to indemnification and subject to refund in the event the indemnifying Party is ultimately held not to be obligated to indemnify the Indemnified Party.

12.4 Special, Indirect and Other Losses. EXCEPT (I) IN THE EVENT OF THE WILLFUL MISCONDUCT OR FRAUD OF A PARTY OR A PARTY'S BREACH OF ITS OBLIGATIONS UNDER ARTICLE 10 OR SECTION 8.4 AND (II) TO THE EXTENT ANY SUCH DAMAGES ARE REQUIRED TO BE PAID TO A THIRD PARTY AS PART OF A CLAIM FOR WHICH A PARTY PROVIDES INDEMNIFICATION UNDER THIS ARTICLE 12, NEITHER PARTY NOR ANY OF ITS AFFILIATES OR SUBLICENSEES SHALL BE LIABLE IN CONTRACT, TORT, NEGLIGENCE, BREACH OF STATUTORY DUTY OR OTHERWISE FOR ANY SPECIAL, INDIRECT, INCIDENTAL, CONSEQUENTIAL OR PUNITIVE DAMAGES OR FOR LOSS OF PROFITS SUFFERED

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BY THE OTHER PARTY, WHETHER FORESEEABLE OR NOT, REGARDLESS OF ANY NOTICE OF SUCH DAMAGES.

12.5 Insurance. Each Party shall have and maintain such types and amounts of insurance covering its Exploitation of the Product as is (i) normal and customary in the medical device industry generally for parties similarly situated and (ii) otherwise required by Applicable Law.

ARTICLE 13 TERM AND TERMINATION

13.1 Term. This Agreement shall commence on the Effective Date and, unless earlier terminated in accordance herewith, shall continue in force and effect until December 31, 2032 ("**Initial Term**") or, if Abbott elects by written notice to Surmodics no later than [**] prior to the last day of the Initial Term, December 31, 2035 ("**Extended Term**") (such period, whether the Initial Term or the Extended Term, the "**Term**").

13.2 Termination for Material Breach.

In General. If either Party (the "Notifying Party") believes that the other Party (the 13.2.1 "Breaching Party") has materially breached one or more of its material obligations under this Agreement, then the Notifying Party may deliver notice of such material breach to the Breaching Party (a "Default Notice"). If the Breaching Party does not dispute that it has committed a material breach of one or more of its material obligations under this Agreement, then if the Breaching Party fails to cure such breach, or fails to take steps as would be considered reasonable to effectively cure such breach, within [**] after receipt of the Default Notice, or, in the case of failure to fulfill payment obligations hereunder, within [**] after receipt of the Default Notice, or if such compliance cannot be fully achieved within such [**] or [**] period, as applicable, and the Breaching Party has failed to commence compliance or has failed to use diligent efforts to achieve full compliance as soon thereafter as is reasonably possible, the Notifying Party may terminate this Agreement upon written notice to the Breaching Party. If the Breaching Party disputes that it has materially breached one or more of its material obligations under this Agreement, the Notifying Party shall not be entitled to terminate the Agreement unless and until (i) a final and non-appealable judgment has been issued pursuant to which the Breaching Party is determined to have been in material breach of one or more of its material obligations under this Agreement (an "Adverse Ruling"), and (ii) either (A) if such Adverse Ruling provides for a remedy for such breach and the Notifying Party has not performed such remedy in the time period provided in such Adverse Ruling or (B) such Adverse Ruling does not provide for a remedy for such breach and permits termination of this Agreement. Any termination of this Agreement must be made by written notice to the Breaching Party.

13.2.2 Invocation of Termination for Material Breach. Notwithstanding the foregoing, the Parties agree that termination pursuant to this Section 13.2 is

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a remedy to be invoked only if the breach cannot be adequately remedied through specific performance, the payment of money damages, or any combination thereof.

13.2.3 **Milestones.** In the event that a Default Notice has been delivered by Abbott under this Section 13.2, then unless and until the corresponding material breach has been cured by Surmodics or Abbott indicates that it no longer intends to terminate for material breach, then any obligation that Abbott may have to pay a Milestone Payment in respect of any Milestone achieved after delivery of such Default Notice shall be suspended unless and until it is determined, in accordance with Section 13.2.1, that a material breach has not occurred. In the event that a termination for material breach occurs pursuant to this Section 13.2, then Abbott's obligation to pay such Milestone Payment(s) shall cease and such suspended Milestone Payment(s) shall no longer be due.

13.3 Additional Termination Rights by Abbott.

13.3.1 For Cause.

(i) Without limiting the rights or obligations of the Parties under Section 5.4, Section 5.6, or Section 5.7, if Abbott reasonably believes that there is a concern with respect to the safety of the Product that makes the continued promotion, marketing, sale or distribution of the Product inadvisable, Abbott may notify Surmodics. Upon delivery of such notice, or upon the delivery of notice by Abbott pursuant to Section 5.7 regarding a disagreement between the Parties regarding the advisability or necessity of any recall or advisory letter (the date of the earlier of either such delivery, the "Suspension Period Commencement Date"), the Agreement shall remain in effect but (a) all of Abbott's obligations to promote, market, sell, distribute, or otherwise Commercialize the Product shall be suspended, (b) Abbott shall have the right to cancel any outstanding POs, (c) all Forecasts shall be deemed to be non-binding, (d) Abbott shall have no right to submit additional POs, and (e) all remaining obligations of either Party to Develop the Product, if any, shall be suspended, in each case ((a), (b), (c), (d), and (e)) for the duration of the Suspension Period (as defined below). Representatives of the Parties shall then meet within [**] to discuss in good faith such concern or such disagreement, determine if Surmodics is capable of addressing such concern or such disagreement, and formulate an action plan so that promotion, marketing, sale, distribution, and other Commercialization, and Development, of the Product may be resumed within a reasonable period of time which shall not exceed [**] from the date of such meeting, provided that if such concern cannot be resolved within [**] the Parties may mutually agree in writing to extend such period of time (the period beginning on the Suspension Period Commencement Date and ending at the end of such period of time, the "Suspension Period"). If the Parties are unable to formulate such action plan to Abbott's reasonable satisfaction within [**] of commencing the discussions contemplated by the foregoing sentence, Abbott shall have the right to terminate this Agreement effective immediately.

(ii) Abbott may terminate this Agreement effective immediately upon written notice to Surmodics if any Milestone listed in Section 1 of Schedule 7 is not achieved by the date that is [**] after the target date specified for such Milestone in Section 1 of Schedule 7.

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- **13.3.2 For Convenience.** Abbott may terminate this Agreement for any or no reason upon one (1) year's prior written notice to Surmodics.
- **13.4 Termination for Patent Challenge.** If Abbott or any of its Affiliates Challenges any of the Surmodics Product Patents or Surmodics Other Patents, then unless, within [**] after written notice thereof by Surmodics, Abbott withdraws or causes to be withdrawn all such Challenges, this Agreement shall automatically terminate upon the expiration of such [**] period.
- 13.5 **Termination for Insolvency.** In the event that either Party (i) files for protection under bankruptcy or insolvency laws, (ii) makes an assignment for the benefit of creditors, (iii) appoints or suffers appointment of a receiver or trustee over substantially all of its property that is not discharged within[**] after such filing, (iv) proposes a written agreement of composition or extension of its debts, (v) proposes or is a party to any dissolution or liquidation, (vi) files a petition under any bankruptcy or insolvency act or has any such petition filed against it that is not discharged within [**] of the filing thereof, or (vii) admits in writing its inability generally to meet its obligations as they fall due in the general course, then the other Party may terminate this Agreement effective immediately upon written notice to such Party.
- 13.6 **Rights in Bankruptcy.** All rights and licenses granted under or pursuant to this Agreement by Abbott or Surmodics are, and shall otherwise be deemed to be, for purposes of Section 365(n) of the U.S. Bankruptcy Code or any analogous provisions in any other country or jurisdiction, licenses of right to "intellectual property" as defined under Section 101 of the U.S. Bankruptcy Code. The Parties agree that the Parties, as licensees of such rights under this Agreement, shall retain and may fully exercise all of their rights and elections under the U.S. Bankruptcy Code or any analogous provisions in any other country or jurisdiction. The Parties further agree that, in the event of the commencement of a bankruptcy proceeding by or against either Party under the U.S. Bankruptcy Code or any analogous provisions in any other country, the Party hereto that is not a Party to such proceeding shall be entitled to a complete duplicate of (or complete access to, as appropriate) any such intellectual property and all embodiments of such intellectual property, which, if not already in the non-subject Party's possession, shall be promptly delivered to it (i) upon any such commencement of a bankruptcy proceeding upon the non-subject Party's written request therefor, unless the Party subject to such proceeding elects to continue to perform all of its obligations under this Agreement, or (ii) if not delivered under clause (i) above, following the rejection of this Agreement by or on behalf of the Party subject to such proceeding upon written request therefor by the non-subject Party. The Parties acknowledge and agree that payments made under Section 7.2 or Section 7.3 shall not (x) constitute royalties within the meaning of Section 365(n) of the U.S. Bankruptcy Code or any analogous provisions in any other country or (y) relate to licenses of intellectual property hereunder.

13.7 Consequences of Expiration or Termination.

13.7.1 Upon Termination for Convenience. In the event of termination of this Agreement by Abbott pursuant to Section 13.3.2, (i) Abbott shall pay Milestone Payment(s) pursuant to Section 7.2 as and to the extent that the applicable Milestone(s) are achieved prior to the effective date of such termination, and (ii) on the effective date of such

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termination, Abbott shall pay the Milestone Payment(s) for any Milestone(s) that have not yet then been achieved, if any, in such amount as if such Milestone(s) were achieved on the effective date of such termination.

- **13.7.2 Fulfillment of Final POs; Sell Off.** Upon expiration or earlier termination of this Agreement for any reason, (i) Surmodics shall, at Abbott's request, fulfill all POs submitted prior to such expiration or termination in accordance with the terms and conditions of this Agreement in effect prior to the date of such expiration or termination until such POs have been fully satisfied by delivery of conforming Product, and (ii) Abbott shall have the right to continue to distribute and sell Abbott's inventory of the Product in the Territory until the expiration of the shelf life of the applicable Products, *provided* that Section 7.3 shall remain in force and effect with respect to any such sales. Notwithstanding the foregoing, (a) from and after the date on which either Party delivers a notice of termination hereunder, Abbott shall not submit any PO with any delivery date that falls after the expected date of expiration of this Agreement, and (b) Abbott shall not submit any PO with any delivery date that falls after the expected date of expiration of this Agreement.
- **13.8 Remedies.** Except as otherwise expressly provided herein, termination of this Agreement in accordance with the provisions hereof shall not limit remedies that may otherwise be available in law or equity.
- 13.9 Accrued Rights; Surviving Obligations. Termination or expiration of this Agreement for any reason shall be without prejudice to any rights that shall have accrued to the benefit of a Party prior to such termination or expiration. Such termination or expiration shall not relieve a Party from obligations that are expressly indicated to survive the termination or expiration of this Agreement. Without limiting the foregoing, Sections 4.1.10, 5.2, 5.4, 5.5, 5.6, 5.7, 7.3, 7.4, 7.5, 7.6, 7.7, 7.8, 7.9, 8.1 (solely for purposes of Abbott's exercise of its rights pursuant to Section 13.7.2), 9.1.1 (solely to the extent any perpetual license grants have been granted pursuant to such Section), 9.2.2 (solely to the extent any perpetual license grants have been granted pursuant to such Section), 9.4, 9.5 (solely to the extent applicable to Section 9.4), 9.6 (solely to the extent applicable to Section 9.4), 9.7 (solely to the extent applicable to Section 9.4), 9.8 (solely to the extent applicable to Section 9.4), 11.3, 12.1, 12.2, 12.3, 12.4, 13.6, 13.7, 13.8, 14.4, 14.6, 14.7, 14.8, 14.9, 14.10, 14.11, 14.12, 14.13, 14.14, 14.15 (solely to the extent applicable to other surviving provisions), 14.17, 14.18, 14.19, 14.20 and this Section 13.9, and Article 1 (solely to the extent applicable to other surviving provisions) and Article 10 of this Agreement shall survive the termination or expiration of this Agreement for any reason.

ARTICLE 14 MISCELLANEOUS

14.1 Force Majeure. Neither Party shall be held liable or responsible to the other Party or be deemed to have defaulted under or breached this Agreement for failure or delay in fulfilling or performing any term of this Agreement (other than an obligation to make payments) when such failure or delay is caused by or results from events beyond the reasonable control of the non-performing Party, including fires, floods, earthquakes, hurricanes, embargoes, shortages, epidemics, quarantines, war, acts of war (whether war be declared or not), terrorist

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acts, insurrections, riots, civil commotion, strikes, lockouts or other labor disturbances (whether involving the workforce of the non-performing Party or of any other Person), acts of God or acts, omissions or delays in acting by any governmental authority (except to the extent such delay results from the breach by the non-performing Party or any of its Affiliates of any term or condition of this Agreement). The non-performing Party shall notify the other Party of such force majeure within [**] after such occurrence by giving written notice to the other Party stating the nature of the event, its anticipated duration and any action being taken to avoid or minimize its effect. The suspension of performance shall be of no greater scope and no longer duration than is necessary and the non-performing Party shall use reasonable efforts to remedy its inability to perform.

14.2 **Export Control.** This Agreement is made subject to any restrictions concerning the export of products or technical information from the United States or other countries that may be imposed on the Parties from time to time. Each Party agrees that it will not export, directly or indirectly, any technical information acquired from the other Party under this Agreement or any products using such technical information to a location or in a manner that at the time of export requires an export license or other governmental approval, without first obtaining the written consent to do so from the appropriate agency or other governmental entity in accordance with Applicable Law.

14.3 Change in Control of Surmodics.

14.3.1 Notice; Parent Guarantee. Not later than [**] following the earlier of (i) the effective date of a Change in Control of Surmodics or Acquisition by Surmodics and (ii) the public announcement by or on behalf of Surmodics of the entry by Surmodics into a definitive agreement providing for a Change in Control of Surmodics or Acquisition by Surmodics, Surmodics (or its successor) shall provide Abbott with written notice informing Abbott of such transaction. Surmodics shall cause its ultimate parent following any such Change in Control of Surmodics to guarantee, pursuant to a written agreement to be entered into between such ultimate parent and Abbott in a form reasonably acceptable to Abbott, all of the obligations of Surmodics hereunder.

14.3.2 Abbott's Rights. If the Change in Control of Surmodics or Acquisition by Surmodics involves a Competitor, or will result in Surmodics controlling, being controlled by, or being under common control with a Competitor (in each case determined at the time of the public announcement of such Change in Control or Acquisition), then, without limiting [**], Abbott shall have the right, in its sole and absolute discretion, by written notice delivered to Surmodics (or its successor) within [**] after the effective date of such Change in Control or Acquisition, to (i) terminate this Agreement effective [**] after delivery of such notice by Abbott; (ii) disband, or terminate the activities of, the JDC; or (iii) require Surmodics and the Change in Control or Acquisition party to adopt reasonable procedures agreed upon in writing to prevent disclosure of the Confidential Information of Abbott.

14.4 Assignment.

14.4.1 In General. Neither Party may assign its rights or, except as provided in Section 3.2 or Section 14.5, delegate its obligations under this Agreement, whether

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by operation of law or otherwise, in whole or in part without the prior written consent of the other Party, except that (a) Abbott shall have the right, without such consent, (i) to perform any or all of its obligations and exercise any or all of its rights under this Agreement through any of its Affiliates or its or their (sub)licensees, and (ii) assign any or all of its rights and delegate any or all of its obligations hereunder to any of its Affiliates or its or their (sub)contractors or (sub)distributors or to any successor in interest (whether by merger, acquisition, asset purchase or otherwise) to all or substantially all of its [**] business, *provided* that Abbott shall provide written notice to Surmodics within thirty (30) days after such assignment or delegation and (b) Surmodics shall have the right to (i) use an Approved Subcontractor to perform those obligations hereunder of Surmodics for which the Approved Subcontractor is approved, and (ii) assign any or all of its rights and delegate any or all of its obligations hereunder to any of its Affiliates or to any successor in interest (whether by merger, acquisition, asset purchase or otherwise) to all or substantially all of its business, provided that Surmodics shall provide written notice to Abbott within [**] after such assignment or delegation. Any permitted successor of a Party or any permitted assignee of all of a Party's rights under this Agreement that has also assumed all of such Party's obligations hereunder in writing shall, upon any such succession or assignment and assumption, be deemed to be a party to this Agreement as though named herein in substitution for the assigning Party, whereupon the assigning Party shall cease to be a party to this Agreement and shall cease to have any rights or obligations under this Agreement. All validly assigned rights of a Party shall inure to the benefit of and be enforceable by, and all validly delegated obligations of such Party shall be binding on and be enforceable against, the permitted successors and assigns of such Party. Any attempted assignment or delegation in violation of this Section 14.4.1 shall be void and of no effect. Notwithstanding any other provision of this Section 14.4.1, the terms of this Agreement may be varied, amended or modified or this Agreement may be suspended, canceled or terminated without the consent of any assignee or delegate that is not deemed pursuant to the provisions of this Section 14.4.1 to have become a party to this Agreement.

14.4.2 Certain Exclusions of Prior IP and Materials of Assignees and New Affiliates. The rights to Information, materials and intellectual property: (i) Controlled by a Third Party permitted assignee of Surmodics, which Information, materials and intellectual property were Controlled by such assignee immediately prior to such assignment; (ii) Controlled by an Affiliate of Surmodics who becomes an Affiliate through any Change in Control of Surmodics, which Information, materials and intellectual property were Controlled by such Affiliate immediately prior to such Change in Control; or (iii) Controlled by an Affiliate of Surmodics who becomes an Affiliate through any Acquisition by Surmodics, which Information, materials and intellectual property were Controlled by such Affiliate immediately prior to such Acquisition, shall be (x) in the case of clauses (i) and (ii) of this Section 14.4.2, automatically excluded from the definition of Surmodics Product Patents, and (y) in each case ((i), (ii), and (iii)), automatically excluded from the definition of Surmodics Other Patents and from the definition of Surmodics Know-How (except to the extent that such Information, materials, or intellectual property are introduced into or are actually practiced in the Product).

14.5 Subcontracting. In the case of any (sub)contracting or (sub)distributing by either Party, such (sub)contracting or (sub)distributing shall not relieve the (sub)contracting or (sub)distributing Party of any of its obligation or liability hereunder and the (sub)contracting or (sub)distributing Party shall be and remain fully responsible and liable therefor (except to the

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extent the applicable obligation has been satisfactorily performed by the applicable (sub)contractor or (sub)distributor).

14.6 Severability. If any provision of this Agreement is held to be illegal, invalid or unenforceable under any present or future law and if the rights or obligations of either Party under this Agreement will not be materially and adversely affected thereby, (i) such provision shall be fully severable, (ii) this Agreement shall be construed and enforced as if such illegal, invalid or unenforceable provisions of this Agreement shall remain in full force and effect and shall not be affected by the illegal, invalid or unenforceable provision or by its severance herefrom and (iv) in lieu of such illegal, invalid or unenforceable provision, there shall be added automatically as a part of this Agreement a legal, valid and enforceable provision as similar in terms to such illegal, invalid or unenforceable provision as may be possible and reasonably acceptable to the Parties. To the fullest extent permitted by Applicable Law, each Party hereby waives any provision of law that would render any provision hereof illegal, invalid or unenforceable in any respect.

14.7 Dispute Resolution.

- **14.7.1 Good Faith Negotiation; Litigation.** Except as provided in Section 4.1.10(ii) or Section 7.9.2, if any dispute arises between the Parties in connection with or relating to this Agreement or any document or instrument delivered in connection herewith (a "**Dispute**"), then either Party shall have the right to refer such Dispute to the Senior Officers for attempted resolution by good faith negotiations during a period of [**]. Any final decision mutually agreed to by the Senior Officers shall be conclusive and binding on the Parties. [**].
- **14.7.2 No Limitation on Equitable Relief.** Section 14.7.1 shall not limit or constrain either Party's ability to seek equitable relief and either Party may institute proceedings therefor in accordance with Section 14.8 without resort to the procedures described in Section 14.7.1.

14.8 Governing Law, Jurisdiction, and Venue.

- **14.8.1 Governing Law.** This Agreement shall be governed by and construed in accordance with the laws of Illinois, excluding any conflicts or choice of law rule or principle that might otherwise refer construction or interpretation of this Agreement to the substantive law of another jurisdiction. The Parties agree to exclude the application to this Agreement of the United Nations Convention on Contracts for the International Sale of Goods.
- **14.8.2 Jurisdiction.** Subject to Section 14.12, the Parties hereby irrevocably and unconditionally consent to the exclusive jurisdiction of the United States District Court for the Northern District of Illinois for any action, suit or proceeding (other than appeals therefrom) arising out of or relating to this Agreement and agree not to commence any action, suit or proceeding (other than appeals therefrom) related thereto except in such court. The Parties irrevocably and unconditionally waive their right to a jury trial.
- **14.8.3 Venue.** The Parties further hereby irrevocably and unconditionally waive any objection to the laying of venue of any action, suit or proceeding (other than appeals therefrom) arising out of or relating to this Agreement in the United States District Court for the

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Northern District of Illinois and hereby further irrevocably and unconditionally waive and agree not to plead or claim in such court that any such action, suit or proceeding brought in such court has been brought in an inconvenient forum.

14.9 Notices.

14.9.1 Notice Requirements. Any notice, request, demand, waiver, consent, approval or other communication permitted or required under this Agreement shall be in writing, shall refer specifically to this Agreement and shall be deemed given only if delivered by hand or sent by facsimile transmission (with transmission confirmed) or by internationally recognized overnight delivery service that maintains records of delivery, addressed to the Parties at their respective addresses specified in Section 14.9.2 or to such other address as the Party to whom notice is to be given may have provided to the other Party in accordance with this Section 14.9.1. Such notice shall be deemed to have been given as of the date delivered by hand or transmitted by facsimile (with transmission confirmed) if delivered before 5:00 p.m. in the time zone of the recipient on a Business Day (or if not delivered before 5:00 p.m. in the time zone of the recipient, on the next Business Day), or on the second Business Day (at the place of delivery) after deposit with an internationally recognized overnight delivery service. Any notice delivered by facsimile shall be confirmed by a hard copy delivered as soon as practicable thereafter. The Parties may from time to time identify different contact persons for POs, forecasts, order acceptances, and notices or communications regarding POs, forecasts, non-conforming product, product testing, acceptance of product and similar supply-related matters.

14.9.2 Address for Notice.

If to Abbott, to:

Abbott Vascular 3200 Lakeside Drive Santa Clara, CA 95045 Attention: [**] Facsimile: [**]

with a copy (which shall not constitute notice) to:

Abbott Vascular 3200 Lakeside Drive, MS 315 Santa Clara, CA 95045 Attention: [**] Facsimile: [**]

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with another copy (which shall not constitute notice) to:

Abbott Laboratories Dept. 32CO; AP6A 100 Abbott Park Road Abbott Park, Illinois 60064 Attention: [**] Facsimile: [**]

If to Surmodics, to:

Surmodics, Inc.
9924 West 74th Street
Eden Prairie, Minnesota 55344-3523
Attention: [**]
Facsimile: [**]

with a copy (which shall not constitute notice) to:

Surmodics, Inc. 9924 West 74th Street Eden Prairie, Minnesota 55344-3523 Attention: [**] Facsimile: [**]

and a copy (which shall not constitute notice) to:

Perkins Coie LLP 11988 El Camino Real, Suite 350 San Diego, CA 92130 Attention: [**] Facsimile: [**]

14.10 Entire Agreement; Amendments. This Agreement, together with the Schedules attached hereto, sets forth and constitutes the entire agreement and understanding between the Parties with respect to the subject matter hereof and all prior agreements, understandings, promises and representations, whether written or oral, with respect thereto are superseded hereby. Each Party confirms that it is not relying on any representations or warranties of the other Party except as specifically set forth in this Agreement. No amendment, modification, release or discharge shall be binding upon the Parties unless in writing and duly executed by authorized representatives of both Parties. In the event of any inconsistencies between this Agreement and any schedules or other attachments hereto, the terms of this Agreement shall control.

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- **14.11 English Language.** This Agreement shall be written and executed in and all other communications under or in connection with this Agreement shall be in, the English language. Any translation into any other language shall not be an official version thereof and in the event of any conflict in interpretation between the English version and such translation, the English version shall control.
- 8.4, Article 4, Article 9, and Article 10 are reasonable and necessary to protect the legitimate interests of the other Party and that such other Party would not have entered into this Agreement in the absence of such restrictions and that any breach or threatened breach of any provision of such Articles will result in irreparable injury to such other Party for which there would be no adequate remedy at law. In the event of a breach or threatened breach of any provision of such Section or Articles, the non-breaching Party shall be authorized and entitled to obtain from any court of competent jurisdiction injunctive relief, whether preliminary or permanent, specific performance and an equitable accounting of all earnings, profits and other benefits arising from such breach, which rights shall be cumulative and in addition to any other rights or remedies to which such non-breaching Party may be entitled in law or equity. Both Parties agree to waive any requirement that the other (i) post a bond or other security as a condition for obtaining any such relief and (ii) show irreparable harm, balancing of harms, consideration of the public interest or inadequacy of monetary damages as a remedy. Nothing in this Section 14.12 is intended, or should be construed, to limit either Party's right to equitable relief or any other remedy for a breach of any other provision of this Agreement.
- 14.13 Waiver and Non-Exclusion of Remedies. Any term or condition of this Agreement may be waived at any time by the Party that is entitled to the benefit thereof, but no such waiver shall be effective unless set forth in a written instrument duly executed by or on behalf of the Party waiving such term or condition. The waiver by either Party hereto of any right hereunder or of the failure to perform or of a breach by the other Party shall not be deemed a waiver of any other right hereunder or of any other breach or failure by such other Party whether of a similar nature or otherwise. The rights and remedies provided herein are cumulative and do not exclude any other right or remedy provided by Applicable Law or otherwise available except as expressly set forth herein.
- **14.14 No Benefit to Third Parties.** Except as provided in Article 12, the covenants and agreements set forth in this Agreement are for the sole benefit of the Parties hereto and their successors and permitted assigns and they shall not be construed as conferring any rights on any other Persons.
- **14.15 Further Assurance.** Each Party shall duly execute and deliver or cause to be duly executed and delivered, such further instruments and do and cause to be done such further acts and things, including the filing of such assignments, agreements, documents and instruments, as may be necessary or as the other Party may reasonably request in connection with this Agreement or to carry out more effectively the provisions and purposes hereof or to better assure and confirm unto such other Party its rights and remedies under this Agreement.

- 14.16 Relationship of the Parties. It is expressly agreed that Surmodics, on the one hand, and Abbott, on the other hand, shall be independent contractors and nothing in this Agreement shall be deemed or construed to create a partnership, joint venture, employment relationship, franchise, fiduciary relationship or agency. Neither Surmodics, on the one hand, nor Abbott, on the other hand, shall have the authority to make any statements, representations or commitments of any kind, or to take any action that will be binding on the other, without the prior written consent of the other Party to do so. All persons employed by a Party shall be employees of such Party and not of the other Party and all costs and obligations incurred by reason of any such employment shall be for the account and expense of such first Party.
- 14.17 Non-Solicitation of Employees. Commencing on the Effective Date and for a period of [**] thereafter, neither Party shall, directly or indirectly, actively recruit or solicit any employee of the other Party with whom such Party has come into contact or interacted for the purposes of performing this Agreement, without the prior consent of the other Party. For purposes of this Section 14.17, "solicit" shall be deemed not to include: (i) circumstances where an employee of one Party or any of its Affiliates initially contacts the other Party or any of such Party's Affiliates seeking employment; or (ii) general solicitations of employment not specifically targeted at such employees.
- **14.18 References.** Unless otherwise specified, (i) references in this Agreement to any Article, Section or Schedule shall mean references to such Article, Section or Schedule of this Agreement, (ii) references in any Section to any clause are references to such clause of such Section and (iii) references to any agreement, instrument or other document in this Agreement refer to such agreement, instrument or other document as originally executed or, if subsequently amended, replaced or supplemented from time to time, as so amended, replaced or supplemented and in effect at the relevant time of reference thereto.
- 14.19 Construction. Except where the context otherwise requires, wherever used, the singular shall include the plural, the plural the singular, the use of any gender shall be applicable to all genders and the word "or" is used in the inclusive sense (and/or). Whenever this Agreement refers to a number of days, unless otherwise specified, such number refers to calendar days. The captions of this Agreement are for convenience of reference only and in no way define, describe, extend or limit the scope or intent of this Agreement or the intent of any provision contained in this Agreement. The term "including," "include," or "includes" as used herein shall mean including, without limiting the generality of any description preceding such term. The language of this Agreement shall be deemed to be the language mutually chosen by the Parties and no rule of strict construction shall be applied against either Party.
- **14.20 Counterparts.** This Agreement may be executed in two (2) or more counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument. This Agreement may be executed by facsimile, PDF format via email or other electronically transmitted signatures and such signatures shall be deemed to bind each Party hereto as if they were original signatures.

[SIGNATURE PAGE FOLLOWS.]

THIS AGREEMENT IS EXECUTED by the authorized representatives of the Parties as of the date first written above.

ABBOTT VASCULAR, INC.

SURMODICS, INC.

By:	[**]	By:	/s/ Gary R. Maharaj
Name:	[**]	Name:	Gary R. Maharaj
Title	[**]	Title	President and CEO

[SIGNATURE PAGE TO DEVELOPMENT AND DISTRIBUTION AGREEMENT]

Schedule 1.50

Existing Serene Trademark

[**]

Schedule 1.51

Existing SurVeil Trademark

[**]

Schedule 1.122

Supply Disruption

[**]

Schedule 1.124

Surmodics Other Patents

[**] [13 additional pages omitted from this Schedule 1.124]

Schedule 2.1.1(ii)

Approved Subcontractors

 $[**]\ [2\ additional\ pages\ omitted\ from\ this\ Schedule\ 2.1.1(ii)]$

Schedule 4.1.2

Purchase Order Requirements

[**] [1 additional page omitted from this Schedule 4.1.2]

Schedule 4.1.7(i)

Specifications

[**] [14 additional pages omitted from this Schedule 4.1.7(i)]

Schedule 7

Certain Financial Information and Definitions

[**] [4 additional pages omitted from this Schedule 7]

Schedule 8.4.1

Exceptions to Exclusivity

[**]

Schedule 10.4

Public Announcements

Abbott and Surmodics Announce Agreement for Next-Generation Drug-Coated Balloon

- COMPANIES TO COLLABORATE ON PRODUCT DEVELOPMENT, CLINICAL TRIALS AND REGULATORY ACTIVITIES TO OBTAIN APPROVAL IN U.S. AND E.U.
- AGREEMENT COMPLEMENTS AND EXTENDS ABBOTT'S BROAD LINE OF VASCULAR CARE PRODUCTS AND DEMONSTRATES VALUE OF SURMODICS'
 PROPRIETARY DRUG DELIVERY AND WHOLE-PRODUCT SOLUTIONS STRATEGY

ABBOTT PARK, Ill., and EDEN PRAIRIE, Minn., (Feb. xx, 2018) — Abbott and Surmodics today announced that the companies have entered into an agreement whereby Abbott will have exclusive worldwide commercialization rights for Surmodics' SurVeil® drug-coated balloon to treat the superficial femoral artery, which is currently being evaluated in a U.S. pivotal clinical trial. Separately, Abbott also received options to negotiate agreements for Surmodics' below-the-knee and arteriovenous (AV) fistula drug-coated balloon products, which are currently in pre-clinical development.

As part of the agreement, Surmodics, a leading provider of medical device and in vitro diagnostic technologies to the healthcare industry, will supply the SurVeil drug-coated balloon to Abbott. The two companies will collaborate on product development, clinical trials and regulatory activities to obtain marketing approval in the U.S. and Europe. The SurVeil drug-coated balloon will complement and extend Abbott's broad line of vascular devices for treating peripheral artery disease (PAD), including stents and vessel closure devices. In addition to its devices for PAD, Abbott has one of the broadest portfolios of medical devices serving the \$30 billion-dollar global cardiovascular market, with leadership positions in several large and fast-growing areas, including cardiac rhythm management, electrophysiology, structural heart and heart failure.

PAD is a serious and often underdiagnosed circulatory condition that can lead to other serious vascular conditions. Drug-coated balloons have emerged as an important treatment option in treating PAD, which affects an estimated 200 million people worldwide. The SurVeil drug-coated balloon includes a proprietary drug-excipient formulation for a durable balloon coating and is manufactured using an innovative process to improve coating uniformity. Pre-clinical data have shown a three- to five-times higher target tissue drug concentration, a more evenly distributed and durable drug effect, and lower incidence of downstream drug particles compared to the control drug-coated balloon. The design of the SurVeil drug-coated balloon reflects Surmodics' industry leadership in the development of surface technology for vascular medical devices.

"Abbott is committed to providing leading treatments for people with peripheral artery disease, and the SurVeil drug-coated balloon is a next-generation device that utilizes best-in-class

technology," said Chuck Brynelsen, senior vice president of Abbott's vascular business. "This agreement enhances our fast-growing endovascular portfolio, and we look forward to offering this solution to physicians to give them more and better options to help their patients live their fullest lives."

"The SurVeil drug-coated balloon is the first device developed by Surmodics that combines our proprietary drug delivery and surface technologies with our exceptional design, development and manufacturing capabilities," said Gary Maharaj, Surmodics' president and chief executive officer. "We are excited to enter this partnership with Abbott given its deep expertise in vascular care products and its worldwide strength in the market. We look forward to working together with Abbott to realize the full potential of our SurVeil drug-coated balloon to help people with peripheral artery disease."

Surmodics' SurVeil drug-coated balloon is currently being evaluated in the TRANSCEND pivotal clinical trial and is being compared with the current market-leading drug-coated balloon in treating PAD in the legs. The SurVeil drug-coated balloon is currently for investigational use only.

Pursuant to the terms of the agreement, Surmodics will receive a \$25 million upfront payment and may earn an additional \$67 million for various product development milestones. Upon the regulatory approval of the device, Surmodics will be responsible for the manufacture and supply of clinical and commercial quantities of the product and will realize revenue based on initial product sales to Abbott as well as a share of profits resulting from third-party sales.

About Peripheral Artery Disease

Worldwide, over 200 million people have PAD,² a serious and underdiagnosed circulatory condition caused by build-up of arterial plaque, most commonly in the legs. Between 12-20 percent of Americans over 60 years old have PAD.³ PAD increases risk of coronary artery disease, heart attack and stroke, and can impair the ability to walk. If left untreated, PAD can lead to gangrene and limb amputation.⁴

About Abbott

Abbott is a global healthcare company devoted to improving life through the development of products and technologies that span the breadth of healthcare. With a portfolio of leading, science-based offerings in diagnostics, medical devices, nutritionals and branded generic pharmaceuticals, Abbott serves people in more than 150 countries and employs approximately 99,000 people.

Visit Abbott at www.abbott.com and connect with us on Twitter at @AbbottNews.

About Surmodics, Inc.

Surmodics is the global leader in surface modification technologies for intravascular medical devices and a leading provider of chemical components for in vitro diagnostic (IVD) immunoassay tests and microarrays. Surmodics is pursuing highly differentiated whole-product solutions that are designed to address unmet clinical needs for its medical device customers 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 SEC.

— Private Securities Litigation Reform Act of 1995 — A Caution Concerning Forward-Looking Statements

Some statements in this news release may be forward-looking statements for purposes of the Private Securities Litigation Reform Act of 1995. Abbott cautions that these forward-looking statements are subject to risks and uncertainties that may cause actual results to differ materially from those indicated in the forward-looking statements. Economic, competitive, governmental, technological and other factors that may affect Abbott's operations are discussed in Item 1A, "Risk Factors" to our Annual Report on Securities and Exchange Commission Form 10-K for the year ended Dec. 31, 2017, and are incorporated by reference. Abbott undertakes no obligation to release publicly any revisions to forward-looking statements as a result of subsequent events or developments, except as required by law.

Surmodics, Inc. 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 Surmodics' strategy to transform to a provider of whole-product vascular solutions. Forward-looking statements involve inherent risks and uncertainties, and important factors could cause actual results to differ materially from those anticipated, including (1) Surmodics' ability to successfully develop and obtain regulatory approval for the SurVeil drug-coated balloon; (2) Surmodics' ability to realize the full potential benefits of its agreement with Abbott; and (3) the factors identified under "Risk Factors" in Part I, Item 1A of Surmodics' Annual Report on Form 10-K for the fiscal year ended Sept. 30, 2017, and updated in its subsequent reports filed with the SEC. These reports are available in the Investors section of Surmodics' website at www.surmodics.com and at the SEC website at www.sec.gov. Forward-looking statements speak only as of the date they are made, and Surmodics undertakes no obligation to update them in light of new information or future events.

Abbott Media:

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Abbott Financial:

Michael Comilla, +1 (224) 668-1872

Surmodics:

Andy LaFrence, +1 (952) 500-7000

- ¹Surmodics data on file
- ² Fowkes FGR, et al. *Lancet* 2013, 382(9901):1329-1340. ³Centers for Disease Control and Prevention. Peripheral Arterial Disease (PAD) Fact Sheet. n.d. Web.
- 4National Institutes of Health. What is Peripheral Artery Disease? n.d. Web.

Schedule 11.2.2

Existing Product Patents

[**] [3 additional pages omitted from this Schedule 11.2.2]

Schedule 11.2.3

In-License Agreements

[**]

CERTIFICATION PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Gary R. Maharaj, certify that:

- 1. I have reviewed this Quarterly Report on Form 10-Q of Surmodics, Inc.;
- 2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
- 3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
- 4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and we have:
 - a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - b. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - c. Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - d. Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
- 5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Dated: May 4, 2018 Signature: /s/ Gary R. Maharaj

Gary R. Maharaj
President and
Chiof Executive Of

Chief Executive Officer

CERTIFICATION PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Andrew D. C. LaFrence, certify that:

- 1. I have reviewed this Quarterly Report on Form 10-Q of Surmodics, Inc.;
- 2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report:
- 3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
- 4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and we have:
 - a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - b. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - c. Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - d. Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
- 5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Dated: May 4, 2018 Signature: /s/ Andrew D.C. LaFrence

Andrew D.C. LaFrence

Vice President of Finance and Information Systems and

Chief Financial Officer

CERTIFICATION PURSUANT TO 18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Quarterly Report of Surmodics, Inc. (the "Company") on Form 10-Q for the quarter ended March 31, 2018, as filed with the Securities and Exchange Commission (the "Report"), I, Gary R. Maharaj, certify, pursuant to 18 U.S.C. §1350, as adopted pursuant to §906 of the Sarbanes-Oxley Act of 2002, that:

- (1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and
- (2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Dated: May 4, 2018 Signature: /s/ Gary R. Maharaj

Gary R. Maharaj President and

Chief Executive Officer

CERTIFICATION PURSUANT TO 18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Quarterly Report of Surmodics, Inc. (the "Company") on Form 10-Q for the quarter ended March 31, 2018, as filed with the Securities and Exchange Commission (the "Report"), I, Andrew D. C. LaFrence, certify, pursuant to 18 U.S.C. §1350, as adopted pursuant to §906 of the Sarbanes-Oxley Act of 2002, that:

- (1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
- (2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Dated: May 4, 2018 Signature: /s/ Andrew D.C. LaFrence

Andrew D.C. LaFrence

Vice President of Finance and Information Systems and

Chief Financial Officer